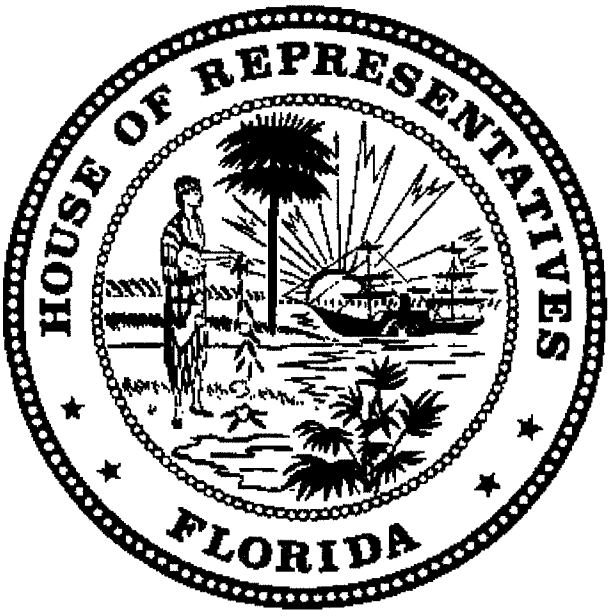

Health & Human Services Quality Subcommittee

Tuesday, January 31, 2012
12:30 PM – 3:00 PM
Reed Hall (102 HOB)

Dean Cannon
Speaker

John Wood
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Quality Subcommittee

Start Date and Time:	Tuesday, January 31, 2012 12:30 pm
End Date and Time:	Tuesday, January 31, 2012 03:00 pm
Location:	Reed Hall (102 HOB)
Duration:	2.50 hrs

Consideration of the following bill(s):

HB 425 Surgical Technology by Renuart
HB 751 Prescription Drug Wholesale Regulations by Brandes
HB 787 Nursing Home Facilities by Trujillo
CS/HB 935 Child Support Enforcement by Civil Justice Subcommittee, Baxley
HB 1019 Treatment Programs for Impaired Professionals by Renuart
HB 1081 Controlled Substances by McBurney

Consideration of the following proposed committee substitute(s):

PCS for HB 1419 -- Health Care Facilities

Consideration of the following proposed committee bill(s):

PCB HSQS 12-03 -- Health Care Coverage Mandates

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, January 30, 2012.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, January 30, 2012.

NOTICE FINALIZED on 01/27/2012 16:10 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 425 Surgical Technology
SPONSOR(S): Renuart
TIED BILLS: **IDEN./SIM. BILLS:** SB 362

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee		Holt	Calamas
2) Rulemaking & Regulation Subcommittee			
3) Health Care Appropriations Subcommittee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

The American College of Surgeons defines "surgical assistants" as those who provide or aid in exposure, hemostasis, closure and other operative technical functions that help the surgeon carry out a safe operation with optimal results. Surgical technologists may function as members of the surgical team in the role of scrub person or with specialized training in the role of surgical first assistant (or assistant-at-surgery). Currently, there is a wide range of non-physician allied health professionals trained and employed as surgical assistants or surgical technologists and the education background varies from certificates of completion to associate's degrees granted from colleges or universities.

The bill amends ch. 468, F.S., creating the requirements for surgical technologists to practice in Florida, such that a person may not practice surgical technology unless the person:

- Completed a nationally accredited educational program for surgical technologist;
- Completed an appropriate training program for surgical technology in the US Armed Forces or Public Health Services Commissioned Corps;
- Provides evidence that the person was employed to practice surgical technology in a health care facility within 2 years before July 1, 2012; or
- Is in the service of the Federal Government, to the extent the person is performing duties related to that service.

The bill prohibits hospitals, mobile surgical facilities, ambulatory surgical centers (healthcare facilities) governed under ch. 395, F.S. from hiring a person to perform surgical technology unless the person is certified. Health care facilities are required to supervise hired surgical technologists for competency, verify continuing education compliance, and maintain credentialing records. The bill provides exemptions, legislative intent, definitions, continuing education requirements, and rulemaking.

The bill has no fiscal impact on the state or local governments.

The bill takes effect July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Surgery

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is a part of the practice of medicine.[1]

Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician).[2]

All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel.[3]

There are numerous health practitioners who collaborate to create a surgical team:[4]

An overview of the surgical team

Role		Who Performs	Who Manages	Tasks
Sterile				
	Surgeon	Surgeon, Dentist, Podiatrist	Surgeon	Perform surgery, manage procedure
	Assistant at Surgery	Surgeon, Physician, Physician Assistant, Resident, Registered Nurse, Surgical Assistant, Surgical Technologist, Licensed Practical Nurse	Surgeon	Provide exposure, control bleeding, close wounds, apply dressing
	Scrub Person	Surgical Technologist, Registered Nurse, Licensed Practical Nurse	Circulating Nurse/Surgeon	Maintain sterile field, pass and count instruments, prepare supplies
Non-sterile				
	Anesthesia Provider	Anesthesiologist, Certified Registered Nurse Anesthetists, Dentist, Physician, Physician Assistant Anesthesiologist Assistant	Anesthesia Provider	Provide and maintain anesthesia, maintain vitals
	Circulator	Registered Nurse	Circulating Nurse	Patient advocate, patient comfort, manage team members, maintain sterile field, emergency assistance

Source: Study into the Need to Regulate, Surgical Assistants & Surgical Technologists in the Commonwealth of Virginia, July 2010

[1] American College of Surgeons, Statement on Surgery Using Lasers, Pulsed Light, Radiofrequency Devices, or Other Techniques, *available at*: http://www.facs.org/fellows_info/statements/st-11.html (last viewed January 25, 2012).
[2] *Id.*
[3] *Id.*
[4] Study into the Need to Regulate: Surgical Assistants & Surgical Technologist in the Commonwealth of Virginia, July 2010, *available at*: www.dhp.state.va.us/.../SurgicalAssistant_TechnologistReportFinal (last viewed January 26, 2012)

State Regulations

Hospitals, ambulatory surgical centers, mobile surgical facilities are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S.

Section 395.1055(1)(a), F.S., requires AHCA to adopt rules to ensure that sufficient numbers and qualified types of personnel and occupational disciplines are on duty and available at all times in a licensed facility to provide necessary and adequate care and safety.

Section 395.0197(1)(b) 3., F.S., prohibits unlicensed persons from assisting or participating in any surgical procedure unless the licensed 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.

In 2006[5], the Legislature required hospitals to comply with the requirements of the Centers for Medicare and Medicaid Services, Conditions of Participation (CoPs) for Hospitals, as they apply to registered nurses who perform circulating duties in the operating room.[6] Section 395.0191(1)(d), F.S., also provides that a circulating nurse be in the operating room for the duration of a surgical procedure.

The CMS regulations provide that hospitals must be in compliance with the federal requirements which are set forth in the Medicare Conditions of Participation, 42 CFR Part 482, in order to receive Medicare or Medicaid payments. The CoPs state that:[7]

- Hospitals must have an organized nursing service that provides 24-hour nursing services. The services must be furnished or supervised by a registered nurse.[8]
- The operating room must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.[9]
- Licensed practical nurses (LPNs) and surgical technologists may serve as "scrub nurses" under the supervision of a registered nurse.[10]
- Qualified registered nurses may perform circulating duties in the operating room.
- LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately[11] available to respond to emergencies.[12]

Surgical Assistants

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. Surgical technologists are individuals with specialized education who function as members of the surgical team in the role of

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[5] Ch. 2006-37, L.O.F.
[6] Section 395.0191(1)(d), F.S.
[7] The Health Care Financing Administration, Survey Protocol, *available at*: http://new.cms.hhs.gov/manuals/downloads/som107ap_a_hospitals.pdf (last viewed January 10, 2006).
[8] 42 CFR Part 482.23
[9] 42 CFR Part 482.51(a)(1)
[10] 42 CFR Part 482.51(a)(2)
[11] According to CMS, the supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical tech.
[12] 42 CFR Part 482.51 (a)(3)

scrub person. With additional education and training, some surgical technologists function in the role of surgical first assistant.[13]

The use of non-physician practitioners and unlicensed persons as assistant-at-surgery is increasing due to a:[14]

- A restriction on resident duty hours promulgated by the Accreditation Council on Graduate Medical Education (ACGME) in 2003,
- Changing reimbursement strategies by Centers for Medicare and Medicaid Services (CMS) and other third-party payers,
- Increased demands on physician and surgeon time, and
- The availability of skilled and experienced unlicensed personnel, particularly those trained in the military.

Certifying Bodies

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.[15]

Accredited programs may be offered in community and junior colleges, vocational and technical schools, the military, universities, and structured hospital programs in surgical technology. The accredited programs vary from nine to 15 months for a diploma or certificate to two years for an associate's degree.[16]

The Commission on Accreditation for Allied Health Education Programs (CAAHEP) is the largest programmatic accreditor in the health sciences field. In collaboration with its Committees on Accreditation, CAAHEP reviews and accredits over 2000 educational programs in 23 health science occupations.[17] Currently, there are 36 accredited CAAHEP programs located in Florida that offer an associate's degree, certificate, or diploma in surgical technology.[18]

The National Board of Surgical Technology and Surgical Assisting (NBSTSA), was established in 1974 as the certifying agency for surgical technologists. NBSTSA is solely responsible for all decisions regarding certification; from determining eligibility to maintaining, denying, granting and renewing the designation. The NBSTSA is the only examination program for surgical technologists and surgical first assistants accredited by the National Commission for Certifying Agencies in the nation.[19]

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[13] American College of Surgeons, Statement on Surgical Technology Training and Certification, available at: http://www.facs.org/fellows_info/statements/st-47.html (last viewed January 25, 2012).
[14] Study into the Need to Regulate: Surgical Assistants & Surgical Technologist in the Commonwealth of Virginia, July 2010, available at: www.dhp.state.va.us/.../SurgicalAssistant_TechnologistReportFinal (last viewed January 26, 2012)
[15] American College of Surgeons, Statement on Surgical Technology Training and Certification, available at: http://www.facs.org/fellows_info/statements/st-47.html (last viewed January 25, 2012).
[16] *Id.*
[17] Commission on Accreditation for Allied Health Education Programs, available at: http://www.caahep.org/ (last viewed January 25, 2012).
[18] Commission on Accreditation for Allied Health Education Programs, available at: http://www.caahep.org/Find-An-Accredited-Program/# (last viewed January 25, 2012).
[19] National Board of Surgical Technology and Surgical Assisting, About, available at: http://nbstsa.org/about/index.html (last viewed January 26, 2012).

Education and Regulation in Other States

According to a study conducted by the U.S. General Accounting Office (GAO) in 2004,[20] 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 states that issue health professional licenses typically require the completion of broad-based institutional health care education, rather than qualifying health professionals based on 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 several other states now regulate surgical technologists: Colorado, Illinois, Indiana, South Carolina, Tennessee, Texas, and Washington.[21]

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	
Other health professions			
Surgical technologist	Associate's degree, military	No	2 years of surgical

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

[21] Sunrise Questionnaire: Surgical Technology Regulation, prepared by the Florida State Assembly of the Association of Surgical Technologist, September 10, 2010, on file with the Health & Human Service Quality Subcommittee staff.

	or non-degree certificate		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

According to a GAO report on Medicare costs in 2004,[22] 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. Generally, the health care industry looks to Medicare and as a basis for reimbursement and payment structure.

As reported by the GAO, Medicare pays for assistant-at-surgery services through both the hospital inpatient prospective payment system (PPS) and the physician fee schedule, and the hospital payments for surgical care are not adjusted when an assistant receives payment under the physician fee schedule. The majority of assistants-at-surgery are employed by hospitals, where the inpatient hospital PPS pays for their services.[23] Generally, the amount Medicare pays under the physician fee schedule is based on the resources needed to perform a service, the physician's time and skill, practice expenses, that include the cost of staff (which may include a surgical tech), equipment, supplies, and the cost of liability insurance.[24]

Depending on the procedure performed, and the qualifications and training of the provider assisting in surgery, the services may be billable to Medicare. Medicare reimburses only assistants-at-surgery who are licensed personnel (such as physicians, clinical nurse specialists, nurse practitioner, and physician assistant) and does not reimburse for surgical assistants included under the physician fee schedule that are non-physicians. Non-physician assistants-at-surgery include certified registered nurse first assistant, orthopedic physician assistants, licensed practical nurses, or certified surgical technologists.[25] These non-physician assistants-at-surgery are usually paid by the hospital from the inpatient PPS or by the surgeon who pays them from the physician fee schedule (also referred to as the surgeons global fee).[26]

Professional Regulation and the Florida Sunrise Act

There are three different types or levels of regulation:[27]

1. Licensure is the most restrictive form of state regulation. Under licensure laws, it is illegal for a person to practice a profession without first meeting all of the standards imposed by the state.

[22] United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] Schmitt, K. & Shimberg, B. (1996). Demystifying Occupational and Professional Regulation: Answers to Questions You May Have Been Afraid to Ask. *Council on Licensure, Enforcement, and Regulation.*

2. Certification grants title protection to those who meet training and other standards. Those who do not meet certification standards cannot use the title, but can still perform the services.

3. Registration the least restrictive form of regulation, and usually only requires individuals to file their name, address and qualifications with a government agency before practicing the occupation.

Section 456.003, F.S., specifies that health care professions be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:

- Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation;
- The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation; and
- Less restrictive means of regulation are not available.

Section 11.62, F.S., the Sunrise Act, provides legislative intent regarding the regulation of new professions and occupations:[28]

- No profession or occupation is 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 is 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, section 11.62(3), F.S., requires the Legislature to consider the following:

- 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;

- 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;

- 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;

- Whether the public is or can be effectively protected by other means; and

- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The Sunrise Act requires proponents of regulation to submit information documenting the need for the proposed regulation. In 2010, a completed sunrise questionnaire was submitted by the Florida State Assembly of the Association of Surgical Technologist (assembly). In 2010, the assembly estimated that fewer than 5,980 surgical technologists (also known by other terms such as operating room technician,

[28] Section 11.62(2), F.S.

"scrub nurse", and surgical technician) would be affected by creating a mandatory regulatory scheme.[29] The legislation proposed in 2010 is substantially different to HB 425, in that the language reflected a traditional regulatory scheme.

Generally, regulatory provisions include the following components: oversight conducted by a governing board or council, penalties allowing for enforcement, licensure by endorsement, title protection, defined supervisory relationships, identified delegable tasks, grounds for disciplinary action, and initial and renewal licensure fees.

Effect of Proposed Changes

The bill provides definitions for health care facility, surgical technologists, and surgical technology. "Surgical technology" is defined to mean surgical patient care performed collaboratively with the surgical team which includes, but is not limited to, the following tasks or functions:

- Preparing the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely;
- Preparing the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile techniques;
- Anticipating the needs of the surgical team based on knowledge of human anatomy and pathophysiology and how those needs relate to the surgical patient and the patient's surgical procedure; and
- Performing tasks at the sterile field, as directed, including:
    - Passing supplies, equipment, or instruments.
    - Sponging or suctioning an operative site.
    - Preparing and cutting suture material.
    - Transferring and irrigating with fluids.
    - Transferring drugs within the sterile field, according to applicable law.
    - Handling specimens.
    - Holding retractors and other instruments.
    - Applying electrocautery[30] to clamps on blood vessels that bleed.
    - Connecting drains to suction apparatus.
    - Applying dressings to closed wounds.
    - Performing sponge, needle, supply, and instrument counts with the registered nurse circulator.

The bill amends ch. 468, F.S., creating the requirements for surgical technologists to practice in Florida. To practice surgical technology in Florida, a person must:

- Complete a nationally accredited educational program for surgical technologist;
- Complete an appropriate training program for surgical technology in the US Armed Forces or Public Health Services Commissioned Corps and completes 15 continuing education annually to remain qualified to practice;
- Provide evidence that the person was employed to practice surgical technology in a health care facility within 2 years before July 1, 2012 and completes 15 continuing education annually to remain qualified to practice; or
- Be in the service of the Federal Government, to the extent the person is performing duties related to that service.

The bill prohibits hospitals, mobile surgical facilities, and ambulatory surgical centers (healthcare facilities) governed under ch. 395, F.S., from hiring a person to perform surgical technology unless the person is certified. The health care facility is required to maintain records on credentials and verify that

[29] Sunrise Questionnaire: Surgical Technology Regulation, prepared by the Florida State Assembly of the Association of Surgical Technologist, September 10, 2010, on file with the Health & Human Service Quality Subcommittee staff.

[30] Electrocautery is the application of a needle or snare heated by electric current for the destruction of tissue, such as for removing warts or polyps and cauterizing small blood vessels to limit blood loss during surgery.

continuing education requirements are met. Additionally, the health care facility is required to supervise each person hired to perform surgical technology to ensure that the person competently performs delegated perioperative tasks.

The bill provides that a person may be employed or contracted to practice surgical technology during the 12-month period immediately following successful completion of a program in surgical technology. However, such a person may not continue the employment or contract beyond the 12-month period without documentation that the person holds and maintains the credential of certified surgical technologist. The bill is silent on how the documentation is to be submitted.

The bill exempts any licensed practitioner who performs tasks or functions related to surgical technology if the person is acting within the scope of his or her license from attaining a certification in surgical technology. Moreover, a medical student, osteopathic student, or resident is not prohibited from performing tasks or functions related to surgical technology if the person is acting within the scope of his or her duties.

The bill prohibits the practice of surgical technology without meeting the new regulatory requirements in the bill. This implies that bill is requiring the profession be regulated by the state. However, the provisions contained in the bill do not include the components of a typical regulatory scheme. The bill is silent on these issues, so its unclear. In addition, the bill's placement in ch. 468, F.S., (which regulates various professions and occupations through the DOH and the DBPR) implies the bill is creating a new licensure scheme for a profession rather than imposing regulatory requirements on hospitals. Similarly, this placement suggests surgical technologists will be regulated by DOH or DBPR, but nothing in the bill addresses this point directly.

The bill provides the Agency for Health Care Administration the authority to adopt rules to administer the provisions of the bill, but does not provide sufficient guidance on the regulatory scheme, thus implicating the delegation doctrine.

B. SECTION DIRECTORY:

Section 1. Creates s. 468.91, 468.92, 468.93, 468.94, 468.95, 468.96, and 468.97, F.S., relating to legislative intent, definitions, training and certification required, continuing education requirements, supervision and compliance, applicability, and rulemaking authority.

Section 2. Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None identified.

2. Expenditures:

   None identified.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

The bill appears to create a regulatory scheme, but does not identify avenues for licensure, enforcement or fee collection that are customary for regulated professions.

Section 216.0236(1), F.S., provides that it is the intent of the Legislature that all costs of providing a regulatory service or regulating a profession should be borne solely by those who receive the service or who are subject to regulation.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

Separation of Powers Doctrine

Article II, section 3 of the Florida Constitution, is also known as the Separation of Powers Doctrine. The Constitution provides that:

> The powers of state government shall be divided into legislative, executive, and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided therein.

An unconstitutional delegation of power from one branch of government to another branch of government violates the Separation of Powers Doctrine. The Florida Supreme Court has held that there is an unconstitutional delegation of legislative power when the criteria provided in a statute is not sufficient to give adequate guidance.[31]

The bill provides AHCA authority to adopt rules to administer the provisions of the bill, but does not provide sufficient guidance on the regulatory structure.

B. RULE-MAKING AUTHORITY:

The provisions of the bill provide sufficient rulemaking authority to AHCA to implement, however, the definition of "health care facility" states that the entities are regulated by the Department of Health (DOH) under ch. 395, F.S.; which are governed by AHCA. It is assumed that this was a drafting error and the intent is to provide the authority to AHCA, but if incorrect, then the bill does not provide DOH authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Legislative intent states, "surgical technologists who fail to meet minimum competencies or who otherwise present a danger to the public health be prohibited from practicing in this state," implies that bill is requiring the profession be regulated by the state. However, the provisions contained in the bill do not include the components of a typical regulatory scheme. Generally, regulatory provisions include the following components: oversight conducted by a governing board or council, penalties allowing for enforcement, licensure by endorsement, title protection, defined supervisory relationships, identified delegable tasks, grounds for disciplinary action, and initial and renewal licensure fees. The bill is silent on these issues, so it is unclear of the intent of the bill. In addition, the bill's placement in ch. 468, F.S.,

[31] *Askew v. Cross Keys Waterways,* 372 So. 2d 913, (Fla. 1978)(stating that "[t]he constitutional doctrine prohibiting delegation of legislative power rests on the premise that the Legislature may not abdicate its responsibility to resolve the „truly fundamental issues; by delegating that function to others or by failing to provide adequate directions for the implementation of its declared policies.").

(which regulates various professions and occupations through the DOH and the DBPR) implies the bill is creating a new licensure scheme for a profession rather than imposing regulatory requirements on hospitals. Similarly, this placement suggests surgical technologists will be regulated by DOH or DBPR, but nothing in the bill addresses this point directly.

On line 60 and 117, discusses direction and delegation, but does not specify the person who authorized supervise or direct tasks.

On lines 100-102, prohibits health care facilities from employing or contracting with a non-qualified surgical technologist, but does not provide a penalty for compliance. It is unclear what the effect of this provision will have without an associated enforcement provision.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to surgical technology; creating part XVII of ch. 468, F.S., relating to minimum requirements to practice surgical technology; providing legislative intent; providing definitions; prohibiting a person from practicing surgical technology in a health care facility unless he or she meets certain criteria; providing an exception for a specified time; prohibiting a health care facility from employing or contracting for the services of a surgical technologist unless the surgical technologist meets certain requirements; requiring continuing education for persons qualified to practice surgical technology; requiring a health care facility to verify that a person who is qualified to practice surgical technology meets continuing education requirements and maintains the credential of certified surgical technologist; requiring a health care facility to supervise persons employed or contracted by a health care facility to practice surgical technology; providing that the act does not prohibit certain licensed health care practitioners and medical and osteopathic students from performing tasks or functions related to surgical technology; requiring the Agency for Health Care Administration to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Part XVII of chapter 468, Florida Statutes, consisting of sections 468.91, 468.92, 468.93, 468.94, 468.95, 468.96, and 468.97, is created to read:

468.91 Legislative intent.—The sole legislative purpose for enacting this part is to ensure that every surgical technologist employed in this state meets minimum requirements for safe practice as a member of the surgical care team. It is the legislative intent that surgical technologists who fail to meet minimum competencies or who otherwise present a danger to the public health and safety be prohibited from practicing in this state.

468.92 Definitions.—As used in this part, the term:

(1) "Health care facility" means a hospital, an ambulatory surgical center, or a mobile surgical facility that is regulated by the Department of Health under chapter 395.

(2) "Surgical technologist" means a person who practices surgical technology.

(3) "Surgical technology" means surgical patient care performed collaboratively with the surgical team which includes, but is not limited to, the following tasks or functions:

(a) Preparing the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely;

(b) Preparing the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile techniques;

(c) Anticipating the needs of the surgical team based on

knowledge of human anatomy and pathophysiology and how those needs relate to the surgical patient and the patient's surgical procedure; and

(d) Performing tasks at the sterile field, as directed, including:

1. Passing supplies, equipment, or instruments.

2. Sponging or suctioning an operative site.

3. Preparing and cutting suture material.

4. Transferring and irrigating with fluids.

5. Transferring drugs within the sterile field, according to applicable law.

6. Handling specimens.

7. Holding retractors and other instruments.

8. Applying electrocautery to clamps on blood vessels that bleed.

9. Connecting drains to suction apparatus.

10. Applying dressings to closed wounds.

11. Performing sponge, needle, supply, and instrument counts with the registered nurse circulator.

468.93 Training and certification required.—

(1) A person may not practice surgical technology in a health care facility in this state unless the person meets one of the following requirements:

(a) Has successfully completed a nationally accredited educational program for surgical technologists and holds and maintains the credential of certified surgical technologist, which is administered by a nationally accredited credentialing body;

(b) Has completed an appropriate training program for surgical technology in the United States Armed Forces or Public Health Service Commissioned Corps;

(c) Provides evidence that the person was employed to practice surgical technology in a health care facility within 2 years before July 1, 2012; or

(d) Is in the service of the Federal Government, to the extent the person is performing duties related to that service.

(2) A person may be employed or contracted to practice surgical technology during the 12-month period immediately following successful completion of a program in surgical technology, but may not continue to be employed or contracted to practice beyond that period without documentation that the employee or contractor holds and maintains the credential of certified surgical technologist.

(3) A health care facility in this state may not employ or otherwise contract for the services of a surgical technologist unless the person meets the requirements of this section.

468.94 Continuing education required.—

(1) A person who qualifies to practice surgical technology in a health care facility under s. 468.93(1)(b) or (c) must annually complete 15 hours of continuing education to remain qualified to practice as a surgical technologist.

(2) A health care facility that employs or contracts with a person to practice surgical technology shall verify that the person meets the continuing education requirements of subsection (1) and, where applicable, maintains the credential of certified surgical technologist.

468.95 Supervision and compliance.—A health care facility shall supervise each person employed or contracted by a health care facility to practice surgical technology according to the health care facility's policies and procedures to ensure that the person competently performs delegated perioperative tasks in accordance with this part and other applicable laws.

468.96 Applicability.—This part does not prohibit any licensed practitioner from performing tasks or functions related to surgical technology if the person is acting within the scope of his or her license. This section also does not prohibit any medical student, osteopathic student, or resident from performing tasks or functions related to surgical technology if the person is acting within the scope of his or her duties.

468.97 Rulemaking authority.—The Agency for Health Care Administration shall adopt rules to administer the requirements of this part.

Section 2. This act shall take effect July 1, 2012.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health & Human Services Quality Subcommittee

Representative Renuart offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsection (2) of section 395.0191, Florida Statutes, is amended to read:

395.0191 Staff membership and clinical privileges.—

(2)(a) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by an advanced registered nurse practitioner licensed and certified under part I of chapter 464, in accordance with the provisions of this section. No licensed facility shall deny such application solely because the applicant is licensed under part I of chapter 464 or because the applicant is not a participant in the Florida Birth-Related Neurological Injury Compensation Plan.

(b) An advanced registered nurse practitioner who is certified as a registered nurse anesthetist licensed under part I of chapter 464 shall administer anesthesia under the onsite medical direction of a professional licensed under chapter 458, chapter 459, or chapter 466, and in accordance with an established protocol approved by the medical staff. The medical direction shall specifically address the needs of the individual patient.

(c) Each licensed facility shall establish rules and procedures for consideration of an application for clinical privileges submitted by a physician assistant licensed pursuant to s. 458.347 or s. 459.022. Clinical privileges granted to a physician assistant pursuant to this subsection shall automatically terminate upon termination of staff membership of the physician assistant's supervising physician.

(d) Each hospital shall meet the requirements of the Medicare and Medicaid Conditions of Participation for Hospitals under 42 C.F.R. s. 482.51(a)(3) as they apply to registered nurses performing circulating duties in the operating room and as provided in the interpretive guidelines provided by the United States Department of Health and Human Services. A circulating nurse shall be present in the operating room for the duration of a surgical procedure.

(e) Each hospital shall establish policies and procedures for employment of persons who may perform surgical technology functions in an operating room. The hospital shall only consider a person who successfully completed a nationally accredited educational program for surgical technologist. Such a

person must hold the credential of certified surgical technologist within 6 months from the date of hire. Persons who are currently employed by a specific hospital or hospital system are exempt from this provision as long said employment is maintained and not terminated. A persons who is licensed pursuant to chapter 458, chapter 459, chapter 464, or who is an intern or resident on a surgical rotation, is exempt from the provisions of this paragraph. The agency shall accept, in lieu of its own periodic inspections for licensure, the survey or inspection of an accrediting organization, providing the accreditation of the licensed facility is not provisional and provided the licensed facility authorizes release of, and the agency receives the report of, the accrediting organization to ensure compliance with this subsection.

Section 2. This act shall take effect October 1, 2012.

T I T L E A M E N D M E N T

Remove the entire title and insert:

A bill to be entitled

An act relating to surgical technology; amending s. 395.0191, F.S., requiring hospitals to establish rules and procedures for consideration of an application submitted by a person who may perform surgical technology functions in an operating room; provide educational and licensure requirements for the person; provide a timeline for employees to acquire the licensure requirement; provide exemption to certain persons; provides the agency authority to accept the survey or inspection conducted by

an accrediting agency as documentation of compliance; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 751 Prescription Drug Wholesale Regulations
SPONSOR(S): Brandes
TIED BILLS: **IDEN./SIM. BILLS:** SB 1006

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee		Poche	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Part I of Chapter 499 requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors. In total, Florida has 20 distinct permits for these entities.

Out-of-state prescription drug wholesale distributors who wish to operate in Florida must obtain an out-of-state prescription drug wholesale distribution permit. In order to obtain the permit, a prospective permittee must comply with and meet many requirements set out in statute and administrative rule.

HB 751 proposes to establish a permit by endorsement for out-of-state prescription drug wholesale distributors. The bill requires DBPR to issue a permit by endorsement if the out-of-state distributor:

- Applies for a permit through DBPR and pays the appropriate fee;
- Demonstrates that it satisfies the requirements of chapter 499, F.S.; and
- Holds a valid drug wholesale distributor license or permit from another state.

For out-of-state wholesale distributors that currently hold a valid permit in Florida, the bill allows those distributors to apply for a permit by endorsement upon expiration of the current permit.

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

The bill provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Regulation of Drugs, Devices, and Cosmetics

Part I of Chapter 499 requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[1] A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors. In total, Florida has 20 distinct permits for these entities. Among many other provisions, the chapter provides for:

- Criminal prohibitions against the distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics;
- Permits for manufacturing and distributing drugs, devices, and cosmetics;
- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers; Regulation of the provision of drug samples;
- The Cancer Drug Donation Program; and
- Numerous enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

Many of these regulations have been significantly strengthened in recent years, including:

- A significantly stronger wholesale distributor permit, requiring, among other items, a posting of a bond and extensive background information for various employees of the wholesale distributor;[2]
- More thorough documentation of the distribution of prescription drugs, including broader application of the pedigree paper to most wholesale distributions;[3]
- Enhanced criminal penalties for, among other things, distribution of contraband prescription drugs;[4] and
- Stronger departmental enforcement authority to protect the prescription drug supply chain.[5]

These stricter regulations were prompted by the report of a Grand Jury convened by the Florida Supreme Court in 2002 at the request of Governor Jeb Bush.[6] The Grand Jury noted that "first tier" wholesale distributors (AmerisourceBergen, Cardinal Health, and McKesson) controlled approximately 90 percent of wholesale prescription drug distribution market. This is the "primary market." The

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[1] S. 27, ch. 2010-161, Law of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Device s, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation. Proposed legislation has been filed for the 2012 Regular Session to make necessary changes to chapter 499 to reflect the change of departmental oversight; *see* Florida House of Representatives, Bills for Regular Session 2012, *HB 5511 Department of Business and Professional Regulation*, available at http://myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=48947.

[2] S. 499.01(2)(d), F.S. (requiring a bond of $100,000 or other means of equivalent security) and s. 499.012(8) and (9), F.S. (requiring, in addition to other information, place of residence for the past 7 years, fingerprints, photograph taken within 30 days, and name, address, occupation, and date and place of birth of each member of the person's immediate family who is 18 years of age or older).

[3] S. 499.01212, F.S. ("Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.")

[4] S. 499.0051(6), F.S. (imposing a second degree felony for "a person who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs").

[5] S. 499.0051(12) and (13), F.S.

[6] *See* First Interim Report of the Seventeenth Statewide Grand Jury, Case No. SC02-2645 (2003).

remaining stock was purchased from "second tier" wholesale distributors, a "secondary market" of hundreds of smaller wholesale distributors. In this secondary market, prescription drugs may move "up, down, and sideways through the distribution system, [creating] opportunities for adulterated drugs that have been diverted from other sources to enter the distribution system." It is this secondary tier that the Grand Jury, much like Congress in the 1980s,[7] identified as one of the primary points of introduction of counterfeit or adulterated drugs. Neither the Grand Jury nor Congress attributed fault to the prescription drug manufacturers in knowingly participating in the introduction of contraband drugs in the secondary market.[8]

The act identifies authorized and proscribed activities for each permitted entity, as well as particular storage, handling, and recordkeeping requirements for each. Administrative and criminal penalties may result for the failure to comply with requirements in the act or administrative rules.[9]

The table below lists all permit types for entities involved in the manufacture, distribution and dispensing of controlled substances in the state of Florida, as regulated by chapter 499, F.S., and the number of licenses or permits issued by DOH for each permit type.[10]

Ch. 499, F.S., Permit Types	Licenses/ Permitees/ Registrants	Complaints
Prescription Drug Manufacturer	106	15
Non-resident Prescription Drug Manufacturer	800	20
Prescription Drug Repackager	29	6
Prescription Drug Wholesale Distributor	131	31
Out-of-State Prescription Drug Wholesale Distributor	254	28
Retail Pharmacy Drug Wholesale Distributor	73	15
Prescription Drug Wholesale Distributor - Broker Only	4	1

Out-of-State Prescription Drug Wholesale Distributor Regulation

A "wholesale distributor" is defined in chapter 499, F.S., as any person engaged in wholesale distribution (the distribution of prescription drugs to persons other that a consumer or patient)[11] of prescription drugs in or into this state, including, but not limited to, manufacturers, repackagers, warehouses, retail pharmacies, and their respective agents that conduct wholesale distributions.[12]

A prescription drug wholesale distributor located in Florida may engage in the distribution of prescription drugs within the state upon receiving a prescription drug wholesale distributor permit.[13] A prospective permittee must complete and submit the proper application to DBPR, along with the

[7] *See* Pub. L. No. 100-293 (1988) (finding that "the existence and operation of a wholesale submarket, commonly known as the 'diversion submarket', prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.").
[8] *See* H.R. Rep. No. 100-76 (1987) and S. Rep. No. 100-303 (1988). The report did note that two practices—providing drug samples and discount sales to health care institutions (e.g., hospitals)—provided potential opportunity for abuse. In particular, "the existing system of providing [drug] samples of pharmaceutical products to physicians through manufacturers" sales representatives invites abuse" (*emphasis added*). In addition, "the resale of prescription drugs by health care entities to persons outside the corporate umbrella of the [entity] helps fuel the diversion market. Such sales . . . are economical only because many manufacturers sell much more cheaply to certain institutions than to wholesale customers" (*emphasis added*).
[9] Chapter 64F-12, Florida Administrative Code, contains the rules adopted under the Act's authority.
[10] The last column of the chart includes the number of complaints received by DOH for each license or permit type in FY 2009-2010.
[11] S. 499.003(54), F.S.; *see also* Rule 64F-12.001, F.A.C.
[12] S. 499.003(55), F.S.
[1313] S. 499.01(2)(d), F.S.; *see also* s. 499.012(8) and (9)(a), F.S.

applicable fee.[14] A prospective permittee must designate in writing at least one natural person to serve as the certified designated representative (CDR). Certification and operating requirements for CDRs include:

- Submission of a CDR application to DBPR;
- Payment of the appropriate fees;
- The CDR must be at least 18 years of age
- The CDR must have not less than two years of verifiable full-time work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs, or have not less than two years of verifiable full-time managerial experience with a prescription drug wholesale distributor licensed in this state or in another state;
- Receipt of a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs;
- The CDR must be employed in a managerial position by the wholesale distributor, actively involved in and aware of actual daily operations and be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; and
- May serve as a designated representative for only one wholesale distributor at any one time.[15]

A prospective permittee must post a surety bond of $100,000, which will be used to pay penalties imposed by DBPR and reimburse the department for fees and costs incurred in investigating and assessing the penalties. Certain individuals associated with the prospective permittee must provide a personal information statement, including a set of fingerprints for a criminal background check, to the DBPR as part of the application process. These individuals include the CDR or CDR candidate, the manager of the establishment and the next four highest ranking employees responsible for prescription drug wholesale operations at the establishment, and all affiliated parties[16] of the establishment. Lastly, the distribution facility must submit to pre-application inspection before the permit can be issued.[17]

Out-of-state prescription drug wholesale distributors are required to obtain a specific permit in order to distribute drugs in the state.[18] They are defined within statute as wholesale distributors located outside of the state that engage in the wholesale distribution of prescription drugs into the state, which must be permitted by DBPR, and which must comply with all provisions required of a wholesale distributor under part I of chapter 499, F.S. They must obtain an out-of-state prescription drug wholesale distributor permit to distribute prescription drugs in the state.[19]

Upon application for a permit, an out-of-state prescription drug wholesale distributor is required to post a bond of $100,000.[20] The bond will be used to pay any administrative penalties imposed by DBPR against the distributor and to pay any fees and costs incurred by DBPR in investigating and assessing

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[14] Rule 64F-12.015(7), F.A.C., contains the complete permitting requirements for a Prescription Drug Wholesale Distributor permit; *see also* Rule 64F-12.018(2)(b), F.A.C., for fee schedule.

[15] Florida Department of Business and Professional Regulation, *DRUGS, DEVICES AND COSMETICS PROGRAM-PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR-REQUIREMENTS*; available at http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugWholesalerDistributor.html (last viewed January 30, 2012); *see also* Rule 64F-12.015(9), F.A.C.

[16] S. 499.003(3), F.S., defines "affiliated party" as (i) directors, officers, trustees, partners, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant; (ii) any person who, directly or indirectly, manages, controls or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant; and (iii) up to five natural individual owners, to the extent that any owns at least five percent of the permittee or applicant.

[17] *See supra* at FN 15.

[18] S. 499.01(1)(e), F.S.

[19] S. 499.01(2)(e), F.S.

[20] *Id.*; *see also* Rule 64F-12.015(7)(e)5., F.A.C.

the penalties.[21] Also, statute requires the wholesale distributor to, at all times, maintain a valid license or permit to operate as a wholesale distributor in the state where it is a resident in order to operate as a wholesale distributor in Florida.[22]

Specific requirements for obtaining an initial out-of-state prescription drug wholesale distributor permit are found in administrative rule.[23] The prospective permittee must obtain an application form and fingerprint cards from DBPR.[24] The completed application form must be completed and submitted to DBPR.[25] Next, a Personal Information Statement must be completed by the prospective permittee's manager, the next four highest ranking employees of the prospective permittee who are responsible for prescription drug operations, and all affiliated parties.[26] Each required party must submit a completed fingerprint card and $47.00 to DBPR.[27] The prospective permittee must submit a copy of the resident state's license or permit which allows the prospective permittee to conduct wholesale distribution of prescription drugs in that state.[28] However, if the resident state does not require a license or permit to engage in wholesale distribution of prescription drugs, then the prospective permittee must submit to DBPR the following:

- Written confirmation on the letterhead of the resident state agency responsible for regulating prescription drugs that a license or permit to engage in wholesale distribution of prescription drugs within the resident state is not required[29]; and
- A signed statement from the prospective permittee that it will comply with all storage, handling, and recordkeeping requirements of the resident state with regard to the sale and distribution of prescription drugs into Florida[30]; or
- If the resident state does not have storage, handling and recordkeeping requirements, a signed statement that the prospective permittee with comply with all storage, handling, and recordkeeping requirements found in the applicable federal statute.[31]

The prospective permittee must identify a person within the company who is certified, pursuant to s. 499.012(16), F.S.,[32] to serve as the designated representative for the prospective permittee.[33] Any change of the certified designated representative must be reported to DBPR.[34] Lastly, the prospective permittee must pay all applicable fees, which include an annual fee of $800, a Certification as Designated Representative fee of $150, and non-refundable Initial Application/On-Site Inspection fee of $150.[35]

Effect of Proposed Changes

The bill requires DBPR to issue a permit by endorsement to an applicant for an out-of-state prescription drug wholesale distributor permit who:

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[21] *Id.*
[22] S. 499.01(2)(e)1., F.S.
[23] Rule 64F-12.015(7)(e), F.A.C.; *see also* s. 499.012, F.S., for additional specific requirements for permitting.
[24] Rule 64F-12.015(7)(e)1., F.A.C.
[25] Rule 64F-12.015(7)(e)2., F.A.C., requires Form DH 2124 to be completed by the prospective permittee. It is likely that the form designation has changed since program administration has been moved to DBPR; however, the Rules have not been updated to reflect the shift in program oversight.
[26] Rule 64F-12.015(7)(e)3., F.A.C., requires Form DH 2125, the "Personal Information Statement", to be filed with DBPR.
[27] Rule 64F-12.015(7)(e)4., F.A.C.
[28] Rule 64F-12.015(7)(e)6., F.A.C.
[29] Rule 64F-12.015(7)(e)6.a., F.A.C.
[30] Rule 64F-12.015(7)(e)6.b., F.A.C.
[31] *Id.*; *see also* 21 C.F.R. 205.50 (2003) for storage, handling, and recordkeeping requirements.
[32] S. 499.012(16), F.S., contains application requirements and qualifying requirements that must be met before a person can be certified as the prospective permittee's designated representative.
[33] Rule 64F-12.015(7)(e)7., F.A.C.
[34] *Id.*; a prospective permittee must use Form DH 2130 to communicate any change in certified designated representative to DBPR.
[35] Rule 64F-12.015(7)(e)8., F.A.C.; *see also* Rule 64F-12.018(3), (4)(a), and (4)(b), F.A.C., outlining applicable fee amounts.

- Applies to DBPR and pays the filing fee set by the board;[36]
- Demonstrates to the board[37] that the applicant satisfies the other requirements of chapter 499, F.S.; and
- Holds a valid drug wholesale distributor license or permit from another state.

The bill also provides that a valid Florida out-of-state prescription drug wholesale distributor permit on the effective date of the bill can continue to operate under the permit until it expires. Once the permit expires, the distributor may then apply for a permit by endorsement, as provided under the bill.

The bill proposes to provide out-of-state wholesale distributors with an alternate permitting process to the current process. The permit by endorsement requires the out-of-state wholesale distributor to prove to DBPR that it holds a license or permit as a wholesale distributor in its resident state. However, the resident state may not have a permitting process as thorough as the permitting process in Florida. The bill may allow less qualified or less legitimate wholesale distributors to obtain a permit or license in a less regulatory intensive state, then apply for a permit by endorsement to operate within Florida, thereby avoiding the level of scrutiny given to companies proceeding through the full permitting process.

However, the bill does not specify which of the other requirements contained in chapter 499, F.S., must be satisfied by an applicant for a permit by endorsement. Section 499.01(2)(e), F.S., requires that an out-of-state prescription drug wholesale distributor comply with all the provisions required of a wholesale distributor found in part I of chapter 499, F.S. Barring any specific language to the contrary, it may be presumed that an out-of-state prescription drug wholesale distributor must satisfy the requirements of an in-state wholesale distributor, which include, but are not limited to, abiding by storage and handling regulations,[38] meeting drug registration requirements,[39] and submitting to inspections and investigations by the Florida Department of Law Enforcement.[40] Therefore, it is not clear from the language of the bill if the permit by endorsement would exempt the out-of-state prescription drug wholesale distributor from the rigorous permitting requirements that are already in place for out-of-state wholesale distributors. In addition, the requirements for an in-state prescription drug wholesale distributor and an out-of-state prescription drug wholesale distributor are similar.

The permit by endorsement may create a situation in which Florida based distributors leave the state, establish residence in a state that has less restrictive requirements to obtain a wholesale distribution license, and then file an application to obtain a permit by endorsement. This allows the distributor to avoid the more rigorous Florida permitting process to which it was subject while a resident of this state.

B. SECTION DIRECTORY:

Section 1: Amends s. 499.01, F.S., relating to permits.
Section 2: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[36] No board exists to regulate these types of permits within DBPR; *see* Section IIIC., Drafting Issues or Other Comments, below.
[37] *Id.*
[38] S. 499.0121, F.S.
[39] S. 499.015, F.S.
[40] S. 499.051, F.S.; *see also* Rule 64F-12.013, F.A.C.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may entice out-of-state prescription drug wholesale distributors which had refrained from applying for a permit to distribute in Florida due the permitting process to enter the Florida market by completing a less onerous license by endorsement process. Additional distributors in the market may increase price competition.

D. FISCAL COMMENTS:

DBPR does not anticipate an increase or decrease in the number of out-of-state prescription drug wholesale distributors licensed by the department.[41] DBPR will be required to modify its online license and information databases as a result of the provisions of this bill, but expects to complete the modifications within current budgetary resources.[42]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

[41] Florida Department of Business and Professional Regulation, Office of Legislative Affairs, *2012 Legislative Analysis Form for SB1006/HB 751*, page 3 (on file with the Health and Human Services Quality Subcommittee).
[42] *Id.*

B. RULE-MAKING AUTHORITY:

DBPR has appropriate rulemaking authority under s. 499.05(1)(c), F.S., sufficient to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Line 4 of the bill refers to the Department of Health as the authority to be required to issue a permit by endorsement to an out-of-state prescription drug wholesale distributor. Effective October 1, 2011, the Drugs, Devices, and Cosmetics program was moved to DBPR.[43] The reference to the Department of Health must be changed to "Department of Business and Professional Regulation" to reflect the proper licensing authority.

Line 47 of the bill requires "the board" to set a filing fee for an out-of-state prescription drug wholesale distributor permit by endorsement. There is no board which oversees prescription drug wholesalers. The department is responsible for regulating these permits. The reference to "the board" must be changed to "the department" to reflect the proper regulating authority.

DBPR is currently required to inspect all permitted prescription drug wholesalers. DBPR has raised a concern that the bill does not address whether inspections of out-of-state prescription drug wholesalers that receive a permit by endorsement are to occur. If so, there may be jurisdictional issues and objections raised by regulating authorities in other state if DBPR were to travel to other states to perform inspections based on Florida law.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[43] S. 27, ch. 2010-161, Laws of Fla.

A bill to be entitled

An act relating to prescription drug wholesale regulations; amending s. 499.01, F.S.; requiring the Department of Health to issue a permit by endorsement to an out-of-state prescription drug wholesale distributor that meets certain requirements; authorizing out-of-state wholesale distributors holding a valid permit to continue to operate under that permit until its expiration; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (e) of subsection (2) of section 499.01, Florida Statutes, is amended to read:

499.01 Permits.—

(2) The following permits are established:

(e) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a

deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

1. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. The department shall issue an out-of-state permit by endorsement to an applicant who, upon applying to the department and remitting a filing fee, set by the board, demonstrates to the board that the applicant satisfies the requirements of this chapter and holds a valid drug wholesale distributor license or permit from another state. An out-of state prescription drug wholesale distributor that holds a valid permit under this chapter on the effective date of this act may continue to operate under that permit until its expiration, after which the distributor may apply for a permit by endorsement as provided in this subparagraph.

2. An out-of-state prescription drug wholesale distributor

permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

Section 2. This act shall take effect July 1, 2012.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED ____ (Y/N)

ADOPTED AS AMENDED ____ (Y/N)

ADOPTED W/O OBJECTION ____ (Y/N)

FAILED TO ADOPT ____ (Y/N)

WITHDRAWN ____ (Y/N)

OTHER

Committee/Subcommittee hearing bill: Health & Human Services Quality Subcommittee

Representative Brandes offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsections (17), (19), (20) and (43) of section 499.003, Florida Statutes, are amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(17) "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense~~.~~, and it does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic

Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredient, but does not include devices or their components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish in a finished dosage form any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20) "Establishment" means a place of business which is at one general physical location, and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For

purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in Florida are also prescription drugs.

Section 2. Paragraphs (c) and (e) of subsection (2) of section 499.01, Florida Statutes, are amended, and subsection (3) of section 499.01, Florida Statutes, is created to read:

499.01 Permits.-

(2) The following permits are established:

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-

state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

~~3. A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the~~

~~active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredient under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredient that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).~~

(e) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the

department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

~~1.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

~~2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.~~

(3) Exemptions.-

(a) A permit issued under this part is not required to distribute prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in

preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval, Abbreviated New Drug Approval, New Animal Drug Approval, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the U.S. market for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by

rule, and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state intended for teaching, testing, research, and development shall bear a label prominently displaying the statement "Caution: Research, Teaching, or Testing Only - Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in

its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file a record of the FDA establishment registration number, if any; the resident state prescription drug wholesale distribution license, permit, or registration number; and a copy of the most recent resident state or FDA inspection report, for all distributors and establishments whom they purchase or receive prescription drugs under this subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs in or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days of receiving any product that is

misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection, which rules are necessary for the protection of the public health, safety, and welfare. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

Section 3. This act shall take effect on July 1, 2012.

T I T L E A M E N D M E N T

Remove the entire title and insert:

A bill to be entitled

an act relating to prescription drug wholesale regulations; amending s. 499.003, F.S.; revising the definitions of "distribute" or "distribution", "drug", "establishment", and "prescription drug"; amending s. 499.01, F.S.; deleting reference to exemption from nonresident prescription drug manufacturer permit in certain circumstances; deleting reference

Amendment No.

to exemption from out-of-state prescription drug wholesale distributor permit for intracompany sale or transfer of prescription drugs in certain circumstances; creating s. 499.01(3), F.S.; providing exemption from permit to distribute prescription drug active pharmaceutical ingredient in certain circumstances; requiring distributor claiming exemption under subsection to maintain valid license, permit or registration in state from which prescription drug was distributed; requiring compliance with recordkeeping requirements; exempting compliance with pedigree paper requirement; providing exemption from permit requirement for distribution of limited quantities of non-repackaged prescription drug for research and development or to a holder of a letter of exemption issued by the Department of Business and Professional Regulation for research, teaching, or testing; granting the Department of Business and Professional Regulation authority to define "limited quantities" and limited the number of transactions and amount of prescription drug distributed in the state; requiring a distributor claiming exemption under this subsection to maintain a valid license, permit, or registration in state from which the prescription drug was distributed; requiring all purchasers and recipients of prescription drugs to ensure products are not resold or used on humans except in lawful clinical trials and biostudies; requiring compliance with recordkeeping requirements; exempting from pedigree paper requirements; establishing labeling requirements for active pharmaceutical ingredient distributed in state for teaching, testing, research and development; exempting from out-of-state prescription drug wholesale distributor permit

requirement intracompany transaction or sale of prescription drug from out-of-state distributor to Florida distributor if using same business name; requiring compliance with recordkeeping and pedigree paper requirements; requiring recipient of prescription drug under exemption to maintain FDA registration number, resident state distributor license or permit number, and most recent resident state or FDA inspection report for all distributors who purchase or receive prescription drugs; confirming that persons claiming exemption under section must comply with part I of chapter 499, F.S.; requiring persons claiming exemption under section to make all records regarding prescription drug distribution available to Department of Business and Professional Regulation within 48 hours of request; requiring submission of a report of mishandled or adulterated prescription drugs within 14 days of receipt; granting rulemaking authority; making a failure to comply with law a violation of s. 499.005(14), F.S.; making a knowing failure to comply with law a violation of s. 499.0051(4), F.S.; stating that the section does not provide relief from all applicable federal and state laws to any person; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 787 Nursing Home Facilities
SPONSOR(S): Trujillo
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee		Guzzo	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill expands the ability of nursing homes to provide additional services to nonresidents of nursing home facilities. Currently, nursing homes must have a standard license, have no class I or class II deficiencies in the previous two years, or have been awarded a Gold Seal, to provide additional services like respite and adult day services. The bill allows all licensed nursing homes to provide additional services, without limitation based on prior deficiencies or recognition as a Gold Seal facility, including respite, adult day services, and therapeutic spa services.

The bill creates the following regulations and provisions for overnight respite care in nursing homes:

- Facilities must have a written abbreviated plan of care and a contract;
- Prospective respite care recipients must provide medical information to the facility;
- Respite care recipients may bring their medications from home if permitted by the facility; and
- Respite care recipients may reside in the facility for 60 days within a contract or calendar year, provided each stay does not exceed 14 consecutive days.

The bill adds to the list of professionals authorized to staff a geriatric outpatient clinic. Currently, geriatric outpatient clinics must be staffed by a registered nurse or a physician assistant. The bill allows a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician to staff a geriatric outpatient clinic.

The bill also removes the requirement for resident care plans to be signed by the director of nursing or another registered nurse employed by the facility. The resident care plan is written and developed by a registered nurse with participation from other staff and the resident, so the requirement for a signature is not necessary.

Currently, nursing home facilities that meet the following requirements are allowed to share programming and staff.

- Be a part of a continuing care facility or a retirement community that operates on a single campus;
- Have a standard license or have been awarded a Gold Seal; and
- Exceed the minimum required hours of licensed nursing and certified nursing assistant direct care;

Facilities that choose to do so must be able to demonstrate compliance with the minimum staffing ratios at the time of inspection and in the semiannual report. The bill eliminates the requirement to prove compliance with staffing ratios in the semiannual report. Facilities will still be required to demonstrate at the time of inspection that minimum staffing requirements are met. The bill also removes the requirement for the facility to be a Gold Seal facility to be able to share programming and staff.

The bill changes the sunset date for the certificate of need moratorium on new nursing home beds to allow the moratorium to last until October 1, 2016.

Finally, the bill allows nursing homes to use a portion of their sheltered nursing home beds to provide assisted living services without giving up their certificate of need for those beds. Current law allows for such flexibility, but the beds must be used to provide extended congregate care rather than standard assisted living care.

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

The bill provides an effective date of July1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Nursing Homes

Geriatric Outpatient Clinics

A geriatric outpatient clinic is a site for providing outpatient health care to individuals at least 60 years of age. Geriatric outpatient clinics must be staffed by a registered nurse, or a physician assistant.[1]

Resident Care Plans

A resident care plan is a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, with participation from other facility staff and the resident. The resident care plan must include the following:[2]

- A comprehensive assessment of the needs of a resident;
- The type and frequency of services required to provide the necessary care for the resident to attain or maintain the highest level of physical, mental, and psychosocial well-being;
- A list of services provided within or outside the facility to meet those needs; and
- An explanation of service goals.

The resident care plan is required to be signed by the director of nursing or another registered nurse employed by the facility and by the resident, the resident's designee, or the resident's legal representative.[3]

Shared Programming and Staff

Currently, nursing home facilities that meet the following requirements are allowed to share programming and staff.[4]

- Be a part of a continuing care facility or a retirement community that operates on a single campus;
- Have a standard license or have been awarded a Gold Seal; and
- Exceed the minimum required hours of licensed nursing and certified nursing assistant direct care;

If the above requirements are met, licensed nurses and certified nursing assistants who work in the facility may be used to provide services elsewhere on campus. Facilities that choose to do so must be able to demonstrate compliance with the minimum staffing ratios at the time of inspection and in the semiannual report.

Respite Care

Section 400.141(1)(f), F.S., allows nursing homes to provide other needed services, including, but not limited to, adult day services, and respite care for people needing short-term or temporary nursing

[1] S. 400.021(8), F.S.
[2] S. 400.021(16), F.S.
[3] *Id.*
[4] S. 400.141(1)(g), F.S.

home services. Respite care means admission to a nursing home for the purpose of providing a short period of rest, relief, or emergency alternative care for the primary caregiver of an individual receiving care at home who, without home-based care, would otherwise require institutional care.[5] Only nursing homes with standard licensure status with no Class I or Class II deficiencies in the past two years or having Gold Seal status may provide respite services. Respite care is required to be provided in accordance with rules adopted by the Agency for Health Care Administration (AHCA) and AHCA may modify requirements by rule for resident assessment, resident care plans, resident contracts, physician orders, and other provisions for short term or temporary nursing home services.

Moratorium on Nursing Home Certificates of Need

The certificate of need (CON) is a regulatory review process administered by AHCA which requires specified health care providers to obtain prior authorization before offering certain new or expanded services or making major capital expenditures. A "Certificate of Need" is defined as: "...a written statement issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice."

Florida's CON program has been in operation since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986.

Pursuant to s. 408.036, F.S., with certain limited exceptions, nursing homes in Florida are subject to CON. In addition to general criteria applicable to CON issuance, pursuant to s. 408.040, F.S., AHCA may issue a CON or exemption based upon a statement of intent from a nursing home. In doing so, AHCA may consider that a specified percentage of the annual patient days at a facility will be utilized by Medicaid recipients. AHCA's issuance of the CON to such nursing homes is issued as a condition of that utilization level, and any change in utilization level requires the certificate holder to seek a modification of conditions from AHCA. Failure to comply with these conditions can result in administrative fines against the certificate holder.

There is currently a moratorium on nursing home certificates of need. Section 408.0435(1), F.S., provides that additional certificates of need for community nursing home beds may not be approved by AHCA until Medicaid Managed Care is implemented statewide, or October 1, 2016, whichever is earlier. Section 409.971, F.S., requires AHCA to begin implementation of Medicaid Managed Care statewide by October 1, 2014.

Sheltered Beds

Section 651.118, F.S., contains provisions relating to AHCA's ability to issue certificates of need for sheltered nursing home beds. Sheltered nursing home beds are those for which a certificate of need has been issued to construct nursing home beds for the exclusive use of the prospective residents of the facility.[6]

Currently, AHCA allows sheltered nursing home beds to be used as extended congregate care beds.[7] Extended congregate care means assistance and care that is beyond that of personal services.[8] The beds must be in a distinct area of the nursing home which can be adapted to meet the requirements for extended congregate care.

[5] S. 400.021(15), F.S.
[6] S. 651.118(3), F.S.
[7] S. 651.118(8), F.S.
[8] S. 429.02(11), F.S.

Adult Day Care Services

Section 429.905(2), F.S., allows licensed assisted living facilities (ALFs), hospitals, and nursing homes to provide adult day care services during the day to adults who are not residents of the facility without being licensed as an adult day care center. AHCA is required to monitor the facility during the regular inspection and at least biennially to ensure adequate space and sufficient staff is provided. However, if an ALF, hospital, or nursing home holds itself out to the public as an adult day care center, it must be licensed as such.

Section 429.901, F.S., defines "adult day care center" as providing basic services, *for a part of the day*, to three or more individuals who are at least 18 years of age, who are not related to the owner or operator by blood or marriage, and who require such services. Currently, AHCA interprets the provision of day care services to be services rendered during a *business* day.[9] Rule 58A-6.002, F.A.C., defines "daily attendance" as the number of participants who, during any one *calendar or business day*, attend the center. According to AHCA, they have informed the public, and denied request for centers wishing to provide services during late-night hours.[10]

Effect of Proposed Changes

Nursing Homes

Geriatric Outpatient Clinics

The bill adds to the list of professionals authorized to staff a geriatric outpatient clinic. Currently, geriatric outpatient clinics must be staffed by a registered nurse or a physician assistant. The bill allows a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician to staff a geriatric outpatient clinic.

Resident Care Plans

The bill removes the requirement for resident care plans to be signed by the director of nursing or another registered nurse employed by the facility. The resident care plan is written and developed by a registered nurse with participation from other staff and the resident.

Shared Programming and Staff

Facilities that choose to share programming and staff are required to prove compliance with minimum staffing requirements at the time of inspection and in the semiannual report. The bill eliminates the requirement to prove compliance with staffing requirements in the semiannual report. Facilities will still be required to demonstrate at the time of inspection that minimum staffing requirements are met. The bill also removes the requirement for the facility to be a Gold Seal facility to be able to share programming and staff. This will allow more facilities with a standard license to participate in shared staffing and be able to move staff to areas where they feel they are needed, provided they are in compliance with the minimum staffing requirements.

Respite Care

The bill amends s. 400.141, F.S., to expand the ability of nursing homes to provide additional services to nonresidents of nursing home facilities.

Currently, nursing homes must have a standard license, have no class I or class II deficiencies in the previous two years, or have been awarded a Gold Seal to provide additional services including, but not limited to, respite, and adult day services. The bill allows all licensed nursing homes to provide additional services without limitation based on prior deficiencies or recognition as a Gold Seal facility.

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[9] AHCA, *Staff Analysis and Economic Impact, House Bill Number 787* (January 28, 2012); Rule 58A-6.002(g), F.A.C.
[10] *Id.*

As a result, more facilities with a standard license will have the opportunity to provide these services to clients.

In addition to respite, and adult day services the bill allows for the provision of therapeutic spa services, and defines such services to mean bathing, nail, hair care, and other similar services related to personal hygiene.

The bill creates s. 400.172, F.S., to include the following regulations and provisions for overnight respite care in nursing homes:

- Requires facilities to have a written abbreviated plan of care and a contract;
- Requires prospective respite care recipients to provide medical information to the facility;
- Allows respite care recipients to bring their medications from home if permitted by the facility; and
- Allows respite care recipients to reside in the facility for 60 days within a contract or calendar year, provided each stay does not exceed 14 consecutive days.

Moratorium on Nursing Home Certificates of Need

The bill changes the sunset date for the certificate of need moratorium on new nursing home beds to the date that Medicaid Managed Care is implemented statewide or October 1, 2016, whichever is later.

Sheltered Beds

The bill amends s. 651.118(8), F.S., to allow sheltered beds to be used not only to provide extended congregate care, but standard and limited nursing services as well. This will result in nursing homes being able to utilize their sheltered beds to provide care to individuals with various levels of acuity.

Adult Day Care Services

The bill amends s. 429.905(2), F.S., defining the term "day" as any portion of a 24-hour day. As a result, ALFs, hospitals and nursing homes will be able to provide adult day services at any time during a 24-hour day. According to AHCA, adult day care centers are inspected during day-time hours.[11] The change will also require inspections of centers and facilities during non-daytime hours, including evenings and weekends. AHCA currently inspects various facility types during evening and weekend hours, but this would require inspections during the hours these facilities choose to perform such services.

B. SECTION DIRECTORY:

Section 1: Amends s. 400.021, F.S., relating to geriatric outpatient clinics, resident care plans, and therapeutic spa services.
Section 2: Amends s. 400.141, F.S., relating to administration and management of nursing home facilities.
Section 3: Creates s. 400.172, F.S., relating to respite care provided in nursing home facilities.
Section 4: Amends s. 400.141, F.S., relating to administration and management of nursing homes.
Section 5: Amends s. 408.0435, F.S., relating to the moratorium on nursing home certificates of need.
Section 6: Amends s. 429.905, F.S., relating to exemptions; monitoring of adult day care center programs collocated with assisted living facilities or licensed nursing home facilities.
Section 7: Amends s. 651.118, F.S., relating to the Agency for Health Care Administration; certificates of need; sheltered beds; and community beds.
Section 8: Provides an effective date of July 1, 2012.

[11] AHCA, *Staff Analysis and Economic Impact, House Bill Number 787* (January 28, 2012).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Sections 2 and 4 of the bill both amend s. 400.141(1), F.S. The provisions of section 4 need to be added to section 2 of the bill.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to nursing home facilities; amending s. 400.021, F.S.; revising definitions of the terms "geriatric outpatient clinic" and "resident care plan" and defining the term "therapeutic spa services"; amending s. 400.141, F.S.; revising provisions relating to facilities eligible to share programming and staff; deleting requirements for the submission of certain reports to the Agency for Health Care Administration; creating s. 400.172, F.S.; providing requirements for a nursing home facility operated by a licensee that provides respite care services; providing for rights of persons receiving respite care in nursing home facilities; requiring a prospective respite care recipient to provide certain information to the nursing home facility; amending s. 400.141, F.S.; revising provisions relating to other needed services provided by licensed nursing home facilities, including respite care, adult day, and therapeutic spa services; amending s. 408.0435, F.S.; revising the period of time allotted for approval of the nursing home moratorium on a certificate of need for additional community nursing home beds; amending s. 429.905, F.S.; defining the term "day" for purposes of day care services provided to adults who are not residents; amending s. 651.118, F.S.; providing a funding limitation on sheltered nursing home beds used to provide assisted living, rather than extended

congregate care services; authorizing certain sharing of areas, services, and staff between such sheltered beds and nursing home beds in those facilities; providing an effective date.

WHEREAS, the Legislature recognizes that the use of nursing homes has decreased over the past decade because of alternatives that are now available to consumers, and

WHEREAS, nursing homes continue to be a valuable resource and should be used to the fullest extent possible to provide traditional nursing care to the most impaired persons as well as providing services to frail or disabled persons who choose to remain in the community or who may need a less skilled level of care, and

WHEREAS, regulatory requirements should be flexible enough to allow nursing homes to diversify but continue to include sufficient protections to ensure the best care possible to consumers, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (8) and (16) of section 400.021, Florida Statutes, are amended, and subsection (19) is added to that section, to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(8) "Geriatric outpatient clinic" means a site for providing outpatient health care to persons 60 years of age or

older, which is staffed by a registered nurse, ~~or~~ a physician assistant, or a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician.

(16) "Resident care plan" means a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, with participation from other facility staff and the resident or his or her designee or legal representative, which includes a comprehensive assessment of the needs of an individual resident; the type and frequency of services required to provide the necessary care for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being; a listing of services provided within or outside the facility to meet those needs; and an explanation of service goals. ~~The resident care plan must be signed by the director of nursing or another registered nurse employed by the facility to whom institutional responsibilities have been delegated and by the resident, the resident's designee, or the resident's legal representative. The facility may not use an agency or temporary registered nurse to satisfy the foregoing requirement and must document the institutional responsibilities that have been delegated to the registered nurse.~~

(19) "Therapeutic spa services" means bathing, nail, and hair care services and other similar services related to personal hygiene.

Section 2. Paragraph (g) of subsection (1) of section 400.141, Florida Statutes, is amended to read:

400.141 Administration and management of nursing home

facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(g) If the facility has a standard license ~~or is a Gold Seal facility~~, exceeds the minimum required hours of licensed nursing and certified nursing assistant direct care per resident per day, and is part of a continuing care facility licensed under chapter 651 or a retirement community that offers other services pursuant to part III of this chapter or part I or part III of chapter 429 on a single campus, be allowed to share programming and staff. At the time of inspection ~~and in the semiannual report required pursuant to paragraph (o)~~, a continuing care facility or retirement community that uses this option must demonstrate through staffing records that minimum staffing requirements for the facility were met. Licensed nurses and certified nursing assistants who work in the ~~nursing home~~ facility may be used to provide services elsewhere on campus if the facility exceeds the minimum number of direct care hours required per resident per day and the total number of residents receiving direct care services from a licensed nurse or a certified nursing assistant does not cause the facility to violate the staffing ratios required under s. 400.23(3)(a). Compliance with the minimum staffing ratios must ~~shall~~ be based on the total number of residents receiving direct care services, regardless of where they reside on campus. If the facility receives a conditional license, it may not share staff until the conditional license status ends. This paragraph does not restrict the agency's authority under federal or state law to

require additional staff if a facility is cited for deficiencies in care which are caused by an insufficient number of certified nursing assistants or licensed nurses. The agency may adopt rules for the documentation necessary to determine compliance with this provision.

Section 3. Section 400.172, Florida Statutes, is created to read:

400.172 Respite care provided in nursing home facilities.—

(1) For each person admitted for respite care as authorized under s. 400.141(1)(f), a nursing home facility operated by a licensee must:

(a) Have a written abbreviated plan of care that, at a minimum, includes nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. The nursing or physician assessments may take the place of all other assessments required for full-time residents.

(b) Have a contract that, at a minimum, specifies the services to be provided to a resident receiving respite care, including charges for services, activities, equipment, emergency medical services, and the administration of medications. If multiple admissions for a single person for respite care are anticipated, the original contract is valid for 1 year after the date the contract is executed.

(c) Ensure that each resident is released to his or her caregiver or an individual designated in writing by the caregiver.

(2) A person admitted under the respite care program shall:

(a) Be exempt from department rules relating to the discharge planning process.

(b) Be covered by the residents' rights specified in s. 400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident are not be considered trust funds subject to the requirements of s. 400.022(1)(h) until the resident has been in the facility for more than 14 consecutive days.

(c) Be allowed to use his or her personal medications during the respite stay if permitted by facility policy. The facility must obtain a physician's order for the medications. The caregiver may provide information regarding the medications as part of the nursing assessment and that information must agree with the physician's order. Medications shall be released with the resident upon discharge in accordance with current physician's orders.

(d) Be entitled to reside in the facility for a total of 60 days within a contract year or for a total of 60 days within a calendar year if the contract is for less than 12 months. However, each single stay may not exceed 14 days. If a stay exceeds 14 consecutive days, the facility must comply with all assessment and care planning requirements applicable to nursing home residents.

(e) Reside in a licensed nursing home bed.

(3) A prospective respite care resident must provide medical information from a physician, physician assistant, or nurse practitioner and any other information provided by the primary caregiver required by the facility before or when the person is admitted to receive respite care. The medical

information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician assistant, or nurse practitioner. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

(4) The facility shall assume the duties of the primary caregiver. To ensure continuity of care and services, the resident may retain his or her personal physician and shall have access to medically necessary services such as physical therapy, occupational therapy, or speech therapy, as needed. The facility shall arrange for transportation of the resident to these services, if necessary.

Section 4. Paragraph (f) of subsection (1) of section 400.141, Florida Statutes, is amended to read:

400.141 Administration and management of nursing home facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(f) Be allowed and encouraged by the agency to provide other needed services under certain conditions. If the facility has a standard licensure status, ~~and has had no class I or class II deficiencies during the past 2 years or has been awarded a Gold Seal under the program established in s. 400.235,~~ it may ~~be encouraged by the agency to~~ provide services, including, but not limited to, respite, therapeutic spa, and adult day services to nonresidents~~, which enable individuals to move in and out~~ of the facility. A facility is not subject to any additional licensure

requirements for providing these services. Respite care may be offered to persons in need of short-term or temporary nursing home services. Respite care must be provided in accordance with this part ~~and rules adopted by the agency. However, the agency shall, by rule, adopt modified requirements for resident assessment, resident care plans, resident contracts, physician orders, and other provisions, as appropriate, for short-term or temporary nursing home services~~. Providers of adult day services must comply with the requirements of s. 429.905(2). The agency shall allow for shared programming and staff in a facility which meets minimum standards and offers services pursuant to this paragraph, but, if the facility is cited for deficiencies in patient care, may require additional staff and programs appropriate to the needs of service recipients. A person who receives respite care may not be counted as a resident of the facility for purposes of the facility's licensed capacity unless that person receives 24-hour respite care. A person receiving either respite care for 24 hours or longer or adult day services must be included when calculating minimum staffing for the facility. Any costs and revenues generated by a nursing home facility from nonresidential programs or services shall be excluded from the calculations of Medicaid per diems for nursing home institutional care reimbursement.

Section 5. Subsection (1) of section 408.0435, Florida Statutes, is amended to read:

408.0435 Moratorium on nursing home certificates of need.—

(1) Notwithstanding the establishment of need as provided for in this chapter, a certificate of need for additional

community nursing home beds may not be approved by the agency until Medicaid managed care is implemented statewide pursuant to ss. 409.961-409.985 or October 1, 2016, whichever is later ~~earlier~~.

Section 6. Subsection (2) of section 429.905, Florida Statutes, is amended to read:

429.905 Exemptions; monitoring of adult day care center programs colocated with assisted living facilities or licensed nursing home facilities.—

(2) A licensed assisted living facility, a licensed hospital, or a licensed nursing home facility may provide services during the day which include, but are not limited to, social, health, therapeutic, recreational, nutritional, and respite services, to adults who are not residents. Such a facility need not be licensed as an adult day care center; however, the agency must monitor the facility during the regular inspection and at least biennially to ensure adequate space and sufficient staff. If an assisted living facility, a hospital, or a nursing home holds itself out to the public as an adult day care center, it must be licensed as such and meet all standards prescribed by statute and rule. For the purpose of this subsection, the term "day" means any portion of a 24-hour day.

Section 7. Subsection (8) of section 651.118, Florida Statutes, is amended to read:

651.118 Agency for Health Care Administration; certificates of need; sheltered beds; community beds.—

(8) A provider may petition the Agency for Health Care Administration to use a designated number of sheltered nursing

home beds to provide assisted living ~~extended congregate care as defined in s. 429.02~~ if the beds are in a distinct area of the nursing home which can be adapted to meet the requirements for an assisted living facility as defined in s. 429.02 ~~extended congregate care~~. The provider may subsequently use such beds as sheltered beds after notifying the agency of the intended change. Any sheltered beds used to provide assisted living ~~extended congregate care~~ pursuant to this subsection may not qualify for funding under the Medicaid waiver. Any sheltered beds used to provide assisted living ~~extended congregate care~~ pursuant to this subsection may share common areas, services, and staff with beds designated for nursing home care, provided that all of the beds are under common ownership. For the purposes of this subsection, fire and life safety codes applicable to nursing home facilities shall apply.

Section 8. This act shall take effect July 1, 2012.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health & Human Services Quality Subcommittee

Representative Trujillo offered the following:

Amendment (with title amendment)

Remove lines 220-228

T I T L E A M E N D M E N T

Remove lines 20-23 and insert:

services; amending s.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 935 Child Support Enforcement
SPONSOR(S): Civil Justice Subcommittee; Baxley
TIED BILLS: None **IDEN./SIM. BILLS:** SB 1342

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Civil Justice Subcommittee	11 Y, 0 N, As CS	Caridad	Bond
2) Health & Human Services Quality Subcommittee		Mathieson	Calamas
3) Government Operations Appropriations Subcommittee			
4) Judiciary Committee			

SUMMARY ANALYSIS

Child support enforcement is a federally funded program that has been administered by the Department of Revenue (DOR) since 1994. A "Title IV-D case" is defined as any case in which the child support enforcement agency is enforcing the child support order pursuant to Title IV-D of the Social Security Act. To remain eligible for the Temporary Assistance for Needy Families (TANF) Block Grant, Florida must have a federally compliant child support program, meaning the state's program must provide certain services such as enforcement of child support orders. Statute provides DOR with alternative means of enforcing such orders, including suspension of an obligor's driver license.

The House Bill 935:

- Provides that an obligor's license will not be suspended if the obligor pays the delinquency through income deduction;
- Authorizes DOR to send notices to a garnishee by secure e-mail or facsimile upon consent by the garnishee;
- Requires the Chief Financial Officer (CFO) and DOR work together to establish an automated method for identifying individuals doing business with the state and owe overdue support so that support payments may be withheld by the state;
- Makes changes related to the use of unclaimed property for payment of past due support; and
- Authorizes DOR to place an administrative lien on certain claims, judgments, and property.

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

The bill provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Child support enforcement is a federally funded program that has been administered by the Department of Revenue (DOR) since 1994.[1] A "Title IV-D case" is defined as any case in which the child support enforcement agency is enforcing the child support order pursuant to Title IV-D of the Social Security Act.[2] DOR provides services under the federally required program in 65 counties and through contracts in two counties.[3]

DOR is responsible for some case-processing activities including opening and closing cases; collecting and maintaining case, location, and financial data; and receiving and responding to verbal and written inquiries. To remain eligible for the Temporary Assistance for Needy Families (TANF) Block Grant,[4] Florida must have a federally compliant child support program.[5] The program must contain the following services:

- Paternity establishment;
- Support order establishment;
- Support order review and modification;
- Location of parents, employers, assets;
- Payment collection and disbursement; and
- Order enforcement.

In Florida, DOR establishes the initial child support order and modifies existing orders when a family's circumstances change.

DOR utilizes various statutory resources in its attempt to collect past due child support. For instance, DOR may suspend the obligor's driver's license. Pursuant to s. 61.13016, F.S., a person (the obligor) who is 15 days delinquent in paying child support may have his or her driver's license suspended after notice and an opportunity for a hearing in circuit court. The obligor may avoid suspension by paying the full amount of the delinquency, entering into a written agreement with DOR to pay the past due amount, or filing a petition in circuit court to contest suspension.[6] Although not provided for in statute, DOR also allows an obligor to begin paying a delinquent support order by income deduction in order to avoid license suspension.

If a person has a support obligation subject to enforcement by DOR, the department may inform all persons with credits or personal property (i.e. wages) belonging to the obligor under their control to not transfer any of the credits or personal property up to the amount listed in the notice, without DOR consent.[7]

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[1] Florida Department of Revenue, http://dor.myflorida.com/dor/childsupport/about_us.html (last visited Jan. 27, 2012).
[2] *See,* 42 U.S.C. ss. 651-669b *et seq.*
[3] *Id.* Miami-Dade County cases are handled by the state attorney's office, and Manatee County cases are handled by the clerk of court.
[4] TANF is a block grant program to help move recipients into work and turn welfare into a program of temporary assistance. Under the welfare reform legislation of 1996, TANF replaced the old welfare programs known as the Aid to Families with Dependent Children (AFDC) program, the Job Opportunities and Basic Skills Training (JOBS) program, and the Emergency Assistance (EA) program. The law ended Federal entitlement to assistance and instead created TANF as a block grant that provides States, Territories, and Tribes Federal funds each year. These funds cover benefits and services targeted to needy families. U.S. Dep't of Health and Human Servs., http://www.acf.hhs.gov/opa/fact_sheets/tanf_factsheet.html (last visited Jan. 27, 2012).
[5] S. 61.1826(1)(d), F.S.
[6] S. 61.13016(1)(c), F.S.
[7] S. 409.25656(1), F.S.

Under current law, DOR must provide notice to the Chief Financial Officer (CFO) identifying the obligor and the amount of support outstanding. The CFO must then withhold all payments to any obligor who provides commodities or services to the state, leases real property to the state, or constructs a public building or public work for the state. DOR may then levy upon the withheld payments.[8]

Effect of Proposed Changes

This bill amends Florida law relating to child support enforcement. Specifically, the bill:

- Allows an obligor to pay any delinquency in child support through income deduction so as to avoid suspension of his or her license;
- Provides that if the garnishee provides written consent, the department may send notices to the garnishee by secure e-mail or facsimile;
- Requires the CFO and DOR to establish an automated method for disclosing to DOR the names of individuals doing business with the state who owe past due support so the state may withhold payments owed to such individuals;[9]

Current law authorizes DOR to intercept unclaimed property for payment of past due support once DFS approves a claim. When a claim is approved, DOR notifies the obligor by certified mail of the intent to intercept the claim up to the amount of past-due support owed. The obligor is also notified of his or her right to contest the action at an administrative hearing pursuant to ch. 120, F.S. If there is a hearing and the action is sustained, DOR enters a final order directing DFS to transfer the property to DOR. DOR is required to enter final orders in all cases, even when the action is uncontested.

The bill provides that:

- If a claim for unclaimed property is approved by DFS, DOR shall send a notice by certified mail to the obligor at the address provided by the obligor to DFS, advising the obligor of the department's intent to intercept the approved claim.
- DFS must retain custody of the property until a final order has been entered and any appeals have concluded or, if the intercept is uncontested, until notified by DOR;
- If an obligor does not request a hearing, DOR must notify DFS, electronically or in writing, to transfer the property to the department;
- Eliminates the requirement for DOR to enter a final order when the obligor does not contest the action.

Under current law, DOR may place an administrative lien on a motor vehicle or vessel that is registered in the name of an obligor who is delinquent in support payments, "if the title to the property is held by a lienholder."[10] The statute does not authorize DOR to place a lien on property owned "free and clear" by the obligor.

The bill authorizes DOR to place an administrative lien for unpaid support on a motor vehicle or vessel, even if owned free and clear by the obligor, and upon a claim, settlement, or judgment that may result in payment to the obligor. The bill further provides that DOR must notify the obligor of the intent to place a lien by regular mail sent to the obligor's address on file with the depository. The notice must state the amount of past due support owed and inform the obligor of the right to contest the lien at an administrative hearing.

[8] S. 409.25656(10), F.S.

[9] Under current law, DOR provides to the CFO a listing of obligors for whom warrants are outstanding. The CFO then withholds all payments to any obligor doing business with the state and DOR may levy upon the withheld payments. The change made by this bill essentially reverses this method, so that the CFO is disclosing to the department a file of individuals to whom the state pays money.

[10] S. 409.2575(1), F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 61.13016, F.S., relating to suspension of driver licenses and motor vehicle registrations.
Section 2: Amends s. 322.058, F.S., relating to suspension of driving privileges due to support delinquency.
Section 3: Amends s. 409.25656, F.S., relating to garnishment.
Section 4: Amends s. 409.25658, F.S., relating to uses of unclaimed property for past due support.
Section 5: Amends s. 409.2575, F.S., relating to administrative liens.
Section 6: Provides for an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not appear to have any impact on state revenues.

2. Expenditures:

   The bill does not appear to have any impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not appear to have any impact on local government revenues.

2. Expenditures:

   The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill does not appear to have any direct economic impact on the private sector.

D. FISCAL COMMENTS:

According to DOR, its procedures must be modified to implement the changes made by this bill. However, the department expects that any operational impact of the bill will be insignificant.[11]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to create a need for rulemaking or rulemaking authority.

[11] Dep't of Revenue, 2012 Bill Analysis, HB 935, p. 5 (Dec. 16, 2011) (on file with the House Civil Justice Subcommittee).

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 25, 2012, the Civil Justice Subcommittee adopted a PCS. The CS/HB 935 differs from the bill as filed in that the PCS:

- Removed provisions that would have allowed service of process by regular mail.
- Removed a provision that would have allowed any caregiver of a child to execute an affidavit alleging paternity of a child.

This analysis is drafted to the committee substitute as passed by the Civil Justice Subcommittee.

A bill to be entitled

An act relating to child support enforcement; amending s. 61.13016, F.S.; providing that a child support obligor may avoid the suspension of his or her driver license and motor vehicle registration by beginning to pay his or her obligation by income deduction within a specified period; amending s. 322.058, F.S.; providing that a child support obligor may avoid the suspension of his or her driver license and motor vehicle registration by beginning to pay his or her obligation by income deduction within a specified period; amending s. 409.25656, F.S.; providing that a garnishee may consent to receive certain notices by secure e-mail or fax; requiring establishment of an automated method for the Chief Financial Officer to periodically provide the Department of Revenue an electronic file of individuals to whom the state pays money for goods or services or who lease real property to the state; requiring garnishment of such payments for past due or overdue support; deleting provisions requiring the Department of Revenue to provide certain information to the Chief Financial Officer for such purpose; amending s. 409.25658, F.S.; revising provisions concerning use of unclaimed property for collection of past due support; amending s. 409.2575, F.S.; revising language concerning who may cause certain liens to be placed for unpaid and delinquent support; authorizing liens on a claim, settlement, or

judgment that may result in payment to the obligor; providing for notice to the obligor; providing requirements for such notice; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1), paragraph (a) of subsection (2), and subsection (3) of section 61.13016, Florida Statutes, are amended to read:

61.13016 Suspension of driver ~~driver's~~ licenses and motor vehicle registrations.—

(1) The driver ~~driver's~~ license and motor vehicle registration of a support obligor who is delinquent in payment or who has failed to comply with subpoenas or a similar order to appear or show cause relating to paternity or support proceedings may be suspended. When an obligor is 15 days delinquent making a payment in support or failure to comply with a subpoena, order to appear, order to show cause, or similar order in IV-D cases, the Title IV-D agency may provide notice to the obligor of the delinquency or failure to comply with a subpoena, order to appear, order to show cause, or similar order and the intent to suspend by regular United States mail that is posted to the obligor's last address of record with the Department of Highway Safety and Motor Vehicles. When an obligor is 15 days delinquent in making a payment in support in non-IV-D cases, and upon the request of the obligee, the depository or the clerk of the court must provide notice to the obligor of the

delinquency and the intent to suspend by regular United States mail that is posted to the obligor's last address of record with the Department of Highway Safety and Motor Vehicles. In either case, the notice must state:

(a) The terms of the order creating the support obligation;

(b) The period of the delinquency and the total amount of the delinquency as of the date of the notice or describe the subpoena, order to appear, order to show cause, or other similar order that ~~which~~ has not been complied with;

(c) That notification will be given to the Department of Highway Safety and Motor Vehicles to suspend the obligor's driver ~~driver's~~ license and motor vehicle registration unless, within 20 days after the date the notice is mailed, the obligor:

1.a. Pays the delinquency in full and any other costs and fees accrued between the date of the notice and the date the delinquency is paid;

b. Enters into a written agreement for payment with the obligee in non-IV-D cases or with the Title IV-D agency in IV-D cases; or in IV-D cases, complies with a subpoena or order to appear, order to show cause, or a similar order; ~~or~~

c. Files a petition with the circuit court to contest the delinquency action; or ~~and~~

d. Begins paying the delinquency by income deduction; and

2. Pays any applicable delinquency fees.

If the obligor in non-IV-D cases enters into a written agreement for payment before the expiration of the 20-day period, the

obligor must provide a copy of the signed written agreement to the depository or the clerk of the court.

(2)(a) Upon petition filed by the obligor in the circuit court within 20 days after the mailing date of the notice, the court may, in its discretion, direct the department to issue a license for driving privileges restricted to business purposes only, as defined by s. 322.271, if the person is otherwise qualified for such a license. As a condition for the court to exercise its discretion under this subsection, the obligor must agree to a schedule of payment on any child support arrearages and to maintain current child support obligations. If the obligor fails to comply with the schedule of payment, the court shall direct the Department of Highway Safety and Motor Vehicles to suspend the obligor's driver ~~driver's~~ license.

(3) If the obligor does not, within 20 days after the mailing date on the notice, pay the delinquency; ~~,~~ enter into a written ~~payment~~ agreement; ~~,~~ comply with the subpoena, order to appear, order to show cause, or other similar order; begin paying the delinquency by income deduction; ~~,~~ or file a motion to contest, the Title IV-D agency in IV-D cases, or the depository or clerk of the court in non-IV-D cases, may ~~shall~~ file the notice with the Department of Highway Safety and Motor Vehicles and request the suspension of the obligor's driver ~~driver's~~ license and motor vehicle registration in accordance with s. 322.058.

Section 2. Subsections (1) and (2) of section 322.058, Florida Statutes, are amended to read:

322.058 Suspension of driving privileges due to support delinquency; reinstatement.—

(1) When the department receives notice from the Title IV-D agency or depository or the clerk of the court that any person licensed to operate a motor vehicle in the State of Florida under the provisions of this chapter has a delinquent support obligation or has failed to comply with a subpoena, order to appear, order to show cause, or similar order, the department shall suspend the driver ~~driver's~~ license of the person named in the notice and the registration of all motor vehicles owned by that person.

(2) The department must reinstate the driving privilege and allow registration of a motor vehicle when the Title IV-D agency in IV-D cases or the depository or the clerk of the court in non-IV-D cases provides to the department an affidavit stating that:

(a) The person has paid the delinquency;

(b) The person has reached a written agreement for payment with the Title IV-D agency or the obligee in non-IV-D cases;

(c) A court has entered an order granting relief to the obligor ordering the reinstatement of the license and motor vehicle registration; ~~or~~

(d) The person has complied with the subpoena, order to appear, order to show cause, or similar order; or

(e) The obligor is paying the delinquency by income deduction.

Section 3. Subsections (4) and (10) of section 409.25656, Florida Statutes, are amended to read:

409.25656 Garnishment.—

(4) A notice that is delivered under this section is effective at the time of delivery against all credits, other personal property, or debts of the obligor which are not at the time of such notice subject to an attachment, garnishment, or execution issued through a judicial process. Upon the garnishee's written consent, the department may send notices to the garnishee by secure e-mail or fax.

(10) The Chief Financial Officer shall work cooperatively with the department to establish an automated method for periodically disclosing to the department an electronic file of individuals to whom the state pays money for goods or services or who lease real property to the state. The department shall use the data provided to identify individuals who owe past due or overdue support and may garnish payments owed to such individuals by the state as provided in this section ~~The department shall provide notice to the Chief Financial Officer, in electronic or other form specified by the Chief Financial Officer, listing the obligors for whom warrants are outstanding. Pursuant to subsection (1), the Chief Financial Officer shall, upon notice from the department, withhold all payments to any obligor who provides commodities or services to the state, leases real property to the state, or constructs a public building or public work for the state. The department may levy upon the withheld payments in accordance with subsection (3)~~. Section 215.422 does not apply from the date the notice is filed with the Chief Financial Officer until the date the department notifies the Chief Financial Officer of its consent to make

payment to the person or 60 days after receipt of the department's notice in accordance with subsection (1), whichever occurs earlier.

Section 4. Subsections (1) and (4) of section 409.25658, Florida Statutes, are amended to read:

409.25658 Use of unclaimed property for past due support.—

(1) In a joint effort to facilitate the collection and payment of past due support, the Department of Revenue, in cooperation with the Department of Financial Services, shall identify persons owing support collected by the department ~~through a court~~ who are presumed to have unclaimed property held by the Department of Financial Services.

(4) Before ~~Prior to~~ paying an obligor's approved claim, the Department of Financial Services shall notify the department that the ~~such~~ claim has been approved. Upon confirmation that the Department of Financial Services has approved the claim, the department shall immediately send a notice by certified mail to the obligor at the address provided by the obligor to the Department of Financial Services, with a copy to the Department of Financial Services, advising the obligor of the department's intent to intercept the approved claim up to the amount of the past due support, and informing the obligor of the obligor's right to request a hearing under chapter 120. The Department of Financial Services shall retain custody of the property until a final order has been entered and any appeals thereon have been concluded, or, if the intercept is uncontested, until notified by the department. If the obligor fails to request a hearing, the department shall notify ~~enter a final order instructing~~ the

Department of Financial Services, electronically or in writing, to transfer to the department the property in the amount stated in the notice or electronic file ~~final order~~. Upon ~~such~~ transfer, the Department of Financial Services shall be released from further liability related to the transferred property.

Section 5. Section 409.2575, Florida Statutes, is amended to read:

409.2575 Administrative liens ~~on motor vehicles and vessels~~.—

(1) The department ~~director of the state IV-D program, or the director's designee,~~ may cause a lien for unpaid and delinquent support to be placed upon motor vehicles, as defined in chapter 320, ~~and~~ upon vessels, as defined in chapter 327, that are registered in the name of an obligor who is delinquent in support payments~~, if the title to the property is held by a lienholder,~~ in the manner provided in chapter 319 or chapter 328, and upon a claim, settlement, or judgment that may result in payment to the obligor. The department shall notify the obligor of the intent to place a lien by certified mail sent to the obligor's address of record on file with the depository. The notice must state the amount of past due support owed and inform the obligor of the right to contest the lien at an administrative hearing as provided by chapter 120. Notice of lien shall not be mailed unless the delinquency in support exceeds $600.

(2) If the first lienholder fails, neglects, or refuses to forward the certificate of title to the appropriate department as requested pursuant to s. 319.24 or s. 328.15, the department

~~director of the IV-D program, or the director's designee,~~ may apply to the circuit court for an order to enforce the requirements of s. 319.24 or s. 328.15, whichever applies.

Section 6. This act shall take effect July 1, 2012.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1019 Treatment Programs for Impaired Professionals
SPONSOR(S): Renuart
TIED BILLS: **IDEN./SIM. BILLS:** SB 1286

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee		Holt	Calamas
2) Business & Consumer Affairs Subcommittee			
3) Appropriations Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Currently, health care practitioners who are impaired as a result of drug or alcohol, abuse, or because of mental or physical conditions which could affect their ability to practice with skill and safety, are eligible for services provided by the impaired practitioner treatment program (program). By entering and successfully completing the impaired practitioner treatment program, a practitioner may avoid formal disciplinary action. Currently, the Department of Health (DOH) contacts with the Professionals Resource Network (PRN) to provide program services to impaired health care practitioners. In Fiscal Year 2010-2011, there were a total of 2,867 participants in the program at a cost of $1,166 per participant.

The bill expands the eligibility criteria for the program to all professions regulated by the Department of Business and Professional Regulation (at the DBPR's discretion), emergency medical technicians, radiologic technologists, and all students enrolled in a school that leads to licensure as a health care practitioner or a veterinarian. Currently, the DOH contract with PRN provides covered services to all legislatively-added health care professions, radiology technologists and student, thus mitigating the fiscal impact until the contract is renegotiated in 2013.

Current law requires the Department of Financial Services (DFS), Division of Risk Management to defend certain lawsuits related to the program. The bill expands the types of lawsuits DFS is required to defend. DFS will be required to represent a claim, suit, action, or proceeding that seeks injunctive, affirmative or declaratory relief against a consultant, the consultant's officers or employees, or individuals acting at the direction of a consultant for the limited purpose of emergency intervention.

Lastly, the bill establishes the custodian of treatment records, clarifies that a program consultant may employ a medical director or a nurse as the executive director, and specifies that the director does not have to possess a license as a substance abuse provider or a mental health provider if the entity hires appropriately trained staff to provide the treatment or evaluation of an impaired individual.

The bill will have a significant negative recurring impact to the Medical Quality Assurance Trust Fund within the Department of Health (*See* Fiscal Analysis).

The bill provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Healthcare Professions

Department of Health (DOH) regulates most health care professions, and each profession has an individual practice act that licensees are required to abide by. Ch. 456 provides general provisions for all health care practitioners within the Division of Medical Quality Assurance (MQA) in the DOH.

Section 456.001(4), F.S., defines "health care practitioner" to mean any person licensed under: ch. 457, F.S., (acupuncture); ch. 458, F.S., (medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathic medicine); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); parts I, II, III, V, X, XIII, and XIV of ch. 468, F.S., (speech-language pathology and audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrology or electrolysis); ch. 480, F.S., (massage therapy); parts III and IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S., (opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (psychology); and ch. 491, F.S. (psychotherapy).

This definition does not include emergency medical technicians, paramedics[1] or radiology technologists[2] and thus these professions are not governed by ch. 456, F.S, and are not within MQA.

The Impaired Practitioner Program – Department of Health

The impaired practitioner treatment program (program) was created to help rehabilitate health care practitioners regulated by the MQA, within the DOH.[3] Health care practitioners (practitioners) who are impaired as a result of drugs or alcohol, abuse, or because of mental or physical conditions, which could affect their ability to practice with skill and safety are eligible for the program.[4] By entering and successfully completing the impaired practitioner treatment program, a practitioner may avoid formal disciplinary action, if the only violation of the licensing statute under which the practitioner is regulated is the impairment.[5] If the practitioner is unable to complete the program, DOH has authority to issue an emergency order suspending or restricting the license practitioner.[6]

DOH is authorized[7] to contract with impaired practitioner consultants for services relating to intervention, evaluation, referral, and monitoring of impaired practitioners who have voluntarily agreed to treatment through a program.[8] The cost of the actual treatment is the responsibility of the impaired person. Currently, there are two vendors under contract with DOH to support the program: the Intervention Project for Nurses (IPN)[9] and the Professionals Resource Network (PRN) [10] The PRN provides services to all eligible professions except nurses. The PRN program is a subsidiary of the Florida Medical Association.[11]

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[1] EMT and paramedics are governed by part III of ch. 401, F.S.
[2] Radiation technologists are governed by part IV of ch. 468, F.S
[3] Section 456.076, (1), F.S.
[4] Section 456.076 (3)(a)
[5] Section 456.076(3)(a), F.S.
[6] Section 456.074, F.S.
[7] Section 456.076, F.S.
[8] 64B31-10.10.001 and 64B31-10.002, F.A.C.
[9] Department of Health, Bill Analysis, Economic Statement and Fiscal Note on HB 1019, dated January 23, 2012.
[10] Department of Health, Bill Analysis, Economic Statement and Fiscal Note on HB 1019, dated January 23, 2012.
[11] Florida Medical Association, *available at*: http://www.flmedical.org/Layout_1Column.aspx?pageid=2752 (last viewed January 27, 2012).

Currently, the DOH licenses over 40 health care professions[12] and has a contract with PRN to provide services to the following professions:[13]

Medical Doctors	Chiropractic Physicians
Physician Assistants	Clinical Social Workers
Osteopathic Physicians	Marriage and Family Therapists
Pharmacists	Mental Health Counselors
Podiatric Physicians	Optometrists
Psychologists	Nursing Home Administrators
Dentists	Medical Physicists
Opticians	Dieticians
Occupational Therapists	Nutritionists
Physical Therapists	Respiratory Therapists
Electrologists	Midwives
Acupuncturists	Speech Language Pathologists
Audiologists	Clinical Laboratory Personnel
Massage Therapists	Athletic Trainers
Orthotists	Orthotists
Prosthetists	Hearing Aid Specialists
Radiologic Technologists,	Pharmacy Technicians
Anesthesia Assistants	

Moreover, the DOH contract with PRN states that the vendor agrees to include all legislatively added professions to the list of practitioners served and recognizes any contract entered into by the vendor with a school for enrolled students in a health practitioner profession is within the scope of the vendor's duties under the contract with the DOH.[14] The budget outlined in the contract is $1.8M annually.[15]

Referrals to the program must be based upon at least one of the following criteria:[16]

- An identified informant has observed specific behavior of a licensee or has knowledge of other evidence suggesting impairment of the licensee.
- The informant identifies a witness who knows the licensee and has observed the licensee's behavior and that witness corroborates the information provided.
- Admission of impairment by the licensee and that corroborates the information provided.

Once in the program, the licensee is monitored by an impairment consultant. The consultant is required to monitor the practitioner's participation and ensure compliance.[17] Consultants do not provide medical treatment, nor do they have the authority to render decisions relating to licensure of a particular practitioner. However, the consultant is required to make recommendations to DOH regarding a practitioner patient's ability to practice.[18]

In Fiscal Year 2010-2011, there were approximately 2,867 practitioners or students enrolled in the program.[19]

[12] Department of Health, Medical Quality Assurance, Annual Report, July 2010-June 2011, *available at*: http://www.doh.state.fl.us/Mqa/reports.htm (last visited January 26, 2012)
[13] Department of Health Contract with PRN, signed July 01, 2010, on file with Health & Human Services Quality Subcommittee staff.
[14] *Id.*
[15] *Id.*
[16] 64B31-10.002, F.A.C.
[17] Department of Health Contract with PRN, signed July 01, 2010, on file with Health & Human Services Quality Subcommittee staff.
[18] Section 456.076(5)(a), F.S.
[19] Department of Health, Bill Analysis, Economic Statement and Fiscal Note on HB 1019, dated January 23, 2012.

Veterinary Medicine

Currently, the Board of Veterinary Medicine and the Board of Pilot Commissioners, within the Department of Business and Professional Regulation (DBPR), provide impaired practitioner treatment programs for licensees.

Section 474.221, F.S., provides that licensed veterinarians shall be governed by the treatment of impaired practitioner provisions as if they were under the jurisdiction of the Division of Medical Quality Assurance at DOH.

Currently, DBPR has a contract with PRN to provide consultant services for impaired veterinarians. In 2011, the DBPR contract with PRN was $48,132 annually. In Fiscal Year 2009-2010, an average of 29 licensees participated in the program.[20]

Department of Financial Services Sovereign Immunity

DFS and the Division of Risk Management are required to defend any claim, suit, action or proceeding against an impaired practitioner consultant acting as an agent of DOH, per s. 456.076(7)(a), F.S. Current law requires consultants to indemnify the state for damages up to the sovereign immunity limits, in ch. 768, F.S.[21] However, according to Department of Financial Services (DFS), this language has not been legally tested. It could be interpreted to include all costs of a claim, including the damages paid, defense fees, expert witnesses, court costs, etc., or it could be held to include only the amount of damages paid, since it refers to the sovereign immunity limits on damages the state will pay for tort claims. In 2011, those limits were increased from $100,000 per person's claim and $200,000 for all claims (from one occurrence), to $200,000 per person and $300,000 for all claims.[22]

Records

DOH rule requires that consultants within impaired practitioner programs serve as the official records custodians of the licensees they monitor.[23] An approved treatment provider must provide information regarding the impairment of a licensee and the licensee's participation in a treatment program to a consultant on request. The information obtained by the consultant is confidential and exempt from public records requirements.[24] If a treatment provider fails to provide such information to the consultant, the treatment provider may no longer provide services under the program.[25] Recently, there was litigation in the Sixth Circuit, in which a medical doctor sued PRN for the production of the investigative file relation to the practitioner's participation in a treatment program.[26] The court held that because there was not a disciplinary proceeding by the board against the practitioner, the release of information was prohibited and the claim was dismissed with prejudice in October, 2010.[27]

Effect of Proposed Changes

The bill expands the services provided by the impaired practitioner treatment program to EMTs, paramedics, radiologic technologists. The bill also expands services provided by the impaired practitioner program to all persons licensed or applying for a license at the discretion of the DBPR.[28]

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[20] DBPR Office of Legislative Affairs 2011 Legislative Analysis Form SB 1742 (2011).
[21] Section 768.28, F.S.
[22] Email correspondence with DFS staff, dated January 26, 2012, on file with the Health & Human Services Quality Subcommittee staff.
[23] Rules 64B31-10.10.004, F.A.C.
[24] Section 456.076(5)(a), F.S.
[25] *Id*
[26] *Doe, M.D., v. Rivernbark*, case no. 10-6495-CI-21 (Fla. 6th Cir. Ct.) (2010)
[27] *Id.*
[28] *See* s. 20.165(4)(a), F.S. The DBPR regulates: the Board of Architecture and Interior Design, Florida Board of Auctioneers, Barber's Board, Florida Building Code Administrators and Inspectors Board, Construction Industry Licensing Board, Board of Cosmetology, Electrical Contractor's Licensing Board, Board of Employee Leasing Companies, Board of Landscape Architecture,

Moreover, the bill provides consultants the ability to contract for compensation with schools whose students are enrolled in a school that leads to licensure as a health care practitioner or a veterinarian. This is an expansion from current law, which only allows students who are enrolled in a school that leads to licensure as a medical doctor, doctor of osteopathic medicine, physician assistants, nurses, or pharmacists.

The bill clarifies that a program consultant may employ a medical director or a nurse as the executive director, and specifies that the director does not have to possess a license as a substance abuse provider or a mental health provider if the entity hires appropriately trained staff to provide the treatment or conduct the evaluation of an impaired individual.

The bill clarifies that impaired practitioner consultants shall serve as record custodians for any licensee they monitor, and any records they maintain shall not be shared with the impaired licensee or a designee unless a disciplinary proceeding is pending.

The bill expands the types of lawsuits DFS is required to defend. DFS will be required to represent a claim, suit, action, or proceeding that seeks injunctive, affirmative or declaratory relief against a consultant, the consultant's officers or employees, or individuals acting at the direction of a consultant for the limited purpose of emergency intervention. According to DFS, this expands their risk management functions beyond what their certificate of authority would allow.[29]

B. SECTION DIRECTORY:

Section 1: Amends s. 20.165, F.S., relating to the Department of Business and Professional Regulation.
Section 2. Creating s. 401.466, F.S., relating to the treatment program for impaired emergency medical technicians and paramedics.
Section 3. Amends s. 456.076, F.S., relating to treatment programs for impaired practitioners
Section 4: Creates s. 458.315, F.S., relating to the treatment program for impaired radiological personnel.
Section 5: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None identified.

2. Expenditures:

   None identified.

Board of Pilot Commissioners, Board of Professional Engineers, Board of Professional Geologists, Board of Veterinary Medicine, Home Inspection Services Licensing Program, Mold-related Services Licensing Program.)

[29] Email correspondence with DFS staff, dated January 26, 2012, on file with the Health & Human Services Quality Subcommittee staff.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Approved treatment providers may experience an increase in demand for services with the additional eligibility groups who may receive in services offered by a program. Based on impairment contracts for licensed practitioners, an impaired person may be required to enter into a contract with a program for up to 5-years.

While in an impairment program a participant is required to pay for all treatment services such as initial evaluations, urinalysis testing and ongoing psychotherapy. Initial evaluations can range from $300-$500 and up to $1000 if chronic pain evaluation is required. The average cost is $42 per urinalysis, the number per month varies depending upon the recovery process. The cost of four group therapy meetings per month can range from $50-$150 per month. If the impairment is found to be physical, then the cost may be nominal. All participants are required to have a primary care physician, but no visits are required. The PRN program offers a loan forgiveness option to eligible participants.

All treatment services are paid directly to the provider or third party administrator and not through the PRN program.

D. FISCAL COMMENTS:

DFS does not project any significant fiscal impact from the provisions of this bill. The DFS analysis takes into consideration the increase in sovereign immunity limits and 11 years of historical claims data which reflects a very low claims risk. Any potential amount expended in total claims costs will come within the limits of the consultant's obligation.[30]

The costs of the impaired practitioner program are twofold: The cost incurred by the impaired practitioner (person receiving treatment services); and the cost incurred by DOH to implement the program (monitoring and enforcement). DOH is anticipating a fiscal impact from the provisions of the bill in 2013, when the contract with PRN is up for renegotiation. The contract with PRN expires June 30, 2013.

In 2008, the Legislature authorized PRN to provide services to students enrolled in schools that provide training for allopathic and osteopathic physicians. In 2008, per participant cost was $1,046 annually.[31] There were an average total of 2,867 participants in the impaired practitioner program in FY 10-11 and the total cost to the program was $3,343,235. Currently, the average cost per participant is $1,166 ($3,343,235 / 2,867), which reflects an approximate increase of $120 per participant from 2008.

For the purposes of this analysis, DOH assumes that the increase will be based on the Emergency Medical Technicians and Paramedics (EMS) participation which is not included in the current contract with PRN.[32]

Based on Fiscal Year 2010-2011 PRN usage by radiologic personnel, there was an average of 48 participants in the impaired practitioner program. During this time, there were a total of 41,303 radiologic personnel licensed equating to 0.12% (48 / 41,303) of the total radiologic personnel population utilizing PRN services.

Based on FY 10-11, EMS had a total of 59,905 licensees. It is anticipated that there will be an average of 70 (.0012 x 59,905) EMS participants per year; therefore, it is estimated that the PRN contract will increase $81,620 (70 * $1,166).

DOH states that they will require additional budget authority to implement the provisions of the bill.[33]

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[30] Department of Financial Services, 1019 Analysis and Fiscal Note on HB 1019, dated January 31, 2012.
[31] Department of Health, Bill Analysis, Economic Statement and Fiscal Note on HB 1019, dated January 23, 2012.
[32] *Id.*
[33] *Id.*

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

Injunctive and declaratory relief claims

Injunctive and declaratory relief claims do not involve a claim for damages, but are filed to have a court declare a particular practice or policy invalid, and to request that the state agency be enjoined from continuing that practice or policy. These claims may or may not be coupled with other claims alleging negligence or civil rights violations that do demand damages. In the current situation addressed by this bill, DFS is not sure how a injunctive and declaratory relief claim would be filed against the consultant (rather than the agency), but the likelihood is that allegedly impaired practitioners would file a injunctive and declaratory relief claim to retain or get back their medical license that could name both the agency and consultant as defendants.[34]

Because injunctive and declaratory relief are not the type of claims covered by insurance programs, as they do not involve claims for damages due to negligence or violation of rights, s. 284.385 provides: "The covered department shall have the responsibility for the settlement of any claim for injunctive or affirmative relief under 42 U.S.C. s.1983 or similar federal or state statutes". These injunctive and declaratory relief claims can be settled only by the agency, since it involves agreeing to change their program or practices. This by its nature includes the responsibility for associated defense and other costs necessary to settle the claim, since in insurance coverage systems, the right to settle a claim belongs to the entity paying the claim defense costs. Otherwise, an agency can unreasonably prolong settlement with no sense of urgency to resolve a clam since our program must continue to pay the defense costs.[35]

Therefore, the DFS current certificate of coverage issued to all state agencies specifically excludes coverage for injunctive and declaratory relief claims. This certificate (DFS-DO-862) has been referenced in and approved by Rule 69H-2.004. This exclusion from coverage has been in place for over 25 years.[36]

The bill if passed would supersede any provisions in the DFS rule or coverage certificate, but DFS is not sure how it will comport with s. 284.385, F.S.[37]

Delegation Doctrine

The bill may implicate Article II, Section 36, of the Florida Constitution, as an unlawful delegation of legislative authority. This section of the Florida Constitution "prohibits the delegation of legislative powers absent ascertainable minimal standards and guidelines."[38] Two exceptions to this non-delegation doctrine are generally recognized where "it is impracticable to lay down a definite comprehensive rule, (1) when the subject of the statute relates to licensing and the determination of the fitness of the applicant to be licensed, and (2) when the statute regulates businesses operated as a privilege rather than as a right which are potentially dangerous to the public."[39]

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[34] Email correspondence with DFS staff, dated January 26, 2012, on file with the Health & Human Services Quality Subcommittee staff.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] Dept of Business Reg., Div. of Alcoholic Beverages and Tobacco v. Jones, 474 So.2d 359, 361 (Fla. 1st DCA 1985)
[39] FL Waterworks Assn. v. FL Public Service Comm'n, 473 So.2d 231, 245 (Fla. 1st DCA)

The bill provides that DBPR may require a person that is licensed or applying for a license from DBPR be governed by the provisions of s. 456.076, F.S., as if the person was under the jurisdiction of the Division of Medical Quality Assurance, within DOH, for the purposes of the impaired practitioner program. The bill does not specify a specific type of license that a person must hold or seek in order to be eligible for the impaired practitioner program, and gives full discretion to DBPR to determine which licensure categories, and individuals, will be subject to s. 456.076, F.S. The bill provides no guidance to DBPR to make this decision. It is unclear whether the fitness or privilege exceptions to the non-delegation rule apply.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provision of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not specify a specific type of license that a person must hold or seek in order to be eligible for the impaired practitioner program. Further, the bill permits DBPR to use its discretion in determining which persons falling under its licensing purview are eligible for the impaired practitioner program.

On line 71-72, the bill states that the costs associated with the treatment rendered to an EMT or paramedic may not be charge to the MQA Trust Fund. The EMTs and paramedics are not within MQA and the fees collected for the regulation of these professions are deposited into the Emergency Medical Trust Fund within the DOH.

Likewise, the language on 178-181, relates to Radiologic Technologists who are also not regulated by MQA. Fees for their regulation are deposited into the Radiation Protection Trust Fund within DOH. The bill is moot on the subject of charging fees associated with the cost of the program. It is not clear why there is delineation between these two professions.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to treatment programs for impaired professionals; amending s. 20.165, F.S.; authorizing the Department of Business and Professional Regulation to require a person licensed by or applying for a license from the department to be governed by provisions providing programs for impaired practitioners under the jurisdiction of the Division of Medical Quality Assurance within the Department of Health; authorizing the Department of Business and Professional Regulation to exercise any of the powers granted to the Department of Health with respect to such programs; creating s. 401.466, F.S.; providing that an emergency medical technician or paramedic who is certified or has applied to be certified may be subject to a treatment program for impaired practitioners at the election of the impaired practitioner consultant; prohibiting charging the associated costs to the Medical Quality Assurance Trust Fund within the Department of Health; amending s. 456.076, F.S.; exempting an entity retained by the Department of Health as an impaired practitioner consultant from certain licensing requirements if the entity employs or contracts with licensed professionals; revising the schools or programs that may contract for impaired practitioner consulting services; limiting the liability of certain medical schools and schools that prepare health care

practitioners and veterinarians for licensure for referring a student to an impaired practitioner consultant; authorizing the Department of Health to refer an applicant for licensure to the consultant; clarifying the types of legal proceedings related to services provided by impaired practitioner consultants which are defended by the Department of Financial Services; clarifying requirements for an impaired practitioner consultant to maintain as confidential certain information concerning an impaired practitioner; authorizing the department and certain other entities to have administrative control over the impaired practitioner consultant to the extent necessary to receive disclosures; creating s. 468.315, F.S.; providing that a radiologic technologist who is certified or who has applied to be certified may be subject to a treatment program for impaired practitioners at the election of an impaired practitioner consultant; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (10) is added to section 20.165, Florida Statutes, to read:

20.165 Department of Business and Professional Regulation.—There is created a Department of Business and Professional Regulation.

(10) The Department of Business and Professional

Regulation may require a person licensed by or applying for a license from the department to be governed by s. 456.076 as if the person were under the jurisdiction of the Division of Medical Quality Assurance. The Department of Business and Professional Regulation may exercise any of the powers granted to the Department of Health by s. 456.076, and the term "board" means the board from which the license was granted or is sought.

Section 2. Section 401.466, Florida Statutes, is created to read:

401.466 Treatment program for impaired emergency medical technicians and paramedics.—An emergency medical technician or paramedic who is certified or has applied to be certified under this part may be subject to s. 456.076 at the election of an impaired practitioner consultant; however, associated costs may not be charged to the Medical Quality Assurance Trust Fund within the Department of Health.

Section 3. Subsection (2), paragraph (d) of subsection (3), and paragraph (b) of subsection (7) of section 456.076, Florida Statutes, are amended, and subsection (8) is added to that section, to read:

456.076 Treatment programs for impaired practitioners.—

(2)(a) The department shall retain one or more impaired practitioner consultants who are each licensees~~. The consultant shall be a licensee~~ under the jurisdiction of the Division of Medical Quality Assurance within the department and who must be:

1. A practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464;~~,~~ or

2. An entity employing a medical director or employing a

registered nurse as an executive director, who must be a practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464.

(b) An entity that is retained as a consultant under this section and employs a medical director or registered nurse as an executive director is not required to be licensed as a substance abuse provider or mental health treatment provider under chapter 394, chapter 395, or chapter 397 in order to operate as a consultant under this section if the entity employs or contracts with licensed professionals to perform or appropriately supervise any specific treatment or evaluation that requires individual licensing or supervision.

(c) The consultant shall assist the probable cause panel and department in carrying out the responsibilities of this section. This includes ~~shall include~~ working with department investigators to determine whether a practitioner is, in fact, impaired. The consultant may contract for services to be provided, for appropriate compensation, if requested by a ~~the~~ school or program, for students enrolled in a school ~~schools~~ for licensure as a health care practitioner under this chapter or a veterinarian under chapter 474 ~~allopathic physicians or physician assistants under chapter 458, osteopathic physicians or physician assistants under chapter 459, nurses under chapter 464, or pharmacists under chapter 465~~ who are alleged to be impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition.

(d) The department is not responsible under any circumstances for paying the costs of care provided by approved

treatment providers, and the department is not responsible for paying the costs of consultants' services provided for such students.

(e) A medical school accredited by the Liaison Committee on Medical Education of the Commission on Osteopathic College Accreditation, or another ~~other~~ school providing for the education of students enrolled in preparation for licensure as a health care practitioner under this chapter or a veterinarian under chapter 474 ~~allopathic physicians under chapter 458 or osteopathic physicians under chapter 459~~, which school is governed by accreditation standards requiring notice and the provision of due process procedures to students, is not liable in any civil action for referring a student to the consultant retained by the department or for disciplinary actions that adversely affect the status of a student when the disciplinary actions are instituted in reasonable reliance on the recommendations, reports, or conclusions provided by such consultant, if the school, in referring the student or taking disciplinary action, adheres to the due process procedures adopted by the applicable accreditation entities and if the school committed no intentional fraud in carrying out the provisions of this section.

(3)

(d) Whenever the department receives a legally sufficient complaint alleging that a licensee or applicant is impaired as described in paragraph (a) and no complaint against the licensee or applicant other than impairment exists, the appropriate board, the board's designee, or the department shall forward all

information in its possession regarding the impaired licensee or applicant to the consultant. For the purposes of this section, a suspension from hospital staff privileges due to the impairment does not constitute a complaint.

(7)

(b) In accordance with s. 284.385, the Department of Financial Services shall defend any claim, suit, action, or proceeding, including a claim, suit, action, or proceeding for injunctive, affirmative, or declaratory relief, against the consultant, the consultant's officers or employees, or those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention that ~~which~~ is brought as a result of any act or omission by any of the consultant's officers and employees and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention when such act or omission arises out of and in the scope of the consultant's duties under its contract with the department.

(8) An impaired practitioner consultant is the official custodian of records concerning any impaired licensee monitored by that consultant. The consultant may not, except to the extent necessary for carrying out the consultant's duties under this section, disclose to the impaired licensee or his or her designee any information that is disclosed to or obtained by the

consultant and is confidential under paragraph (5)(a). The department, and any other entity to which the consultant contracts, shall have direct administrative control over the consultant to the extent necessary to receive disclosures from the consultant as allowed by federal law. If a disciplinary proceeding is pending, an impaired licensee may obtain such information from the department under s. 456.073(10).

Section 4. Section 468.315, Florida Statutes, is created to read:

468.315 Treatment program for impaired radiological personnel.—A radiologic technologist who is certified or who has applied to be certified under this part may be subject to s. 456.076 at the election of an impaired practitioner consultant.

Section 5. This act shall take effect July 1, 2012.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION		
ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	_____	

Committee/Subcommittee hearing bill: Health & Human Services Quality Subcommittee

Representative Renuart offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 401.466, Florida Statutes, is created to read:

401.466 Treatment program for impaired emergency medical technicians and paramedics.—An emergency medical technician or paramedic who is certified or has applied to be certified under this part may be subject to s. 456.076 at the election of an impaired practitioner consultant; however, associated costs may not be charged to the department.

Section 2. Subsection (2), paragraph (d) of subsection (3), and paragraph (b) of subsection (7) of section 456.076, Florida Statutes, are amended, and subsection (8) is added to that section, to read:

456.076 Treatment programs for impaired practitioners.—

(2)(a) The department shall retain one or more impaired practitioner consultants who are each licensees~~. The consultant shall be a licensee~~ under the jurisdiction of the Division of Medical Quality Assurance within the department and who must be:

1. A practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464;~~,~~ or

2. An entity employing a medical director who must be a ~~practitioner~~ physician or recovered ~~practitioner~~ physician licensed under chapter~~—~~458, or chapter 459. For an entity that solely treats nurses, the entity may employ an executive director who is a registered nurse or nurse practitioner licensed under~~—or—~~part I of chapter 464 ~~in~~ lieu of a medical director.

3. For the treatment of any other practitioner, an entity employing a medical director who is a physician licensed under chapter 458, or chapter 459.

(b) An entity that is retained as a consultant under this section and employs a medical director or registered nurse as an executive director is not required to be licensed as a substance abuse provider or mental health treatment provider under chapter 394, chapter 395, or chapter 397 in order to operate as a consultant under this section if the entity employs or contracts with licensed professionals to perform or appropriately supervise any specific treatment or evaluation that requires individual licensing or supervision.

(c) The consultant shall assist the probable cause panel and department in carrying out the responsibilities of this section. This includes ~~shall include~~ working with department

investigators to determine whether a practitioner is, in fact, impaired. The consultant may contract for services to be provided, for appropriate compensation, if requested by a ~~the~~ school or program, for students enrolled in a school ~~schools~~ for licensure as allopathic physicians or physician assistants under chapter 458, osteopathic physicians or physician assistants under chapter 459, nurses under chapter 464, or pharmacists under chapter 465 who are alleged to be impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition.

(d) The department is not responsible under any circumstances for paying the costs of care provided by approved treatment providers, and the department is not responsible for paying the costs of consultants' services provided for such students.

(e) A medical school accredited by the Liaison Committee on Medical Education of the Commission on Osteopathic College Accreditation, or another ~~other~~ school providing for the education of students enrolled in preparation for licensure as allopathic physicians under chapter 458 or osteopathic physicians under chapter 459, which school is governed by accreditation standards requiring notice and the provision of due process procedures to students, is not liable in any civil action for referring a student to the consultant retained by the department or for disciplinary actions that adversely affect the status of a student when the disciplinary actions are instituted in reasonable reliance on the recommendations, reports, or conclusions provided by such consultant, if the school, in

referring the student or taking disciplinary action, adheres to the due process procedures adopted by the applicable accreditation entities and if the school committed no intentional fraud in carrying out the provisions of this section.

(3)

(d) Whenever the department receives a legally sufficient complaint alleging that a licensee or applicant is impaired as described in paragraph (a) and no complaint against the licensee or applicant other than impairment exists, the appropriate board, the board's designee, or the department shall forward all information in its possession regarding the impaired licensee or applicant to the consultant. For the purposes of this section, a suspension from hospital staff privileges due to the impairment does not constitute a complaint.

(7)

(b) In accordance with s. 284.385, the Department of Financial Services shall defend any claim, suit, action, or proceeding against the consultant, the consultant's officers or employees, or those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention that ~~which~~ is brought as a result of any act or omission by any of the consultant's officers and employees and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to

perform such intervention when such act or omission arises out of and in the scope of the consultant's duties under its contract with the department.

(8) An impaired practitioner consultant is the official custodian of records concerning any impaired licensee monitored by that consultant. The consultant may not, except to the extent necessary for carrying out the consultant's duties under this section, disclose to the impaired licensee or his or her designee any information that is disclosed to or obtained by the consultant and is confidential under paragraph (5)(a). The department, and any other entity to which the consultant contracts, shall have direct administrative control over the consultant to the extent necessary to receive disclosures from the consultant as allowed by federal law. If a disciplinary proceeding is pending, an impaired licensee may obtain such information from the department under s. 456.073(10).

Section 3. Section 468.315, Florida Statutes, is created to read:

468.315 Treatment program for impaired radiological personnel.—A radiologic technologist who is certified or who has applied to be certified under this part may be subject to s. 456.076 at the election of an impaired practitioner consultant.

Section 4. This act shall take effect July 1, 2012.

T I T L E A M E N D M E N T

Remove the entire title and insert:

A bill to be entitled

Amendment No. 1

An act relating to treatment programs for impaired professionals; creating s. 401.466, F.S.; providing that an emergency medical technician or paramedic who is certified or has applied to be certified may be subject to a treatment program for impaired practitioners at the election of the impaired practitioner consultant; prohibiting charging the associated costs to the Department of Health; amending s. 456.076, F.S.; exempting an entity retained by the Department of Health as an impaired practitioner consultant from certain licensing requirements if the entity employs or contracts with licensed professionals; authorizing the Department of Health to refer an applicant for licensure to the consultant; clarifying requirements for an impaired practitioner consultant to maintain as confidential certain information concerning an impaired practitioner; authorizing the department and certain other entities to have administrative control over the impaired practitioner consultant to the extent necessary to receive disclosures; creating s. 468.315, F.S.; providing that a radiologic technologist who is certified or who has applied to be certified may be subject to a treatment program for impaired practitioners at the election of an impaired practitioner consultant; providing an effective date.

HB 1081

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1081 Controlled Substances
SPONSOR(S): McBurney
TIED BILLS: **IDEN./SIM. BILLS:** SB 1246, SB 1364

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee		Mathieson	Calamas
2) Criminal Justice Subcommittee			
3) Justice Appropriations Subcommittee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Pharmaceutical companies have developed patented tamper-resistant technologies for brand name Schedule II controlled substances that have been approved by the Food and Drug Administration (FDA) for public use. This is not be confused with tamper resistant packaging, which refers to the medication container. Pharmacists are directed by s. 465.025, F.S., and in the Medicaid program s. 409.908(14), F.S., to substitute less expensive generic drugs for brand name, under certain circumstances.

House Bill 1081:

- Provides that knowingly using a Schedule II controlled substance in a form or manner other than the manufacturer or prescriber intended it to be used shall be a first degree misdemeanor.
- Directs the Board of Pharmacy to compile a list of FDA-approved tamper-resistant schedule II opioid medications.
- Prohibits a licensed pharmacist from interchanging or substituting a prescription for a tamper-resistant schedule II opioid medication for a non tamper-resistant schedule II opioid medication.
    - Provides an exception for a pharmacist to substitute a substantially similar schedule II opioid medication from the list compiled by the Board, or if the prescriber consents in writing.

The bill has an indeterminate fiscal impact on the state.

The bill provides for an effective date of October 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act, and classifies controlled substances into five categories, known as schedules. The distinguishing factor between the schedules is the potential for abuse[1] of the substance and whether there is a currently accepted medical use. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[2]

- A **Schedule I** substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.
- A **Schedule II** substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.
- A **Schedule III** substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A **Schedule IV** substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.
- A **Schedule V** substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

Many people who take prescription medications do so responsibly. However, the nonmedical use or abuse of prescription drugs remains a significant public health concern in the Union. Certain prescription drugs – opioid substances, central nervous system depressants and stimulants – when abused can lead to psychological and physiological dependence. According to research by the National Institute on Drug Abuse,[3] the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).

In the 2011 Legislative Session, HB 7095 was enacted, which sought to deal with the prescription drug abuse issue in the state. The misuse of prescription drugs in the state is a serious public health emergency, and HB 7095 enacted a variety of measures to combat, including for example, prohibiting practitioners dispensing controlled substances.

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[1] S. 893.02(19), F.S.
[2] *See,* s. 893.03, F.S.
[3] *See* http://www.drugabuse.gov/drugs-abuse/prescription-medications (last visited January 25, 2012).

The Pharmaceutical Industry and the FDA

The Food and Drug Administration (FDA), which is administratively housed within the federal Department of Health and Human Services (HHS), is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the U.S. food supply, cosmetics, and products that emit radiation.[4]. Specifically, Congress has required that an application for a new drug must include: [5]

- Full reports of investigations which show whether the drug is both safe and effective for use;
- A list of all the components of the drug;
- A statement of the composition of the drug;
- A description of the manufacturing process, including packaging;
- Samples of the drug, or components thereof, as required by the Secretary of HHS;
- Specimens of the proposed labeling; and[6]
- Patent information.[7]

The FDA has promulgated rules, pursuant to the federal Food, Drug, and Cosmetic Act,[8] for the approval process for human medications.[9] Case law has interpreted the purpose of these provisions to be a requirement on what must be submitted with an application for approval, the adequacy of what is submitted, is strictly for determination by the FDA.[10]

In April, 2011, the federal Office of National Drug Control Policy (ONDCP), which is administratively housed in the Executive Office of the President, released the administration's prescription drug abuse plan.[11] *Epidemic: Responding to America's Prescription Drug Abuse Crisis,*[12] included strategies such as prescriber education, monitoring programs, safe disposal and enforcement.

One of the strategies that the ONDCP is pursuing is to incentivize the production of technological innovations that make medications more difficult to abuse.[13] In conjunction with these federal efforts, the pharmaceutical industry has been working to develop technologies that make the adulteration of prescription medications more difficult. This has led to "tamper-resistant" or "abuse-deterrent" formulations of drugs. Tamper-resistant formulations are designed to be difficult to crush or dissolve, and as such, would prevent chewing, snorting or injecting the medication.[14] Abuse-deterrent is defined as a drug which does not necessarily resist tampering, but contain substances that make the formulation less attractive to abusers.[15] This is different from tamper-resistant packaging, in that it is the drug itself that contains the technology, not the container.

Currently, there are five FDA-approved drugs that incorporate tamper-resistant technologies; Embeda;[16] Opana ER;[17] OxyContin;[18] Nucynta ER;[19] and Oxecta.[20] Given that this is relatively new

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[4] *See,* http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited January 27, 2012).
[5] Congress has provided the legislative framework for approving new medications in 21 U.S.C. s. 355.
[6] *See,* 21 U.S.C. s. 355(b).
[7] 21 U.S.C. s. 117.
[8] *See,* 21 U.S.C. ss. 301-399, *et. seq.* Rules promulgated by the FDA are codified in 21 C.F.R. ss. 314.100 (2012), *et. seq.*
[9] *See,* 21 C.F.R. s. 314.50 (2012). The FDA standards for clinical studies for a new drug are codified at 21 C.F.R. s. 314.216 (2012).
[10] *Toole v. Richardson-Merrell Inc.*, 60 Cal.Rptr. 398, 410 (Cal. App. 1967).
[11] http://www.whitehouse.gov/ondcp/news-releases-remarks/obama-administration-releases-action-plan (last visited January 26, 2012).
[12] Available at: http://www.whitehouse.gov/ondcp/prescription-drug-abuse (last visited January 26, 2012)
[13] *Id.*
[14] *See* Jeffery P. Schneider, Michelle Matthews and Robert Jamison, *Abuse-Deterrent and Tamper-Resistant Opioid Formulations. What is their Role in Addressing Prescription Opioid Abuse?* 10 CNS DRUGS 805, 806 (October 2010).
[15] *Id.*
[16] Approved as N022321 by the FDA in August, 2009, this drug is manufactured by Alpharma King, the last patent on this drug expires in 2027. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022321&TABLE1=OB_Rx (last visited January 25, 2012).
[17] Approved as N0201655 by the FDA in December 2012, this drug is manufactured by Endo Pharmaceuticals, the last patent on this drug expires in 2023. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=201655&TABLE1=OB_Rx (last visited January 25, 2012).

technology, it is not currently not possible to quantify the impact that such technology has on prescription drug misuse.[21]

Generic Drug Substitution

Section 456.025, F.S., requires a less expensive "generically equivalent drug product"[22] be substituted for a brand name drug unless the patient objects or the prescribing health care practitioner affirmatively prohibits the substitution by noting this on the prescription.[23] The pharmacist must keep a record of any substitution that is made.[24]

The Legislature has directed the Agency for Health Care Administration (AHCA) to purchase medical goods and services for Medicaid that provide quality care for the recipient and cost efficiency for the state.[25] As a part of the strategy to manage prescription drug expenses, the Legislature created the Medicaid Pharmaceutical and Therapeutics Committee.[26] The committee recommends drugs for inclusion on a Preferred Drug List (PDL) to the agency, which makes the final determination. A drug [27] not on the list is subject to prior authorization for payment.[28] The PDL does not currently include any controlled substances that incorporate tamper-resistant technology.[29]

Section 409.908(14), F.S., requires that pharmacies dispense generic drugs, when available at a lower cost, and AHCA has not determined that the branded product is more cost effective. An exception is provided for a prescriber that receives prior approval from the agency.[30] The PDL currently contains 19 generic narcotic analgesics, in varying doses and formulations, for Medicaid recipients.[31]

AHCA estimates that, in the fee-for-service pharmaceutical program, the average cost for a brand name drug is around $270 per prescription, and around $15 for a generic equivalent.[32] In Fiscal Year

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[18] Approved as N022272 by the FDA in April 2010, this drug is manufactured by Purdue Pharmaceuticals, the last patent on the drug expires in 2025. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022272&TABLE1=OB_Rx (last visited January 25, 2012).

[19] Approved as N200533 by the FDA in August 2011, this drug is manufactured by Jannsen Pharmaceuticals, the last patent expires on this drug expires in 2025. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=200533&TABLE1=OB_Rx (last visited January 25, 2012).

[20] Approved as N202080 by the FDA in June 2011, this drug is manufactured by King Pharmaceuticals, the last patent expires on this drug in 2025. *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=202080&TABLE1=OB_Rx (last visited January 25, 2012).

[21] *See e.g.,* Stephen Butler, Ryan Black, Theresa Cassidy, Taryn Daily, and Simon Budman, *Abuse Risks and Routes of Administration of Different Prescription Opioid Compounds and Formulations,* 8 HARM REDUCTION JOURNAL, 29 (October, 2011); Lynn Webster and Perry Fine, *Approaches to Improve Pain Relief While Minimizing Opioid Abuse Liability*, 11 THE JOURNAL OF PAIN, 602 (July, 2010).

[22] S. 465.025(1)(b), F.S. defines a "generically equivalent drug product" as a drug product with the same active ingredient, finished dosage form, and strength.

[23] A prescriber may do this on a handwritten prescription by writing "MEDICALLY NECESSARY" in their own handwriting; in the case of an oral prescription, by telling the pharmacist that the brand name drug is medically necessary; or in the case of an electronic prescription, by using the brand name the prescriber is deemed to have indicated that it is medically necessary. S. 465.025(1), F.S.

[24] S. 465.025(4), F.S.

[25] S. 409.912, F.S.

[26] S. 409.91195, F.S.

[27] Other than an anti-retroviral drug.

[28] S. 409.91195(4), F.S. *See, Medicaid Prescribed Drug Program. Spending Control Initiative. For Quarters Ended September 30, 2010 and December 31, 2010*, http://ahca.myflorida.com/medicaid/Prescribed_Drug/presentations.shtml (site last visited January 26, 2012).

[29] *See* http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/fmpdl.shtml (site last visited January 25, 2012). In a December 2010, report by AHCA, the agency estimated that it received 7,000 requests for prior approval each month. *See, Medicaid Prescribed Drug Program. Spending Control Initiative. For Quarters Ended September 30, 2010 and December 31, 2010*, http://ahca.myflorida.com/medicaid/Prescribed_Drug/presentations.shtml (site last visited January 26, 2012).

[30] S. 409.908(14), F.S.

[31] AHCA has classified these as H3A in the PDL. *Supra,* note 23.

[32] After any applicable rebates, the average cost for a brand name prescription is around $140, and $14 for a generic equivalent. Email from AHCA on file with Health and Human Services Committee staff, January 26, 2012.

2010-2011, almost 16 million prescriptions were filled under the Medicaid fee-for-service program.[33] For the quarter ending June 30, 2011, branded drugs represented 18% of prescriptions written, and accounted for 74% of the program cost, and generic drugs represented 82% of prescriptions written, and accounted for 26% of the program cost.[34]

Pharmacy

Chapter 465, F.S., governs the practice of pharmacy in the state. The Board of Pharmacy (Board), within the Department of Health (DOH) is authorized to adopt rules to implement ch. 456, F.S.[35] Section 465.003, F.S., defines the practice of pharmacy to include:

- Compounding, dispensing and consulting contents, therapeutic values, and uses of any medicinal drug; and
- Consulting concerning therapeutic values and interactions of patent and proprietary preparations.

A pharmacist may perform these functions, with or without a prescription or physician order to perform them.

Effect of Proposed Changes

The bill amends s. 893.13, F.S., providing that knowingly using a Schedule II controlled substance in a form or manner other than the manufacturer or prescriber intended it to be used is a misdemeanor of the first degree.[36] It is not clear from the bill how a prosecutor would establish what the intention of the drug manufacturer or prescriber was, in relation to a specific Schedule II controlled substance. This provision of the bill could also have unintended consequences on the use of such drugs on patients who may have legitimate reasons for taking medications in a way that the prescriber or manufacturer did not intend – such as breaking a pill in half, or potential off-label uses.

The bill creates an unnumbered section of law that prohibits licensed pharmacists from substituting a tamper-resistant opioid drug for an opioid drug, whether brand named or generic.[37] The Board is directed to create a list of tamper-resistant opioid drugs that, based on submissions from the drug manufacturer, have been approved by the FDA. To be listed, the drug does not have to bear an FDA labeling claim related to the reduction of tampering, abuse or abuse potential. The bill requires that, for any drug to be deemed approved by the FDA, the submission to the Board must include at least one human study of the drug's tamper or abuse resistance properties, or a laboratory study of the tamper or abuse resistance potential, when compared to at least one FDA-approved opioid analgesic that serves as a positive control. It is not clear that the FDA requires such tests to be conducted during the approval process. Such a human test would require the researcher to give test subjects medications that have significant potential for psychological and physiological dependence.

The bill uses the term "abuse potential" in the FDA approval process without definition.

Further, the Board is directed to include in the list opioid drugs that have substantially similar tamper resistant technologies, based on studies submitted by the manufacturer.

The bill provides that a pharmacist may only substitute an opioid drug for an opioid drug incorporating tamper-resistant properties by:

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[33] *Id.*
[34] *Id.*
[35] S. 465.005, F.S.
[36] A first degree misdemeanor is punishable by a fine not exceeding $1,000 or imprisonment not exceeding one year. Ss. 775.082, 775.083, F.S
[37] Similar legislation has been filed in California (SB 632 in the 2011-2012 session by Sen. Emmerson); New York (A 7634 in the 2011-2012 session by Rep. Bronson); Pennsylvania (H 1635 in the 2011-2012 session by Rep. Barrar); Tennessee (H 2567 in the 2012 session by Casala); and Texas (SB 1756 in the 2011 session by Sen. Uresti). A similar measure has also been filed in Massachusetts, requiring any prescription for a drug that contains more than 10mg of oxycodone to contain tamper-resistant technology. (*See* S 1000 in the 2011 session by Rep. Tolman).

- Verifying the opioid drug is on the list of drugs that provides substantially similar tamper-resistant properties, as approved by the Board; or
- Obtaining the written, signed consent of the physician.

The effect of this provision is that any prescription for an opioid drug with tamper-resistant technology, where the physician does not consent to a substitution or there is not a drug with substantially similar tamper resistant properties on the Board-approved list, would have to be filled as written. This would occur regardless of whether the tamper resistant drug is name brand or generic, and what the patient's insurance may cover. This bill would prevent a pharmacist acting pursuant to the authority of s. 465.025, F.S., to substitute a less expensive generic equivalent drug.

Currently, such medications are not on the Medicaid PDL. A physician may obtain a prior authorization from AHCA to prescribe a tamper-resistant opioid Schedule II medication; however, because the technology remains patented, no generic versions currently exist. If a Medicaid recipient were prescribed such a drug, this bill would prevent a pharmacist from following the statutory mandate in s. 409.908(14), F.S., to dispense generic drugs when available at a lower cost, and the agency has not determined that the branded product is more cost effective. In the absence of prior approval from the agency or written consent from the prescriber, this bill would require the pharmacist to dispense the prescription for a tamper-resistant Schedule II opioid medication, as written. This could have the effect of either the pharmacy absorbing the cost because Medicaid does not cover such a drug, or refusing to fill such a prescription.

The bill provides conforming changes to s. 893.055, F.S., 893.0551, F.S., and s. 921.0022, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.13, F.S., related to prohibited acts; penalties.
Section 2: Amends s. 893.055, F.S., related to prescription drug monitoring program.
Section 3: Amends s. 893.0551, F.S., related to public records exemption for the prescription drug monitoring program.
Section 4: Amends s. 921.0022, F.S., related to the criminal punishment code; offence severity ranking chart.
Section 5: Creates an unnumbered section of law.
Section 6: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The effect of this bill on the Medicaid program is unclear. Because the bill prevents certain drug substitutions, it may be interpreted to require Medicaid reimbursement for tamper-resistant drugs, regardless of whether they are on the PDL. This would have an indeterminate and negative fiscal impact on the Medicaid program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By prohibiting the substitution of a non tamper-resistant medication for a tamper-resistant medication, health insurance companies and patients receiving prescriptions for such medications will have to purchase a potentially more expensive product than s. 465.025, F.S., would currently permit.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to the Board to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Lines 255-256, 270 and 278, use the terms "abuse resistance" and "abuse potential" without definition.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to controlled substances; amending s. 893.13, F.S.; prohibiting the knowing use of a Schedule II controlled substance in a form or manner other than that in which the manufacturer or prescriber intended it to be used; providing criminal penalties; amending ss. 893.055, 893.0551, and 921.0022, F.S.; conforming cross-references; providing definitions; requiring the Board of Pharmacy to create a list of opioid analgesic drugs that incorporate a tamper-resistance technology and have been approved by the United States Food and Drug Administration; prohibiting substitution for such an opioid analgesic drug with another opioid analgesic drug without meeting specified requirements; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (7) of section 893.13, Florida Statutes, is amended to read:

893.13 Prohibited acts; penalties.—

(7)(a) A person may not:

1. Distribute or dispense a controlled substance in violation of this chapter.

2. Refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.

3. Refuse entry into any premises for any inspection or refuse to allow any inspection authorized by this chapter.

4. Distribute a controlled substance named or described in s. 893.03(1) or (2) except pursuant to an order form as required by s. 893.06.

5. Keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.

6. Use to his or her own personal advantage, or reveal, any information obtained in enforcement of this chapter except in a prosecution or administrative hearing for a violation of this chapter.

7. Possess a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is an agent or employee of that practitioner, is a pharmacist, or is a supplier of prescription forms who is authorized by that practitioner to possess those forms.

8. Knowingly use a Schedule II controlled substance in a form or manner other than that in which the manufacturer or prescriber intended it to be used.

9.~~8.~~ Withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a

prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

10.~~9.~~ Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

11.~~10.~~ Affix any false or forged label to a package or receptacle containing a controlled substance.

12.~~11.~~ Furnish false or fraudulent material information in, or omit any material information from, any report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

13.~~12.~~ Store anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia or is not constructed in accordance with sound engineering, agricultural, or commercial practices.

14.~~13.~~ With the intent to obtain a controlled substance or combination of controlled substances that are not medically necessary for the person or an amount of a controlled substance or substances that is not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this subparagraph, a material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph 9. ~~8.~~

(b) A health care practitioner, with the intent to provide

a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or an amount of controlled substances that is not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)9. ~~(a)8.~~

(c) Any person who violates ~~the provisions of~~ subparagraphs (a)1.-8. ~~(a)1.-7.~~ commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083; except that, upon a second or subsequent violation, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d) Any person who violates ~~the provisions of~~ subparagraphs (a)9.-13. ~~(a)8.-12.~~ commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(e) A person or health care practitioner who violates ~~the provisions of~~ subparagraph (a)14. ~~(a)13.~~ or paragraph (b) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

Section 2. Paragraph (a) of subsection (1), paragraph (b) of subsection (2), and paragraph (f) of subsection (7) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(1) As used in this section, the term:

(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)9. ~~893.13(7)(a)8.~~ The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

(2)

(b) The department, when the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription

drug monitoring program, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)9. ~~893.13(7)(a)8.~~ The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

(7)

(f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)9. ~~893.13(7)(a)8.~~, (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

Section 3. Subsection (4) of section 893.0551, Florida Statutes, is amended to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

(4) The department shall disclose such confidential and

exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(f). The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of s. 893.13(7)(a)9. ~~893.13(7)(a)8.~~, s. 893.13(8)(a), or s. 893.13(8)(b).

Section 4. Paragraph (c) of subsection (3) of section 921.0022, Florida Statutes, is amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(c) LEVEL 3

Florida Statute	Felony Degree	Description
119.10(2)(b)	3rd	Unlawful use of confidential information from police reports.
316.066 (3)(b)-(d)	3rd	Unlawfully obtaining or using confidential crash reports.
316.193(2)(b)	3rd	Felony DUI, 3rd conviction.
316.1935(2)	3rd	Fleeing or attempting to elude

			law enforcement officer in patrol vehicle with siren and lights activated.
186			
	319.30(4)	3rd	Possession by junkyard of motor vehicle with identification number plate removed.
187			
	319.33(1)(a)	3rd	Alter or forge any certificate of title to a motor vehicle or mobile home.
188			
	319.33(1)(c)	3rd	Procure or pass title on stolen vehicle.
189			
	319.33(4)	3rd	With intent to defraud, possess, sell, etc., a blank, forged, or unlawfully obtained title or registration.
190			
	327.35(2)(b)	3rd	Felony BUI.
191			
	328.05(2)	3rd	Possess, sell, or counterfeit fictitious, stolen, or fraudulent titles or bills of sale of vessels.
192			

328.07(4)	3rd	Manufacture, exchange, or possess vessel with counterfeit or wrong ID number.
376.302(5)	3rd	Fraud related to reimbursement for cleanup expenses under the Inland Protection Trust Fund.
379.2431 (1)(e)5.	3rd	Taking, disturbing, mutilating, destroying, causing to be destroyed, transferring, selling, offering to sell, molesting, or harassing marine turtles, marine turtle eggs, or marine turtle nests in violation of the Marine Turtle Protection Act.
379.2431 (1)(e)6.	3rd	Soliciting to commit or conspiring to commit a violation of the Marine Turtle Protection Act.
400.9935(4)	3rd	Operating a clinic without a license or filing false license application or other required information.

440.1051(3)	3rd	False report of workers' compensation fraud or retaliation for making such a report.
501.001(2)(b)	2nd	Tampers with a consumer product or the container using materially false/misleading information.
624.401(4)(a)	3rd	Transacting insurance without a certificate of authority.
624.401(4)(b)1.	3rd	Transacting insurance without a certificate of authority; premium collected less than $20,000.
626.902(1)(a) & (b)	3rd	Representing an unauthorized insurer.
697.08	3rd	Equity skimming.
790.15(3)	3rd	Person directs another to discharge firearm from a vehicle.

796.05(1)	3rd	Live on earnings of a prostitute.
806.10(1)	3rd	Maliciously injure, destroy, or interfere with vehicles or equipment used in firefighting.
806.10(2)	3rd	Interferes with or assaults firefighter in performance of duty.
810.09(2)(c)	3rd	Trespass on property other than structure or conveyance armed with firearm or dangerous weapon.
812.014(2)(c)2.	3rd	Grand theft; $5,000 or more but less than $10,000.
812.0145(2)(c)	3rd	Theft from person 65 years of age or older; $300 or more but less than $10,000.
815.04(4)(b)	2nd	Computer offense devised to defraud or obtain property.
817.034(4)(a)3.	3rd	Engages in scheme to defraud

		(Florida Communications Fraud Act), property valued at less than $20,000.
817.233	3rd	Burning to defraud insurer.
817.234 (8)(b)-(c)	3rd	Unlawful solicitation of persons involved in motor vehicle accidents.
817.234(11)(a)	3rd	Insurance fraud; property value less than $20,000.
817.236	3rd	Filing a false motor vehicle insurance application.
817.2361	3rd	Creating, marketing, or presenting a false or fraudulent motor vehicle insurance card.
817.413(2)	3rd	Sale of used goods as new.
817.505(4)	3rd	Patient brokering.
828.12(2)	3rd	Tortures any animal with intent to inflict intense pain,

			serious physical injury, or death.
220			
	831.28(2)(a)	3rd	Counterfeiting a payment instrument with intent to defraud or possessing a counterfeit payment instrument.
221			
	831.29	2nd	Possession of instruments for counterfeiting drivers' licenses or identification cards.
222			
	838.021(3)(b)	3rd	Threatens unlawful harm to public servant.
223			
	843.19	3rd	Injure, disable, or kill police dog or horse.
224			
	860.15(3)	3rd	Overcharging for repairs and parts.
225			
	870.01(2)	3rd	Riot; inciting or encouraging.
226			
	893.13(1)(a)2.	3rd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1.,

			(2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) drugs).
227			
	893.13(1)(d)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) drugs within 1,000 feet of university.
228			
	893.13(1)(f)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) drugs within 1,000 feet of public housing facility.
229			
	893.13(6)(a)	3rd	Possession of any controlled substance other than felony possession of cannabis.
230			
	893.13(7)(a)9. ~~893.13(7)(a)8.~~	3rd	Withhold information from practitioner regarding previous receipt of or prescription for

		a controlled substance.
893.13(7)(a)10. ~~893.13(7)(a)9.~~	3rd	Obtain or attempt to obtain controlled substance by fraud, forgery, misrepresentation, etc.
893.13(7)(a)11. ~~893.13(7)(a)10.~~	3rd	Affix false or forged label to package of controlled substance.
893.13(7)(a)12. ~~893.13(7)(a)11.~~	3rd	Furnish false or fraudulent material information on any document or record required by chapter 893.
893.13(8)(a)1.	3rd	Knowingly assist a patient, other person, or owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practitioner's practice.
893.13(8)(a)2.	3rd	Employ a trick or scheme in the practitioner's practice to

			assist a patient, other person, or owner of an animal in obtaining a controlled substance.
893.13(8)(a)3.		3rd	Knowingly write a prescription for a controlled substance for a fictitious person.
893.13(8)(a)4.		3rd	Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing the prescription is a monetary benefit for the practitioner.
918.13(1)(a)		3rd	Alter, destroy, or conceal investigation evidence.
944.47 (1)(a)1.-2.		3rd	Introduce contraband to correctional facility.
944.47(1)(c)		2nd	Possess contraband while upon the grounds of a correctional institution.

985.721	3rd	Escapes from a juvenile facility (secure detention or residential commitment facility).

Section 5. Substitution of opioid analgesic for opioid analgesic incorporating tamper-resistance technology prohibited; exceptions.—

(1) As used in this section, the term:

(a) "Interchange or substitute an opioid analgesic drug" means to substitute any opioid analgesic drug, whether brand-name or generic, for the opioid analgesic drug incorporating a tamper-resistance technology originally prescribed, irrespective of whether the substituted drug is rated as pharmaceutically and therapeutically equivalent by the United States Food and Drug Administration or the Board of Pharmacy or whether the opioid analgesic drug with tamper-resistance technology bears a labeling claim with respect to reduction of tampering, abuse, or abuse potential.

(b) "Opioid analgesic drug" means a drug in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release form, that may or may not be combined with other drug substances to form a single tablet or other dosage form.

(c) "Opioid analgesic drug incorporating a tamper-resistance technology" means an opioid analgesic drug listed as such by the Board of Pharmacy based upon a submission of evidence by the drug manufacturer or distributor that the drug

incorporates a tamper-resistance technology and has been approved by the United States Food and Drug Administration pursuant to an application that includes at least one human tampering or abuse potential study or a laboratory study comparing the tamper or abuse resistance properties of the drug to one or more opioid analgesic drugs that have been approved by the United States Food and Drug Administration and serve as a positive control.

(2) The Board of Pharmacy shall create a list of opioid analgesic drugs for which information has been submitted as described in paragraph (1)(c). Inclusion of a drug on the list does not require that the drug bear a labeling claim with respect to reduction of tampering, abuse, or abuse potential at the time of listing. Such a list must also include a determination by the Board of Pharmacy as to which listed opioid analgesic drugs incorporating tamper-resistance technologies provide substantially similar tamper-resistance properties based solely upon studies submitted by the drug manufacturer consistent with paragraph (1)(c).

(3) Notwithstanding s. 465.025, Florida Statutes, a pharmacist may not interchange or substitute an opioid analgesic drug, whether brand-name or generic, for an opioid analgesic drug incorporating a tamper-resistance technology that is listed pursuant to subsection (2) without:

(a) Verifying that the opioid analgesic drug has been listed by the Board of Pharmacy under subsection (2) as providing tamper-resistant properties substantially similar to the prescribed opioid analgesic drug incorporating a tamper-

resistance technology; or

(b) Obtaining written, signed consent from the prescribing physician for the interchange or substitution.

Section 6. This act shall take effect October 1, 2012.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health & Human Services Quality Subcommittee

Representative McBurney offered the following:

Amendment (with title amendment)

Remove lines 50-52 and insert:

8. Knowingly use a Schedule II controlled substance, intended by the prescriber to be administered orally, in another manner.

T I T L E A M E N D M E N T

Remove lines 3-6 and insert:

893.13, F.S.; prohibiting the knowing use of a Schedule II controlled substance intended to be administered orally, in another manner; providing criminal

PCS for HB 1419

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 1419 Health Care Facilities
SPONSOR(S): Health & Human Services Quality Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Quality Subcommittee		Guzzo	Calamas

SUMMARY ANALYSIS

The bill amends the Health Care Licensing Procedures Act (Act) and the various authorizing statutes of entities regulated by the Agency for Health Care Administration (AHCA) to reduce, streamline, and clarify regulations for those providers. The bill makes the following changes to current law:

- Repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law;
- Resolves conflicts among and between provisions in the Act and various authorizing statutes for individual provider types;
- Makes various revisions to update terminology and conforms current law to prior legislative changes;
- Amends the Health Care Clinic Act to provide additional exemptions;
- Amends various licensure provisions, including those related to bankruptcy notifications, licensure renewal notices, billing complaints, accrediting organizations, licensure application document submissions, staffing in geriatric outpatient clinics, medical records, property statements, AHCA inspection staff, litigation notices, and health care clinic licensure exemptions;
- Adds Det Norske Veritas to the list of private accrediting organizations that can accredit a licensed hospital;
- Clarifies that all new hospice inpatient facilities are subject to certificate of need (CON) review and enables CON applicants to submit an audit of their parent corporation in an audit of the applicant does not exist;
- Revises the definition of "remuneration" to allow home health agencies to distribute certain novelty items with a value of up to $15 that are intended solely for promotional and advertising purposes;
- Revises the definition of "hospice" to include limited liability companies;
- Requires hospital housekeeping and sanitations staff to wear masks and gloves while cleaning patient rooms and disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used;
- Requires AHCA to step edit the list of drugs that are subject to prior authorization;
- Revises the composition of the Medicaid Pharmaceutical and Therapeutics Committee;
- Designates the Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for diabetes research in prevention and treatment;
- Clarifies what constitutes a kickback in a clinical laboratory by prohibiting placement of a specimen collector in a physician's office; and
- Directs the Division of Statutory Revision to provide committees of the Senate and the House of Representatives with assistance, upon request, in preparing draft legislation to correct the names of accrediting organizations in the related Florida Statutes.

The bill does not appear to have a significant impact on state or local government.

The bill has an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

The Agency for Health Care Administration (AHCA) regulates over 41,000 health care providers under various regulatory programs. Regulated providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act (ss. 112.0455, 440.102, F.S.).
- Birth centers (Ch. 383, F.S.).
- Abortion clinics (Ch. 390, F.S.).
- Crisis stabilization units (Pts. I and IV of Ch. 394, F.S.).
- Short-term residential treatment facilities (Pt. I and IV of Ch. 394, F.S.).
- Residential treatment facilities (Pt. IV of Ch. 394, F.S.).
- Residential treatment centers for children and adolescents (Pt. IV of Ch. 394, F.S.).
- Hospitals (Part I of Ch. 395, F.S.).
- Ambulatory surgical centers (Pt. I of Ch. 395, F.S.).
- Mobile surgical facilities (Pt. I of Ch. 395, F.S.).
- Health care risk managers (Pt. I of Ch. 395, F.S.).
- Nursing homes (Pt. II of Ch. 400, F.S.).
- Assisted living facilities (Pt. I of Ch. 429, F.S.).
- Home health agencies (Pt. III of Ch. 400, F.S.).
- Nurse registries (Pt. III of Ch. 400, F.S.).
- Companion services or homemaker services providers (Pt. III of Ch. 400, F.S.).
- Adult day care centers (Pt. III of Ch. 429, F.S.).
- Hospices (Pt. IV of Ch. 400, F.S.).
- Adult family-care homes (Pt. II of Ch. 429, F.S.).
- Homes for special services (Pt. V of Ch. 400, F.S.).
- Transitional living facilities (Pt. V of Ch. 400, F.S.).
- Prescribed pediatric extended care centers (Pt. VI of Ch. 400, F.S.).
- Home medical equipment providers (Pt. VII of Ch. 400, F.S.).
- Intermediate care facilities for persons with developmental disabilities (Pt. VIII of Ch. 400, F.S.).
- Health care services pools (Pt. IX of Ch. 400, F.S.).
- Health care clinics (Pt. X of Ch. 400, F.S.).
- Clinical laboratories (Pt. I of Ch. 483, F.S.).
- Multi-phasic health testing centers (Pt. II of Ch. 483, F.S.).
- Organ, tissue, and eye procurement organizations (Pt. V of Ch. 765, F.S.).

Health Care Licensing Procedures Act

Providers are regulated under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S. The Act provides uniform licensing procedures and standards applicable to most AHCA-regulated entities. The Act contains basic licensing standards for 29 provider types in areas such as licensure application requirements, ownership disclosure, staff background screening, inspections, administrative sanctions, license renewal notices, and bankruptcy and eviction notices.

In addition to the Act, each provider type has an authorizing statute which includes unique provisions for licensure beyond the uniform criteria. Pursuant to s. 408.832, F.S., in the case of conflict between the Act and an individual authorizing statute, the Act prevails. There are several references in authorizing statutes that conflict with or duplicate provisions in the Act, including references to the classification of deficiencies, penalties for an intentional or negligent act by a provider, provisional licenses, proof of financial ability to operate, inspection requirements and plans of corrections from

providers. Chapter 2009-223, L.O.F., made changes to part II of chapter 408, F.S., which supersede components of the specific licensing statutes.

This bill repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law like the Act. The bill also makes changes to the Act to reduce, streamline, or clarify regulations for all providers regulated by AHCA.

The bill changes individual licensing statutes to reflect updates to the uniform standards in the Act. The bill makes corresponding changes to provider licensing statutes to reflect the changes made to the Act to eliminate conflicts and obsolete language.

Certificates of Need

A certificate of need (CON) is a written statement issued by AHCA providing evidence of community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[1] Section 408.037, F.S., requires the applicants for CON to be audited. According to AHCA, the applicant is frequently a sub-entity of a larger corporation and usually has no operations yet.[2] Therefore, the applicant has to go through the expense of getting a separate audit on the sub-entity company to meet the filing requirement.[3]

The bill modifies s. 408.037, F.S., to allow audited financial statements of an applicant's parent corporation in exchange for the audited financial statements of an applicant when such statements do not exist.

License Renewal Notices

Section 408.806, F.S., requires AHCA to notify licensees by mail or electronically when it is time to renew their licenses. AHCA mails renewal notices to over 30,000 providers every two years. While the statute does not specify the manner of mailing notices, AHCA sends them by certified mail to verify receipt by the providers. The cost of certified mail is approximately $56,000 annually. According to AHCA, some certified mail is returned, as providers do not pick it up or the post office is unable to obtain necessary signatures for delivery. AHCA has also encountered situations in which licensees did not timely renew their licenses and claimed that their lack of receipt of a renewal reminder was a reason for that failure.

The bill clarifies that renewal notices are courtesy reminders only and do not excuse the licensees from the requirement to file timely licensure applications. The revised language gives AHCA clear flexibility to use or not use certified mail to send courtesy renewal reminders.

Background Screening

Persons screened under the Agency for Health Care Administration (AHCA) must be rescreened every five years.[4] In 2010, authority was given to AHCA to establish by rule a staggered schedule for the rescreening of all persons who have a controlling interest in, is employed by, or contracts with a licensee on July 31, 2010.[5] All such persons must be rescreened by July 31, 2015.[6]

The bill delays until July 31, 2013, the start of the staggered period for rescreens of persons who have a controlling interest in, is employed by, or contracts with a licensee on July 31, 2010. The bill adds the schedule to statute eliminating the need for a rule.

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[1] S. 408.032(2), F.S.
[2] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[3] Id.
[4] S. 408.809(2), F.S.
[5] Ch. 2010-114, L.O.F.
[6] *Id.*

Classification and Fines for Violations

Section 408.813, F.S., includes criteria for the classification of deficiencies for all providers licensed by AHCA. Some authorizing statutes also contain criteria for the classification of deficiencies, some of which do not match the provisions contained in the Act. The provisions in the Act legally supersede conflicting provisions in the authorizing statutes. However, the dual provisions may be confusing, and some conflicts still exist. Additionally, authorizing statutes are inconsistent related to fines for unclassified deficiencies such as failure to maintain insurance or exceeding licensed bed capacity.

The bill modifies the classification of licensure violations related to home health agencies, intermediate care facilities for the developmentally disabled and adult family care homes to refer to the scope and severity in s. 408.813, F.S. Fine amounts for violations are unchanged. For intermediate care facilities for the developmentally disabled, the amount of fines for Class I, II, and III violations are unchanged, but a new Class IV is added for consistency with s. 408.813, F.S., with a fine not to exceed $500. The addition of the Class IV violation creates a lower category for minor violations by those facilities. This resolves conflicting or confusing differences between the Act and the authorizing statutes, and resolves inconsistencies between these three authorizing statutes.

In addition, the bill establishes uniform sanction authority for unclassified deficiencies of up to $500 per violation. Examples of unclassified deficiencies include failure to maintain insurance and other administrative requirements, exceeding licensed capacity, or violating a moratorium. Without fine authority, AHCA would be required to initiate revocation action for violations against those providers that do not have general fine authority. These violations may not warrant such a severe sanction.

Billing Complaint Authority

The Act provides authority to review billing complaints across all programs and gives the impression that AHCA can take licensure action regarding billing practices. Section 408.10(2), F.S., requires AHCA to investigate consumer complaints regarding billing practices and determine if the facility has engaged in billing practices which are unreasonable and unfair to the consumer. However, the Act does not provide specific standards for billing practices which AHCA can use to cite violations and discipline a provider's license. Nor does the Act define what activities would be unreasonable and unfair. Several providers' authorizing statutes do include billing standards, including nursing homes and assisted living facilities.[7] However, other authorizing statutes are silent on billing standards, including hospitals, labs, crisis stabilization units and residential treatment facilities.

For calendar year 2011, AHCA received 436 complaints that alleged billing-related issues.[8] Of those, 126 were for providers that have billing standards in their licensure statutes. The remaining 310 were related to billing issues for which no regulatory authority existed for billing matters. When the agency receives a billing complaint regarding one of the providers which does not have statutory billing standards, it is the agency's policy to review the complaint and encourage the parties to work together to resolve the problem. However, the provider is not cited or disciplined due to lack of authority.

The bill repeals AHCA's independent authority related to billing complaints in the Act. However, a review for regulatory compliance will continue to be conducted when a complaint is received for one of the providers over which AHCA has well-defined statutory billing authority. This review could possibly result in citations and discipline.

License Display

Section 408.804, F.S., makes it unlawful to provide or offer services that require licensure without first obtaining a license. This section of law also makes licenses valid only for entities and locations for which they are issued. Licensees are required to display licenses in a conspicuous place readily visible to the clients. The Act does not currently address falsification or ill-usage of license documents.

[7] S. 400.23, F.S., (Nursing Homes) and s. 429.19, F.S., (Assisted Living Facilities).
[8] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

The bill makes it a second degree misdemeanor to knowingly alter, deface, or falsify a license and is punishable by up to 60 days in jail and a fine of up to $500. The bill makes it an administrative violation for a licensee to display an altered, defaced, or falsified license. Such violations are subject to licensure revocation and a fine of up to $1,000 per day.

Maternal and Infant Health Care

The bill repeals s. 383.325, F.S., relating to inspection report requirements for birth centers. The section is duplicative of the inspection report requirements contained in part II of chapter 408, F.S.

Diabetes Research

The bill creates s. 385.2031, F.S., designating the Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for diabetes research in prevention and treatment.

Hospital Licensure

Accreditation Organizations

Currently, Florida law allows AHCA to consider and use hospital accreditation by certain accrediting organizations for various purposes, including accepting accreditation surveys in lieu of AHCA surveys, requiring accreditation for designation as certain specialty hospitals, and setting standards for quality improvement programs. Section 395.002, F.S., defines "accrediting organizations" as the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc.

The bill amends s. 395.002(1), F.S., adding Det Norske Veritas to the list of private accrediting organizations that can accredit a licensed hospital.

Private Utilization Review

The bill also deletes obsolete definitions in this section referring to "private review agent", "utilization review" and "initial denial determination". These definitions relate to private utilization review which was repealed by ch. 2009-223, L.O.F.

Specialty Licensed Hospitals

Specialty licensed hospitals are those which meet the characteristics of general hospitals, and which regularly make available:[9]

- The range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population;
- A restricted range of services appropriate to the diagnosis, care and treatment of patients with specific categories of illness; or
- Intensive residential treatment programs for children and adolescents.

Section 395.003(6), F.S. prohibits specialty hospitals from providing any service beyond those specified in its license. The bill amends s. 395.003(6), F.S., to allow pediatric specialty hospitals, with at least 50 total licensed neonatal intensive care unit beds, to offer obstetrical services when either the mother or the fetus has at least one maternal or fetal characteristic that would characterize the pregnancy or delivery as high risk.

[9] S. 395.002(28), F.S.

Currently, there are two hospitals that have 50 total licensed neonatal intensive care unit beds. Miami Children's Hospital has 51 and All Children's, in Saint Petersburg has 97.[10]

Complaint Investigation Procedures

Complaint investigation procedures for hospitals exist in the hospital authorizing statutes as well as in the Act. Section 395.1046, F.S., provides special procedures for hospital complaints regarding emergency access issues. AHCA may investigate emergency access complaints even if the complaint is withdrawn. When the investigation is complete, AHCA shall prepare an investigative report that makes a probable cause determination. AHCA reports that the federal process for emergency access complaints dictates that these complaints should not be handled any differently from other types of complaints.

The bill repeals s. 395.1046, F.S., which eliminates the special procedures for investigating hospital emergency access complaints and would allow AHCA to employ existing hospital complaint investigation procedures used for all other types of complaints.

Infection Control

Section 395.1055(1), F.S., requires AHCA to adopt rules requiring hospitals to meet certain minimum standards of patient care and safety. The rules must include:

- Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patients; and
- Conforming of licensed facility beds to minimum space, equipment, and furnishings standards as specified by DOH.

AHCA Rule 59A-3.250, F.A.C., was promulgated in 1995 to comply with the provisions of s. 395.1055, F.S.

Hospitals use chemical disinfectants to control infection in their facilities. The Environmental Protection Agency (EPA) has been testing hospital sterilants, disinfectants, and tuberculocides since 1991 to ensure that products meet stringent efficacy standards.[11] If disinfectants meet these standards, they are given a registration number that appears on the product label, along with other required statements.[12] One of the label requirements is the recommended contact time for the disinfectant to be effective. The labels of most registered disinfectants specify a contact time of 10 minutes. However, EPA will approve a shortened contact time if a product manufacturer submits confirmatory efficacy data.[13]

The bill amends s. 395.1055(1)(b), F.S., to require AHCA to adopt rules requiring hospital sanitation and housekeeping staff to:

- Wear gloves and masks while cleaning patient rooms; and
- Disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used by the hospital and document compliance.

The bill provides authority for AHCA to impose an administrative fine for each day that a violation of these provisions occurs.

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[10] AHCA, email dated January 23, 2012 on file with Subcommittee Staff.
[11] *See*, Antimicrobial Testing Program, U.S. Environmental Protection Agency, *available at* http://www.epa.gov/oppad001/antimicrobial-testing-program.html (last viewed January 26, 2012).
[12] *Id.*
[13] *Id.*

The bill also amends s. 395.1055(1)(e), F.S., providing that licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by AHCA, the Florida Building Code, and the Florida Fire Prevention Code, instead of DOH.

Licensure Inspection

Section 395.0161(3), F.S., requires hospital license applicants to pay a fee at the time of inspection. The fee cannot be less than $8 per bed, and cannot be more than $12 per bed, with a minimum fee of $400 per facility.

The bill removes the requirement for the fees to be paid at the time of inspection, allowing for a single collection of fees when the license is renewed, rather than separate billing after each inspection.

Patient Records

Hospital patient records are considered confidential and must not be disclosed without the consent of the patient or the patient's legal representative.[14] However, AHCA may obtain patient records upon subpoena issued pursuant to s. 456.071, F.S., but the records must be used solely for the purpose of an investigation, prosecution, or appeal of disciplinary proceedings.

Section 456.071, F.S., provides authority for DOH to issue subpoenas for the purpose of an investigation. The bill amends s. 395.3025(4), F.S., to reference the DOH instead of AHCA, to align with current statutory authority relating to subpoena of patient records.

Hospital Statutory Revisions

The bill makes the following changes to update correct statutory cross references, and remove obsolete, or duplicative statutory provisions:

- Amends s. 394.4787, F.S., to update a cross reference relating to the definition of "specialty psychiatric hospitals";
- Amends s. 395.0193, F.S., to update a reference to the correct authority of DOH instead of AHCA relating to medical staff peer review;
- Amends s. 395.1023, F.S. to clarify that referrals regarding child abuse or neglect are referred to DCF by correcting a cross reference to Department;
- Amends s. 395.3036, F.S., to update a cross reference relating to public lessors and private lessees;
- Amends s. 395.3037, F.S., to repeal duplicative definitions of DOH and AHCA; and
- Amends s. 395.602, F.S., deleting an obsolete provision relating to the definition of "rural hospital"

Nursing Home Licensure

Nursing Home License Application

An application for nursing home licensure must include the following:

- A signed affidavit disclosing financial or ownership interest of a nursing home controlling interest in the last five years in any health or residential facility which has closed, filed bankruptcy, has a receiver appointed or an injunction placed against it, or been denied, suspended, or revoked by a regulatory agency.[15]
- A plan for quality assurance and risk management.[16]

[14] S. 395.3025(4), F.S.
[15] SS. 400.071(1)(b), and 400.111, F.S.
[16] S. 400.071(5), F.S.

- The total number of beds including those certified for Medicare and Medicaid. This information is also required by s. 408.806(1)(d), F.S.
- Copies of any civil verdicts or judgments involving the applicant rendered within the last 10 years.

The bill amends s. 400.071(1)(b), F.S., to remove the requirement for prospective licensees to routinely submit a signed affidavit disclosing financial or ownership interest at the time of licensure and provides AHCA the authority to request the documents if needed.

The bill amends s. 400.071(5), F.S., to remove the requirement for prospective licensees to submit with their applications a plan for quality assurance and for conducting risk management. The plans for quality assurance and risk management are reviewed by AHCA as part of its licensure inspection process.[17]

The bill amends s. 400.071(1)(c), F.S., to remove to duplicative language requiring prospective licensees to submit the total number of beds including those certified for Medicare and Medicaid at the time of licensure. This information is also required under s. 408.806(1)(d), F.S.

The bill amends s. 400.071(1)(e), F.S., to remove the requirement for applicants to submit with their applications copies of civil verdicts or judgments involving the applicant rendered within the last 10 years and provides AHCA the authority to request the documents if needed.

The bill also amends s. 400.0712, F.S., relating to inactive licensure of nursing homes, to remove duplicative language. Inactive licenses may be issued by AHCA to nursing homes for all or a portion of its beds, pursuant to part II of chapter 400, F.S., and s. 400.0712(1), F.S.

Nursing Home Geriatric Outpatient Clinics

Currently, nursing homes may establish a geriatric outpatient clinic as authorized in s. 400.021, F.S., to provide outpatient health care to persons 60 years of age or older. The clinic can be staffed by a registered nurse or a physician's assistant.

Section 400.021(16), F.S., defines "resident care plan" as a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, which includes a comprehensive assessment of the needs of an individual resident. The resident care plan is required to be signed by the director of nursing or another registered nurse employed by the facility.

The bill expands the health care professionals that may staff a geriatric outpatient clinic in a nursing home to include licensed practical nurses under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician.

The bill also removes the requirement that the director of nursing or other administrative nurse sign the resident care plan.

Nursing Home Records

Personnel Records

Section 400.141(1)(j), F.S., requires licensees to maintain full patient records. AHCA Rule 59A-4.118, F.A.C., establishes certain requirements regarding the credentials of nursing home records personnel. Specifically, the rule requires nursing homes to employ or contract with a person who is eligible for certification as a registered record administrator or an accredited record technician by the American Health Information Management Association or is a graduate of a school of medical record science that is accredited jointly by the Council on Medical Education of the American Medical Association and the American Health Information Management Association. AHCA Rule 59A-4.118, F.A.C., was

[17] S. 400.147(11), F.S.

promulgated in 1994 and the credentialing organizations referred to in the rule presently do not exist as listed. There is also no authorizing statute that requires nursing homes to contract with a medical records consultant.

The bill amends s. 440.141(1)(j), F.S., to include federal language regarding maintenance of medical records consistent with federal medical records regulations contained in Title 42, Code of Federal Regulations. Specifically, the federal regulations require nursing homes to maintain medical records in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.[18] The addition of these federal standards will require the repeal of AHCA Rule 59A-4.118, F.A.C., related to the credentials of medical records personnel.

Patient Records

Section 400.145, F.S., requires nursing homes to furnish copies of resident records to the spouse, guardian, surrogate, proxy, or attorney of a resident upon receipt of a written request. The frequency of obtaining records and the fee the facility may charge are also defined in this section. Section 400.191, F.S., addresses the availability, distribution, and posting of reports and records. Resident rights are also provided under federal law pursuant to the federal Health Insurance Portability and Accountability Act (HIPAA). Under HIPAA, the resident or the residents' legal representative has the right to access all records, including clinical records, within 24 hours of a written or oral request.[19] After receipt of his or her records, the resident may purchase photocopies of the records at a cost not to exceed the community standard for photocopies.[20]

The bill repeals s. 400.145, F.S., relating to copies of medical records. The bill amends s. 400.141, F.S., to retain the language from s. 400.145, F.S., defining the amount a facility may charge for copying resident's records. A resident's right to access clinical records is sufficiently addressed in the HIPAA.

Grievances

Section 400.1183, F.S., requires nursing homes to maintain records of all grievances, and to report to the agency, upon licensure renewal, various data regarding those grievances. The bill retains the requirement for nursing homes to maintain all grievance records, but removes the requirement that nursing homes report the grievance information at the time of relicensure. The bill requires nursing homes to retain a log to be made available for inspection by AHCA.

Nursing Home Resident Transfer and Discharge

The landlord tenant laws under part II of chapter 83, F.S., apply generally to the rental of a dwelling unit.[21] Nursing home facilities are governed by the specific transfer and discharge requirements contained in s. 400.0255, F.S, which apply to transfers and discharges that are initiated by the nursing home facility. Facilities are required to provide at least 30 days advance notice of a proposed transfer or discharge to the resident.[22] The notice must be in writing and must contain all information required by state and federal law, rules, or regulations applicable to Medicaid or Medicare cases.[23] Residents are entitled to a fair hearing to challenge a facility's proposed transfer or discharge.[24] The Department of Children and Family Services' Office of Appeals Hearings is tasked with conducting the hearings. A hearing decision must be rendered within 90 days after receipt of request for the hearing.[25]

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[18] 42 C.F.R. 483.75.
[19] 42 C.F.R. 483.10(b)(2)
[20] *Id.*
[21] S. 83.41, F.S.
[22] S. 400.0255(7), F.S.
[23] S. 400.0255(8), F.S.
[24] S. 400.0255(10)(a), F.S.
[25] S. 400.0255(15), F.S.

The bill adds language to clarify that nursing home residents are excluded from the landlord tenant laws found under part II of chapter 83, F.S. The transfer and discharge procedures under s. 400.0255, F.S., govern all transfers and discharges for residents of all facilities licensed under part II of chapter 400, F.S.

Nursing Home Staffing Ratios - General

Nursing homes must comply with staff-to-resident ratios requirements. Under s. 400.141(1)(o), F.S., nursing homes are required to semiannually submit to AHCA information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. The ratio must be reported as an average of the most recent calendar quarter. Staff turnover must be reported for the most recent 12-month period. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.

If a nursing home fails to comply with minimum staffing requirements for two consecutive days, the facility must cease new admissions until the staffing ratio has been achieved for six consecutive days. Failure to self-impose this moratorium on admissions results in a Class II deficiency cited by AHCA. All other citations for a Class II deficiency represent current ongoing non-compliance that AHCA determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being. Use of the Class II deficiency for a failure to cease admissions is an inconsistent use of a "Class II" deficiency in comparison to all other violations. No nursing homes were cited for this violation in 2010.

The bill removes the requirements under s. 400.141(1)(o), F.S., for reporting staff-to-resident ratio information semiannually to AHCA.

The bill modifies the penalty for nursing homes that fail to self-impose an admissions moratorium for insufficient staffing to a fine of $1,000 instead of a Class II deficiency.

Nursing Home Staffing Requirements

Section 400.23(5), F.S., requires AHCA, in collaboration with the Division of Children's Medical Services within the Department of Health (DOH), to adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. In 1997, Rule 59A-4.1295, F.A.C., was adopted to provide these additional standards of care for pediatric nursing homes which consist of the following:

- For residents who require **skilled care**, each nursing home must provide an average of 3.5 hours of nursing care per patient per day. A maximum of 1.5 hours may be provided by a certified nursing assistant (CNA), and no less than 1 hour of care must be provided by a licensed nurse.
- For residents who are **fragile,** each nursing home must provide an average of 5 hours of direct care per patient per day. A maximum of 1.5 hours of care may be provided by a CNA, and no less than 1.7 hours of care must be provided by a licensed nurse.

Section 400.23(3)(a), F.S., establishes general nursing home staffing standards. Until 2001, s. 400.23(3)(a) did not require a minimum number of licensed nurses or certified nursing assistants. When Rule 59A-4.1295, F.A.C., was adopted in 1997, it was in compliance with s. 400.23(3)(a), F.S., because there were no minimum staffing standards required in the statute at that time. However, the minimum staffing requirements in s. 400.23(3)(a), F.S., have changed since the Rule language above was adopted.

In 2001, s. 400.23(3)(a), F.S., was amended to include a minimum staffing standard, which is still in effect today. Currently, s. 400.23(3)(a), F.S., establishes general nursing home staffing standards and requires at least 3.6 hours of licensed nursing and CNA direct care per resident per day. Minimums of

2.5 hours of direct care by a CNA and 1 hour of direct care by a licensed nurse are required. The minimum staffing requirements for pediatric nursing homes in Rule 59A-4.1295, F.A.C., are inconsistent with those required for general nursing homes in s. 400.23(3)(a), F.S. The rule limits CNA care to no more than 1.5 hours per day for both fragile and skilled patients, while the statute allows a minimum of 2.5 hours of CNA care per day.

The bill requires AHCA and the Children's Medical Services Network to adopt rules for minimum staffing requirements for nursing homes that serve individuals less than 21 years of age. Further, the bill provides that these rules are to apply in lieu of the standards contained in s. 400.23(3)(a), F.S. The staffing requirements are as follows:

- For individuals under age 21 who require **skilled** care, each nursing home facility must provide a minimum combined average of licensed nurses, respiratory therapists, and certified nursing assistants of 3.9 hours of direct care per resident per day.
- For individuals under age 21 who are **fragile**, each nursing home must include a minimum combined average of licensed nurses, respiratory therapists, and certified nursing assistances of 5.0 hours of direct care per resident per day.

Current General 400.23(3)(a)	**Current Pediatric Skilled 59A-4.1295(8)(a)**	**HB 119 Pediatric Skilled**	**Current Pediatric Medically Fragile 59A-4.1295(8)(b)**	**HB 119 Pediatric Medically Fragile**
Nurse – 1 hr.	Nurse – 1 hr. minimum	3.9 hrs.	Nurse – 1.7 hrs. minimum	5 hrs.
CNAs – 2.5 hrs. minimum	CNAs – 1.5 hrs. maximum	Can be all CNAs	CNAs – 1.5 hrs. maximum	Can be all CNAs

Nursing Home Do Not Resuscitate Orders

Section 400.142, F.S., requires AHCA to develop rules relating to implementation of do not resuscitate orders (DNRs) for nursing home residents. Criteria for DNRs are found in s. 401.45, F.S., which allows for emergency pre-hospital treatment to be provided by any licensee and provides that resuscitation may be withheld from a patient by an emergency medical technician (EMT) or paramedic if evidence of a DNR is presented.[26] Section 401.45, F.S., also provides rule-making authority to DOH to implement this section and requires DOH, in consultation with the Department of Elderly Affairs and AHCA, to develop a standardized DNR identification system with devices that signify, when carried or worn, that the patient has been issued an order not to administer cardiopulmonary resuscitation by a physician.[27]

DOH developed rule 64J-2.018, F.A.C., which became effective October, 1 2008, while AHCA has yet to promulgate any rules relating to the implementation of DNRs. Rule 64J-2.018, F.A.C., provides the following:[28]

- An EMT or paramedic must withhold or withdraw cardiopulmonary resuscitation if presented with an original or completed copy of DH Form 1896 (Florida DNR Form).
- The DNR Order form must be printed on yellow paper and have the words "DO NOT RESUSCITATE ORDER" printed in black.
- A patient identification device is a miniature version of DH Form 1896 and is a voluntary device intended to provide convenient and portable DNR order form.
- The DNR order form and patient identification device must be signed by the patient's physician.

[26] Section 401.45, F.S.
[27] *Id.*
[28] Florida Department of Health Rule 64J-2.018, F.A.C.

- An EMT or paramedic must verify the identity of the patient in possession of the DNR order form or patient identification device by means of the patient's driver license or a witness in the presence of the patient.
- During transport, the EMT must ensure that a copy of the DNR order form or the patient identification device accompanies the live patient.
- A DNR may be revoked at any time by the patient.

The bill removes the requirement for AHCA to promulgate rules related to the implementation of DNRs for nursing home residents. This requirement appears to be duplicative of DOH rulemaking authority in s. 401.45(5), F.S.

Nursing Home Inspections and Surveys

AHCA employs surveyors to inspect nursing homes. Pursuant to s. 400.275, F.S., newly hired nursing home surveyors must spend two days in a nursing home as part of basic training in a non-regulatory role. Federal regulations prescribe an extensive training process for nursing home inspection staff. Staff must pass the federal Surveyor Minimum Qualifications Test. Federal regulations prohibit an AHCA staff person who formerly worked in a nursing home from inspecting a nursing home within two years of employment with that home; state law requires a five year lapse.

The bill removes the requirement for new AHCA nursing home inspection staff to spend two days in a nursing home as part of basic training and aligns staff requirements with federal regulations. AHCA nursing home staff must still be fully qualified under federal requirements for the Surveyor Minimum Qualifications Test.

Nursing Home Internal Risk Management and Quality Assurance Program

Sections 400.147(10) and 400.0233, F.S., require nursing homes to report civil notices of intent to litigate and civil complaints filed with clerks of courts by a resident or representative of a resident. This information has been used to produce the Semi-Annual Report on Nursing Homes required by s. 400.195, F.S. However, s. 400.195, F.S., was repealed in 2010.

Section 400.147(7), F.S., requires nursing homes to initiate an investigation and notify AHCA within one business day after the risk manager has received an incident report. The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery.

The bill eliminates the requirement to report notices of intent to litigate and civil complaints. The bill also eliminates the requirement that nursing homes notify AHCA in writing when they initiate an investigation. However, providers must still initiate their own evaluation within one day. A full report is also still required to be sent to AHCA within 15 calendar days if the incident is determined to be an adverse incident.

Nursing Home Respite Care

Section 400.141(1)(f), F.S., allows nursing homes to provide respite care for people needing short-term or temporary nursing home services. Only nursing homes with standard licensure status with no Class I or Class II deficiencies in the past two years or having Gold Seal status may provide respite services. AHCA is authorized to promulgate rules for the provision of respite services.

The bill amends s. 400.141, F.S., to expand the ability of nursing homes to provide respite services not exceeding 60 days per year and individual stays may not exceed 14 days. The bill allows all licensed nursing homes to provide respite services without limitations based on prior deficiencies. The bill provides additional criteria for the provision of respite services. For each patient, the nursing home must:

- Have an abbreviated plan of care for each respite patient, covering nutrition, medication, physician orders, nursing assessments and dietary preferences;

- Have a contract that covers the services to be provided;
- Ensure patient release to the proper person; and
- Assume the duties of the patient's primary caregiver.

The bill provides that respite patients are exempt from discharge planning requirements, allowed to use his or her personal medication with a physician's order, and covered by the resident rights as delineated in s. 400.022, F.S., except those related to transfer, choice of physician, bed reservation policies, and discharge challenges. The bill requires prospective respite patients to provide certain medical information to the nursing home and entitles the patient to retain his or her personal physician.

Notice of Bankruptcy and Eviction

Currently, nursing homes are required to notify AHCA of bankruptcy filing pursuant to s. 400.141(1)(r), F.S. However, nursing homes are not required to notify AHCA of eviction, and there is no statutory requirement for other types of facility providers to notify AHCA if served with an eviction notice or of bankruptcy filing.

The bill amends s. 408.810, F.S., to require providers' controlling interests to notify AHCA within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings. This applies to any such action to which the controlling interest is a petitioner or defendant.

Nursing Home Statutory Revisions

The bill makes the following changes to update correct statutory cross references, and remove obsolete, or duplicative statutory provisions:

- Amends s. 400.0234, F.S., removing a cross reference to s. 400.145, F.S., which the bill repeals;
- Amends s. 400.0255, F.S., updating an obsolete cross reference relating to fair hearings for Medicaid cases;
- Amends s. 400.063, F.S., removing an obsolete cross reference; and
- Amends s. 400.915, F.S., removing an obsolete cross reference in the licensing standards for Prescribed Pediatric Extended Care Centers.

Home Health Agency Licensure

A home health agency is an organization that provides home health services and staffing services.[29] Home health agencies are regulated by AHCA pursuant to part III of chapter 400, F.S. Florida law regulates the business relationships of home health agencies, prohibiting "self-referral" situations, in which home health agencies provide monetary incentives for referrals. Section 400.474(6), F.S., provides AHCA the authority to deny, revoke, or suspend the license of a home health agency and impose a fine of $5,000 against a home health agency that gives remuneration to:

- Another home health agency with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A health services pool with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A physician without a medical director contract, and the home health agency has received a patient referral in the preceding 12 months from that physician;
- A physician, and the home health agency has more than one medical director contract in effect at one time, and the home health agency has received a patient referral in the preceding 12 months from that physician;
- A member of the physician's office staff, and the home health agency has received a patient referral in the preceding 12 months from that physician; or

[29] S. 400.462(12), F.S.

- An immediate family member of the physician, and the home health agency has received a patient referral in the preceding 12 months from that physician.

Remuneration is defined as any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.[30]

The bill amends s. 400.462(27), F.S., revising the definition of "remuneration" to allow home health agencies to distribute items with an individual value of up to $15 and which include, but are not limited to, plaques, certificates, trophies, or novelties that are intended solely for promotional, recognition, or advertising purposes.

Homemaker and Companion Organizations

Section 400.509, F.S., requires the registration of organizations that provide homemaker and companion or sitter services to disabled adults and elderly persons. Homemakers provide services such as housekeeping, errands, shopping, and meal preparation. Companions or sitters keep people company and take them to recreational activities, shopping or appointments. Homemakers and companions cannot provide any hands-on personal care.[31] Personal care must be provided by home health aides and CNAs that work for licensed home health agencies and nurse registries.

There are currently 2,303 registered organizations providing homemaker and companion services.[32] Of that total, 503 are contractors of the Agency for Persons with Disabilities (APD) who provide companion services through the Developmental Disabilities Medicaid Waiver.[33] APD requires training and experience as well as background screening, while AHCA only requires background screening prior to registration.

The 1999 Florida Legislature exempted from home health agency and nurse registry licensure, the companion and sitter organizations that were registered by AHCA on January 1, 1999, and were authorized to provide personal services to developmentally disabled persons on January 1, 1999, and permitted the organizations to continue to provide services to any past, present and future clients who need personal care services.[34] Currently there are seven organizations that are exempt under this law.[35]

The bill amends s. 400.509, F.S., to exempt organizations that only provide companion services to developmentally disabled persons under contract with APD from registration by AHCA. The exemption is expected to result in estimated annual savings to providers of $123,486.[36]

Additionally, the bill amends s. 400.464, F.S., deleting the January 1, 1999 date. The deletion of the date allows any companion or sitter organization that is registered and is a developmental disability provider to provide personal care to any past, present and future client who needs personal care, without being licensed.

Nurse Registry Licensure

A nurse registry is defined as any person that procures, offers, promises, or attempts to secure health-care-related contracts for registered nurses, licensed practical nurses, CNAs, home health aides, companions, or homemakers, who are compensated by fees as independent contractors to provide services to patients, or staffing services to facilities.[37] Nurse registries are regulated by AHCA pursuant

[30] S. 400.462(27), F.S.
[31] S. 400.462(7),(16), F.S.
[32] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[33] *Id.*
[34] S. 400.464(5)(b)4, F.S.
[35] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[36] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[37] S. 400.462(21), F.S.

to part III of chapter 400, F.S. Florida law regulates the business relationships of nurse registries, prohibiting "self-referral" situations, in which nurse registries provide monetary incentives for referrals.

Hospice Licensure

Section 400.601(3), F.S., defines "hospice" as a centrally administered corporation providing a continuum of palliative and supportive care for a terminally ill patient and his or her family.

Section 408.810(8) F.S., requires any hospice initial or change of ownership applicant show anticipated provider revenue and expenditures, the basis for financing anticipated cash flow requirements and access to contingency financing. Section 400.606(1)(l), F.S., requires that an annual operating budget be submitted, which duplicates the financial information now required in the Act.

The hospice authorizing statutes and federal regulations require that hospices have inpatient beds for pain control, symptom management, and respite care. Inpatient beds may be in a hospital, skilled nursing facility or a freestanding inpatient facility operated by a hospice. Section 408.043, F.S., requires that there be a certificate of need for a hospice freestanding facility "primarily engaged in providing inpatient care and related services." This provision is repeated in the Act.

The bill amends s. 400.601(3), F.S., to include limited liability companies in the definition of "hospice".

The bill removes the requirement for hospice licensure applicants to submit a projected annual operating budget. Financial projections are already submitted as part of the proof of financial ability to operate as required in the Act; therefore, this removes duplicative requirements.

The bill amends both the Act and the hospice authorizing statutes related to certificates of need for inpatient hospice facilities. The bill eliminates the modifier "primarily" to provide that any provision of inpatient hospice care, in any facility not already licensed as a health care facility (like a hospital or nursing home), requires a certificate of need. In effect, the bill provides that no exemptions to this requirement exist.

Home Medical Equipment Licensure

Section 400.931(2), F.S., allows a bond be posted as an alternative to submitting proof of financial ability to operate for a home medical equipment provider. Section 408.8065, F.S., requires the submission of financial statements demonstrating the ability to fund start up costs, working capital, and contingency requirements.

The bill deletes the provisions of s. 400.931, F.S., related to the ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act. In addition, the bill requires out-of-state home medical equipment providers to be accredited to be licensed in Florida.

Health Care Clinic Licensure

Part X of chapter 400, F.S., contains the Health Care Clinic Act. This act was passed in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. Florida's Motor Vehicle No-Fault Law[38] requires motor vehicle owners to maintain $10,000 of PIP insurance. PIP benefits are available for certain express damages sustained in a motor vehicle accident, regardless of fault.

Pursuant to the Health Care Clinic Act, AHCA licenses entities that meet the definition of a "clinic": "an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services...".[39] Licensure applications must identify the owners, medical

[38] Sections 627.730-627.7405, F.S., the Florida Motor Vehicle No-Fault Law, were repealed on October 1, 2007 pursuant to s. 19, ch. 2003-411 L.O.F. The No-Fault Law was revived and reenacted effective January 1, 2008 pursuant to ch. 2007-324 L.O.F.
[39] Section 400.9905(4), F.S.

director, and medical providers employed by the clinic. Applicants must provide proof of compliance with applicable rules and financial ability to operate. A level two background screening is required of each applicant for clinic licensure, and certain criminal offenses bar licensure. Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

AHCA may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to $5,000 per violation pursuant to s. 400.995, F.S.

Although all clinics must be licensed, s. 400.9905(4), F.S., contains a listing of entities that are not considered a "clinic" for purposes of licensure, including:

- Entities licensed or registered by the state under one or more specified practice acts and that only provide services within the scope of their license, and entities that own such entities, and entities under common ownership with such entities;
- Entities that are exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- Community college and university clinics;
- Entities owned or operated by the federal or state government;
- Clinical facilities affiliated with an accredited medical school which provides certain training;
- Entities that provide only oncology or radiation therapy services by physicians and are owned by publicly-traded corporations;
- Clinical facilities affiliated with an accredited certain college of chiropractic which provides certain training;
- Entities that provide a certain amount of practitioner staffing or anesthesia services to hospitals;
- Orthotic or prosthetic facilities owned by publicly-traded corporations; and

The bill expands an existing exemption from health care clinic licensure for clinics that are wholly owned, directly or indirectly, by a publicly traded corporation to include pediatric cardiology, perinatology, or anesthesia clinics. The bill also creates exemptions from licensure for entities:

- Owned by a corporation generating more than $250 million in annual sales and which have at least one owner who is a health care practitioner;
- Owned directly or indirectly by a publically traded entity with $100 million or more in total annual revenues derived from providing health care services by employed or contracted licensed health care practitioners; and
- Entities that employ 50 or more licensed health care practitioners where the billing for medical services is under a single tax identification number.

Licensure for health care clinics includes mobile clinics and portable equipment providers. The bill provides that portable service providers, such as mobile ultrasound providers, are subject to health care clinic licensure even though they do not deliver care at the clinic's location.

Section 400.991(4), F.S., allows a bond to be posted as an alternative to submitting proof of financial ability to operate for health care clinics. The bill deletes provisions in s. 400.991(4), F.S., related to the

ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act.

Local Health Councils

Local health councils are established in s. 408.033, F.S., as public or private nonprofit agencies to provide certain health related services to the counties of a district. Funding for local health councils is provided in s. 408.033(2), F.S., which states the cost of local health councils is to be borne by assessments on selected health care facilities subject to facility licensure by AHCA. Currently there is no timetable in statute addressing when fees are to be paid.

The bill requires fees to be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Assisted Living Facility Licensure

Section 429.11, F.S., provides that, in addition to the license categories available in part II of chapter 408, F.S., a provisional license may be issued to an individual who submits an initial or change of ownership application.

Section 429.915, F.S., allows AHCA to issue a conditional license to an individual who submits an application for license renewal or change of ownership and the applicant fails to meet all standards and requirements for licensure. The conditional license issued by AHCA must not be valid for longer than six months, and must be accompanied by an approved plan of correction.

Section 429.195, F.S., prohibits ALFs from contracting to pay or receive any commission, bonus, kickback, or rebate with any person for resident referrals. These actions are considered patient brokering and are punishable as a third degree felony as provided in s. 817.505, F.S.

ALFs are required to provide complete copies of a resident's records within its control or possession for investigation of resident's rights violations and defenses within ten days, in accordance with the provisions of s. 400.145, F.S.[40]

The bill amends s. 429.11, F.S., eliminating the ALF provisional license.

The bill amends s. 429.915, F.S., removing the requirement that AHCA must issue an approved plan of correction upon issuing a conditional license.

The bill amends s. 429.294(1), F.S., deleting a cross reference to s. 400.145, F.S., relating to furnishing copies of records of care and treatment of residents in nursing homes, which the bill repeals.

The bill amends s. 429.195(3), F.S., providing that the following activities are not prohibited patient brokering by ALFs and are not punishable as third degree felonies:

- Employing or contracting for marketing services;
- Referral services which provide information, consultation, or referrals to consumers; or
- Referrals to an ALF by residents of the ALF.

Drug Free Workplace Act

Section 112.0455, F.S., contains the Drug Free Workplace Act (Act). The purpose of the Act is to:

- Promote the goal of drug-free workplaces within government through fair and reasonable testing methods for the protection of public employees and employers;

[40] S. 429.294(1), F.S.

- Encourage employers to provide employees who have drug use problems with an opportunity to participate in an employee assistance program or an alcohol and drug rehabilitation program;
- Provide for confidentiality of testing results.

Section 112.0455(12), F.S., establishes drug testing standards for laboratories licensed under part II of chapter 408. Laboratories are required to submit a monthly report with statistical information regarding the testing of employees and job applicants to AHCA. The reports must include the following information:[41]

- The methods of analyses conducted;
- Drugs tested for;
- The number of positive and negative results for both initial and confirmation tests; and
- Any other information deemed appropriate by AHCA.

Identical language requiring the same report to be submitted to AHCA can be found in s. 440.102(9)(d), F.S., as it relates to the drug free workplace program requirements of the workers' compensation program.

The bill removes the requirement for laboratories to submit a monthly report to AHCA from s. 112.0455, F.S., as well as s. 440.102, F.S. The laboratory reports are not used by AHCA, so the removal of this requirement would reduce regulation that requires unnecessary reporting and save providers approximately $11,300.[42]

Clinical Laboratories

Advanced Registered Nurse Practitioners

Part I of chapter 483, F.S., contains licensure requirements for, and regulation of, clinical laboratories operated by practitioners for exclusive use. Section 483.035(1), F.S., requires clinical laboratories licensed by one or more practitioners under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466 to be licensed under, and comply with the provisions of part I of chapter 483. It provides authority for AHCA to adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon the standards contained in the federal Clinical Laboratory Improvement Amendments (CLIAs) of 1988.

Currently, the above list does not include advanced registered nurse practitioners (ARNPs). A laboratory owned or operated by an ARNP is required to have a laboratory director qualified in accordance with part III of chapter 483, F.S., and the Department of Health (DOH) Rule 64B-3, F.A.C. Rule 64B3-5.007, F.A.C., requires any laboratory director to have specialty/subspecialty specific qualifications and be a licensed physician or dentist, or hold a doctoral degree and be licensed by DOH as a clinical laboratory director.

The bill adds ARNPs to the list of exclusive use laboratory providers in s. 483.035(1), F.S., which means CLIA staffing requirements apply to ARNPs instead of the current clinical laboratory director qualification requirements.

CLIA Certificates

Section 483.051, F.S., provides authority for AHCA to adopt rules to implement the provisions of part I of chapter 483, F.S. The rules must include, but are not limited to licensure qualifications. Section 483.051(1), F.S., requires AHCA to provide for biennial licensure of all clinical laboratories and prescribe the qualifications necessary for such licensure.

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[41] Section 112.0455(12)(d), F.S.
[42] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

Currently, AHCA processes federal CLIA certificates for all laboratories, but only processes state licenses for non-waived (complex) clinical laboratories. The federal Centers for Medicare and Medicaid Services conduct a test to determine qualification for a certificate of waiver under the CLIAs.

The bill amends s. 483.051(1), F.S., clarifying that AHCA must provide for biennial licensure of all "non-waived" clinical laboratories and provides a definition for non-waived laboratories to make sure the distinction is clear.

Prohibited Rebates

Section 483.245, F.S., prohibits clinical laboratories from providing any commission, bonus, kickback, or rebate to any person or organization in return for patient referrals and requires AHCA to adopt rules that assess administrative penalties for such acts. Current law does not define what constitutes a rebate, commission, bonus, split-fee arrangement or kickback. However, AHCA defines the term "kickback" under Rule 59A-7.020(14), F.A.C., but the definition is broad and could be interpreted a number of different ways. As a result, there is currently pending litigation related to AHCA's interpretation of what constitutes a kickback as defined under Rule 59A-7.020(14), F.A.C.[43]

A collection station is a facility operated by a clinical laboratory where materials or specimens are withdrawn or collected from patients for subsequent delivery to another location for examination.[44] AHCA Rule 59A-7.024, F.A.C., authorizes clinical laboratories to maintain one or more collection stations provided they first obtain written approval from AHCA and they can only forward specimens to the clinical laboratory by which they are maintained.

The bill amends s. 483.245(1), F.S., providing that a clinical laboratory is prohibited from placing a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the same entity.

Multi-Phasic Health Testing Centers

Multi-phasic health testing centers (centers) are facilities which take human specimens for delivery to clinical laboratories for testing and may perform other basic human measurement functions. Centers are licensed and regulated under part II of chapter 483, F.S. Section 483.294, F.S., requires AHCA to inspect centers at least annually.

The bill amends the inspection schedule requiring AHCA to inspect centers biennially.

Brain and Spinal Cord Injury Trust Fund

Under current law, specified traffic fines may be used to provide an enhanced Medicaid rate to nursing homes that serve clients with brain and spinal cord injuries. According to AHCA, funds collected from these fines have not been sufficient to support a Medicaid nursing home supplemental rate for the estimated 100 adult ventilator-dependent patients.

The bill redirects the revenue to the Brain and Spinal Cord Injury Trust Fund within DOH, to be used for Medicaid recipients who have sustained a brain or spinal cord injury and who are technologically and respiratory dependent.

[43] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[44] S. 483.041(5), F.S.

Medicaid Pharmaceutical and Therapeutics Committee

Section 409.91195, F.S., was adopted during the 2000 legislative session[45] to provide for the creation of the Medicaid Pharmaceutical and Therapeutics Committee (committee) within AHCA for the purpose of developing a Medicaid preferred drug list.

Current law requires the committee to be composed of 11 members appointed by the Governor. The 11 members must consist of:[46]

- Four licensed physicians;
- One licensed osteopathic physician;
- Five licensed pharmacists; and
- One consumer representative.

The committee is required to ensure that all interested parties have an opportunity to present public testimony to the committee with information supporting inclusion of a product on the preferred drug list.[47] Public testimony must occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list.[48] In developing its preferred drug list recommendations, the committee must consider the clinical efficacy, safety, and cost-effectiveness of a product.[49]

Currently, AHCA limits public presentations at committee meetings to 10 speakers at two minutes each.[50] Overall, the public testimony portion consumes approximately 30 minutes of the four hour meeting slot.[51]

The bill amends s. 409.91195(1), F.S., changing the composition of the committee by requiring nine professional organizations and one advocacy group to nominate licensed professionals for appointment to the committee by the Governor. Professional organizations and advocacy groups currently have the option to ask members to apply for appointment to the committee.[52]

The bill amends s. 409.91195(7), F.S., requiring the committee to allow an unlimited number of speakers to provide public testimony of three minutes each at committee meetings. Committee meetings are currently limited to four hours and unlimited public participation could consume significant portions of each meeting.[53] The bill also requires AHCA to notify committee members in writing whenever it does not follow a recommendation by the committee.

Prior Authorization

Prior authorizations are currently used when a physician does not use the Medicaid preferred drug list when prescribing medication. A prior authorization is required to ensure there is an appropriate reason for Medicaid to pay for a drug not on the Medicaid preferred drug list. When a prior authorization is requested it is reviewed and tested for compliance with certain criteria.

Physicians are required to provide information to AHCA about the rationale and supporting medical evidence for the use of a drug. Currently, AHCA is authorized but not required to electronically post prior authorization criteria, protocol, and updates to the list of drugs that are subject to prior authorization without amending its rule or engaging in additional rulemaking.

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[45] Ch. 2000-367, s. 72, L.O.F.
[46] S. 409.91195(1), F.S.
[47] S. 409.91195(7), F.S.
[48] *Id.*
[49] S. 409.91195(8), F.S.
[50] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[51] *Id.*
[52] *Id.*
[53] *Id.*

The bill amends s. 409.912, F.S., to require AHCA to electronically post prior authorization and step edit criteria, protocol, and updates to the list of drugs that are subject to prior authorization on their website. In addition, the bill requires AHCA to post the information on their website within 21 days after the prior authorization and step edit information is approved by AHCA and removes the exemption from rulemaking for prior authorization. The bill provides a definition of the term "step edit" as an automatic review of certain medications subject to prior authorization.

According to AHCA, requiring AHCA to electronically post prior authorization criteria could allow physicians to inappropriately circumvent prior authorizations protocols, which could result in a cost increase to the program.[54]

Statutory Revisions

The bill deletes definitions for and references to private review agents and utilization review in s. 395.002, F.S., to conform to the repeal made in chapter 2009-223, L.O.F. The bill repeals unused or unnecessary definitions, including definitions for "department" and "agency".

The bill makes technical corrections and repeals requested by the Division of Statutory Revision, such as repealing obsolete dates, amending cross-references, and updating the reference to an obsolete rule.

B. SECTION DIRECTORY:

Section 1: Amends s. 83.42, F.S., relating to exclusions from application of part.
Section 2: Amends s. 112.0455, F.S., relating to the Drug-Free Workplace Act.
Section 3: Amends s. 318.21, F.S., relating to the disposition of civil penalties by county courts.
Section 4: Repeals s. 383.325, F.S., relating to inspection reports.
Section 5: Creates s. 385.2031, F.S., relating to a resource for research in the prevention and treatment of diabetes.
Section 6: Amends s. 394.4787, F.S., relating to specialty psychiatric hospitals.
Section 7: Amends s. 395.002, F.S., relating to accrediting organizations and specialty hospitals.
Section 8: Amends s. 395.003, F.S., relating to licensure; denial; suspension and revocation.
Section 9: Amends s. 395.0161, F.S., relating to licensure inspection.
Section 10: Amends s. 395.0193, F.S., relating to licensed facilities; peer review; disciplinary powers; and agency or partnership with physicians.
Section 11: Amends s. 395.1023, F.S., relating to child abuse and neglect cases.
Section 12: Amends s. 395.1041, F.S., relating to access to emergency services and care.
Section 13: Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
Section 14: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 15: Amends s. 395.3025, F.S., relating to patient and personnel records; copies; and examination.
Section 16: Amends s. 395.3036, F.S., relating to confidentiality of records and meetings of corporations that lease public hospitals or other public health care facilities.
Section 17: Repeals s. 395.3037, F.S., relating to definitions of "department" and "agency".
Section 18: Amends s. 395.602, F.S., relating to rural hospitals.
Section 19: Amends s. 400.021, F.S., relating to geriatric outpatient clinics.
Section 20: Amends s. 400.0234, F.S., relating to availability of facility records for investigation of resident's rights violations and defenses.
Section 21: Amends s. 400.0255, F.S., relating to resident transfer or discharge; requirements and procedures; hearings.
Section 22: Amends s. 400.063, F.S., relating to resident protection.
Section 23: Amends s. 400.071, F.S., relating to application for license.
Section 24: Amends s. 400.0712, F.S., relating to application for inactive license.

[54] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

Section 25: Amends s. 400.111, F.S., relating to disclosure of controlling interest.
Section 26: Amends s. 400.1183, F.S., relating to resident grievance procedures.
Section 27: Amends s. 400.141, F.S., relating to administration and management of nursing home facilities.
Section 28: Amends s. 400.142, F.S., relating to emergency medication kits; orders not to resuscitate.
Section 29: Repeals s. 400.145, F.S., relating to records of care and treatment of residents; copies to be furnished.
Section 30: Amends s. 400.147, F.S., relating to internal risk management and quality assurance program.
Section 31: Amends s. 400.19, F.S., relating to right of entry and inspection.
Section 32: Amends s. 400.23, F.S., relating to rules; evaluation and deficiencies; licensure status.
Section 33: Amends s. 400.275, F.S., relating to agency duties.
Section 34: Amends s. 400.462, F.S., relating to home health agency remuneration.
Section 35: Amends s. 400.464, F.S., relating to home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.
Section 36: Amends s. 400.484, F.S., relating to right of inspection; violations and fines.
Section 37: Amends s. 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
Section 38: Amends s. 400.509, F.S., relating to registration of particular service providers exempt from licensure.
Section 39: Amends s. 400.601, F.S., relating to definitions.
Section 40: Amends s. 400.606, F.S., relating to license application, renewal, conditional license or permits and certificates of need.
Section 41: Amends s. 400.915, F.S., relating to construction and renovation requirements.
Section 42: Amends s. 400.931, F.S., relating to application for licensure.
Section 43: Amends s. 400.967, F.S., relating to rules and classification of violations.
Section 44: Amends s. 400.9905, F.S., relating to clinics and portable health service or equipment providers.
Section 45: Amends s. 400.991, F.S., relating to license requirements; background screening; prohibitions.
Section 46: Amends s. 408.033, F.S., relating to local and state health planning.
Section 47: Amends s. 408.034, F.S., relating to duties and responsibilities of the agency.
Section 48: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 49: Amends s. 408.037, F.S., relating to application content.
Section 50: Amends s. 408.043, F.S., relating to special provisions.
Section 51: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 52: Amends s. 408.07, F.S., relating to rural hospitals.
Section 53: Amends s. 408.10, F.S., relating to consumer complaints.
Section 54: Amends s. 408.7056, F.S., relating to the subscriber assistance program.
Section 55: Amends s. 408.802, F.S., relating to applicability.
Section 56: Amends s. 408.804, F.S., relating to license required; display.
Section 57: Amends s. 408.806, F.S., relating to license application process.
Section 58: Amends s. 408.8065, F.S., relating to additional licensure requirements for home health agencies; home medical equipment providers, and health care clinics.
Section 59: Amends s. 408.809, F.S., relating to background screening; prohibited offenses.
Section 60: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 61: Amends s. 408.813, F.S., relating to administrative fines; violations.
Section 62: Amends s. 409.91195, F.S., relating to the Medicaid Pharmaceutical and Therapeutics Committee.
Section 63: Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.
Section 64: Amends s. 429.11, F.S., relating to initial application for license.
Section 65: Amends s. 429.294, F.S., relating to availability of facility records for investigation of resident's rights violations and defenses.
Section 66: Amends s. 429.71, F.S., relating to classification of violations.
Section 67: Amends s. 429.195, F.S., relating to rebates prohibited; penalties.
Section 68: Amends s. 429.915, F.S., relating to conditional licensure.

Section 69: Amends s. 430.80, F.S., relating to implementation of a teaching nursing home pilot project.
Section 70: Amends s. 430.81, F.S., relating to implementation of a teaching agency for home and community-based care.
Section 71: Amends s. 440.102, F.S., relating to drug-free workplace program requirements.
Section 72: Amends s. 483.035, F.S., relating to clinical laboratories operated by practitioners for exclusive use; licensure and regulation.
Section 73: Amends s. 483.051, F.S., relating to powers and duties of the agency.
Section 74: Amends s. 483.245, F.S., relating to rebates prohibited; penalties.
Section 75: Amends s. 483.294, F.S., relating to inspection of centers.
Section 76: Amends s. 651.118, F.S., relating to the Agency for Health Care Administration.
Section 77: Amends s. 817.505, F.S., relating to patient brokering prohibited; exceptions; penalties.
Section 78: In an unnamed section of law, requiring the Division of Statutory Revision, in the interim between this act becoming law and the 2013 Regular Session of the Legislature, to provide the relevant substantive committees of the Senate and the House of Representatives with assistance, upon request, to enable such committees to prepare draft legislation to correct the names of accrediting organizations in the related Florida Statutes.
Section 79: Provides an effective date of July 1, 2012.

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 bill is expected to result in combined annual savings of approximately $2,113,476 for providers and applicants.[55]

The following provisions are expected to save providers an estimated $1,413,476 annually:

- Removing the requirement for nursing homes to employ or contract with a medical records consultant – saving $335,000;
- Removing the requirement for toxicology and Drug-free Work Place laboratories to submit monthly statistical reports to the Agency for Health Care Administration (AHCA) – saving $11,300;
- Allowing nurse registries to share an administrator for up to five nurse registries with common controlling interests – saving $943,690; and

[55] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

- Removing the requirement for companion organizations that are also contractors of the Agency for Persons with Disabilities to be registered with AHCA – saving $123,486.

Modifying certificate of need requirements to allow audited financial statements of an applicant's parent corporation is expected to result in savings of $700,000 annually for applicants.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to AHCA to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health care facilities; amending s. 83.42, F.S., relating to exclusions from part II of ch. 83, F.S., the Florida Residential Landlord and Tenant Act; clarifying that the procedures in s. 400.0255, F.S., for transfers and discharges are exclusive to residents of a nursing home licensed under part II of ch. 400, F.S.; amending s. 112.0455, F.S., relating to the Drug-Free Workplace Act; deleting a provision regarding retroactivity of the act; deleting a provision that the act does not abrogate the right of an employer under state law to conduct drug test before a specified date; deleting a provision that requires a laboratory to submit to the Agency for Health Care Administration a monthly report containing statistical information regarding the testing of employees and job applicants; amending s. 381.21, F.S.; providing that a portion of the additional fines assessed for traffic violations within an enhanced penalty zone be remitted to the Department of Revenue and deposited into the Brain and Spinal Cord Injury Trust Fund of the Department of Health to serve certain Medicaid recipients; repealing s. 383.325, F.S., relating to confidentiality of inspection reports of licensed birth center facilities; creating s. 385.2031, F.S.; designating the Florida Hospital/Sandford-Burnham Translational Research Institute for Metabolism and Diabetes as a

resource for research in the prevention and treatment of diabetes; amending s. 394.4787, F.S.; conforming a cross-reference; amending s. 395.002, F.S.; revising and deleting definitions applicable to the regulation of hospitals and other licensed facilities; conforming a cross-reference; amending s. 395.003, F.S.; deleting an obsolete provision; conforming a cross-reference; providing for certain specialty-licensed children's hospitals to provide specified obstetrical services; amending s. 395.0161, F.S.; deleting a requirement that facilities licensed under part I of ch. 395, F.S., pay licensing fees at the time of inspection; amending s. 395.0193, F.S.; requiring a licensed facility to report certain peer review information and final disciplinary actions to the Division of Medical Quality Assurance of the Department of Health rather than the Division of Health Quality Assurance of the Agency for Health Care Administration; amending s. 395.1023, F.S.; providing for the Department of Children and Family Services rather than the Department of Health to perform certain functions with respect to child protection cases; requiring certain hospitals to notify the Department of Children and Family Services of compliance; amending s. 395.1041, F.S., relating to hospital emergency services and care; deleting obsolete provisions; repealing s. 395.1046, F.S., relating to complaint investigation procedures; amending s. 395.1055, F.S.; requiring

additional housekeeping and sanitation procedures in licensed facilities for infection control purposes; authorizing the Agency for Health Care Administration to impose a fine for failure to comply with housekeeping and sanitation procedures requirements; requiring that licensed facility beds conform to standards specified by the Agency for Health Care Administration, the Florida Building Code, and the Florida Fire Prevention Code; amending s. 395.3025, F.S.; authorizing the disclosure of patient records to the Department of Health rather than the Agency for Health Care Administration in accordance with an issued subpoena; requiring the department, rather than the agency, to make available, upon written request by a practitioner against whom probable cause has been found, any patient records that form the basis of the determination of probable cause; amending s. 395.3036, F.S.; correcting a cross-reference; repealing s. 395.3037, F.S., relating to redundant definitions for the Department of Health and the Agency for Health Care Administration; amending s. 395.602, F.S.; revising the definition of the term "rural hospital" to delete an obsolete provision; amending s. 400.021, F.S.; revising the definitions of the terms "geriatric outpatient clinic" and "resident care plan"; amending s. 400.0234, F.S., relating to medical records; conforming provisions to changes made by the act; amending s. 400.0255, F.S.; correcting an obsolete

cross-reference to administrative rules; amending s. 400.063, F.S.; deleting an obsolete provision governing moneys received for the care of residents in a nursing home facility; amending ss. 400.071 and 400.0712, F.S.; revising applicability of general licensure requirements under part II of ch. 408, F.S., to applications for nursing home licensure; revising provisions governing inactive licenses; amending s. 400.111, F.S.; providing for disclosure of the controlling interest of a nursing home facility upon request by the Agency for Health Care Administration; amending s. 400.1183, F.S.; revising grievance record maintenance and reporting requirements for nursing homes; amending s. 400.141, F.S.; providing criteria for the provision of respite services by nursing homes; requiring a written plan of care; requiring a contract for services; requiring that the release of a resident to caregivers be designated in writing; providing an exemption to the application of rules for discharge planning; providing for residents' rights; providing for the use of personal medications; providing for terms of respite stay; providing for communication of patient information; requiring a physician's order for care and proof of a physical examination; providing for services for respite patients and duties of facilities with respect to such patients; conforming a cross-reference; requiring facilities to maintain clinical records that meet

specified standards; providing a fine for failing to comply with an admissions moratorium; deleting a requirement for facilities to submit certain information related to management companies to the agency; deleting a requirement for facilities to notify the agency of certain bankruptcy filings, to conform to changes made by the act; authorizing a facility to charge a fee to copy a resident's records; amending s. 400.142, F.S., relating to orders not to resuscitate; deleting provisions relating to agency adoption of rules; repealing s. 400.145, F.S., relating to requirements for furnishing the records of residents in a licensed nursing home to certain specified parties; amending s. 400.147, F.S.; revising reporting requirements for licensed nursing home facilities relating to adverse incidents; amending s. 400.19, F.S.; revising inspection requirements for nursing homes; amending s. 400.23, F.S.; deleting an obsolete provision; correcting a reference; deleting a requirement that the rules for minimum standards of care for persons under 21 years of age include a certain methodology; directing the agency to adopt rules for minimum staffing standards in nursing homes that serve persons under 21 years of age; providing minimum staffing standards; amending s. 400.275, F.S.; revising agency duties with regard to training nursing home surveyor teams; revising requirements for team members; amending s. 400.462, F.S.; redefining the

term "remuneration" for purposes of the Home Health Services Act; amending s. 400.484, F.S.; revising the classification of violations by a home health agency for which the agency imposes an administrative fine; amending s. 400.506, F.S.; authorizing an administrator to manage up to five nurse registries under certain circumstances; requiring an administrator to designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence; amending s. 400.509, F.S.; providing that organizations that provide companion services only to persons with developmental disabilities, under contract with the Agency for Persons with Disabilities, are exempt from registration with the Agency for Health Care Administration; reenacting ss. 400.464(5)(b) and 400.506(6)(a), F.S., relating to home health agencies and licensure of nurse registries, respectively, to incorporate the amendment made to s. 400.509, F.S., in references thereto; amending s. 400.601, F.S.; revising the definition of the term "hospice" to include limited liability companies; amending s. 400.606, F.S.; revising the content requirements of the plan accompanying an initial or change-of-ownership application for licensure of a hospice; revising requirements relating to certificates of need for certain hospice facilities; amending s. 400.915, F.S.; correcting an obsolete cross-reference to

administrative rules; amending s. 400.931, F.S.; requiring each applicant for initial licensure, change of ownership, or license renewal to operate a licensed home medical equipment provider at a location outside the state to submit documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the Agency for Health Care Administration; requiring an applicant that has applied for accreditation to provide proof of accreditation within a specified time; deleting a requirement that an applicant for a home medical equipment provider license submit a surety bond to the agency; amending s. 400.967, F.S.; revising the classification of violations by intermediate care facilities for the developmentally disabled; providing a penalty for certain violations; amending s. 400.9905, F.S.; revising the definitions of the terms "clinic" and "portable equipment provider"; revising requirements for an application for exemption from health care clinic licensure requirements for certain entities; providing for the agency to deny or revoke the exemption under certain circumstances; including health services provided to multiple locations within the definition of the term "portable health service or equipment provider"; amending s. 400.991, F.S.; conforming terminology; revising application requirements relating to documentation of financial ability to operate a mobile clinic; amending s.

408.033, F.S.; providing that fees assessed on selected health care facilities and organizations may be collected prospectively at the time of licensure renewal and prorated for the licensing period; amending s. 408.034, F.S.; revising agency authority relating to licensing of intermediate care facilities for the developmentally disabled; amending s. 408.036, F.S.; deleting an exemption from certain certificate-of-need review requirements for a hospice or a hospice inpatient facility; amending s. 408.037, F.S.; revising requirements for the financial information to be included in an application for a certificate of need; amending s. 408.043, F.S.; revising requirements for certain freestanding inpatient hospice care facilities to obtain a certificate of need; amending s. 408.061, F.S.; revising data reporting requirements for health care facilities; amending s. 408.07, F.S.; deleting a cross-reference; amending s. 408.10, F.S.; removing agency authority to investigate certain consumer complaints; amending s. 408.7056, F.S.; providing that, as of a specified date, the Subscriber Assistance Program applies only to plans that meet federal requirements for the preservation of the right to maintain existing health plan coverage; amending s. 408.802, F.S.; removing applicability of part II of ch. 408, F.S., relating to general licensure requirements, to private review agents; amending s. 408.804, F.S.; providing penalties for altering,

defacing, or falsifying a license certificate issued by the agency or displaying such an altered, defaced, or falsified certificate; amending s. 408.806, F.S.; revising agency responsibilities for notification of licensees of impending expiration of a license; requiring payment of a late fee for a license application to be considered complete under certain circumstances; amending s. 408.8065, F.S.; revising the requirements for becoming licensed as a home health agency, home medical equipment provider, or health care clinic; amending s. 408.809, F.S.; revising provisions to include a schedule for background rescreenings of certain employees; amending s. 408.810, F.S.; requiring that the controlling interest of a health care licensee notify the agency of certain court proceedings; providing a penalty; amending s. 408.813, F.S.; authorizing the agency to impose fines for unclassified violations of part II of ch. 408, F.S.; amending s. 409.91195, F.S.; revising the composition of the Medicaid Pharmaceutical and Therapeutics Committee; revising provisions relating to public testimony; providing for committee members to be notified in writing if the agency reverses their recommendation regarding preferred drugs; amending s. 409.912, F.S.; revising provisions requiring the agency to post certain information relating to drugs subject to prior authorization on its Internet website; providing a definition of the term "step

edit"; amending s. 429.11, F.S.; revising licensure application requirements for assisted living facilities to eliminate provisional licenses; amending s. 429.294, F.S.; deleting a cross-reference; amending s. 429.71, F.S.; revising the classification of violations by adult family-care homes; amending s. 429.195, F.S.; providing exceptions to applicability of assisted living facility rebate restrictions; amending s. 429.915, F.S.; revising agency responsibilities regarding the issuance of conditional licenses; amending ss. 430.80 and 430.81, F.S.; conforming cross-references; repealing s. 440.102(9)(d), F.S., relating to a laboratory's requirement to submit to the Agency for Health Care Administration a monthly report containing statistical information regarding the testing of employees and job applicants; amending s. 483.035, F.S.; providing for a clinical laboratory to be operated by certain nurses; amending s. 483.051, F.S.; requiring the Agency for Health Care Administration to provide for biennial licensure of all nonwaived laboratories that meet certain requirements; requiring the agency to prescribe qualifications for such licensure; defining nonwaived laboratories as laboratories that do not have a certificate of waiver from the Centers for Medicare and Medicaid Services; deleting requirements for the registration of an alternate site testing location when the clinical laboratory applies to renew

its license; amending s. 483.245, F.S.; prohibiting a clinical laboratory from placing a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the same entity; providing for damages and injunctive relief; amending s. 483.294, F.S.; revising the frequency of agency inspections of multiphasic health testing centers; amending s. 651.118, F.S.; conforming a cross-reference; amending s. 817.505, F.S.; providing an exception to provisions prohibiting patient brokering; providing a directive to the Division of Statutory Revision; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 83.42, Florida Statutes, is amended to read:

83.42 Exclusions from application of part.—This part does not apply to:

(1) Residency or detention in a facility, whether public or private, when residence or detention is incidental to the provision of medical, geriatric, educational, counseling, religious, or similar services. <u>For residents of a facility licensed under part II of chapter 400, the provisions of s. 400.0255 are the exclusive procedures for all transfers and discharges.</u>

Section 2. Present paragraphs (f) through (k) of

subsection (10) of section 112.0455, Florida Statutes, are redesignated as paragraphs (e) through (j), respectively, and present paragraph (e) of subsection (10), subsection (12), and paragraph (e) of subsection (14) of that section are amended to read:

112.0455 Drug-Free Workplace Act.—

(10) EMPLOYER PROTECTION.—

~~(e) Nothing in this section shall be construed to operate retroactively, and nothing in this section shall abrogate the right of an employer under state law to conduct drug tests prior to January 1, 1990. A drug test conducted by an employer prior to January 1, 1990, is not subject to this section.~~

(12) DRUG-TESTING STANDARDS; LABORATORIES.—

(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this section and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to this section. A license issued by the agency is required in order to operate a laboratory.

(b) A laboratory may analyze initial or confirmation drug specimens only if:

1. The laboratory is licensed and approved by the Agency for Health Care Administration using criteria established by the United States Department of Health and Human Services as general guidelines for modeling the state drug testing program and in accordance with part II of chapter 408. Each applicant for licensure and licensee must comply with all requirements of part II of chapter 408.

2. The laboratory has written procedures to ensure chain of custody.

3. The laboratory follows proper quality control procedures, including, but not limited to:

a. The use of internal quality controls including the use of samples of known concentrations which are used to check the performance and calibration of testing equipment, and periodic use of blind samples for overall accuracy.

b. An internal review and certification process for drug test results, conducted by a person qualified to perform that function in the testing laboratory.

c. Security measures implemented by the testing laboratory to preclude adulteration of specimens and drug test results.

d. Other necessary and proper actions taken to ensure reliable and accurate drug test results.

(c) A laboratory shall disclose to the employer a written test result report within 7 working days after receipt of the sample. All laboratory reports of a drug test result shall, at a minimum, state:

1. The name and address of the laboratory which performed the test and the positive identification of the person tested.

2. Positive results on confirmation tests only, or negative results, as applicable.

3. A list of the drugs for which the drug analyses were conducted.

4. The type of tests conducted for both initial and confirmation tests and the minimum cutoff levels of the tests.

5. Any correlation between medication reported by the

employee or job applicant pursuant to subparagraph (8)(b)2. and a positive confirmed drug test result.

A ~~No~~ report may not ~~shall~~ disclose the presence or absence of any drug other than a specific drug and its metabolites listed pursuant to this section.

~~(d) The laboratory shall submit to the Agency for Health Care Administration a monthly report with statistical information regarding the testing of employees and job applicants. The reports shall include information on the methods of analyses conducted, the drugs tested for, the number of positive and negative results for both initial and confirmation tests, and any other information deemed appropriate by the Agency for Health Care Administration. No monthly report shall identify specific employees or job applicants.~~

(d) ~~(e)~~ Laboratories shall provide technical assistance to the employer, employee, or job applicant for the purpose of interpreting any positive confirmed test results which could have been caused by prescription or nonprescription medication taken by the employee or job applicant.

(14) DISCIPLINE REMEDIES.—

(e) Upon resolving an appeal filed pursuant to paragraph (c), and finding a violation of this section, the commission may order the following relief:

1. Rescind the disciplinary action, expunge related records from the personnel file of the employee or job applicant and reinstate the employee.

2. Order compliance with paragraph (10)(f) ~~(10)(g)~~.

3. Award back pay and benefits.

4. Award the prevailing employee or job applicant the necessary costs of the appeal, reasonable attorney's fees, and expert witness fees.

Section 3. Subsection (15) of section 318.21, Florida Statutes, is amended to read:

318.21 Disposition of civil penalties by county courts.—All civil penalties received by a county court pursuant to the provisions of this chapter shall be distributed and paid monthly as follows:

(15) Of the additional fine assessed under s. 318.18(3)(e) for a violation of s. 316.1893, 50 percent of the moneys received from the fines shall be remitted to the Department of Revenue and deposited into the Brain and Spinal Cord Injury Trust Fund of Department of Health and appropriated to the Department of Health ~~Agency for Health Care Administration~~ as general revenue to ~~provide an enhanced Medicaid payment to nursing homes that~~ serve Medicaid recipients who have ~~with~~ brain and spinal cord injuries that are medically complex and who are technologically and respiratory dependent. The remaining 50 percent of the moneys received from the enhanced fine imposed under s. 318.18(3)(e) shall be remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Trust Fund to provide financial support to certified trauma centers in the counties where enhanced penalty zones are established to ensure the availability and accessibility of trauma services. Funds deposited into the Emergency Medical Services Trust Fund under this subsection

shall be allocated as follows:

(a) Fifty percent shall be allocated equally among all Level I, Level II, and pediatric trauma centers in recognition of readiness costs for maintaining trauma services.

(b) Fifty percent shall be allocated among Level I, Level II, and pediatric trauma centers based on each center's relative volume of trauma cases as reported in the Department of Health Trauma Registry.

Section 4. Section 383.325, Florida Statutes, is repealed.

Section 5. Section 385.2031, Florida Statutes, is created to read:

385.2031 Resource for research in the prevention and treatment of diabetes.—The Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes is designated as a resource in this state for research in the prevention and treatment of diabetes.

Section 6. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(26) ~~s. 395.002(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 7. Present subsections (15) through (33) of section 395.002, Florida Statutes, are redesignated as subsections (14) through (29), respectively, and present subsections (1), (14), (24), (28), (30), and (31) of that

section are amended, to read:

395.002 Definitions.—As used in this chapter:

(1) "Accrediting organizations" means the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, ~~and~~ the Accreditation Association for Ambulatory Health Care, Inc, and Det Norske Veritas.

~~(14) "Initial denial determination" means a determination by a private review agent that the health care services furnished or proposed to be furnished to a patient are inappropriate, not medically necessary, or not reasonable.~~

~~(24) "Private review agent" means any person or entity which performs utilization review services for third-party payors on a contractual basis for outpatient or inpatient services. However, the term shall not include full-time employees, personnel, or staff of health insurers, health maintenance organizations, or hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, when performing utilization review for their respective hospitals, health maintenance organizations, or insureds of the same insurance group. For this purpose, health insurers, health maintenance organizations, and hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, include such entities engaged as administrators of self-insurance as defined in s. 624.031.~~

(26) ~~(28)~~ "Specialty hospital" means any facility which meets the provisions of subsection (12), and which regularly makes available either:

(a) The range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population, or both;

(b) A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or

(c) Intensive residential treatment programs for children and adolescents as defined in subsection (14) ~~(15)~~.

~~(30) "Urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care to patients with or without an appointment. It does not include the emergency department of a hospital.~~

~~(31) "Utilization review" means a system for reviewing the medical necessity or appropriateness in the allocation of health care resources of hospital services given or proposed to be given to a patient or group of patients.~~

Section 8. Paragraph (c) of subsection (1), paragraph (b) of subsection (2), and subsection (6) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)

~~(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.~~

(2)

(b) The agency shall, at the request of a licensee that is a teaching hospital as defined in s. 408.07(45), issue a single license to a licensee for facilities that have been previously

licensed as separate premises, provided such separately licensed facilities, taken together, constitute the same premises as defined in s. 395.002(22) ~~s. 395.002(23)~~. Such license for the single premises shall include all of the beds, services, and programs that were previously included on the licenses for the separate premises. The granting of a single license under this paragraph shall not in any manner reduce the number of beds, services, or programs operated by the licensee.

(6) A specialty hospital may not provide any service or regularly serve any population group beyond those services or groups specified in its license. A specialty-licensed children's hospital that is authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery services may provide cardiovascular service to adults who, as children, were previously served by the hospital for congenital heart disease, or to those patients who are referred for a specialized procedure only for congenital heart disease by an adult hospital, without obtaining additional licensure as a provider of adult cardiovascular services. The agency may request documentation as needed to support patient selection and treatment. This subsection does not apply to a specialty-licensed children's hospital that is already licensed to provide adult cardiovascular services. A specialty-licensed children's hospital with at least 50 total licensed neonatal intensive care unit beds may provide obstetrical services, including labor and delivery services, restricted to the diagnosis, care, and treatment of pregnant women of any age who have at least one maternal or fetal characteristic or condition which would

characterize the pregnancy or delivery as high risk or pregnant women of any age who have received medical advice or a diagnosis indicating that the fetus will require at least one perinatal intervention.

Section 9. Subsection (3) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.—

(3) In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. With the exception of state-operated licensed facilities, each facility licensed under this part shall pay to the agency~~, at the time of inspection,~~ the following fees:

(a) Inspection for licensure.—A fee shall be paid which is not less than $8 per hospital bed, nor more than $12 per hospital bed, except that the minimum fee shall be $400 per facility.

(b) Inspection for lifesafety only.—A fee shall be paid which is not less than 75 cents per hospital bed, nor more than $1.50 per hospital bed, except that the minimum fee shall be $40 per facility.

Section 10. Subsections (2) and (4) of section 395.0193, Florida Statutes, are amended to read:

395.0193 Licensed facilities; peer review; disciplinary powers; agency or partnership with physicians.—

(2) Each licensed facility, as a condition of licensure, shall provide for peer review of physicians who deliver health care services at the facility. Each licensed facility shall

develop written, binding procedures by which such peer review shall be conducted. Such procedures must ~~shall~~ include:

(a) Mechanism for choosing the membership of the body or bodies that conduct peer review.

(b) Adoption of rules of order for the peer review process.

(c) Fair review of the case with the physician involved.

(d) Mechanism to identify and avoid conflict of interest on the part of the peer review panel members.

(e) Recording of agendas and minutes which do not contain confidential material, for review by the Division of Medical Quality Assurance of the department ~~Health Quality Assurance of the agency~~.

(f) Review, at least annually, of the peer review procedures by the governing board of the licensed facility.

(g) Focus of the peer review process on review of professional practices at the facility to reduce morbidity and mortality and to improve patient care.

(4) Pursuant to ss. 458.337 and 459.016, any disciplinary actions taken under subsection (3) shall be reported in writing to the Division of Medical Quality Assurance of the department ~~Health Quality Assurance of the agency~~ within 30 working days after its initial occurrence, regardless of the pendency of appeals to the governing board of the hospital. The notification shall identify the disciplined practitioner, the action taken, and the reason for such action. All final disciplinary actions taken under subsection (3), if different from those which were reported to the department ~~agency~~ within 30 days after the

initial occurrence, shall be reported within 10 working days to the Division of Medical Quality Assurance of the department ~~Health Quality Assurance of the agency~~ in writing and shall specify the disciplinary action taken and the specific grounds therefor. The division shall review each report and determine whether it potentially involved conduct by the licensee that is subject to disciplinary action, in which case s. 456.073 shall apply. The reports are not subject to inspection under s. 119.07(1) even if the division's investigation results in a finding of probable cause.

Section 11. Section 395.1023, Florida Statutes, is amended to read:

395.1023 Child abuse and neglect cases; duties.—Each licensed facility shall adopt a protocol that, at a minimum, requires the facility to:

(1) Incorporate a facility policy that every staff member has an affirmative duty to report, pursuant to chapter 39, any actual or suspected case of child abuse, abandonment, or neglect; and

(2) In any case involving suspected child abuse, abandonment, or neglect, designate, at the request of the Department of Children and Family Services, a staff physician to act as a liaison between the hospital and the Department of Children and Family Services office which is investigating the suspected abuse, abandonment, or neglect, and the child protection team, as defined in s. 39.01, when the case is referred to such a team.

Each general hospital and appropriate specialty hospital shall comply with the provisions of this section and shall notify the agency and the Department of Children and Family Services of its compliance by sending a copy of its policy to the agency and the Department of Children and Family Services as required by rule. The failure by a general hospital or appropriate specialty hospital to comply shall be punished by a fine not exceeding $1,000, to be fixed, imposed, and collected by the agency. Each day in violation is considered a separate offense.

Section 12. Subsection (2) and paragraph (d) of subsection (3) of section 395.1041, Florida Statutes, are amended to read:

395.1041 Access to emergency services and care.—

(2) INVENTORY OF HOSPITAL EMERGENCY SERVICES.—The agency shall establish and maintain an inventory of hospitals with emergency services. The inventory shall list all services within the service capability of the hospital, and such services shall appear on the face of the hospital license. Each hospital having emergency services shall notify the agency of its service capability in the manner and form prescribed by the agency. The agency shall use the inventory to assist emergency medical services providers and others in locating appropriate emergency medical care. The inventory shall also be made available to the general public. ~~On or before August 1, 1992, the agency shall request that each hospital identify the services which are within its service capability. On or before November 1, 1992, the agency shall notify each hospital of the service capability to be included in the inventory. The hospital has 15 days from the date of receipt to respond to the notice. By December 1,~~

~~1992, the agency shall publish a final inventory.~~ Each hospital shall reaffirm its service capability when its license is renewed and shall notify the agency of the addition of a new service or the termination of a service prior to a change in its service capability.

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—

(d)1. Every hospital shall ensure the provision of services within the service capability of the hospital, at all times, either directly or indirectly through an arrangement with another hospital, through an arrangement with one or more physicians, or as otherwise made through prior arrangements. A hospital may enter into an agreement with another hospital for purposes of meeting its service capability requirement, and appropriate compensation or other reasonable conditions may be negotiated for these backup services.

2. If any arrangement requires the provision of emergency medical transportation, such arrangement must be made in consultation with the applicable provider and may not require the emergency medical service provider to provide transportation that is outside the routine service area of that provider or in a manner that impairs the ability of the emergency medical service provider to timely respond to prehospital emergency calls.

3. A hospital <u>is</u> ~~shall~~ not ~~be~~ required to ensure service capability at all times as required in subparagraph 1. if, prior to the receiving of any patient needing such service capability, such hospital has demonstrated to the agency that it lacks the

ability to ensure such capability and it has exhausted all reasonable efforts to ensure such capability through backup arrangements. In reviewing a hospital's demonstration of lack of ability to ensure service capability, the agency shall consider factors relevant to the particular case, including the following:

a. Number and proximity of hospitals with the same service capability.

b. Number, type, credentials, and privileges of specialists.

c. Frequency of procedures.

d. Size of hospital.

4. The agency shall publish ~~proposed~~ rules implementing a reasonable exemption procedure ~~by November 1, 1992~~. ~~Subparagraph 1. shall become effective upon the effective date of said rules or January 31, 1993, whichever is earlier. For a period not to exceed 1 year from the effective date of subparagraph 1., a hospital requesting an exemption shall be deemed to be exempt from offering the service until the agency initially acts to deny or grant the original request.~~ The agency has 45 days after ~~from~~ the date of receipt of the request to approve or deny the request. ~~After the first year from the effective date of subparagraph 1.,~~ If the agency fails to initially act within that ~~the~~ time period, the hospital is deemed to be exempt from offering the service until the agency initially acts to deny the request.

Section 13. Section 395.1046, Florida Statutes, is repealed.

Section 14. Paragraphs (b) and (e) of subsection (1) of section 395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

(b) Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patient care and safety are established and implemented. These procedures shall require housekeeping and sanitation staff to wear masks and gloves when cleaning patient rooms, to disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used by the hospital, and to document compliance. The agency may impose an administrative fine for each day that a violation of this paragraph occurs.

(e) Licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by the agency, the Florida Building Code, and the Florida Fire Prevention Code ~~department~~.

Section 15. Paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.—

(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without

such consent to:

(e) The department ~~agency~~ upon subpoena issued pursuant to s. 456.071.~~, but~~ The records obtained thereby must be used solely for the purpose of the agency, the department, and the appropriate professional board in an ~~its~~ investigation, prosecution, and appeal of disciplinary proceedings. If the department ~~agency~~ requests copies of the records, the facility shall charge a fee pursuant to this section ~~no more than its actual copying costs, including reasonable staff time~~. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency, the department, or the appropriate regulatory board. However, the department ~~agency~~ must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

Section 16. Subsection (2) of section 395.3036, Florida Statutes, is amended to read:

395.3036 Confidentiality of records and meetings of corporations that lease public hospitals or other public health care facilities.—The records of a private corporation that leases a public hospital or other public health care facility are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, and the meetings of the governing board of a private corporation are exempt from

s. 286.011 and s. 24(b), Art. I of the State Constitution when the public lessor complies with the public finance accountability provisions of s. 155.40(5) with respect to the transfer of any public funds to the private lessee and when the private lessee meets at least three of the five following criteria:

(2) 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 pursuant to s. 155.40 ~~subsection (2)~~.

Section 17. Section 395.3037, Florida Statutes, is repealed.

Section 18. Paragraph (e) of subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

(2) DEFINITIONS.—As used in this part:

(e) "Rural hospital" means an acute care hospital licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:

1. The sole provider within a county with a population density of no greater than 100 persons per square mile;

2. An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;

3. A hospital supported by a tax district or subdistrict

whose boundaries encompass a population of 100 persons or fewer per square mile;

~~4. A hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax pursuant to law and in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency pursuant to chapter 125, and has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits and a Medicaid inpatient utilization rate greater than 15 percent;~~

4.~~5.~~ A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Policy Analysis at the Agency for Health Care Administration; or

5.~~6.~~ A hospital designated as a critical access hospital, as defined in s. 408.07(15).

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2015, if the hospital continues to have 100 or fewer licensed

beds and an emergency room~~, or meets the criteria of subparagraph 4~~. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation to the Agency for Health Care Administration.

Section 19. Subsections (8) and (16) of section 400.021, Florida Statutes, are amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(8) "Geriatric outpatient clinic" means a site for providing outpatient health care to persons 60 years of age or older, which is staffed by a registered nurse or a physician assistant, or by a licensed practical nurse who is under the direct supervision of a registered nurse, an advanced registered nurse practitioner, a physician assistant, or a physician.

(16) "Resident care plan" means a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, with participation from other facility staff and the resident or his or her designee or legal representative, which includes a comprehensive assessment of the needs of an individual resident; the type and frequency of services required to provide the necessary care for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being; a listing of services provided within or outside the facility to meet those needs; and an explanation of service goals. ~~The resident care plan must be signed by the director of nursing or another registered nurse employed by the~~

~~facility to whom institutional responsibilities have been delegated and by the resident, the resident's designee, or the resident's legal representative. The facility may not use an agency or temporary registered nurse to satisfy the foregoing requirement and must document the institutional responsibilities that have been delegated to the registered nurse.~~

Section 20. Subsection (1) of section 400.0234, Florida Statutes, is amended to read:

400.0234 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility ~~in accordance with s. 400.145~~ shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 21. Subsection (15) of section 400.0255, Florida Statutes, is amended to read:

400.0255 Resident transfer or discharge; requirements and procedures; hearings.—

(15)(a) The department's Office of Appeals Hearings shall conduct hearings under this section. The office shall notify the facility of a resident's request for a hearing.

(b) The department shall, by rule, establish procedures to be used for fair hearings requested by residents. These

procedures shall be equivalent to the procedures used for fair hearings for other Medicaid cases appearing in s. 409.285 and applicable rules~~, chapter 10-2, part VI, Florida Administrative Code~~. The burden of proof must be clear and convincing evidence. A hearing decision must be rendered within 90 days after receipt of the request for hearing.

(c) If the hearing decision is favorable to the resident who has been transferred or discharged, the resident must be readmitted to the facility's first available bed.

(d) The decision of the hearing officer is ~~shall be~~ final. Any aggrieved party may appeal the decision to the district court of appeal in the appellate district where the facility is located. Review procedures shall be conducted in accordance with the Florida Rules of Appellate Procedure.

Section 22. Subsection (2) of section 400.063, Florida Statutes, is amended to read:

400.063 Resident protection.—

(2) The agency is authorized to establish for each facility, subject to intervention by the agency, a separate bank account for the deposit to the credit of the agency of any moneys received from the Health Care Trust Fund or any other moneys received for the maintenance and care of residents in the facility, and the agency is authorized to disburse moneys from such account to pay obligations incurred for the purposes of this section. The agency is authorized to requisition moneys from the Health Care Trust Fund in advance of an actual need for cash on the basis of an estimate by the agency of moneys to be spent under the authority of this section. Any bank account

established under this section need not be approved in advance of its creation as required by s. 17.58, but shall be secured by depository insurance equal to or greater than the balance of such account or by the pledge of collateral security ~~in conformance with criteria established in s. 18.11~~. The agency shall notify the Chief Financial Officer of any such account so established and shall make a quarterly accounting to the Chief Financial Officer for all moneys deposited in such account.

Section 23. Subsections (1) and (5) of section 400.071, Florida Statutes, are amended to read:

400.071 Application for license.—

(1) In addition to the requirements of part II of chapter 408, the application for a license shall be under oath and must contain the following:

(a) The location of the facility for which a license is sought and an indication, as in the original application, that such location conforms to the local zoning ordinances.

~~(b) A signed affidavit disclosing any financial or ownership interest that a controlling interest as defined in part II of chapter 408 has held in the last 5 years in any entity licensed by this state or any other state to provide health or residential care which has closed voluntarily or involuntarily; has filed for bankruptcy; has had a receiver appointed; has had a license denied, suspended, or revoked; or has had an injunction issued against it which was initiated by a regulatory agency. The affidavit must disclose the reason any such entity was closed, whether voluntarily or involuntarily.~~

~~(c) The total number of beds and the total number of~~

~~Medicare and Medicaid certified beds.~~

(b) ~~(d)~~ Information relating to the applicant and employees which the agency requires by rule. The applicant must demonstrate that sufficient numbers of qualified staff, by training or experience, will be employed to properly care for the type and number of residents who will reside in the facility.

~~(c) Copies of any civil verdict or judgment involving the applicant rendered within the 10 years preceding the application, relating to medical negligence, violation of residents' rights, or wrongful death. As a condition of licensure, the licensee agrees to provide to the agency copies of any new verdict or judgment involving the applicant, relating to such matters, within 30 days after filing with the clerk of the court. The information required in this paragraph shall be maintained in the facility's licensure file and in an agency database which is available as a public record.~~

(5) As a condition of licensure, each facility must establish ~~and submit with its application~~ a plan for quality assurance and for conducting risk management.

Section 24. Section 400.0712, Florida Statutes, is amended to read:

400.0712 Application for inactive license.—

~~(1) As specified in this section, the agency may issue an inactive license to a nursing home facility for all or a portion of its beds. Any request by a licensee that a nursing home or portion of a nursing home become inactive must be submitted to the agency in the approved format. The facility may not initiate~~

~~any suspension of services, notify residents, or initiate inactivity before receiving approval from the agency; and a licensee that violates this provision may not be issued an inactive license.~~

(1)~~(2)~~ In addition to the powers granted under part II of chapter 408, the agency may issue an inactive license for a portion of the total beds to a nursing home that chooses to use an unoccupied contiguous portion of the facility for an alternative use to meet the needs of elderly persons through the use of less restrictive, less institutional services.

(a) An inactive license issued under this subsection may be granted for a period not to exceed the current licensure expiration date but may be renewed by the agency at the time of licensure renewal.

(b) A request to extend the inactive license must be submitted to the agency in the approved format and approved by the agency in writing.

(c) Nursing homes that receive an inactive license to provide alternative services shall not receive preference for participation in the Assisted Living for the Elderly Medicaid waiver.

(2)~~(3)~~ The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.

Section 25. Section 400.111, Florida Statutes, is amended to read:

400.111 Disclosure of controlling interest.—In addition to the requirements of part II of chapter 408, when requested by the agency, the licensee shall submit a signed affidavit

disclosing any financial or ownership interest that a controlling interest has held within the last 5 years in any entity licensed by the state or any other state to provide health or residential care which entity has closed voluntarily or involuntarily; has filed for bankruptcy; has had a receiver appointed; has had a license denied, suspended, or revoked; or has had an injunction issued against it which was initiated by a regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntarily or involuntarily.

Section 26. Subsection (2) of section 400.1183, Florida Statutes, is amended to read:

400.1183 Resident grievance procedures.—

(2) Each facility shall maintain records of all grievances and shall retain a log for agency inspection of ~~report to the agency at the time of relicensure~~ the total number of grievances handled ~~during the prior licensure period~~, a categorization of the cases underlying the grievances, and the final disposition of the grievances.

Section 27. Subsection (1) of section 400.141, Florida Statutes, is amended, and subsection (3) is added to that section to read:

400.141 Administration and management of nursing home facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(a) Be under the administrative direction and charge of a licensed administrator.

(b) Appoint a medical director licensed pursuant to

chapter 458 or chapter 459. The agency may establish by rule more specific criteria for the appointment of a medical director.

(c) Have available the regular, consultative, and emergency services of physicians licensed by the state.

(d) Provide for resident use of a community pharmacy as specified in s. 400.022(1)(q). Any other law to the contrary notwithstanding, a registered pharmacist licensed in Florida, that is under contract with a facility licensed under this chapter or chapter 429, shall repackage a nursing facility resident's bulk prescription medication that ~~which~~ has been packaged by another pharmacist licensed in any state in the United States into a unit dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. In order to be eligible for the repackaging, a resident or the resident's spouse must receive prescription medication benefits provided through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. s. 831, or a long-term care policy as defined in s. 627.9404(1). A pharmacist who correctly repackages and relabels the medication and the nursing facility that ~~which~~ correctly administers such repackaged medication under this paragraph may not be held liable in any civil or administrative action arising from the repackaging. In order to be eligible for the repackaging, a nursing facility resident for whom the medication is to be repackaged shall sign an informed consent form provided by the

facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided in this paragraph. A pharmacist who repackages and relabels prescription medications, as authorized under this paragraph, may charge a reasonable fee for costs resulting from the implementation of this provision.

(e) Provide for the access of the facility residents to dental and other health-related services, recreational services, rehabilitative services, and social work services appropriate to their needs and conditions and not directly furnished by the licensee. When a geriatric outpatient nurse clinic is conducted in accordance with rules adopted by the agency, outpatients attending such clinic shall not be counted as part of the general resident population of the nursing home facility, nor shall the nursing staff of the geriatric outpatient clinic be counted as part of the nursing staff of the facility, until the outpatient clinic load exceeds 15 a day.

(f) Be allowed and encouraged by the agency to provide other needed services under certain conditions. If the facility has a standard licensure status~~, and has had no class I or class II deficiencies during the past 2 years or has been awarded a Gold Seal under the program established in s. 400.235~~, it may ~~be encouraged by the agency to~~ provide services, including, but not limited to, respite and adult day services, which enable individuals to move in and out of the facility. A facility is not subject to any additional licensure requirements for providing these services under the following conditions:~~.~~

1. Respite care may be offered to persons in need of

short-term or temporary nursing home services. For each person admitted under the respite care program, the facility licensee must:

a. Have a written abbreviated plan of care that, at a minimum, includes nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. The nursing or physician assessments may take the place of all other assessments required for full-time residents.

b. Have a contract that, at a minimum, specifies the services to be provided to the respite resident, including charges for services, activities, equipment, emergency medical services, and the administration of medications. If multiple respite admissions for a single person are anticipated, the original contract is valid for 1 year after the date of execution.

c. Ensure that each resident is released to his or her caregiver or an individual designated in writing by the caregiver.

2. A person admitted under the respite care program is:

a. Exempt from requirements in rule related to discharge planning.

b. Covered by the residents' rights set forth in s. 400.022(1)(a)-(o) and (r)-(t). Property or funds of a resident are not considered trust funds that are subject to the requirements of s. 400.022(1)(h) until the resident has been in the facility for more than 14 consecutive days.

c. Allowed to use his or her personal medications for the respite stay if permitted by facility policy. The facility must

obtain a physician's order for the medications. The caregiver may provide information regarding the medications as part of the nursing assessment and that information must be in conformance with the physician's order. Medications shall be released with the resident upon discharge in accordance with a physician's current orders.

3. A person receiving respite care is entitled to reside in the facility for a total of 60 days within a contract year or within a calendar year if the contract is for less than 12 months. However, each single stay may not exceed 14 days. If a stay exceeds 14 consecutive days, the facility must comply with all requirements for assessment and care planning which apply to nursing home residents.

4. A person receiving respite care must reside in a licensed nursing home bed.

5. A prospective respite resident must provide medical information from a physician, a physician assistant, or a nurse practitioner and other information from the primary caregiver as may be required by the facility prior to or at the time of admission to receive respite care. The medical information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician assistant, or nurse practitioner. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

6. The facility must assume the duties of the primary caregiver. To ensure continuity of care and services, the resident is entitled to retain his or her personal physician and

must have access to medically necessary services such as physical therapy, occupational therapy, or speech therapy, as needed. The facility must arrange for transportation to these services if necessary. ~~Respite care must be provided in accordance with this part and rules adopted by the agency. However, the agency shall, by rule, adopt modified requirements for resident assessment, resident care plans, resident contracts, physician orders, and other provisions, as appropriate, for short-term or temporary nursing home services.~~

7. The agency shall allow for shared programming and staff in a facility which meets minimum standards and offers services pursuant to this paragraph, but, if the facility is cited for deficiencies in patient care, may require additional staff and programs appropriate to the needs of service recipients. A person who receives respite care may not be counted as a resident of the facility for purposes of the facility's licensed capacity unless that person receives 24-hour respite care. A person receiving either respite care for 24 hours or longer or adult day services must be included when calculating minimum staffing for the facility. Any costs and revenues generated by a nursing home facility from nonresidential programs or services shall be excluded from the calculations of Medicaid per diems for nursing home institutional care reimbursement.

(g) If the facility has a standard license ~~or is a Gold Seal facility~~, exceeds the minimum required hours of licensed nursing and certified nursing assistant direct care per resident per day, and is part of a continuing care facility licensed under chapter 651 or a retirement community that offers other

services pursuant to part III of this chapter or part I or part III of chapter 429 on a single campus, be allowed to share programming and staff. ~~At the time of inspection and in the semiannual report required pursuant to paragraph (o),~~ A continuing care facility or retirement community that uses this option must demonstrate through staffing records that minimum staffing requirements for the facility were met. Licensed nurses and certified nursing assistants who work in the nursing home facility may be used to provide services elsewhere on campus if the facility exceeds the minimum number of direct care hours required per resident per day and the total number of residents receiving direct care services from a licensed nurse or a certified nursing assistant does not cause the facility to violate the staffing ratios required under s. 400.23(3)(a). Compliance with the minimum staffing ratios shall be based on total number of residents receiving direct care services, regardless of where they reside on campus. If the facility receives a conditional license, it may not share staff until the conditional license status ends. This paragraph does not restrict the agency's authority under federal or state law to require additional staff if a facility is cited for deficiencies in care which are caused by an insufficient number of certified nursing assistants or licensed nurses. The agency may adopt rules for the documentation necessary to determine compliance with this provision.

(h) Maintain the facility premises and equipment and conduct its operations in a safe and sanitary manner.

(i) If the licensee furnishes food service, provide a

wholesome and nourishing diet sufficient to meet generally accepted standards of proper nutrition for its residents and provide such therapeutic diets as may be prescribed by attending physicians. In making rules to implement this paragraph, the agency shall be guided by standards recommended by nationally recognized professional groups and associations with knowledge of dietetics.

(j) Keep full records of resident admissions and discharges; medical and general health status, including medical records, personal and social history, and identity and address of next of kin or other persons who may have responsibility for the affairs of the residents; and individual resident care plans including, but not limited to, prescribed services, service frequency and duration, and service goals. The records shall be open to inspection by the agency. The facility must maintain clinical records for each resident in accordance with accepted professional standards and practices and which are complete, accurately documented, readily accessible, and systematically organized.

(k) Keep such fiscal records of its operations and conditions as may be necessary to provide information pursuant to this part.

(l) Furnish copies of personnel records for employees affiliated with such facility, to any other facility licensed by this state requesting this information pursuant to this part. Such information contained in the records may include, but is not limited to, disciplinary matters and any reason for termination. Any facility releasing such records pursuant to

this part shall be considered to be acting in good faith and may not be held liable for information contained in such records, absent a showing that the facility maliciously falsified such records.

(m) Publicly display a poster provided by the agency containing the names, addresses, and telephone numbers for the state's abuse hotline, the State Long-Term Care Ombudsman, the Agency for Health Care Administration consumer hotline, the Advocacy Center for Persons with Disabilities, the Florida Statewide Advocacy Council, and the Medicaid Fraud Control Unit, with a clear description of the assistance to be expected from each.

~~(n) Submit to the agency the information specified in s. 400.071(1)(b) for a management company within 30 days after the effective date of the management agreement.~~

~~(o)1. Submit semiannually to the agency, or more frequently if requested by the agency, information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. For purposes of this reporting:~~

~~a. Staff-to-resident ratios must be reported in the categories specified in s. 400.23(3)(a) and applicable rules. The ratio must be reported as an average for the most recent calendar quarter.~~

~~b. Staff turnover must be reported for the most recent 12-month period ending on the last workday of the most recent calendar quarter prior to the date the information is submitted.~~

~~The turnover rate must be computed quarterly, with the annual rate being the cumulative sum of the quarterly rates. The turnover rate is the total number of terminations or separations experienced during the quarter, excluding any employee terminated during a probationary period of 3 months or less, divided by the total number of staff employed at the end of the period for which the rate is computed, and expressed as a percentage.~~

~~c. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.~~

(n)1.~~d.~~ Comply with minimum-staffing requirements. A nursing facility that fails ~~has failed~~ to comply with state minimum-staffing requirements for 2 consecutive days may not accept ~~is prohibited from accepting~~ new admissions until the facility achieves ~~has achieved~~ the minimum-staffing requirements for ~~a period of~~ 6 consecutive days. For the purposes of this subparagraph ~~sub-subparagraph~~, any person who was a resident of the facility and was absent from the facility for the purpose of receiving medical care at a separate location or was on a leave of absence is not considered a new admission. Failure to impose such an admissions moratorium is subject to a $1,000 fine ~~constitutes a class II deficiency~~.

2.~~e.~~ A nursing facility that ~~which~~ does not have a conditional license may be cited for failure to comply with the standards in s. 400.23(3)(a)1.b. and c. only if it fails ~~has~~

~~failed~~ to meet those standards on 2 consecutive days or if it fails ~~has failed~~ to meet at least 97 percent of those standards on any one day.

3.~~f.~~ A facility that ~~which~~ has a conditional license must be in compliance with the standards in s. 400.23(3)(a) at all times.

~~2. This paragraph does not limit the agency's ability to impose a deficiency or take other actions if a facility does not have enough staff to meet the residents' needs~~.

(o)~~(p)~~ Notify a licensed physician when a resident exhibits signs of dementia or cognitive impairment or has a change of condition in order to rule out the presence of an underlying physiological condition that may be contributing to such dementia or impairment. The notification must occur within 30 days after the acknowledgment of such signs by facility staff. If an underlying condition is determined to exist, the facility shall arrange, with the appropriate health care provider, the necessary care and services to treat the condition.

(p)~~(q)~~ If the facility implements a dining and hospitality attendant program, ensure that the program is developed and implemented under the supervision of the facility director of nursing. A licensed nurse, licensed speech or occupational therapist, or a registered dietitian must conduct training of dining and hospitality attendants. A person employed by a facility as a dining and hospitality attendant must perform tasks under the direct supervision of a licensed nurse.

~~(r) Report to the agency any filing for bankruptcy~~

~~protection by the facility or its parent corporation, divestiture or spin-off of its assets, or corporate reorganization within 30 days after the completion of such activity.~~

(q) ~~(s)~~ Maintain general and professional liability insurance coverage that is in force at all times. In lieu of general and professional liability insurance coverage, a state-designated teaching nursing home and its affiliated assisted living facilities created under s. 430.80 may demonstrate proof of financial responsibility as provided in s. 430.80(3)(g).

(r) ~~(t)~~ Maintain in the medical record for each resident a daily chart of certified nursing assistant services provided to the resident. The certified nursing assistant who is caring for the resident must complete this record by the end of his or her shift. This record must indicate assistance with activities of daily living, assistance with eating, and assistance with drinking, and must record each offering of nutrition and hydration for those residents whose plan of care or assessment indicates a risk for malnutrition or dehydration.

(s) ~~(u)~~ Before November 30 of each year, subject to the availability of an adequate supply of the necessary vaccine, provide for immunizations against influenza viruses to all its consenting residents in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Subject to these exemptions, any consenting person who becomes a resident of the facility after November 30 but before March 31 of the following year must be

immunized within 5 working days after becoming a resident. Immunization shall not be provided to any resident who provides documentation that he or she has been immunized as required by this paragraph. This paragraph does not prohibit a resident from receiving the immunization from his or her personal physician if he or she so chooses. A resident who chooses to receive the immunization from his or her personal physician shall provide proof of immunization to the facility. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

(t) ~~(v)~~ Assess all residents for eligibility for pneumococcal polysaccharide vaccination (PPV) and vaccinate residents when indicated within 60 days after the effective date of this act in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Residents admitted after the effective date of this act shall be assessed within 5 working days after ~~of~~ admission and, when indicated, vaccinated within 60 days in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Immunization shall not be provided to any resident who provides documentation that he or she has been immunized as required by this paragraph. This paragraph does not prohibit a resident from receiving the immunization from his or her personal physician if he or she so chooses. A resident who chooses to receive the immunization from his or her personal physician shall provide

proof of immunization to the facility. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

(u) ~~(w)~~ Annually encourage and promote to its employees the benefits associated with immunizations against influenza viruses in accordance with the recommendations of the United States Centers for Disease Control and Prevention. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

This subsection does not limit the agency's ability to impose a penalty for a deficiency or take other actions if a facility fails to maintain an adequate number of staff to meet the residents' needs.

(3) A facility may charge a reasonable fee for copying resident records. The fee may not exceed $1 per page for the first 25 pages and 25 cents per page for each page in excess of 25 pages.

Section 28. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate.—

(3) Facility staff may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The agency shall adopt rules providing for the implementation of such orders.~~ Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~

considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and rules adopted by the agency. The absence of an order not to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 29. Section 400.145, Florida Statutes, is repealed.

Section 30. Present subsections (9), (11), (12), (13), (14), and (15) of section 400.147, Florida Statutes, are redesignated as subsections (8), (9), (10), (11), (12), and (13), respectively, and present subsections (7), (8), and (10) of that section are amended to read:

400.147 Internal risk management and quality assurance program.—

(7) The facility shall initiate an investigation ~~and shall notify the agency~~ within 1 business day after the risk manager or his or her designee has received a report pursuant to paragraph (1)(d). Each facility shall complete the investigation and submit a report to the agency within 15 calendar days if the incident is determined to be an adverse incident as defined in subsection (5). ~~The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery.~~ The agency shall develop a form for reporting this information, and the notification must include the name of the risk manager of the facility, information regarding the identity of the affected resident, the type of adverse incident, the

initiation of an investigation by the facility, and whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The notification is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

~~(8)(a) Each facility shall complete the investigation and submit an adverse incident report to the agency for each adverse incident within 15 calendar days after its occurrence. If, after a complete investigation, the risk manager determines that the incident was not an adverse incident as defined in subsection (5), the facility shall include this information in the report. The agency shall develop a form for reporting this information.~~

~~(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the incidents potentially involved conduct by a health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.~~

~~(c) The report submitted to the agency must also contain~~

~~the name of the risk manager of the facility.~~

~~(d) The adverse incident report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board.~~

~~(10) By the 10th of each month, each facility subject to this section shall report any notice received pursuant to s. 400.0233(2) and each initial complaint that was filed with the clerk of the court and served on the facility during the previous month by a resident or a resident's family member, guardian, conservator, or personal legal representative. The report must include the name of the resident, the resident's date of birth and social security number, the Medicaid identification number for Medicaid-eligible persons, the date or dates of the incident leading to the claim or dates of residency, if applicable, and the type of injury or violation of rights alleged to have occurred. Each facility shall also submit a copy of the notices received pursuant to s. 400.0233(2) and complaints filed with the clerk of the court. This report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in such actions brought by the agency to enforce the provisions of this part.~~

Section 31. Subsection (3) of section 400.19, Florida Statutes, is amended to read:

400.19 Right of entry and inspection.—

(3) The agency shall every 15 months conduct at least one unannounced inspection to determine compliance by the licensee

with statutes, and with rules adopted ~~promulgated~~ under the provisions of those statutes, governing minimum standards of construction, quality and adequacy of care, and rights of residents. The survey shall be conducted every 6 months for the next 2-year period if the facility has been cited for a class I deficiency, has been cited for two or more class II deficiencies arising from separate surveys or investigations within a 60-day period, or has had three or more substantiated complaints within a 6-month period, each resulting in at least one class I or class II deficiency. In addition to any other fees or fines in this part, the agency shall assess a fine for each facility that is subject to the 6-month survey cycle. The fine for the 2-year period shall be $6,000, one-half to be paid at the completion of each survey. The agency may adjust this fine by the change in the Consumer Price Index, based on the 12 months immediately preceding the increase, to cover the cost of the additional surveys. The agency shall verify through subsequent inspection that any deficiency identified during inspection is corrected. However, the agency may verify the correction of a class III or class IV deficiency ~~unrelated to resident rights or resident care~~ without reinspecting the facility if adequate written documentation has been received from the facility, which provides assurance that the deficiency has been corrected. The giving or causing to be given of advance notice of such unannounced inspections by an employee of the agency to any unauthorized person shall constitute cause for suspension of not less ~~fewer~~ than 5 working days according to the provisions of chapter 110.

Section 32. Subsection (5) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(5)(a) The agency, in collaboration with the Division of Children's Medical Services Network of the Department of Health, must~~, no later than December 31, 1993,~~ adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. ~~The rules must include a methodology for reviewing a nursing home facility under ss. 408.031-408.045 which serves only persons under 21 years of age.~~ A facility may be exempt from these standards for specific persons between 18 and 21 years of age, if the person's physician agrees that minimum standards of care based on age are not necessary.

(b) The agency, in collaboration with the Division of Children's Medical Services Network, shall adopt rules for minimum staffing requirements for nursing home facilities that serve persons under 21 years of age, which shall apply in lieu of the standards contained in subsection (3).

1. For persons under 21 years of age who require skilled care, the requirements shall include a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants of 3.9 hours of direct care per resident per day for each nursing home facility.

2. For persons under 21 years of age who are fragile, the requirements shall include a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants of 5 hours of

direct care per resident per day for each nursing home facility.

Section 33. Subsection (1) of section 400.275, Florida Statutes, is amended to read:

400.275 Agency duties.—

(1) ~~The agency shall ensure that each newly hired nursing home surveyor, as a part of basic training, is assigned full-time to a licensed nursing home for at least 2 days within a 7-day period to observe facility operations outside of the survey process before the surveyor begins survey responsibilities. Such observations may not be the sole basis of a deficiency citation against the facility.~~ The agency may not assign an individual to be a member of a survey team for purposes of a survey, evaluation, or consultation visit at a nursing home facility in which the surveyor was an employee within the preceding 2 ~~5~~ years.

Section 34. Subsection (27) of section 400.462, Florida Statutes, is amended to read:

400.462 Definitions.—As used in this part, the term:

(27) "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. However, when the term is used in any provision of law relating to a health care provider, such term does not mean an item with an individual value of up to $15, including, but not limited to, plaques, certificates, trophies, or novelties that are intended solely for presentation or are customarily given away solely for promotional, recognition, or advertising purposes.

Section 35. For the purpose of incorporating the amendment

made by this act to section 400.509, Florida Statutes, in a reference thereto, paragraph (b) of subsection (5) of section 400.464, Florida Statutes, is reenacted and amended to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(5) The following are exempt from the licensure requirements of this part:

(b) Home health services provided by a state agency, either directly or through a contractor with:

1. The Department of Elderly Affairs.

2. The Department of Health, a community health center, or a rural health network that furnishes home visits for the purpose of providing environmental assessments, case management, health education, personal care services, family planning, or followup treatment, or for the purpose of monitoring and tracking disease.

3. Services provided to persons with developmental disabilities, as defined in s. 393.063.

4. Companion and sitter organizations that were registered under s. 400.509(1) ~~on January 1, 1999,~~ and were authorized to provide personal services under a developmental services provider certificate ~~on January 1, 1999,~~ may continue to provide such services to past, present, and future clients of the organization who need such services, notwithstanding the provisions of this act.

5. The Department of Children and Family Services.

Section 36. Section 400.484, Florida Statutes, is amended to read:

400.484 Right of inspection; violations ~~deficiencies~~; fines.—

(1) In addition to the requirements of s. 408.811, the agency may make such inspections and investigations as are necessary in order to determine the state of compliance with this part, part II of chapter 408, and applicable rules.

(2) The agency shall impose fines for various classes of violations ~~deficiencies~~ in accordance with the following schedule:

(a) A class I violation is defined in s. 408.813 ~~deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury~~. Upon finding a class I violation ~~deficiency~~, the agency shall impose an administrative fine in the amount of $15,000 for each occurrence and each day that the violation ~~deficiency~~ exists.

(b) A class II violation is defined in s. 408.813 ~~deficiency is any act, omission, or practice that has a direct adverse effect on the health, safety, or security of a patient~~. Upon finding a class II violation ~~deficiency~~, the agency shall impose an administrative fine in the amount of $5,000 for each occurrence and each day that the violation ~~deficiency~~ exists.

(c) A class III violation is defined in s. 408.813 ~~deficiency is any act, omission, or practice that has an indirect, adverse effect on the health, safety, or security of a patient~~. Upon finding an uncorrected or repeated class III violation ~~deficiency~~, the agency shall impose an administrative

fine not to exceed $1,000 for each occurrence and each day that the uncorrected or repeated violation ~~deficiency~~ exists.

(d) A class IV violation is defined in s. 408.813 ~~deficiency is any act, omission, or practice related to required reports, forms, or documents which does not have the potential of negatively affecting patients~~. These violations are of a type that the agency determines do not threaten the health, safety, or security of patients. Upon finding an uncorrected or repeated class IV violation ~~deficiency~~, the agency shall impose an administrative fine not to exceed $500 for each occurrence and each day that the uncorrected or repeated violation ~~deficiency~~ exists.

(3) In addition to any other penalties imposed pursuant to this section or part, the agency may assess costs related to an investigation that results in a successful prosecution, excluding costs associated with an attorney's time.

Section 37. For the purpose of incorporating the amendment made by this act to section 400.509, Florida Statutes, in a reference thereto, paragraph (a) of subsection (6) of section 400.506, Florida Statutes, is reenacted, and subsection (16) of that section is amended, to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(6)(a) A nurse registry may refer for contract in private residences registered nurses and licensed practical nurses registered and licensed under part I of chapter 464, certified nursing assistants certified under part II of chapter 464, home health aides who present documented proof of successful

completion of the training required by rule of the agency, and companions or homemakers for the purposes of providing those services authorized under s. 400.509(1). A licensed nurse registry shall ensure that each certified nursing assistant referred for contract by the nurse registry and each home health aide referred for contract by the nurse registry is adequately trained to perform the tasks of a home health aide in the home setting. Each person referred by a nurse registry must provide current documentation that he or she is free from communicable diseases.

(16) An administrator may manage only one nurse registry, except that an administrator may manage up to five registries if all five registries have identical controlling interests as defined in s. 408.803 and are located within one agency geographic service area or within an immediately contiguous county. An administrator shall designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence. ~~In addition to any other penalties imposed pursuant to this section or part, the agency may assess costs related to an investigation that results in a successful prosecution, excluding costs associated with an attorney's time.~~

Section 38. Subsection (1) of section 400.509, Florida Statutes, is amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

(1) Any organization that provides companion services or

homemaker services and does not provide a home health service to a person is exempt from licensure under this part. However, any organization that provides companion services or homemaker services must register with the agency. An organization under contract with the Agency for Persons with Disabilities which provides companion services only for persons with a developmental disability, as defined in s. 393.063, is exempt from registration.

Section 39. Subsection (3) of section 400.601, Florida Statutes, is amended to read:

400.601 Definitions.—As used in this part, the term:

(3) "Hospice" means a centrally administered corporation or a limited liability company as defined in s. 608.4351 providing a continuum of palliative and supportive care for the terminally ill patient and his or her family.

Section 40. Paragraph (i) of subsection (1) and subsection (4) of section 400.606, Florida Statutes, are amended to read:

400.606 License; application; renewal; conditional license or permit; certificate of need.—

(1) In addition to the requirements of part II of chapter 408, the initial application and change of ownership application must be accompanied by a plan for the delivery of home, residential, and homelike inpatient hospice services to terminally ill persons and their families. Such plan must contain, but need not be limited to:

~~(i) The projected annual operating cost of the hospice.~~

If the applicant is an existing licensed health care provider,

the application must be accompanied by a copy of the most recent profit-loss statement and, if applicable, the most recent licensure inspection report.

(4) A freestanding hospice facility that is ~~primarily~~ engaged in providing inpatient and related services and that is not otherwise licensed as a health care facility shall ~~be required to~~ obtain a certificate of need. However, a freestanding hospice facility that has ~~with~~ six or fewer beds is ~~shall~~ not ~~be~~ required to comply with institutional standards such as, but not limited to, standards requiring sprinkler systems, emergency electrical systems, or special lavatory devices.

Section 41. Section 400.915, Florida Statutes, is amended to read:

400.915 Construction and renovation; requirements.—The requirements for the construction or renovation of a PPEC center shall comply with:

(1) The provisions of chapter 553, which pertain to building construction standards, including plumbing, electrical code, glass, manufactured buildings, accessibility for the physically disabled;

(2) The provisions of s. 633.022 and applicable rules pertaining to physical ~~minimum~~ standards for nonresidential child care ~~physical~~ facilities ~~in rule 10M-12.003, Florida Administrative Code, Child Care Standards~~; and

(3) The standards or rules adopted pursuant to this part and part II of chapter 408.

Section 42. Section 400.931, Florida Statutes, is amended

to read:

400.931 Application for license; fee~~; provisional license; temporary permit~~.—

(1) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the home medical equipment provider is in compliance with this part and applicable rules, including:

(a) A report, by category, of the equipment to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of equipment include:

1. Respiratory modalities.
2. Ambulation aids.
3. Mobility aids.
4. Sickroom setup.
5. Disposables.

(b) A report, by category, of the services to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of services include:

1. Intake.
2. Equipment selection.
3. Delivery.
4. Setup and installation.
5. Patient training.
6. Ongoing service and maintenance.
7. Retrieval.

(c) A listing of those with whom the applicant contracts,

both the providers the applicant uses to provide equipment or services to its consumers and the providers for whom the applicant provides services or equipment.

(2) An applicant for initial licensure, change of ownership, or license renewal to operate a licensed home medical equipment provider at a location outside the state must submit documentation of accreditation or an application for accreditation from an accrediting organization that is recognized by the agency. An applicant that has applied for accreditation must provide proof of accreditation that is not conditional or provisional within 120 days after the date the agency receives the application for licensure or the application shall be withdrawn from further consideration. Such accreditation must be maintained by the home medical equipment provider in order to maintain licensure. ~~As an alternative to submitting proof of financial ability to operate as required in s. 408.810(8), the applicant may submit a $50,000 surety bond to the agency.~~

(3) As specified in part II of chapter 408, the home medical equipment provider must also obtain and maintain professional and commercial liability insurance. Proof of liability insurance, as defined in s. 624.605, must be submitted with the application. The agency shall set the required amounts of liability insurance by rule, but the required amount must not be less than $250,000 per claim. In the case of contracted services, it is required that the contractor have liability insurance not less than $250,000 per claim.

(4) When a change of the general manager of a home medical

equipment provider occurs, the licensee must notify the agency of the change within 45 days.

(5) In accordance with s. 408.805, an applicant or a licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be established by rule and may not exceed $300 per biennium. The agency shall set the fees in an amount that is sufficient to cover its costs in carrying out its responsibilities under this part. However, state, county, or municipal governments applying for licenses under this part are exempt from the payment of license fees.

(6) An applicant for initial licensure, renewal, or change of ownership shall also pay an inspection fee not to exceed $400, which shall be paid by all applicants except those not subject to licensure inspection by the agency as described in s. 400.933.

Section 43. Section 400.967, Florida Statutes, is amended to read:

400.967 Rules and classification of violations ~~deficiencies~~.—

(1) It is the intent of the Legislature that rules adopted and enforced under this part and part II of chapter 408 include criteria by which a reasonable and consistent quality of resident care may be ensured, the results of such resident care can be demonstrated, and safe and sanitary facilities can be provided.

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Agency for Persons with

Disabilities and the Department of Elderly Affairs, shall adopt and enforce rules to administer this part and part II of chapter 408, which shall include reasonable and fair criteria governing:

(a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The agency shall update or revise the criteria as the need arises. All facilities must comply with those lifesafety code requirements and building code standards applicable at the time of approval of their construction plans. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. The agency shall adopt fair and reasonable rules setting forth conditions under which existing facilities undergoing additions, alterations, conversions, renovations, or repairs are required to comply with the most recent updated or revised standards.

(b) The number and qualifications of all personnel, including management, medical nursing, and other personnel, having responsibility for any part of the care given to residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof.

(g) The preparation and annual update of a comprehensive emergency management plan. The agency shall adopt rules establishing minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management

agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(h) The use of restraint and seclusion. Such rules must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff during an incident of restraint or seclusion; establish procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

(3) The agency shall adopt rules to provide that, when the criteria established under this part and part II of chapter 408 are not met, such violations ~~deficiencies~~ shall be classified according to the nature of the violation ~~deficiency~~. The agency shall indicate the classification on the face of the notice of violation ~~deficiencies~~ as follows:

(a) A class I violation is defined in s. 408.813 ~~deficiencies are those which the agency determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical harm~~

~~would result therefrom~~. ~~The condition or practice constituting a class I violation must be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction.~~ A class I violation ~~deficiency~~ is subject to a civil penalty in an amount not less than $5,000 and not exceeding $10,000 for each violation ~~deficiency~~. A fine may be levied notwithstanding the correction of the violation ~~deficiency~~.

(b) A class II violation is defined in s. 408.813 ~~deficiencies are those which the agency determines have a direct or immediate relationship to the health, safety, or security of the facility residents, other than class I deficiencies~~. A class II violation ~~deficiency~~ is subject to a civil penalty in an amount not less than $1,000 and not exceeding $5,000 for each violation ~~deficiency~~. A citation for a class II violation ~~deficiency~~ shall specify the time within which the violation ~~deficiency~~ must be corrected. If a class II violation ~~deficiency~~ is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

(c) A class III violation is defined in s. 408.813 ~~deficiencies are those which the agency determines to have an indirect or potential relationship to the health, safety, or security of the facility residents, other than class I or class II deficiencies~~. A class III violation ~~deficiency~~ is subject to a civil penalty of not less than $500 and not exceeding $1,000 for each violation ~~deficiency~~. A citation for a class III violation ~~deficiency~~ shall specify the time within which the violation ~~deficiency~~ must be corrected. If a class III violation

~~deficiency~~ is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

(d) A class IV violation is defined in s. 408.813. Upon finding an uncorrected or repeated class IV violation, the agency shall impose an administrative fine not to exceed $500 for each occurrence and each day that the uncorrected or repeated violation exists.

(4) The agency shall approve or disapprove the plans and specifications within 60 days after receipt of the final plans and specifications. The agency may be granted one 15-day extension for the review period, if the secretary of the agency so approves. If the agency fails to act within the specified time, it is deemed to have approved the plans and specifications. When the agency disapproves plans and specifications, it must set forth in writing the reasons for disapproval. Conferences and consultations may be provided as necessary.

(5) The agency may charge an initial fee of $2,000 for review of plans and construction on all projects, no part of which is refundable. The agency may also collect a fee, not to exceed 1 percent of the estimated construction cost or the actual cost of review, whichever is less, for the portion of the review which encompasses initial review through the initial revised construction document review. The agency may collect its actual costs on all subsequent portions of the review and construction inspections. Initial fee payment must accompany the initial submission of plans and specifications. Any subsequent payment that is due is payable upon receipt of the invoice from

the agency. Notwithstanding any other provision of law, all money received by the agency under this section shall be deemed to be trust funds, to be held and applied solely for the operations required under this section.

Section 44. Subsections (4) and (7) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.—

(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable health service or equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(a) Entities licensed or registered by the state under chapter 395; or entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; or

entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or

indirectly, with an entity licensed or registered by the state pursuant to chapter 395; or entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more

of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or

chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, perinatology, or anesthesia clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners when one or more of the owners of the entity is a health care practitioner who is licensed in this state, is responsible for supervising the business activities of the entity, and is legally responsible for the entity's compliance with state law for purposes of this section.

(n) Entities that are owned or controlled, directly or indirectly, by a publicly traded entity with $100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners that are employed or contracted by an entity described in this paragraph.

(o) Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 when the billing for medical services is under a single tax identification number. The application for exemption from licensure requirements under this paragraph shall contain the name, residence address, business address, and phone numbers of the entity that owns the clinic; a complete list of the names and contact information of all the officers and directors of the corporation; the name, residence address, business address, and medical practitioner license number of each health care practitioner employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity; and a certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under personal injury protection insurance coverage for the preceding year. If the agency determines that an entity that is exempt under this paragraph has received payments for medical services under personal injury protection insurance coverage, the agency may

deny or revoke the exemption from licensure under this paragraph.

(7) "Portable health service or equipment provider" means an entity that contracts with or employs persons to provide portable health services or equipment to multiple locations ~~performing treatment or diagnostic testing of individuals~~, that bills third-party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).

Section 45. Paragraph (b) of subsection (1) and subsection (4) of section 400.991, Florida Statutes, are amended to read:

400.991 License requirements; background screenings; prohibitions.—

(1)

(b) Each mobile clinic must obtain a separate health care clinic license and must provide to the agency, at least quarterly, its projected street location to enable the agency to locate and inspect such clinic. A portable health service or equipment provider must obtain a health care clinic license for a single administrative office and is not required to submit quarterly projected street locations.

(4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

(a) A listing of services to be provided either directly by the applicant or through contractual arrangements with existing providers;

(b) The number and discipline of each professional staff

member to be employed; and

(c) Proof of financial ability to operate as required under ss. ~~s.~~ 408.810(8) and 408.8065. ~~As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least $500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond.~~

Section 46. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and

prorated for the licensure period.

Section 47. Subsection (2) of section 408.034, Florida Statutes, is amended to read:

408.034 Duties and responsibilities of agency; rules.—

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under chapters 393 and 395 and parts II, ~~and~~ IV, and VIII of chapter 400, the agency may not issue a license to any health care facility or health service provider that fails to receive a certificate of need or an exemption for the licensed facility or service.

Section 48. Paragraph (d) of subsection (1) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(g), are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(d) The establishment of a hospice or hospice inpatient facility~~, except as provided in s. 408.043~~.

Section 49. Paragraph (c) of subsection (1) of section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

(1) Except as provided in subsection (2) for a general hospital, an application for a certificate of need must contain:

(c) An audited financial statement of the applicant or the

applicant's parent corporation if audited financial statements of the applicant do not exist. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

Section 50. Subsection (2) of section 408.043, Florida Statutes, is amended to read:

408.043 Special provisions.—

(2) HOSPICES.—When an application is made for a certificate of need to establish or to expand a hospice, the need for such hospice shall be determined on the basis of the need for and availability of hospice services in the community. The formula on which the certificate of need is based shall discourage regional monopolies and promote competition. The inpatient hospice care component of a hospice which is a freestanding facility, or a part of a facility, ~~which is primarily engaged in providing inpatient care and related services~~ and is not licensed as a health care facility shall also be required to obtain a certificate of need. Provision of hospice care by any current provider of health care is a significant change in service and therefore requires a certificate of need for such services.

Section 51. Paragraph (a) of subsection (1) of section 408.061, Florida Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(1) The agency shall require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties. Specifications for data to be collected under this section shall be developed by the agency with the assistance of technical advisory panels including representatives of affected entities, consumers, purchasers, and such other interested parties as may be determined by the agency.

(a) Data submitted by health care facilities, including the facilities as defined in chapter 395, shall include, but are not limited to: case-mix data, patient admission and discharge data, hospital emergency department data which shall include the number of patients treated in the emergency department of a licensed hospital reported by patient acuity level, data on hospital-acquired infections as specified by rule, data on complications as specified by rule, data on readmissions as specified by rule, with patient and provider-specific identifiers included, actual charge data by diagnostic groups, financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, depreciation expenses based on the expected useful life of the property and equipment involved, and demographic data. The agency shall adopt nationally recognized risk adjustment methodologies or software consistent with the standards of the Agency for Healthcare Research and Quality and as selected by the agency for all data submitted as required by this section. Data may be obtained from documents such as, but not limited to: leases, contracts, debt instruments, itemized

patient bills, medical record abstracts, and related diagnostic information. Reported data elements shall be reported electronically and ~~in accordance with rule 59E-7.012, Florida Administrative Code. Data submitted shall be~~ certified by the chief executive officer or an appropriate and duly authorized representative or employee of the licensed facility that the information submitted is true and accurate.

Section 52. Subsection (43) of section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.—As used in this chapter, with the exception of ss. 408.031-408.045, the term:

(43) "Rural hospital" means an acute care hospital licensed under chapter 395, having 100 or fewer licensed beds and an emergency room, and which is:

(a) The sole provider within a county with a population density of no greater than 100 persons per square mile;

(b) An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from another acute care hospital within the same county;

(c) A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer per square mile;

(d) A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this paragraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's

discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Policy Analysis at the Agency for Health Care Administration; or

(e) A critical access hospital.

Population densities used in this subsection must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2015, if the hospital continues to have 100 or fewer licensed beds and an emergency room~~, or meets the criteria of s. 395.602(2)(e)4~~. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this subsection shall be granted such designation upon application, including supporting documentation, to the Agency for Health Care Administration.

Section 53. Section 408.10, Florida Statutes, is amended to read:

408.10 Consumer complaints.—The agency shall~~:~~

~~(1)~~ publish and make available to the public a toll-free telephone number for the purpose of handling consumer complaints and shall serve as a liaison between consumer entities and other private entities and governmental entities for the disposition of problems identified by consumers of health care.

~~(2) Be empowered to investigate consumer complaints relating to problems with health care facilities' billing~~

~~practices and issue reports to be made public in any cases where the agency determines the health care facility has engaged in billing practices which are unreasonable and unfair to the consumer.~~

Section 54. Effective upon this act becoming a law, section 408.7056, Florida Statutes, is amended to read:

408.7056 Subscriber Assistance Program.—

(1) As used in this section, the term:

(a) "Agency" means the Agency for Health Care Administration.

(b) "Department" means the Department of Financial Services.

(c) "Grievance procedure" means an established set of rules that specify a process for appeal of an organizational decision.

(d) "Health care provider" or "provider" means a state-licensed or state-authorized facility, a facility principally supported by a local government or by funds from a charitable organization that holds a current exemption from federal income tax under s. 501(c)(3) of the Internal Revenue Code, a licensed practitioner, a county health department established under part I of chapter 154, a prescribed pediatric extended care center defined in s. 400.902, a federally supported primary care program such as a migrant health center or a community health center authorized under s. 329 or s. 330 of the United States Public Health Services Act that delivers health care services to individuals, or a community facility that receives funds from the state under the Community Alcohol, Drug Abuse, and Mental

Health Services Act and provides mental health services to individuals.

(e) "Managed care entity" means a health maintenance organization or a prepaid health clinic certified under chapter 641, a prepaid health plan authorized under s. 409.912, or an exclusive provider organization certified under s. 627.6472.

(f) "Office" means the Office of Insurance Regulation of the Financial Services Commission.

(g) "Panel" means a subscriber assistance panel selected as provided in subsection (11).

(2) The agency shall adopt and implement a program to provide assistance to subscribers, including those whose grievances are not resolved by the managed care entity to the satisfaction of the subscriber. The program shall consist of one or more panels that meet as often as necessary to timely review, consider, and hear grievances and recommend to the agency or the office any actions that should be taken concerning individual cases heard by the panel. The panel shall hear every grievance filed by subscribers on behalf of subscribers, unless the grievance:

(a) Relates to a managed care entity's refusal to accept a provider into its network of providers;

(b) Is part of an internal grievance in a Medicare managed care entity or a reconsideration appeal through the Medicare appeals process which does not involve a quality of care issue;

(c) Is related to a health plan not regulated by the state such as an administrative services organization, third-party administrator, or federal employee health benefit program;

(d) Is related to appeals by in-plan suppliers and providers, unless related to quality of care provided by the plan;

(e) Is part of a Medicaid fair hearing pursued under 42 C.F.R. ss. 431.220 et seq.;

(f) Is the basis for an action pending in state or federal court;

(g) Is related to an appeal by nonparticipating providers, unless related to the quality of care provided to a subscriber by the managed care entity and the provider is involved in the care provided to the subscriber;

(h) Was filed before the subscriber completed the entire internal grievance procedure of the managed care entity, the managed care entity has complied with its timeframes for completing the internal grievance procedure, and the circumstances described in subsection (6) do not apply;

(i) Has been resolved to the satisfaction of the subscriber who filed the grievance, unless the managed care entity's initial action is egregious or may be indicative of a pattern of inappropriate behavior;

(j) Is limited to seeking damages for pain and suffering, lost wages, or other incidental expenses, including accrued interest on unpaid balances, court costs, and transportation costs associated with a grievance procedure;

(k) Is limited to issues involving conduct of a health care provider or facility, staff member, or employee of a managed care entity which constitute grounds for disciplinary action by the appropriate professional licensing board and is

not indicative of a pattern of inappropriate behavior, and the agency, office, or department has reported these grievances to the appropriate professional licensing board or to the health facility regulation section of the agency for possible investigation; or

(l) Is withdrawn by the subscriber. Failure of the subscriber to attend the hearing shall be considered a withdrawal of the grievance.

(3) The agency shall review all grievances within 60 days after receipt and make a determination whether the grievance shall be heard. Once the agency notifies the panel, the subscriber, and the managed care entity that a grievance will be heard by the panel, the panel shall hear the grievance either in the network area or by teleconference no later than 120 days after the date the grievance was filed. The agency shall notify the parties, in writing, by facsimile transmission, or by phone, of the time and place of the hearing. The panel may take testimony under oath, request certified copies of documents, and take similar actions to collect information and documentation that will assist the panel in making findings of fact and a recommendation. The panel shall issue a written recommendation, supported by findings of fact, to the subscriber, to the managed care entity, and to the agency or the office no later than 15 working days after hearing the grievance. If at the hearing the panel requests additional documentation or additional records, the time for issuing a recommendation is tolled until the information or documentation requested has been provided to the panel. The proceedings of the panel are not subject to chapter

120.

(4) If, upon receiving a proper patient authorization along with a properly filed grievance, the agency requests records from a health care provider or managed care entity, the health care provider or managed care entity that has custody of the records has 10 days to provide the records to the agency. Records include medical records, communication logs associated with the grievance both to and from the subscriber, and contracts. Failure to provide requested records may result in the imposition of a fine of up to $500. Each day that records are not produced is considered a separate violation.

(5) Grievances that the agency determines pose an immediate and serious threat to a subscriber's health must be given priority over other grievances. The panel may meet at the call of the chair to hear the grievances as quickly as possible but no later than 45 days after the date the grievance is filed, unless the panel receives a waiver of the time requirement from the subscriber. The panel shall issue a written recommendation, supported by findings of fact, to the office or the agency within 10 days after hearing the expedited grievance.

(6) When the agency determines that the life of a subscriber is in imminent and emergent jeopardy, the chair of the panel may convene an emergency hearing, within 24 hours after notification to the managed care entity and to the subscriber, to hear the grievance. The grievance must be heard notwithstanding that the subscriber has not completed the internal grievance procedure of the managed care entity. The panel shall, upon hearing the grievance, issue a written

emergency recommendation, supported by findings of fact, to the managed care entity, to the subscriber, and to the agency or the office for the purpose of deferring the imminent and emergent jeopardy to the subscriber's life. Within 24 hours after receipt of the panel's emergency recommendation, the agency or office may issue an emergency order to the managed care entity. An emergency order remains in force until:

(a) The grievance has been resolved by the managed care entity;

(b) Medical intervention is no longer necessary; or

(c) The panel has conducted a full hearing under subsection (3) and issued a recommendation to the agency or the office, and the agency or office has issued a final order.

(7) After hearing a grievance, the panel shall make a recommendation to the agency or the office which may include specific actions the managed care entity must take to comply with state laws or rules regulating managed care entities.

(8) A managed care entity, subscriber, or provider that is affected by a panel recommendation may within 10 days after receipt of the panel's recommendation, or 72 hours after receipt of a recommendation in an expedited grievance, furnish to the agency or office written evidence in opposition to the recommendation or findings of fact of the panel.

(9) No later than 30 days after the issuance of the panel's recommendation and, for an expedited grievance, no later than 10 days after the issuance of the panel's recommendation, the agency or the office may adopt the panel's recommendation or findings of fact in a proposed order or an emergency order, as

provided in chapter 120, which it shall issue to the managed care entity. The agency or office may issue a proposed order or an emergency order, as provided in chapter 120, imposing fines or sanctions, including those contained in ss. 641.25 and 641.52. The agency or the office may reject all or part of the panel's recommendation. All fines collected under this subsection must be deposited into the Health Care Trust Fund.

(10) In determining any fine or sanction to be imposed, the agency and the office may consider the following factors:

(a) The severity of the noncompliance, including the probability that death or serious harm to the health or safety of the subscriber will result or has resulted, the severity of the actual or potential harm, and the extent to which provisions of chapter 641 were violated.

(b) Actions taken by the managed care entity to resolve or remedy any quality-of-care grievance.

(c) Any previous incidents of noncompliance by the managed care entity.

(d) Any other relevant factors the agency or office considers appropriate in a particular grievance.

(11)(a) The panel shall consist of the Insurance Consumer Advocate, or designee thereof, established by s. 627.0613; at least two members employed by the agency and at least two members employed by the department, chosen by their respective agencies; a consumer appointed by the Governor; a physician appointed by the Governor, as a standing member; and, if necessary, physicians who have expertise relevant to the case to be heard, on a rotating basis. The agency may contract with a

medical director, a primary care physician, or both, who shall provide additional technical expertise to the panel but shall not be voting members of the panel. The medical director shall be selected from a health maintenance organization with a current certificate of authority to operate in Florida.

(b) A majority of those panel members required under paragraph (a) shall constitute a quorum for any meeting or hearing of the panel. A grievance may not be heard or voted upon at any panel meeting or hearing unless a quorum is present, except that a minority of the panel may adjourn a meeting or hearing until a quorum is present. A panel convened for the purpose of hearing a subscriber's grievance in accordance with subsections (2) and (3) shall not consist of more than 11 members.

(12) Every managed care entity shall submit a quarterly report to the agency, the office, and the department listing the number and the nature of all subscribers' and providers' grievances which have not been resolved to the satisfaction of the subscriber or provider after the subscriber or provider follows the entire internal grievance procedure of the managed care entity. The agency shall notify all subscribers and providers included in the quarterly reports of their right to file an unresolved grievance with the panel.

(13) A proposed order issued by the agency or office which only requires the managed care entity to take a specific action under subsection (7) is subject to a summary hearing in accordance with s. 120.574, unless all of the parties agree otherwise. If the managed care entity does not prevail at the

hearing, the managed care entity must pay reasonable costs and attorney's fees of the agency or the office incurred in that proceeding.

(14)(a) Any information that identifies a subscriber which is held by the panel, agency, or department pursuant to this section is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. However, at the request of a subscriber or managed care entity involved in a grievance procedure, the panel, agency, or department shall release information identifying the subscriber involved in the grievance procedure to the requesting subscriber or managed care entity.

(b) Meetings of the panel shall be open to the public unless the provider or subscriber whose grievance will be heard requests a closed meeting or the agency or the department determines that information which discloses the subscriber's medical treatment or history or information relating to internal risk management programs as defined in s. 641.55(5)(c), (6), and (8) may be revealed at the panel meeting, in which case that portion of the meeting during which a subscriber's medical treatment or history or internal risk management program information is discussed shall be exempt from the provisions of s. 286.011 and s. 24(b), Art. I of the State Constitution. All closed meetings shall be recorded by a certified court reporter.

(15) Effective May 1, 2012, this section applies only to plans that meet the requirements of 45 C.F.R. s. 147.140.

Section 55. Subsections (12) through (30) of section 408.802, Florida Statutes, are renumbered as subsections (11)

through (29), respectively, and present subsection (11) of that section is amended to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

~~(11) Private review agents, as provided under part I of chapter 395.~~

Section 56. Subsection (3) is added to section 408.804, Florida Statutes, to read:

408.804 License required; display.—

(3) Any person who knowingly alters, defaces, or falsifies a license certificate issued by the agency, or causes or procures any person to commit such an offense, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Any licensee or provider who displays an altered, defaced, or falsified license certificate is subject to the penalties set forth in s. 408.815 and an administrative fine of $1,000 for each day of illegal display.

Section 57. Paragraph (d) of subsection (2) of section 408.806, Florida Statutes, is amended, and paragraph (e) is added to that subsection, to read:

408.806 License application process.—

(2)

(d) ~~The agency shall notify the licensee by mail or electronically at least 90 days before the expiration of a license that a renewal license is necessary to continue~~

~~operation.~~ The licensee's failure to timely file ~~submit~~ a renewal application and license application fee with the agency shall result in a $50 per day late fee charged to the licensee by the agency; however, the aggregate amount of the late fee may not exceed 50 percent of the licensure fee or $500, whichever is less. The agency shall provide a courtesy notice to the licensee by United States mail, electronically, or by any other manner at its address of record or mailing address, if provided, at least 90 days before the expiration of a license. This courtesy notice must inform the licensee of the expiration of the license. If the agency does not provide the courtesy notice or the licensee does not receive the courtesy notice, the licensee continues to be legally obligated to timely file the renewal application and license application fee with the agency and is not excused from the payment of a late fee. If an application is received after the required filing date and exhibits a hand-canceled postmark obtained from a United States post office dated on or before the required filing date, no fine will be levied.

(e) The applicant must pay the late fee before a late application is considered complete and failure to pay the late fee is considered an omission from the application for licensure pursuant to paragraph (3)(b).

Section 58. Paragraph (b) of subsection (1) of section 408.8065, Florida Statutes, is amended to read:

408.8065 Additional licensure requirements for home health agencies, home medical equipment providers, and health care clinics.—

(1) An applicant for initial licensure, or initial

licensure due to a change of ownership, as a home health agency, home medical equipment provider, or health care clinic shall:

(b) Submit projected ~~pro forma~~ financial statements, including a balance sheet, income and expense statement, and a statement of cash flows for the first 2 years of operation which provide evidence that the applicant has sufficient assets, credit, and projected revenues to cover liabilities and expenses.

All documents required under this subsection must be prepared in accordance with generally accepted accounting principles and may be in a compilation form. The financial statements must be signed by a certified public accountant.

Section 59. Section 408.809, Florida Statutes, is amended to read:

408.809 Background screening; prohibited offenses.—

(1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who are considered employees for the purposes of conducting screening under chapter 435:

(a) The licensee, if an individual.

(b) The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider.

(c) The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider.

(d) Any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any

offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the conviction at the time of license application.

(e) Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients. Evidence of contractor screening may be retained by the contractor's employer or the licensee.

(2) Every 5 years following his or her licensure, employment, or entry into a contract in a capacity that under subsection (1) would require level 2 background screening under chapter 435, each such person must submit to level 2 background rescreening as a condition of retaining such license or continuing in such employment or contractual status. For any such rescreening, the agency shall request the Department of Law Enforcement to forward the person's fingerprints to the Federal Bureau of Investigation for a national criminal history record check. If the fingerprints of such a person are not retained by the Department of Law Enforcement under s. 943.05(2)(g), the person must file a complete set of fingerprints with the agency and the agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of

Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check. The fingerprints may be retained by the Department of Law Enforcement under s. 943.05(2)(g). The cost of the state and national criminal history records checks required by level 2 screening may be borne by the licensee or the person fingerprinted. Proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of the agency, the Department of Health, the Agency for Persons with Disabilities, the Department of Children and Family Services, or the Department of Financial Services for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under chapter 651 satisfies the requirements of this section if the person subject to screening has not been unemployed for more than 90 days and such proof is accompanied, under penalty of perjury, by an affidavit of compliance with the provisions of chapter 435 and this section using forms provided by the agency.

(3) All fingerprints must be provided in electronic format. Screening results shall be reviewed by the agency with respect to the offenses specified in s. 435.04 and this section, and the qualifying or disqualifying status of the person named in the request shall be maintained in a database. The qualifying or disqualifying status of the person named in the request shall be posted on a secure website for retrieval by the licensee or designated agent on the licensee's behalf.

(4) In addition to the offenses listed in s. 435.04, all

persons required to undergo background screening pursuant to this part or authorizing statutes must not have an arrest awaiting final disposition for, must not have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, and must not have been adjudicated delinquent and the record not have been sealed or expunged for any of the following offenses or any similar offense of another jurisdiction:

(a) Any authorizing statutes, if the offense was a felony.

(b) This chapter, if the offense was a felony.

(c) Section 409.920, relating to Medicaid provider fraud.

(d) Section 409.9201, relating to Medicaid fraud.

(e) Section 741.28, relating to domestic violence.

(f) Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.

(g) Section 817.234, relating to false and fraudulent insurance claims.

(h) Section 817.505, relating to patient brokering.

(i) Section 817.568, relating to criminal use of personal identification information.

(j) Section 817.60, relating to obtaining a credit card through fraudulent means.

(k) Section 817.61, relating to fraudulent use of credit cards, if the offense was a felony.

(l) Section 831.01, relating to forgery.

(m) Section 831.02, relating to uttering forged instruments.

(n) Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.

(o) Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.

(p) Section 831.30, relating to fraud in obtaining medicinal drugs.

(q) Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

(5) A person who serves as a controlling interest of, is employed by, or contracts with a licensee on July 31, 2010, who has been screened and qualified according to standards specified in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015, in accordance with the schedule provided in paragraphs (a)-(c). ~~The agency may adopt rules to establish a schedule to stagger the implementation of the required rescreening over the 5-year period, beginning July 31, 2010, through July 31, 2015.~~ If, upon rescreening, such person has a disqualifying offense that was not a disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency within 30 days after receipt of the rescreening results by the person. The

rescreening schedule shall be as follows:

(a) Individuals whose last screening was conducted before December 31, 2003, must be rescreened by July 31, 2013.

(b) Individuals whose last screening was conducted between January 1, 2004, through December 31, 2007, must be rescreened by July 31, 2014.

(c) Individuals whose last screening was conducted between January 1, 2008, through July 31, 2010, must be rescreened by July 31, 2015.

(6) ~~(5)~~ The costs associated with obtaining the required screening must be borne by the licensee or the person subject to screening. Licensees may reimburse persons for these costs. The Department of Law Enforcement shall charge the agency for screening pursuant to s. 943.053(3). The agency shall establish a schedule of fees to cover the costs of screening.

(7) ~~(6)~~ (a) As provided in chapter 435, the agency may grant an exemption from disqualification to a person who is subject to this section and who:

1. Does not have an active professional license or certification from the Department of Health; or

2. Has an active professional license or certification from the Department of Health but is not providing a service within the scope of that license or certification.

(b) As provided in chapter 435, the appropriate regulatory board within the Department of Health, or the department itself if there is no board, may grant an exemption from disqualification to a person who is subject to this section and who has received a professional license or certification from

the Department of Health or a regulatory board within that department and that person is providing a service within the scope of his or her licensed or certified practice.

(8)~~(7)~~ The agency and the Department of Health may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section, chapter 435, and authorizing statutes requiring background screening and to implement and adopt criteria relating to retaining fingerprints pursuant to s. 943.05(2).

(9)~~(8)~~ There is no unemployment compensation or other monetary liability on the part of, and no cause of action for damages arising against, an employer that, upon notice of a disqualifying offense listed under chapter 435 or this section, terminates the person against whom the report was issued, whether or not that person has filed for an exemption with the Department of Health or the agency.

Section 60. Subsection (9) of section 408.810, Florida Statutes, is amended to read:

408.810 Minimum licensure requirements.—In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license.

(9) A controlling interest may not withhold from the agency any evidence of financial instability, including, but not limited to, checks returned due to insufficient funds, delinquent accounts, nonpayment of withholding taxes, unpaid utility expenses, nonpayment for essential services, or adverse court action concerning the financial viability of the provider

or any other provider licensed under this part that is under the control of the controlling interest. A controlling interest shall notify the agency within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings concerning the provider in which the controlling interest is a petitioner or defendant. Any person who violates this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation is a separate offense.

Section 61. Subsection (3) is added to section 408.813, Florida Statutes, to read:

408.813 Administrative fines; violations.—As a penalty for any violation of this part, authorizing statutes, or applicable rules, the agency may impose an administrative fine.

(3) The agency may impose an administrative fine for a violation that is not designated as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine may not exceed $500 for each violation. Unclassified violations include:

(a) Violating any term or condition of a license.

(b) Violating any provision of this part, authorizing statutes, or applicable rules.

(c) Exceeding licensed capacity.

(d) Providing services beyond the scope of the license.

(e) Violating a moratorium imposed pursuant to s. 408.814.

Section 62. Subsections (1), (7), and (8) of section 409.91195, Florida Statutes, are amended to read:

409.91195 Medicaid Pharmaceutical and Therapeutics

Committee.—There is created a Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(1) The committee shall be composed of 11 members appointed by the Governor, consisting of one member licensed under chapter 458 or chapter 459 nominated by the Florida Medical Association; one member licensed under chapter 459 nominated by the Florida Osteopathic Medical Association; one member licensed under chapter 458 or chapter 459 nominated by the Florida chapter of the American Academy of Family Physicians; one member licensed under chapter 458 or chapter 459 nominated by the Florida chapter of the American Academy of Pediatrics; one member licensed under chapter 458 or chapter 459 nominated by the Florida Psychiatric Society; one member licensed under chapter 465 nominated by the Florida Pharmacy Association; one member licensed under chapter 465 nominated by the Florida Society of Health System Pharmacists, Inc.; one member licensed under chapter 465 nominated by the Florida Retail Federation; one member licensed under chapter 465 who works in a retail setting for an independent, nonchain pharmacy; one member licensed under chapter 458 or chapter 459 nominated by the Florida Academy of Physician Assistants; and one member who represents a patient advocacy group and who shall be a consumer representative. All members of the committee, except the consumer representative, must be licensed to practice in the state, must practice in the state, and must participate in the Florida Medicaid fee-for-service pharmacy program. ~~Four members shall be physicians, licensed under chapter 458; one member~~

~~licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative.~~ The members shall be appointed to serve for terms of 2 years after ~~from~~ the date of their appointment. Members may be appointed to no more than one term. ~~The agency shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the committee represent Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a preferred drug list. At least one of the members shall represent the interests of pharmaceutical manufacturers.~~

(7) The committee shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committee with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list, allow for members of the committee to ask questions of the presenters of the public testimony, and allow 3 minutes of testimony per drug reviewed. The number of interested parties providing public testimony may not be limited by the agency. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food and Drug Administration under a priority review classification will be

reviewed by the committee at the next regularly scheduled meeting following 3 months of distribution of the drug to the general public.

(8) The committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. Whenever the agency does not follow a recommendation by the committee, it must notify the committee members in writing of its action at the next committee meeting after the reversal of the committee's recommendation.

Section 63. Subsection (37) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to

minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance

standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(37)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list

on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

3. The agency shall develop and implement a process for

managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing

practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of

the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on

serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Family Services, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations

from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

11. The agency shall implement a Medicaid prescription drug management system.

a. The agency may contract with a vendor that has experience in operating prescription drug management systems in

order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

12. The agency may contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

13. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

14. The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall ~~may~~ post prior authorization and step edit criteria and protocol and updates to the list of drugs that are subject to prior authorization on the agency's ~~an~~ Internet website within 21 days after the prior

authorization and step edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step edit" means an automatic electronic review of certain medications subject to prior authorization ~~without amending its rule or engaging in additional rulemaking~~.

15. The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

16. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior

authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

17. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual

basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spending-control program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.

Section 64. Section 429.11, Florida Statutes, is amended to read:

429.11 Initial application for license~~; provisional license~~.—

(1) Each applicant for licensure must comply with all provisions of part II of chapter 408 and must:

(a) Identify all other homes or facilities, including the addresses and the license or licenses under which they operate, if applicable, which are currently operated by the applicant or administrator and which provide housing, meals, and personal services to residents.

(b) Provide the location of the facility for which a license is sought and documentation, signed by the appropriate local government official, which states that the applicant has met local zoning requirements.

(c) Provide the name, address, date of birth, social security number, education, and experience of the administrator, if different from the applicant.

(2) The applicant shall provide proof of liability insurance as defined in s. 624.605.

(3) If the applicant is a community residential home, the applicant must provide proof that it has met the requirements specified in chapter 419.

(4) The applicant must furnish proof that the facility has received a satisfactory firesafety inspection. The local authority having jurisdiction or the State Fire Marshal must conduct the inspection within 30 days after written request by the applicant.

(5) The applicant must furnish documentation of a satisfactory sanitation inspection of the facility by the county health department.

~~(6) In addition to the license categories available in s. 408.808, a provisional license may be issued to an applicant making initial application for licensure or making application for a change of ownership. A provisional license shall be limited in duration to a specific period of time not to exceed 6 months, as determined by the agency.~~

(6)~~(7)~~ A county or municipality may not issue an occupational license that is being obtained for the purpose of operating a facility regulated under this part without first ascertaining that the applicant has been licensed to operate such facility at the specified location or locations by the agency. The agency shall furnish to local agencies responsible

for issuing occupational licenses sufficient instruction for making such determinations.

Section 65. Subsection (1) of section 429.294, Florida Statutes, is amended to read:

429.294 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility within 10 days~~, in accordance with the provisions of s. 400.145,~~ shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 66. Section 429.71, Florida Statutes, is amended to read:

429.71 Classification of violations ~~deficiencies~~; administrative fines.—

(1) In addition to the requirements of part II of chapter 408 and in addition to any other liability or penalty provided by law, the agency may impose an administrative fine on a provider according to the following classification:

(a) Class I violations are defined in s. 408.813 ~~those conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical or emotional harm would result~~

~~therefrom~~. ~~The condition or practice that constitutes a class I violation must be abated or eliminated within 24 hours, unless a fixed period, as determined by the agency, is required for correction.~~ A class I violation ~~deficiency~~ is subject to an administrative fine in an amount not less than $500 and not exceeding $1,000 for each violation. ~~A fine may be levied notwithstanding the correction of the deficiency.~~

(b) Class II violations are defined in s. 408.813 ~~those conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines directly threaten the physical or emotional health, safety, or security of the residents, other than class I violations~~. A class II violation is subject to an administrative fine in an amount not less than $250 and not exceeding $500 for each violation. ~~A citation for a class II violation must specify the time within which the violation is required to be corrected. If a class II violation is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.~~

(c) Class III violations are defined in s. 408.813 ~~those conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines indirectly or potentially threaten the physical or emotional health, safety, or security of residents, other than class I or class II violations~~. A class III violation is subject to an administrative fine in an amount not less than $100 and not exceeding $250 for each violation. ~~A citation for a class III violation shall specify the time within which the~~

~~violation is required to be corrected.~~ If a class III violation is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated violation ~~offense~~.

(d) Class IV violations are defined in s. 408.813 ~~those conditions or occurrences related to the operation and maintenance of an adult family-care home, or related to the required reports, forms, or documents, which do not have the potential of negatively affecting the residents~~. ~~A provider that does not correct~~ A class IV violation ~~within the time limit specified by the agency~~ is subject to an administrative fine in an amount not less than $50 and not exceeding $100 for each violation. Any class IV violation that is corrected during the time the agency survey is conducted will be identified as an agency finding and not as a violation, unless it is a repeat violation.

(2) The agency may impose an administrative fine for violations which do not qualify as class I, class II, class III, or class IV violations. The amount of the fine shall not exceed $250 for each violation or $2,000 in the aggregate. Unclassified violations may include:

(a) Violating any term or condition of a license.

(b) Violating any provision of this part, part II of chapter 408, or applicable rules.

(c) Failure to follow the criteria and procedures provided under part I of chapter 394 relating to the transportation, voluntary admission, and involuntary examination of adult family-care home residents.

(d) Exceeding licensed capacity.

(e) Providing services beyond the scope of the license.

(f) Violating a moratorium.

(3) Each day during which a violation occurs constitutes a separate offense.

(4) In determining whether a penalty is to be imposed, and in fixing the amount of any penalty to be imposed, the agency must consider:

(a) The gravity of the violation.

(b) Actions taken by the provider to correct a violation.

(c) Any previous violation by the provider.

(d) The financial benefit to the provider of committing or continuing the violation.

~~(5) As an alternative to or in conjunction with an administrative action against a provider, the agency may request a plan of corrective action that demonstrates a good faith effort to remedy each violation by a specific date, subject to the approval of the agency.~~

(5)~~(6)~~ The department shall set forth, by rule, notice requirements and procedures for correction of deficiencies.

Section 67. Section 429.195, Florida Statutes, is amended to read:

429.195 Rebates prohibited; penalties.—

(1) It is unlawful for any assisted living facility licensed under this part to contract or promise to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any person, health care provider, or health care facility as provided in s. 817.505 ~~physician, surgeon, organization, agency,~~

~~or person, either directly or indirectly, for residents referred to an assisted living facility licensed under this part~~. ~~A facility may employ or contract with persons to market the facility, provided the employee or contract provider clearly indicates that he or she represents the facility. A person or agency independent of the facility may provide placement or referral services for a fee to individuals seeking assistance in finding a suitable facility; however, any fee paid for placement or referral services must be paid by the individual looking for a facility, not by the facility.~~

(2) This section does not apply to:

(a) An individual employed by the assisted living facility or with whom the facility contracts to market the facility, if the individual clearly indicates that he or she works with or for the facility.

(b) Payments by an assisted living facility to a referral service that provides information, consultation, or referrals to consumers to assist them in finding appropriate care or housing options for seniors or disabled adults if such referred consumers are not Medicaid recipients.

(c) A resident of an assisted living facility who refers a friend, family member, or other individuals with whom the resident has a personal relationship to the assisted living facility, in which case the assisted living facility may provide a monetary reward to the resident for making such referral.

(3) ~~(2)~~ A violation of this section shall be considered patient brokering and is punishable as provided in s. 817.505.

Section 68. Section 429.915, Florida Statutes, is amended

to read:

429.915 Conditional license.—In addition to the license categories available in part II of chapter 408, the agency may issue a conditional license to an applicant for license renewal or change of ownership if the applicant fails to meet all standards and requirements for licensure. A conditional license issued under this subsection must be limited to a specific period not exceeding 6 months, as determined by the agency~~, and must be accompanied by an approved plan of correction~~.

Section 69. Subsection (3) of section 430.80, Florida Statutes, is amended to read:

430.80 Implementation of a teaching nursing home pilot project.—

(3) To be designated as a teaching nursing home, a nursing home licensee must, at a minimum:

(a) Provide a comprehensive program of integrated senior services that include institutional services and community-based services;

(b) Participate in a nationally recognized accreditation program and hold a valid accreditation, such as the accreditation awarded by the Joint Commission on Accreditation of Healthcare Organizations, or, at the time of initial designation, possess a Gold Seal Award as conferred by the state on its licensed nursing home;

(c) Have been in business in this state for a minimum of 10 consecutive years;

(d) Demonstrate an active program in multidisciplinary education and research that relates to gerontology;

(e) Have a formalized contractual relationship with at least one accredited health profession education program located in this state;

(f) Have senior staff members who hold formal faculty appointments at universities, which must include at least one accredited health profession education program; and

(g) Maintain insurance coverage pursuant to s. 400.141(1)(q) ~~s. 400.141(1)(s)~~ or proof of financial responsibility in a minimum amount of $750,000. Such proof of financial responsibility may include:

1. Maintaining an escrow account consisting of cash or assets eligible for deposit in accordance with s. 625.52; or

2. Obtaining and maintaining pursuant to chapter 675 an unexpired, irrevocable, nontransferable and nonassignable letter of credit issued by any bank or savings association organized and existing under the laws of this state or any bank or savings association organized under the laws of the United States that has its principal place of business in this state or has a branch office which is authorized to receive deposits in this state. The letter of credit shall be used to satisfy the obligation of the facility to the claimant upon presentment of a final judgment indicating liability and awarding damages to be paid by the facility or upon presentment of a settlement agreement signed by all parties to the agreement when such final judgment or settlement is a result of a liability claim against the facility.

Section 70. Paragraph (h) of subsection (2) of section 430.81, Florida Statutes, is amended to read:

430.81 Implementation of a teaching agency for home and community-based care.—

(2) The Department of Elderly Affairs may designate a home health agency as a teaching agency for home and community-based care if the home health agency:

(h) Maintains insurance coverage pursuant to s. 400.141(1)(q) ~~s. 400.141(1)(s)~~ or proof of financial responsibility in a minimum amount of $750,000. Such proof of financial responsibility may include:

1. Maintaining an escrow account consisting of cash or assets eligible for deposit in accordance with s. 625.52; or

2. Obtaining and maintaining, pursuant to chapter 675, an unexpired, irrevocable, nontransferable, and nonassignable letter of credit issued by any bank or savings association authorized to do business in this state. This letter of credit shall be used to satisfy the obligation of the agency to the claimant upon presentation of a final judgment indicating liability and awarding damages to be paid by the facility or upon presentment of a settlement agreement signed by all parties to the agreement when such final judgment or settlement is a result of a liability claim against the agency.

Section 71. Paragraph (d) of subsection (9) of section 440.102, Florida Statutes, is repealed.

Section 72. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more

practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, ~~or~~ chapter 466, or as an advanced registered nurse practitioner licensed under part I in chapter 464, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 73. Subsections (1) and (9) of section 483.051, Florida Statutes, are amended to read:

483.051 Powers and duties of the agency.—The agency shall adopt rules to implement this part, which rules must include, but are not limited to, the following:

(1) LICENSING; QUALIFICATIONS.—The agency shall provide for biennial licensure of all nonwaived clinical laboratories meeting the requirements of this part and shall prescribe the qualifications necessary for such licensure, including, but not limited to, application for or proof of a federal Clinical Laboratory Improvement Amendment (CLIA) certificate. For purposes of this section, the term "nonwaived clinical laboratories" means laboratories that perform any test that the Centers for Medicare and Medicaid Services has determined does not qualify for a certificate of waiver under the Clinical

Laboratory Improvement Amendments of 1988 and the federal rules adopted thereunder.

(9) ALTERNATE-SITE TESTING.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping requirements. ~~Alternate-site testing locations must register when the clinical laboratory applies to renew its license.~~ For purposes of this subsection, the term "alternate-site testing" means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

Section 74. Subsection (1) of section 483.245, Florida Statutes, is amended, and subsection (3) is added to that section, to read:

483.245 Rebates prohibited; penalties.—

(1) It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any dialysis facility, physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a clinical laboratory licensed under this part. A clinical laboratory licensed under this part is prohibited from placing, directly or indirectly, through an independent staffing company or lease arrangement, or otherwise, a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the same entity.

(3) Any person aggrieved by a violation of this section may bring a civil action for appropriate relief, including an action for a declaratory judgment, injunctive relief, and actual damages.

Section 75. Section 483.294, Florida Statutes, is amended to read:

483.294 Inspection of centers.—In accordance with s. 408.811, the agency shall biennially~~, at least once annually,~~ inspect the premises and operations of all centers subject to licensure under this part.

Section 76. Subsection (13) of section 651.118, Florida Statutes, is amended to read:

651.118 Agency for Health Care Administration; certificates of need; sheltered beds; community beds.—

(13) Residents, as defined in this chapter, are not

considered new admissions for the purpose of s. 400 141(1)(n)1.d ~~s. 400.141(1)(o)1.d~~.

Section 77. Paragraph (j) is added to subsection (3) of section 817.505, Florida Statutes, to read:

817.505 Patient brokering prohibited; exceptions; penalties.—

(3) This section shall not apply to:

(j) Payments by an assisted living facility, as defined in s. 429.02, or an agreement for or solicitation, offer, or receipt of such payment by a referral service permitted under s. 429.195(2).

Section 78. In the interim between this act becoming law and the 2013 Regular Session of the Legislature, the Division of Statutory Revision shall provide the relevant substantive committees of the Senate and the House of Representatives with assistance, upon request, to enable such committees to prepare draft legislation to correct the names of accrediting organizations in the related Florida Statutes.

Section 79. Except as otherwise expressly provided in this act, and except for this section and section 78, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2012.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HSQS 12-03 Health Care Coverage Mandates
SPONSOR(S): Health & Human Services Quality Subcommittee; Wood
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Quality Subcommittee		Poche	Calamas

SUMMARY ANALYSIS

PCB HSQS 12-03 proposes the repeal of the following health insurance coverage mandates:

- Section 627.669, F.S., regarding substance and alcohol abuse treatment;
- Section 627.42395, F.S., regarding enteral nutrition;
- Section 627.668, F.S., regarding mental and nervous disorders;
- Section 641.31(24), F.S., regarding osteopathic hospitals;
- Sections 627.6686, F.S., and 641.31098, F.S., relating to autism and developmental disabilities;
- Section 627.4236, F.S., relating to bone marrow transplant procedures;
- Sections 627.64193, F.S., 627.66911, F.S., and 641.31(35), F.S., relating to cleft lip and cleft palate;
- Section 627.6617, F.S., relating to home health care;
- Sections 627.6403, F.S., and 627.6618, F.S., relating to payment to acupuncturists;
- Section 627.419(4), F.S., relating to chiropractic physicians;
- Sections 627.6407, F.S., 627.6619, F.S., and 641.31(37), F.S., relating to massage therapists;
- Section 627.419(4), F.S., relating to podiatrists; and
- Sections 627.6471(6), F.S., 627.6472(15), F.S., and 627.668, F.S., relating to mandated eligibility provisions for participation in a network by marriage and family therapists, professional counselors, psychologists, and psychiatric nurses.

The PCB amends several statutes to conform cross-references to the statutes proposed for repeal.

The PCB appears to have an indeterminate positive fiscal impact on state and local government.

The PCB provides an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Health Insurance Mandates and Mandated Offerings

A health insurance mandate is a legal requirement that an insurance company or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Mandated offerings, on the other hand, do not mandate that certain benefits be provided. Rather, a mandated offering law can require that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require a higher premium and which the insured is free to accept or reject. A mandated offering law in the context of mental health can require that insurers offer an option of coverage for mental illness, which may require a higher premium and which the insured is free to accept or reject or require that, if insurers offer mental illness coverage, the benefits must be equivalent to other types of benefits.

Florida currently has at least 59 mandates.[1] The Council for Affordable Health Insurance estimates that mandated benefits currently increase the cost of basic health coverage by a little less than 20 percent, but possibly higher depending on the number of mandates, the benefit design and the cost of the initial premium.[2] Each mandate adds to the cost of a plan's premiums, in a range of less than 1 percent to 10 percent, depending on the mandate.[3] Higher costs resulting from mandates are most likely to be experienced in the small group market since these are the plans that are subject to state regulations. The national average cost of insurance for a family of four is $15,073.[4]

Selected Florida Mandates

Podiatrists and Chiropractic Physicians

Section 627.419(3), F.S., requires any health insurance policy, health care services plan or other contract that covers services within the scope of practice of a podiatrist to provide for payment to a podiatrist who provides those services.[5]

Section 627.419(4), F.S., requires any health insurance policy, health care services plan or other contract that covers services within the scope of practice of a chiropractic physician to provide for payment to a chiropractic physician who provides those services.[6]

At least thirty-two other states have an insurance mandate requiring coverage of treatment by a podiatrist and at least forty three other states have an insurance mandate requiring coverage of treatment by a chiropractor.[7]

Bone Marrow Transplant Procedures

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[1] *See* Florida House of Representatives, Health and Human Services Quality Subcommittee, *Meeting Packet for November 15, 2011*, pages 7-9 (available at http://myfloridahouse.gov/Sections/Documents/publications.aspx?CommitteeId=2612&PublicationType=Committees&DocumentType=Meeting Packets&Session=2012&SessionId=70); *but see also* Council for Affordable Health Insurance , *Health Insurance Mandates in the States 2010- Table 1: Total Mandates by State*, page 3 (on file with Health and Human Services Quality Subcommittee).

[2] *Id.* at page 7.

[3] *Id.* at pages 4-6.

[4] Kaiser Family Foundation, *Employer Health Benefits 2011 Annual Survey- Summary of Findings*, page 1, available at: http://ehbs.kff.org/pdf/8226.pdf (last viewed January 26, 2012).

[5] The scope of practice of a podiatrist is governed by chapter 461, F.S.

[6] The scope of practice of a chiropractic physician is governed by chapter 460, F.S.

[7] *See supra* at FN 1, Council for Affordable Health Insurance, *Health Insurance Mandates in the States 2010*, at page 6.

A bone marrow transplant is a procedure to replace damaged or destroyed bone marrow with healthy bone marrow stem cells. Bone marrow is the soft, fatty tissue located on the inside of bones. Stem cells are immature cells in the bone marrow that give rise to all blood cells.[8] There are three kinds of bone marrow transplants:

- **Autologous bone marrow transplant**- Stem cells are removed from an individual before he or she receives high-dose chemotherapy or radiation treatment. After these treatments are done, the stems cells are put back in the body. This is also referred to as a "rescue" transplant.
- **Allogeneic bone marrow transplant**- Stem cells are removed from another person, called a donor. Most times, the donor must have the same genetic makeup as the patient, so that the blood is a "match". Special blood tests are done to determine if a donor is a good match. A brother or sister is most likely to be a good match. However, sometimes parents, children, and other relatives may be also be good matches. Donors who are not related to the patient may be found through national bone marrow registries.
- **Umbilical cord blood transplant**- Stem cells are removed from a newborn baby's umbilical cord immediately after being born. The stem cells are stored until they are needed for a transplant. Umbilical cord blood cells are so immature, there is less of a concern that they will not match.[9]

Minor surgery may be needed to collect bone marrow and stem cells from a donor. This is called a bone marrow harvest. The surgery is done under general anesthesia, which means the donor will be asleep and pain-free during the procedure. The bone marrow is removed from the hip bones.[10]

Section 627.4236, F.S., prohibits an insurer or HMO from excluding coverage for bone marrow transplant procedures, recommended by a referring physician and treating physician, on the basis of a policy exclusion for experimental, clinical investigative, educational or similar procedures in a policy or contract that covers cancer.[11] The use of the recommended bone marrow transplant procedure must be accepted within the appropriate oncological specialty and not experimental in nature, pursuant to rules established by the Agency for Health Care Administration (AHCA).[12]

Eight other states mandate insurance coverage for bone marrow transplants.[13]

Enteral Nutrition

Section 627.42395, F.S., requires any health insurance policy or group health insurance plan to offer coverage for nutrient and food supplements prescribed by a physician as medically necessary to treat inherited metabolic diseases or congenital defects that cause malabsorption. These supplements, known as enteral nutrition, are introduced to the body through one or more tube feeding options as a result of the symptoms of metabolic disease or congenital defects which prevent a person from eating or swallowing properly.[14] Coverage is required for modified, low protein food products up to $2,500 annually for any insured individual through the age of 24.[15]

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[8] The New York Times, Health Guide, *Bone Marrow Transplant*, available at http://health.nytimes.com/health/guides/surgery/bone-marrow-transplant/overview.html (last viewed on January 27, 2012).

[9] Bishop MR, Pavletic SZ. *Hematopoietic stem cell transplantation*. In: Abeloff MD, Armitage JO, Niederhuber JE, Kastan MB, McKena WG, eds. *Clinical Oncology* . 4th ed. Philadelphia, Pa: Elsevier Churchill Livingstone; 2008:chap 32.

[10] Vose JM, Pavletic SZ. *Hematopoietic stem cell transplantation*. In: Goldman L, Ausiello D. Cecil, *Medicine* . 23rd ed., Philadelphia, Pa: Saunders Elsevier; 2007:chap 184.

[11] S. 627.4236(2), F.S.

[12] *Id.*; *see also* s. 627.4236(3)(a), F.S.; Rule 59B-12.001, F.A.C. contains the bone marrow transplant procedures that are determined to be accepted and appropriate procedures.

[13] *See supra* at FN 1, page 4.

[14] American Society for Parenteral and Enteral Nutrition (ASPEN), *What is Enteral Nutrition?*, available at http://www.nutritioncare.org/wcontent.aspx?id=266.

[15] S. 627.42395, F.S.

Acupuncturists

The term "acupuncture" describes a family of procedures involving the stimulation of anatomical points on the body using a variety of techniques. The acupuncture technique that has been most often studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.[16]

The report from a Consensus Development Conference on Acupuncture held at the National Institutes of Health (NIH) in 1997 stated that acupuncture is being "widely" practiced—by thousands of physicians, dentists, acupuncturists, and other practitioners—for relief or prevention of pain and for various other health conditions.[17] According to the 2007 National Health Interview Survey, which included a comprehensive survey of CAM use by Americans, an estimated 3.1 million U.S. adults and 150,000 children had used acupuncture in the previous year. Between the 2002 and 2007 NHIS, acupuncture use among adults increased by approximately 1 million people.[18]

Research has shown that acupuncture reduces nausea and vomiting after surgery and chemotherapy, can relieve pain. Researchers do not fully understand how acupuncture works; it might aid the activity of the body's pain-killing chemicals and affect how the body releases chemicals that regulate blood pressure and flow.[19]

Section 627.6403, F.S., and s. 627.6618, F.S., require any individual health insurance policy that covers acupuncture to pay for the services of a licensed acupuncturist[20] to the same extent and degree as the services of a licensed physician.

At least eleven other states have an insurance mandate requiring payment of services provided by an acupuncturist.[21]

Massage Therapists

Section 627.6407, F.S., s. 627.6619, F.S., and s. 641.31(37), F.S., require any individual health insurance policy that covers massage to cover the services of a licensed massage therapist[22] if the massage is prescribed by a licensed physician as medically necessary and the prescription specifies the number of treatments.

Cleft Lip and Cleft Palate

Cleft lip and cleft palate are the two most common forms of orofacial clefts found in Florida.[23] These types of clefts occur when the structures of the mouth fail to form properly. This typically occurs early in fetal development between four and ten weeks after conception. Cleft lip and palate may occur separately or together. A cleft lip involves the space between the upper lip and the nostrils. Clefts of the palate may occur in the front of the palate, which involves underlying bone, or in the back area involving soft tissue. Infants born with a cleft typically undergo surgery and receive speech therapy and

[16] National Institutes of Health, National Center for Complementary and Alternative Medicine, *Acupuncture: An Introduction*, NCCAM Pub. No. D404, December 2007 (updated August 2011), available at http://nccam.nih.gov/health/acupuncture/introduction.htm (last viewed on January 27, 2012).
[17] *Id.*
[18] *Id.*
[19] National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Acupuncture*, available at http://www.nlm.nih.gov/medlineplus/acupuncture.html (last viewed on January 27, 2012).
[20] Chapter 457, F.S., governs the licensing of acupuncturists in Florida; *see also* Chapter 64B1-4, F.A.C.
[21] *See supra* at FN 1, page 5.
[22] Massage therapists are governed by chapter 480, F.S. and chapters 64B7-24 through -33, F.A.C.
[23] Florida Department of Health, Bureau of Environmental Public Health, Florida Birth Defects Registry, *Orofacial Clefts*, available at: http://www.fbdr.org/2005/birthdefects/cleft.asp (last viewed on January 26, 2012).

orthodontic care. From 1998 through 2007, Florida saw 2,909 cases of cleft lip or cleft palate, an average of 291 cases per year during that time period.[24]

Section 627.64193, F.S., s. 627.66911, F.S., and s. 641.31(35), F.S., require a health insurance policy or HMO contract that provides coverage for a child under the age of 18 to cover treatment of cleft lip and cleft palate for the child. Treatment must include medical, dental and speech therapy, audiology, and nutrition services if determined to be medically necessary and consequent to the treatment of cleft lip or cleft palate. This coverage mandate does not apply to specified-accident, specified-disease, hospital indemnity, limited benefit disability income, or long-term care insurance policies.

Sixteen other states mandate insurance coverage for cleft lip and cleft palate.[25]

Mandated Eligibility Criteria for Participation in a Provider Network

Section 627.6471(6), F.S., and s. 627.6472(15), F.S., require an insurer, where psychotherapeutic services are covered by the policy, to provide eligibility criteria for allopathic and osteopathic physicians, psychologists[26], marriage and family therapists and mental health counselors[27], and psychiatric advanced registered nurse practitioners[28] to be added to the provider network.

At least forty-three other states have some form of insurance mandate related to psychologists.[29] At least sixteen other states have some form of insurance mandate related to marriage and family therapists.[30] At least sixteen other states have some form of insurance mandate related to professional counselors.[31] At least seventeen other states have some form of insurance mandate related to psychiatric nurses.[32]

Home Health Care

Home health care covers a wide range of services, including occupational and physical therapy, speech therapy, and skilled nursing. It may involve helping the elderly with activities of daily living such as bathing, dressing, and eating. Home health care may also include assistance with cooking, cleaning, other housekeeping jobs, and monitoring one's daily regimen of prescription and over-the-counter medications.[33]

Section 627.6617, F.S., requires any group health insurance policy to provide coverage for home health care performed by a home health care agency licensed under part III of chapter 400, F.S. The home health care provided can range from basic assistance with activities of daily living by a home health aide to skilled nursing care provided by a registered nurse. Coverage in the amount of at least $1,000 must be provided annually for home health care prescribed by a physician and provided by a licensed agency.

Nineteen other states mandate insurance coverage for home health care.[34]

Mental Health Parity and Addiction Equity Act

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[24] Florida Department of Health, Bureau of Environmental Public Health, Florida Birth Defects Registry, *Orofacial Cleft Defects in Florida, 1998-2007*, available at: http://www.fbdr.org/gfx/data/cleft_table.jpg (last viewed on January 26, 2012).
[25] *See supra* at FN 13.
[26] Chapter 490, F.S., governs the licensing of psychologists in Florida.
[27] Chapter 491, F.S., governs the licensing of marriage and family therapists and mental health counselors in Florida.
[28] Psychiatric advanced registered nurse practitioners are licensed pursuant to s. 464.012, F.S..
[29] *See supra* at FN 1, page 6.
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] U.S. Department of Health and Human Services, Administration on Aging, Eldercare Locator, *What is Home Health Care?*, available at http://www.eldercare.gov/Eldercare.NET/Public/Resources/Factsheets/Home_Health_Care.aspx (last viewed on January 27, 2012).
[34] *See supra* at FN 13.

In 2010, an estimated 45.9 million adults aged 18 or older in the United States had any mental illness[35] in the past year.[36] This represents 20.0 percent of all adults in this country.[37] These estimates were stable between 2009 (45.1 million, 19.9 percent) and 2010.[38] In 2010, there were an estimated 11.4 million adults aged 18 or older in the United States with serious mental illness[39] in the past year.[40] This represented 5.0 percent of all adults in this country in 2010.[41] These estimates of adults with serious mental illness in 2010 were similar to those in 2009 (11.0 million, 4.8 percent).[42]

On October 2, 2008, President George W. Bush signed into law H.R. 1424, which contains the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the Act). The Act applies to employer-sponsored ERISA group health plans and large group health insurance plans. The Act will preempt all state laws that apply to the same group health insurance policies (large group plans) while allowing for state laws that expand upon the federal mandate. Any state parity legislation regarding group health insurance will only apply to small group health insurance (2-50 employees) and large group health insurance to the extent that the state act expands the benefits provided under the Act.

Pursuant to the Act, a group health plan that provides medical and surgical benefits and offers benefits for the treatment of mental health conditions or substance abuse must apply financial requirements and treatment limitations to mental health disorders and substance abuse that are no more restrictive than those predominantly applied to medical and surgical benefits under the policy. Parity with regard to financial requirements includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but not annual and lifetime limits. Parity with regard to treatment limitations includes limits on treatment frequency, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Annual and lifetime coverage limits for mental health benefits must be equivalent to the limits on substantially all medical and surgical benefits; if no limit is applied to medical and surgical benefits then a limit may not be applied to mental health benefits. Additionally, out-of-network benefits for mental health and substance abuse treatment must be provided on par with out-of-network medical and surgical benefits.

The Act does not specify a set of mental health benefits that must be provided. Instead, the Act requires that benefits for mental health and substance abuse be defined under the terms of the health care plan, in accordance with applicable state and federal law. As discussed above, current Florida law requires an offer of coverage for mental and nervous disorders as defined by the standard nomenclature of the American Psychiatric Association (APA) subject to the right of the applicant for a group policy or contract to select any alternative benefits or level of benefits as may be offered. Thus, insurers must offer a policy covering all conditions defined by the APA, but may also offer policies that provide benefits for a greater or lesser number of conditions, so long as the benefits are provided in accordance with the minimum limits contained in statute.

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[35] "Any mental illness" is defined as currently or at any time in the past year having had a diagnosable mental, behavioral, or emotional disorder (excluding developmental and substance use disorders) of sufficient duration to meet diagnostic criteria specified within the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV; American Psychiatric Association [APA], 1994). Adults who had a diagnosable mental, behavioral, or emotional disorder in the past year, regardless of their level of functional impairment, were defined as having any mental illness; *see* Substance Abuse and Mental Health Services Administration (SAMHSA), *Results from the 2010 National Survey on Drug Use and Health: Mental Health Findings*, NSDUH Series H-42, HHS Publication No. (SMA) 11-4667. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. Available at http://www.samhsa.gov/data/NSDUH/2k10MH_Findings/2k10MHResults.htm#1.1 (last viewed on January 27, 2012).

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] SAMHSA defined serious mental illness as persons aged 18 or older who currently or at any time in the past year have had a diagnosable mental, behavioral, or emotional disorder (excluding developmental and substance use disorders) of sufficient duration to meet diagnostic criteria specified within DSM-IV (APA, 1994) that has resulted in serious functional impairment, which substantially interferes with or limits one or more major life activities; *see supra* at FN 28.

[40] *Id.*

[41] *Id.*

[42] *Id.*

It appears that under the Act, in Florida, a large group health plan must offer a coverage plan providing coverage for mental and nervous disorders as defined by the standard nomenclature of the APA and that meets the requirements of the federal parity law. Alternative coverage plans may also be offered pursuant to Florida law, but such coverage would have to provide benefits in conformity with the federal parity mandate.

The Act exempts employers that have an average of between two and 50 employees (small groups). The Act also exempts health plans if application of parity for benefits results in a 2 percent or greater increase in total plan costs for the first year parity is applied, and an increase of 1 percent or greater in subsequent plan years. To qualify for an exemption, the determination that plan costs exceed the applicable percentage must be made in a written report by a qualified and licensed actuary that is a member in good standing of the American Academy of Actuaries. If an insurer or group health plan claims an exemption it must notify federal and state regulators, as well as plan participants and beneficiaries. Federal and state regulators both are authorized to conduct an audit of the books, records, and actuarial reports of a group health plan or insurer claiming an exemption

Many studies have examined the effect of mental health parity laws on the cost of health care coverage, with varying results. Recognizing these differing results, the Substance Abuse and Mental Health Services Administration (SAMHSA) within the United States Department of Health and Human Services designed a study to analyze the costs of parity.[43] At the time of the study most states had parity laws that were limited to serious mental illnesses and did not include substance abuse, small plans, or government employees. The study found that these types of plans with tightly managed care have a small effect on premiums; however, plans with full parity for mental health and substance abuse increased premiums by an average of 3.6 percent.[44]

Section 627.668, F.S., regulates the provision of mental and nervous disorder services by insurers, (HMOs), and nonprofit hospital and medical service plan corporations providing group health insurance or prepaid health care. Specifically, these entities must make mental and nervous disorder services available to a policyholder for an additional premium. Florida's law is a mandated offering law. Similarly, the Act does not require insurers, HMOs, or other providers of health insurance to provide coverage for mental and nervous disorder services. If a health insurance plan or contract offer these services, the Act requires coverage to be equal to the coverage provided for medical treatment and services. The Act is a mandated parity law.

Forty-one other states have a general mental health insurance mandate and forty seven other states have some form of mental health parity mandate.[45]

Autism

Autism spectrum disorder (ASD) refers to any of a group of developmental disorders (such as autism and Asperger's syndrome) marked by impairments in the ability to communicate and interact socially and by the presence of repetitive behaviors or restricted interests.[46] The Centers for Disease Control estimates that 1 in every 110 children in the United States has ASD.[47] Individuals with an ASD had average medical expenditures that exceeded those without an ASD by $4,110–$6,200 per year.[48]

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[43] Merrile Sing, et al, *The Costs and Effects of Parity for Mental Health and Substance Abuse Insurance Benefits*, DHHS Publication No. MC99-80 (1998), Substance Abuse and Mental Health Services Administration, available at http://mentalhealth.about.com/library/mc/bltyexsm.htm (last viewed on January 27, 2012).

[44] *Id.*

[45] *See supra* at FN 21.

[46] *See* www.merriam-webster.com/dictionary/autism%20spectrum%20disorder (last viewed January 26, 2012).

[47] Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, *Autism Spectrum Disorders (ASDs)-Data and Statistics-Prevalence*, available at http://www.cdc.gov/ncbddd/autism/data.html#prevalence (last viewed January 26, 2012).

[48] Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, *Autism Spectrum Disorders (ASDs)-Data and Statistics-Economic Costs*, available at http://www.cdc.gov/ncbddd/autism/data.html#economic (last viewed January 26, 2012).

Recent studies have estimated that the lifetime cost to care for an individual with an ASD is $3.2 million.[49]

Section 627.6686, F.S., and section 641.31098, F.S. (applying to HMOs) requires coverage for well-baby and well-child screening for diagnosis of autism spectrum disorder.[50] Both statutes also require coverage for treatment of autism spectrum disorder through speech, occupational, and physical therapy and behavior therapy analysis.[51] The amount of coverage for screening and treatment is limited to $36,000 per year, with a lifetime maximum coverage limit of $200,000.[52]

At least twenty-seven other states have an insurance mandate for coverage of screening for and treatment of ASD.[53] Of those, Arkansas, Rhode Island, and West Virginia enacted an ASD mandate in 2011.[54]

Substance and Alcohol Abuse Treatment

Section 627.669, F.S., requires group health insurance plans and HMOs to offer coverage for treatment of substance abuse.[55] Coverage must provide a minimum lifetime benefit of $2,000.[56] Also, coverage must provide for a maximum of 44 out-patient treatment visits, with a maximum "per visit" benefit of $35.[57]

At least forty-five other states have some form of insurance mandate to provide coverage for treatment of alcoholism and substance abuse, and at least thirty-three other states have some form of insurance mandate to provide treatment of drug abuse.[58]

Osteopathic Hospitals

Section 641.31(24), F.S., requires HMO contracts that provide for in-patient and out-patient treatment at an allopathic hospital to provide the option for similar treatment at an osteopathic hospital, when those services are available in the HMO service area. According to AHCA, there are no osteopathic hospitals in Florida.[59]

Effect of Proposed Changes

PCB HSQS 12-03 proposes the repeal of the preceding mandates. The PCB also makes conforming changes to the statutory provisions included in sections 18 through 26 to reflect the repeal of the preceding mandates.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.419, F.S., relating to construction of policies;
Section 2: Repeals s. 627.4236, F.S., relating to coverage for bone marrow transplant procedures;
Section 3: Repeals s. 627.42395, F.S., relating to coverage for certain prescription and nonprescription enteral formulas;

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[49] *Id.*
[50] S. 627.6686(3)(a), F.S., and s. 641.31098(3)(a), F.S.
[51] S. 627.6686(3)(b), F.S., and s. 641.31098(3)(b), F.S.
[52] S. 627.6686(4)(b), F.S., and s. 641.31098(4)(b), F.S.
[53] *See supra* at FN 13.
[54] National Conference of State Legislatures, *2011 Health Insurance Reform Enacted State Laws Related to the Affordable Care Act*, available at http://www.ncsl.org/issues-research/health/2011-health-insurance-reform-enacted-state-laws-re.aspx (last viewed on January 27, 2012).
[55] S. 627.669(1), F.S.
[56] S. 627.669(2)(b)2., F.S.
[57] S. 627.669(2)(b)3. and 4., F.S.
[58] *See supra* at FN 13.
[59] Email correspondence from AHCA legislative affairs staff to Health and Human Services Quality Subcommittee staff dated January 26, 2012 (on file with the Subcommittee).

Section 4: Repeals s. 627.6403, F.S., relating to payment of acupuncture benefits to certified acupuncturists;
Section 5: Repeals s. 627.6407, F.S., relating to massage;
Section 6: Repeals s. 627.64193, F.S., relating to required coverage for cleft lip and cleft palate;
Section 7: Amends s. 627.6471, F.S., relating to contracts for reduced rates of payment; limitations; coinsurance and deductibles;
Section 8: Amends s. 627.6472, F.S., relating to exclusive provider organizations;
Section 9: Repeals s. 627.6617, F.S., relating to coverage for home health care services;
Section 10: Repeals s. 627.6618, F.S., relating to payment of acupuncture benefits to certified acupuncturists;
Section 11: Repeals s. 627.6619, F.S., relating to massage;
Section 12: Repeals 627.668, F.S., relating to optional coverage for mental and nervous disorders required; exception;
Section 13: Repeals s. 627.6686, F.S., relating to coverage for individuals with autism spectrum disorder required; exception;
Section 14: Repeals s. 627.669, F.S., relating to optional coverage required for substance abuse impaired persons; exception;
Section 15: Repeals s. 627.66911, F.S., relating to required coverage for cleft lip and cleft palate;
Section 16: Amends s. 641.31, F.S., relating to health maintenance contracts;
Section 17: Repeals s. 641.31098, F.S., relating to coverage for individuals with developmental disabilities;
Section 18: Amends s. 409.815, F.S., relating to health benefits coverage; limitations;
Section 19: Amends s. 409.906, F.S., relating to optional Medicaid coverage;
Section 20: Amends s. 624.916, F.S., relating to developmental disabilities compact;
Section 21: Amends s. 627.6472, F.S., relating to exclusive provider organizations;
Section 22: Amends s. 627.6515, F.S., relating to out-of-state-groups;
Section 23: Amends s. 627.6675, F.S., relating to conversion on termination of eligibility;
Section 24: Amends s. 627.6699, F.S., relating to Employee Health Care Access Act;
Section 25: Amends s. 641.2018, F.S., relating to limited coverage for home health care authorized;
Section 26: Amends s. 1002.66, F.S., relating to specialized instructional services for children with disabilities; and
Section 27: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Division of State Group Insurance may realize a reduction in health insurance costs statewide as both PPO plans and HMO plans lower premiums in response to the removal of several coverage mandates and mandated offerings of coverage, assuming the Division chooses not continue purchasing coverage for those benefits and assuming that insurers adjust their rates.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

Local governments, as employers, may realize reduction in health insurance costs as health insurance plans and HMOs lower premiums in response to the removal of several coverage mandates and mandated offerings of coverage, assuming local governments choose not to continue purchasing coverage for those benefits and assuming that insurers adjust their rates.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Employers, employees, and individual insureds may realize a reduction in premiums due to the elimination of coverage mandates, assuming they choose to continue purchasing coverage for those benefits, and assuming insurers adjust their rates.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health care coverage mandates; repealing s. 627.419(3) and (4), F.S.; relating to construction of policies requiring payment to chiropractors and podiatrists for services provided within scope of practice; repealing s. 627.4236, F.S., relating to coverage for bone marrow transplant procedures; repealing s. 627.42395, F.S., relating to coverage for certain prescription and nonprescription enteral formulas; repealing s. 627.6403, F.S., relating to payment of acupuncture benefits to certified acupuncturists; repealing s. 627.6407, F.S., relating to payment of services provided by massage therapist; repealing s. 627.64193, F.S., relating to required coverage for cleft lip and cleft palate; repealing s. 627.6471(6), F.S., relating to mandated eligibility provision for participation in provider network by therapist, counselor, psychologist, or psychiatric nurse; repealing s. 627.6472(15), F.S., relating to mandated eligibility provision for participation in provider network by therapist, counselor, psychologist, or psychiatric nurse; repealing s. 627.6617, F.S., relating to coverage for home health care services; repealing s. 627.6618, F.S., relating to payment of acupuncture benefits to certified acupuncturists; repealing s. 627.6619, F.S., relating to payment of services provided by massage therapist; repealing s. 627.6686, F.S., relating to

coverage for individuals with autism spectrum disorder; repealing s. 627.668, F.S., relating to optional coverage for mental and nervous disorders; repealing s. 627.669, F.S., relating to optional coverage required for substance abuse impaired persons; repealing s. 627.66911, F.S., relating to required coverage for cleft lip and cleft palate; repealing s. 641.31(24), (35) and (37), F.S., relating to payment for treatment at an osteopathic hospital in certain circumstances, required coverage for cleft lip and cleft palate, and payment for services provided by massage therapist; repealing s. 641.31098, F.S., relating to coverage for individuals with developmental disabilities; amending ss. 409.815, F.S.; 409.906, F.S.; 624.916, F.S.; 627.6472, F.S.; 627.6515, F.S.; 627.6675, F.S.; 627.6699, F.S.; 641.2018, F.S.; and 1002.66, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (3) and (4) of section 627.419, Florida Statutes, are repealed.

Section 2. Section 627.4236, Florida Statutes, is repealed.

Section 3. Section 627.42395, Florida Statutes, is repealed.

Section 4. Section 627.6403, Florida Statutes, is repealed.

Section 5. Section 627.6407, Florida Statutes, is repealed.

Section 6. Section 627.64193, Florida Statutes, is repealed.

Section 7. Subsection (6) of section 627.6471, Florida Statutes, is repealed.

Section 8. Subsection (15) of section 627.6472, Florida Statutes, is repealed.

Section 9. Section 627.6617, Florida Statutes, is repealed.

Section 10. Section 627.6618, Florida Statutes, is repealed.

Section 11. Section 627.6619, Florida Statutes, is repealed.

Section 12. Section 627.668, Florida Statutes, is repealed.

Section 13. Section 627.6686, Florida Statutes, is repealed.

Section 14. Section 627.669, Florida Statutes, is repealed.

Section 15. Section 627.66911, Florida Statutes, is repealed.

Section 16. Subsections (24), (35), and (37) of section 641.31, Florida Statutes, are repealed.

Section 17. Section 641.31098, Florida Statutes, is repealed.

Section 18. Paragraph (e) of subsection (2) of section 409.815, Florida Statutes, is amended to read:

409.815 Health benefits coverage; limitations.—

(2)

(e) Organ transplantation services.—Covered services include pretransplant, transplant, and postdischarge services and treatment of complications after transplantation for transplants deemed necessary and appropriate within the guidelines set by the Organ Transplant Advisory Council under s. 765.53 ~~or the Bone Marrow Transplant Advisory Panel under s. 627.4236~~.

Section 19. Subsection (26) of section 409.906, Florida Statutes, is amended to read:

409.906 Optional Medicaid services.—

(26) HOME AND COMMUNITY-BASED SERVICES FOR AUTISM SPECTRUM DISORDER AND OTHER DEVELOPMENTAL DISABILITIES.—The agency is authorized to seek federal approval through a Medicaid waiver or a state plan amendment for the provision of occupational therapy, speech therapy, physical therapy, behavior analysis, and behavior assistant services to individuals who are 5 years of age and under and have a diagnosed developmental disability as defined in s. 393.063, autism spectrum disorder ~~as defined in s. 627.6686~~, or Down syndrome, a genetic disorder caused by the presence of extra chromosomal material on chromosome 21. Causes of the syndrome may include Trisomy 21, Mosaicism, Robertsonian Translocation, and other duplications of a portion of chromosome 21. Coverage for such services shall be limited to $36,000 annually and may not exceed $108,000 in total lifetime benefits. The agency shall submit an annual report beginning on January 1, 2009, to the President of the Senate, the Speaker of the House

of Representatives, and the relevant committees of the Senate and the House of Representatives regarding progress on obtaining federal approval and recommendations for the implementation of these home and community-based services. The agency may not implement this subsection without prior legislative approval.

Section 20. Paragraph (b) of subsection (6) and paragraph (c) of subsection (8) of section 624.916, Florida Statutes, is amended to read:

624.916 Developmental disabilities compact.—

(6) Beginning February 15, 2009, and continuing annually thereafter, the Office of Insurance Regulation shall provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the implementation of the agreement negotiated under this section. The report shall include:

(b) An analysis of the coverage provided under the agreement ~~in comparison to the coverage required under ss. 627.6686 and 641.31098~~.

(8) As used in this section, the term "developmental disabilities" includes:

(c) Autism spectrum disorder~~, as defined in s. 627.6686~~.

Section 21. Paragraph (c) of subsection (1) of section 627.6472, Florida Statutes, is amended to read:

627.6472 Exclusive provider organizations.—

(1) As used in this section, the term:

(c) "Exclusive provider" means a provider of health care, or a group of providers of health care, that has entered into a written agreement with the insurer to provide benefits under a

health insurance policy issued under this section~~, which agreement shall include any health care provider listed in s. 627.419(3) and (4) and shall provide reasonable access to such health care providers~~.

Section 22. Paragraph (c) of subsection (2) of section 627.6515, Florida Statutes, is amended to read:

627.6515 Out-of-state groups.—

(2) Except as otherwise provided in this part, this part does not apply to a group health insurance policy issued or delivered outside this state under which a resident of this state is provided coverage if:

(c) The policy provides the benefits specified in ss. 627.419, 627.6574, 627.6575, 627.6579, 627.6612, 627.66121, 627.66122, 627.6613, 627.667, 627.6675, and 627.6691, ~~and 627.66911,~~ and complies with the requirements of s. 627.66996.

Section 23. Subsection (8) of section 627.6675, Florida Statutes, is amended to read:

627.6675 Conversion on termination of eligibility.—

(8) BENEFITS OFFERED.—

(a) An insurer shall not be required to issue a converted policy that provides benefits in excess of those provided under the group policy from which conversion is made.

~~(b) An insurer shall offer the benefits specified in s. 627.668 and the benefits specified in s. 627.669 if those benefits were provided in the group plan.~~

(b)~~(c)~~ An insurer shall offer maternity benefits and dental benefits if those benefits were provided in the group plan.

Section 24. Paragraph (b) of subsection (12) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(12) STANDARD, BASIC, HIGH DEDUCTIBLE, AND LIMITED HEALTH BENEFIT PLANS.—

(b)7. Sections 627.419(2), ~~(3), and (4),~~ 627.6574, 627.6612, 627.66121, 627.66122, and 627.6616~~, 627.6618, 627.668, and 627.66911~~ apply to the standard health benefit plan and to the basic health benefit plan. However, notwithstanding said provisions, the plans may specify limits on the number of authorized treatments, if such limits are reasonable and do not discriminate against any type of provider.

Section 25. Subsection (1) of section 641.2018, Florida Statutes, is amended to read:

641.2018 Limited coverage for home health care authorized.—

(1) Notwithstanding other provisions of this chapter, a health maintenance organization may issue a contract that limits coverage to home health care services only. The organization and the contract shall be subject to all of the requirements of this part that do not require or otherwise apply to specific benefits other than home care services. To this extent, all of the requirements of this part apply to any organization or contract that limits coverage to home care services, except the requirements for providing comprehensive health care services as provided in ss. 641.19(4), (11), and (12), and 641.31(1), except ss. 641.31(9), (12), (17), (18), (19), (20), (21), and ~~(24) and~~ 641.31095.

Section 26. Paragraph (a) of subsection (2) of section 1002.66, Florida Statutes, is amended, and subsequent paragraphs are renumbered, to read:

1002.66 Specialized instructional services for children with disabilities.—

(2) The parent of a child who is eligible for the prekindergarten program for children with disabilities may select one or more specialized instructional services that are consistent with the child's individual educational plan. These specialized instructional services may include, but are not limited to:

~~(a) Applied behavior analysis as defined in ss. 627.6686 and 641.31098.~~

Section 27. This act shall take effect July 1, 2012.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing PCB: Health & Human Services Quality Subcommittee

Representative Wood offered the following:

Amendment (with title amendment)

Remove lines 49-50 and insert:

Section 1. Subsections (3) and (4) of section 627.419, Florida Statutes, are amended, and subsequent subsections are renumbered, to read:

627.419 Construction of policies.-

(3) Notwithstanding any other provision of law, when any health insurance policy, health care services plan, or other contract provides for the payment for procedures specified in the policy or contract which are within the scope of an optometrist's ~~or podiatric physician's~~ professional license, such policy shall be construed to include payment to an optometrist ~~or podiatric physician~~ who performs such procedures. ~~In the case of podiatric services, such payments shall be made~~

~~in accordance with the coverage now provided for medical and surgical benefits.~~

~~(4) Notwithstanding any other provision of law, when any health insurance policy, health care services plan, or other contract provides for the payment for medical expense benefits or procedures, such policy, plan, or contract shall be construed to include payment to a chiropractic physician who provides the medical service benefits or procedures which are within the scope of a chiropractic physician's license. Any limitation or condition placed upon payment to, or upon services, diagnosis, or treatment by, any licensed physician shall apply equally to all licensed physicians without unfair discrimination to the usual and customary treatment procedures of any class of physicians.~~

T I T L E A M E N D M E N T

Remove line 3 and insert:

amending s. 627.419(3) and (4), F.S.; relating to

COMMITTEE/SUBCOMMITTEE AMENDMENT

PCB Name: PCB HSQS 12-03 (2012)

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing PCB: Health & Human Services Quality Subcommittee

Representative Randolph offered the following:

Amendment

Remove lines 92-93