Health & Human Services Quality Subcommittee

Thursday, January 12, 2012
8:00 AM – 10:30 AM
306 HOB

Dean Cannon
Speaker

John Wood
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Quality Subcommittee

Start Date and Time:	Thursday, January 12, 2012 08:00 am
End Date and Time:	Thursday, January 12, 2012 10:30 am
Location:	306 HOB
Duration:	2.50 hrs

Consideration of the following bill(s):

HB 309 Radiological Personnel by Oliva
HB 381 Electrolysis by Logan
HB 475 Blood Establishments by Eisnaugle
HB 621 Nursing Homes and Related Health Care Facilities by Frishe
HB 711 Sale or Lease of a County, District, or Municipal Hospital by Hooper

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Wednesday, January 11, 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., Wednesday, January 11, 2012.

Appearance forms can be found on myfloridahouse.gov. Please print and bring 2 copies of the form to the meeting and give them to the administrative assistant.

NOTICE FINALIZED on 01/10/2012 16:13 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 309 Radiological Personnel
SPONSOR(S): Oliva
TIED BILLS: **IDEN./SIM. BILLS:** SB 376

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 Division of Environmental Health in collaboration with the Division of Medical Quality Assurance within the Department of Health (DOH) regulates the certification of radiologic personnel pursuant to chapter 468, part IV, F.S.

The bill creates a new licensure type called the "specialty technologist" for a licensed radiologic technologist. The bill is not creating a new profession; instead the bill is adding a skill modifier called the "specialty technologist" to the existing radiology technologist license. A specialty technologist is a person who is qualified by education and certification to use radiation on humans under the specific direction and general supervision of a licensed practitioner.

The bill authorizes DOH to issue a certificate by endorsement to practice as a specialty technologist and collect a nonrefundable fee not to exceed $100 if the applicant demonstrates that he or she is currently certified or registered by the national registry in an advanced, postprimary, or specialty area. The national registry is maintained by the American Registry of Radiologic Technologists. The bill directs DOH to approve letter designations by rule for each specialty area, consistent with the designation used by the national registry and authorizes DOH to determine the duties of a specialty technologist by rule. The bill specifies that the duties must be consistent with the scope of practice of the national registry for each particular advanced, post primary, or specialty area. The bill prohibits individuals from obtaining a specialty technologist license by examination.

The bill removes the term "ionizing" from the declaratory policy statement that people must be protected against the harmful effects of excessive and improper exposure to ionizing radiation. The bill adds to the definition of "radiation" language enabling the DOH to add other types of radiation to the definition by rule promulgation to accommodate changes in imaging or therapy technology or procedures.

The bill has an insignificant positive fiscal impact to the Medical Quality Assurance trust fund within the Department of Health (See Fiscal Analysis).

The bill takes effect July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Medical Quality Assurance

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA supports licensure and disciplinary activities for 43 professions and 37 types of facilities/establishments, and works with 22 boards and 6 councils.

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[1] Boards are responsible for approving or denying applications for licensure and making disciplinary decisions on whether a practitioner practices within the authority of their practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

Radiology

The Division of Environmental Health in collaboration with the Division of Medical Quality Assurance within the Department of Health regulates the certification of radiologic personnel pursuant to chapter 468, part IV, F.S.

Radiological personnel certification is governed by chapter 468, part IV, F.S., the Radiologic Personnel Certification Act. Radiation is the emission of x-rays and gamma rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.[2] In 1973, the state began regulating persons who use radiation and radiation-emitting equipment.[3] In 1981, the federal Consumer-Patient Radiation Health and Safety Act[4] was passed, which required the Secretary of the U.S. Department of Health and Human Services to establish standards for the accreditation of radiologic programs, the education of certain persons who administer radiologic procedures, and for the credentialing of such persons. Section 468.3003, F.S., declares that it is the policy of the state that the health and safety of the people must be protected against the harmful effects of excessive and improper exposure to ionizing radiation by establishing standards of education, training, and experience and to require the examination and certification of users of radiation and radiation-emitting equipment. The federal Consumer-Patient Radiation Health and Safety Act defines radiation to include ionizing and non-ionizing radiation in amounts beyond normal background levels from sources such as medical and dental radiologic procedures.[5]

The term radiologic personnel generally refers to anyone who is trained as a basic x-ray machine operator, general radiographer, radiologic technologist, radiology assistant, or a radiologist.[6] A basic x-ray machine operator[7] is a person who is employed by a licensed practitioner to perform certain

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[1] S. 456.001, F.S.
[2] S. 468.301(14), F.S.
[3] Ch. 73-383, L.O.F.
[4] 42 U.S.C. § 10004
[5] 42 U.S.C. §10003(1)
[6] S. 468.301, F.S.
[7] The state regulates two basic x-ray machine operator types: the basic x-ray machine and the basic x-ray operator-podiatric medicine. The only difference is that the latter is employed by and under the direct supervision of a licensed podiatric physician to perform only those radiographic functions that are within the scope of practice of a podiatric physician licensed pursuant to chapter 461, F.S.

radiographic functions under direct supervision.[8] A basic x-ray operated is not permitted to perform nuclear medicine or radiation therapy procedures. A general radiographer is a person who is employed and certified in radiography, other than a basic x-ray machine operator. A radiologic technologist is a person uses radiation on human beings under the specific direction and general supervision[9] of a licensed practitioner[10]. A radiologist assistant is a person who is an advanced-level radiologic technologist who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the medical imaging environment. A radiologist is a licensed physician who specializes in radiology and is certified by the American Board of Radiology or the American Osteopathic Board of Radiology, the British Royal College of Radiology, or the Canadian College of Physicians and Surgeons.[11]

Radiology Technologist

All applicants for certification as a radiology technologist may not receive a Florida license to practice until they have successfully passed an examination administered by the American Registry of Radiologic Technologists.[12]

There are four types of designations that a radiology technologist may currently receive in Florida: certified radiologic technologist-radiographer (CRT-R), certified radiologic technologist-computed tomography (CRT-T), certified radiologic technologist-therapy (CRT-T), and certified radiologic technologist-nuclear medicine (CRT-N).[13] A person who holds a certificate as a radiologic technologist may only use radiation or radiation-producing equipment on human beings for diagnostic or therapeutic purposes while operating under the general supervision of a licensed practitioner and only if the application of radiation is limited to a person or parts of the human body the CRT is authorized to treat.[14] CRT's are required to complete 4-hours of HIV/AIDS continuing education every biennium, and twelve additional continuing education hours in the radiologic technology practice area.[15]

As of June 30, 2011, there were 24,057 individuals who possessed active in-state licenses as a radiologic technologist and 11,323 in-state licenses were in delinquency[16] status.[17]

National Organizations

The American Society of Radiologic Technologists (ASRT) is the largest and oldest membership association for individuals in the radiologic sciences. Founded in 1920, the ASRT now has more than 142,000 members. ASRT is also the only association that represents all medical imaging technologists, no matter what their area of practice. Fifty-two associations are affiliates of the ASRT.[18]

The Joint Review Committee on Education in Radiologic Technology (JRCERT) is the largest of three programmatic agencies that evaluates and accredits degree-granting colleges and universities that

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[8] Direct supervision means supervision and control by a licensed practitioner who assumes legal liability for the services rendered by the basic x-ray machine operator or basic x-ray machine operator-podiatric medicine. Supervision requires the physical presence of the licensed practitioner for consultation and direction of the actions of the basic x-ray machine operator or basic x-ray machine operator-podiatric medicine.

[9] General supervision is supervision whereby a practitioner authorizes services to be performed by a radiologic technologist, except emergency situations. Supervision requires the easy availability or physical presence of the licensed practitioner for consultation and direction of the actions of the radiologic technologist.

[10] A licensed practitioner is a person who is a physician, chiropractor, podiatrist, or a naturopath.

[11] *Supra* at FN 5.

[12] S. 468.306, F.S. and 64E-3.004, F.A.C.

[13] S. 468.302(2), F.S.

[14] S. 468.302(4), F.S.

[15] 64E-3.009, 64E-3.008, and 64E-3.003(4), F.A.C.

[16] A delinquency status of a license means that a licensee has an in-state mailing address of record and is not authorized to practice in the state because he or she has failed to renew the license.

[17] The Florida Department of Health, Division of Medical Quality Assurance, 2010-2011 Annual Report, *available at*: http://www.doh.state.fl.us/mqa/reports.htm (last viewed December 28, 2011).

[18] American Society of Radiologic Technologists, History of the American Society of Radiologic Technologists, *available at*: https://www.asrt.org/content/aboutasrt/history.aspx (last viewed December 27, 2011).

offer degrees in radiologic science.[19] In 2010, the JRCERT accredited 629 radiography programs, 82 radiation therapy programs, 15 medical dosimetry[20] programs, and 3 magnetic resonance programs.[21] There are 42 JRCERT accredited programs in Florida.[22]

The American Registry of Radiologic Technologists (ARRT) was founded in 1922 as the Radiological Society of North America, with the support of the American Roentgen Ray Society and the American Society of Radiologic Technologists (formerly called the American Society of X-Ray Technicians).[23] ARRT is a certifying body that certifies and registers individuals in 17 disciplines. Candidates for ARRT certification must meet basic education, ethics, and clinical experience requirements to become eligible to take a certification examination. The ARRT awards the following designations for a registered technologist (RT):[24]

- (R) for Radiography
- (N) for Nuclear Medicine Technology
- (T) for Radiation Therapy
- (MR) for Magnetic Resonance Imaging
- (S) for Sonography
- (M) for Mammography
- (CT) for Computed Tomography
- (QM) for Quality Management
- (BD) for Bone Densitometry
- (CI) for Cardiac-Interventional Radiography
- (VI) for Vascular-Interventional Radiography
- (CV) for Cardiovascular-Interventional Radiography
- (VS) for Vascular Sonography
- (BS) for Breast Sonography

RTs must renew their registration each year in order to maintain their certification. Continuing Education (CE) requirements must be fulfilled every biennium. The biennium cycle is defined in relation to the RT's birth month. There are three options for meeting the CE requirements. Only one option must be met to satisfy the requirements. The options are: (1) earn 24 CE A+ or A[25] level credits that meet the criteria set forth by the ARRT; or (2) pass a primary examination in a discipline not previously passed and for which the individual is eligible and which the ARRT recognizes for this purpose; or (3) pass one of the post-primary examinations[26] not previously passed and for which the individual is eligible and recognized by ARRT.[27]

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[19] American Society of Radiologic Technologists, Radiologic Science Organizations, *available at*: https://www.asrt.org/content/aboutasrt/alphabet_soup.aspx (last viewed December 28, 2011).

[20] A Medical Dosimetrist is a member of the radiation oncology team who has knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy (internal radiotherapy) and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologist. *See* American Association of Medical Dosimetrist, *available at*: http://www.medicaldosimetry.org/generalinformation/medical_dosimetrist.cfm (last viewed December 28, 2011).

[21] *Ibid.*

[22] Joint Review Committee on Education in Radiologic Technology Accreditation, Accredited Programs, *available at*: http://www.jrcert.org/cert/results.jsp# (last viewed December 28, 2011).

[23] American Registry of Radiologic Technologists, History, *available at*: https://www.arrt.org/About-ARRT/History (last viewed December 27, 2011).

[24] American Registry of Radiologic Technologists, Designation Awarded by ARRT, *available at*: https://www.arrt.org/About-ARRT/Designation-Awarded (last viewed December 27, 2011).

[25] The distinction between Category A and A+ activities is not based on the nature of the activity itself, but rather is based upon whether the activity has been submitted to, reviewed by, and approved by a Recognized Continuing Education Evaluation Mechanism (RCEEM) or a RCEEM+. ARRT uses RCEEM as a quality control mechanism for CE activities.

[26] The ARRT offers two categories of certification: primary and post-primary. Candidates for post-primary certification must meet two sets of educational requirements: registration by ARRT in an appropriate supporting category and completion of clinical experience requirements. ARRT currently offers certification via the post-primary category for: mammography, computed tomography, quality management, bone densitometry, cardiac-interventional radiography, vascular-interventional radiography, vascular sonography, breast sonography, or in magnetic resonance imaging or sonography.

[27] American Registry of Radiologic Technologists, Education, *available at*: https://www.arrt.org/Education/#CQR (last viewed December 28, 2011).

Beginning January 1, 2011, any certifications earned in any specialty designation are time limited to 10 years, at which time an RT will need to demonstrate continuing qualifications as part of the Continuing Qualifications Requirements (CQR). To renew registration of such certificates after 10 years have lapsed, individuals will be subject to Continuing Qualifications Requirements (CQR) as well as Continuing Education requirements.[28] The first time-limited certificates for RTs won't be subject to the CQ requirements until 2021. CQR will apply to RRAs beginning in 2015.[29]

Effects of Proposed Changes

The bill removes the term "ionizing" from the declaratory policy statement that people must be protected against the harmful effects of excessive and improper exposure to ionizing radiation. This makes the statement more general by applying to both types of radiation: ionizing and non-ionizing. The change will increase the scope of regulatory authority by including non-ionizing types of radiation such as, electric and magnetic fields, radio waves, microwaves, infrared, ultraviolet and visible radiation.

The bill adds to the definition of "radiation" language enabling the DOH to add other types of radiation to the definition by rule promulgation to accommodate changes in imaging or therapy technology or procedures. According to DOH, this change will allow them greater flexibility in adapting to changes in medical imaging or therapy technology. However, granting DOH authority to change the definition through the rule promulgation process may implicate the separation of powers doctrine.

The bill provides a new licensure type called the "specialty technologist" for a licensed radiologic technologist. A specialty technologist is a person, other than a licensed practitioner, who is qualified §§education and certification to use radiation on humans under the specific direction and general supervision of a licensed practitioner. To qualify as a specialty technologist an individual must demonstrate to the department that he or she is currently holds a certification or registration in an advanced, postprimary, or specialty area of radiologic technology such as CT or PET. The certification or registration must be from a national registry recognized by DOH.

Typically, individuals may obtain licensure by two pathways: licensure by endorsement and licensure by examination. The bill prohibits individuals from obtaining a license by examination. The bill authorizes DOH to issue a certificate by endorsement to practice as a specialty technologist and collect a nonrefundable fee not to exceed $100 if the applicant demonstrates that he or she meets the licensure requirements.

The bill provides that a person who holds a license as a specialty technologist may use the title "Certified Radiologic Technologist -X" or the letters "CRT-X". The "X" is a placeholder to represent a single or multiple-letter designation of a particular specialty area. The bill provides examples of how the new designation would work. One such example is that if an individual holds a national registry designation in CT he or she may use the letters "CRT-CT". The bill directs DOH to approve letter designations by rule for each specialty area, consistent with the designation used by the national registry. Furthermore, the bill authorizes DOH to determine the duties of a specialty technologist by rule. The bill specifies that the duties must be consistent with the scope of practice of the national registry for each particular advanced, post primary, or specialty area.

B. SECTION DIRECTORY:

Section 1. Amends s. 468.3003, F.S., relating to the declaration of policy statement.
Section 2. Amends s. 468.301, F.S., relating to definitions.
Section 3. Amends s. 468.302, F.S., relating to the use of radiation and identification of certified persons.
Section 4. Amends s. 468.304, F.S., relating to certification.
Section 5. Amends s. 468.306, F.S., relating to examinations.

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[28] As of December 28, 2011, the CQR requirements are still under development and details are unavailable.
[29] American Registry of Radiologic Technologists, Education, *available at*: https://www.arrt.org/Education/#CQR (last viewed December 28, 2011).

Section 6. Amends s. 468.3065, F.S., relating to certification by endorsement.
Section 7. Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to DOH, the ARRT web site indicates that approximately 9,549 advanced, post-primary and specialty certifications are issued to technologists with Florida addresses. Since a technologist may hold multiple certifications at the same time, the actual number of technologists is actually less than 9,549 (DOH estimates one-third fewer, noting the proportion of Florida certifications to Florida technologists listed on the site is a ratio of 1.33 to 1.) Therefore, DOH concludes that approximately 6,398 Floridians hold ARRT technologists certifications.

Many of the technologists who hold ARRT post-primary certifications are already Florida-certified as general radiographers. Radiography includes CT (both use x-rays); so many Florida-certified general radiographers are probably not going to seek Florida CT certification, at least for now. Given this fact, we estimate that only about 10-20% of the 6,398 ARRT technologists may seek state certification.

DOH revenue estimate uses the upper 20% figure of 1,280 applicants to calculate the potential increase in revenue to the MQA trust fund over a two year period. The bill authorizes DOH to collect an endorsement fee not to exceed $100.

The revenue estimate projects collecting a $45 endorsement fee per applicant. DOH projects an increase in revenue to the MQA trust fund of $28,800 for the first two years of implementation.

2. Expenditures:

MQA believes that there will be minimal expenditures since the bill is not setting up a new profession, just adding more categories or a skill modifier to the existing radiological technologist profession in the COMPAS licensure system. There will be minimal operational cost to mail and print the specialty technologist certificate. The Division of Environmental health does not anticipate a need for additional staff or equipment to process the endorsement requests for this type of certification.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None identified.

2. Expenditures:

None identified.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals seeking a license as a specialty technologist will have to remit a fee not to exceed $100.

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:

   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.[30]

   The bill adds to the definition of "radiation" language enabling the DOH to add other types of radiation to the definition by rule promulgation to accommodate changes in imaging or therapy technology or procedures. The bill does not provide criteria or guidance on what types of radiation may be added to the definition in the future.

B. RULE-MAKING AUTHORITY:

   The bill provides DOH sufficient authority to promulgate rules to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   Current law defines "national organization" means a professional association or registry, approved by the department, that examines, registers, certifies, or approves individuals and educational programs relating to operators of sources of radiation. However, the bill references a "national registry," and this term is not defined. It is not clear what the difference is or if there is a difference, between a national organization and a national registry.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[30] *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.").

A bill to be entitled

An act relating to radiological personnel; amending s. 468.3003, F.S.; clarifying legislative policy; amending s. 468.301, F.S.; redefining the term "radiation" and defining the term "specialty technologist" as those terms relate to the certification of radiological personnel; amending s. 468.302, F.S.; providing titles for persons who hold a certificate as a specialty technologist; authorizing a person holding a certificate as a specialty technologist to perform the specific duties allowed for a specialty technologist as defined by the Department of Health; requiring that the duties be consistent with the scope of practice of a national registry for the particular advanced, postprimary, or specialty area; amending s. 468.304, F.S.; providing criteria for certification as a specialty technologist; amending s. 468.306, F.S.; providing for an applicant for certification as a specialty technologist to be certified only by endorsement rather than by examination; amending s. 468.3065, F.S.; authorizing the department to issue a certificate by endorsement to practice as a specialty technologist to an applicant who meets certain criteria; providing an effective date.

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

Section 1. Section 468.3003, Florida Statutes, is amended to read:

468.3003 Declaration of policy.—It is declared to be the policy of the state that the health and safety of the people must be protected against the harmful effects of excessive and improper exposure to ~~ionizing~~ radiation. Such protection can in some major measure be accomplished by requiring adequate training and experience of persons who use radiation and radiation-emitting equipment in each particular case under the specific direction of licensed practitioners. It is the purpose of this part to establish standards of education, training, and experience and to require the examination and certification of users of radiation and radiation-emitting equipment.

Section 2. Subsection (14) of section 468.301, Florida Statutes, is amended, and subsection (18) is added to that section, to read:

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

(14) "Radiation" means X rays and gamma rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles. The department may by rule add other types of radiation to this definition in order to accommodate changes in imaging or therapy technology or procedures.

(18) "Specialty technologist" means a person, other than a licensed practitioner, who is qualified by education and certification, as set forth in s. 468.304, to use radiation on humans under the specific direction and general supervision of a licensed practitioner.

Section 3. Paragraph (h) is added to subsection (2) and

paragraph (i) is added to subsection (3) of section 468.302, Florida Statutes, to read:

468.302 Use of radiation; identification of certified persons; limitations; exceptions.—

(2)

(h) A person holding a certificate as a specialty technologist may use the title "Certified Radiologic Technologist-X" or the letters "CRT-X" where "X" represents a single- or multiple-letter designation signifying the advanced, postprimary, or specialty area of radiologic technology, such as "CT" for computed tomography or "PET" for positron emission tomography, in which the person is certified by a national registry that is recognized by the department. The department shall approve these letter designations by rule for each area, consistent with the designation used by the national registry.

No other person is entitled to so use a title or letters contained in this subsection or to hold himself or herself out in any way, whether orally or in writing, expressly or by implication, as being so certified.

(3)

(i) A person holding a certificate as a specialty technologist may perform the specific duties allowed for a specialty technologist as defined by department by rule. These duties must be consistent with the scope of practice of the national registry for that particular advanced, postprimary, or specialty area.

Section 4. Subsection (3) of section 468.304, Florida

Statutes, is amended to read:

468.304 Certification.—The department shall certify any applicant who meets the following criteria:

(3) Submits satisfactory evidence, verified by oath or affirmation, that she or he:

(a) Is at least 18 years of age at the time of application;

(b) Is a high school, vocational school, technical school, or college graduate or has successfully completed the requirements for a graduate equivalency diploma (GED) or its equivalent;

(c) Is of good moral character;

(d) Has passed an examination as specified in s. 468.306 or meets the requirements specified in s. 468.3065; and

(e)1. Has successfully completed an educational program, which program may be established in a hospital licensed pursuant to chapter 395 or in an accredited postsecondary academic institution which is subject to approval by the department as maintaining a satisfactory standard; or

2.a. With respect to an applicant for a basic X-ray machine operator's certificate, has completed a course of study approved by the department with appropriate study material provided the applicant by the department;

b. With respect to an applicant for a basic X-ray machine operator-podiatric medicine certificate, has completed a course of study approved by the department, provided that such course of study shall be limited to that information necessary to perform radiographic procedures within the scope of practice of

a podiatric physician licensed pursuant to chapter 461;

c. With respect only to an applicant for a general radiographer's certificate who is a basic X-ray machine operator certificateholder, has completed an educational program or a 2-year training program that takes into account the types of procedures and level of supervision usually and customarily practiced in a hospital, which educational or training program complies with the rules of the department;

d. With respect only to an applicant for a nuclear medicine technologist's certificate who is a general radiographer certificateholder, has completed an educational program or a 2-year training program that takes into account the types of procedures and level of supervision usually and customarily practiced in a hospital, which educational or training program complies with the rules of the department; ~~or~~

e. With respect to an applicant for a radiologist assistant's certificate who demonstrates to the department that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists; or~~.~~

f. With respect to an applicant for a specialty technologist's certificate, demonstrates to the department that he or she is currently certified or registered by a national registry that is recognized by the department in an advanced, postprimary, or specialty area of radiologic technology, such as computed tomography or positron emission tomography.

The department may not certify any applicant who has committed

an offense that would constitute a violation of any of the provisions of s. 468.3101 or applicable ~~the~~ rules ~~adopted thereunder~~ if the applicant had been certified by the department at the time of the offense. An ~~No~~ application for a limited computed tomography certificate may not ~~shall~~ be accepted. A person ~~All persons~~ holding a valid computed tomography certificate ~~certificates~~ as of October 1, 1984, is ~~are~~ subject to ~~the provisions of~~ s. 468.309.

Section 5. Section 468.306, Florida Statutes, is amended to read:

468.306 Examinations.—An applicant ~~All applicants~~ for certification as a radiologic technologist, basic X-ray machine operator, or basic X-ray machine operator-podiatric medicine, except an applicant ~~those~~ certified pursuant to s. 468.3065, shall be required to pass an examination. An applicant for certification as a specialty technologist shall be certified only in accordance with s. 468.3065. An application for certification as a specialty technologist by examination may not be accepted. In lieu of an examination for a radiologist assistant certificate, the department shall accept a demonstration by the applicant for such a certificate that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists. The department may develop or use examinations for each type of certificate. The department may require an applicant who does not pass an examination after five attempts to complete additional remedial education, as specified by rule of the department, before admitting the applicant to subsequent

examinations.

(1) The department may contract with organizations that develop such test examinations. Examinations may be administered by the department or the contracting organization.

(2) Examinations shall be given for each type of certificate at least twice a year at such times and places as the department may determine to be advantageous for applicants.

(3) All examinations shall be written and include positioning, technique, and radiation protection. The department shall ~~either~~ pass or fail each applicant on the basis of his or her final grade. The examination for a basic X-ray machine operator must ~~shall~~ include basic positioning and basic techniques directly related to the skills necessary to safely operate radiographic equipment.

(4) A nonrefundable fee not to exceed $75 plus the actual per-applicant cost for purchasing the examination from a national organization shall be charged for any subsequent examination.

Section 6. Subsection (3) is added to section 468.3065, Florida Statutes, to read:

468.3065 Certification by endorsement.—

(3) The department may issue a certificate by endorsement to practice as a specialty technologist to an applicant who, upon applying to the department and remitting a nonrefundable fee not to exceed $100, demonstrates to the department that he or she holds a current certificate, license, or registration from a national registry that is recognized by the department to practice in an advanced, postprimary, or specialty area of

radiologic technology, such as computed tomography or positron emission tomography, if the requirements for such certificate, license, or registration are deemed by the department to be substantially equivalent to those established under this part and rules adopted under this part.

Section 7. 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 Oliva offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Delete everything after the enacting clause and insert:

Section 1. Subsection (18) is added to section 468.301, Florida Statutes, to read:

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

(18) "Specialty technologist" means a person, other than a licensed practitioner, who is qualified by education and certification, as set forth in s. 468.304, to use radiation on human beings under the specific direction and general supervision of a licensed practitioner.

Section 2. Paragraph (h) is added to subsection (2) and paragraph (i) is added to subsection (3) of section 468.302, Florida Statutes, to read:

468.302 Use of radiation; identification of certified

persons; limitations; exceptions.—

(2)

(h) A person holding a certificate as a specialty technologist may use the title "Certified Radiologic Technologist-X" or the letters "CRT-X" after his or her name, where "X" represents a single- or multiple-letter designation signifying the advanced, postprimary, or specialty area of radiologic technology, such as "CT" for computed tomography or "PET" for positron emission tomography, in which the person is certified by a national organization. The department shall approve these letter designations by rule for each area, consistent with the designation used by a national organization.

No other person is entitled to so use a title or letters contained in this subsection or to hold himself or herself out in any way, whether orally or in writing, expressly or by implication, as being so certified.

(3)

(i) A person holding a certificate as a specialty technologist may perform the specific duties allowed for a specialty technologist as defined by rule of the department. These duties must fall within the scope of practice for that particular advanced, postprimary, or specialty area as set by a national organization.

Section 3. Subsection (3) of section 468.304, Florida Statutes, is amended to read:

468.304 Certification.—The department shall certify any applicant who meets the following criteria:

(3) Submits satisfactory evidence, verified by oath or

affirmation, that she or he:

(a) Is at least 18 years of age at the time of application;

(b) Is a high school, vocational school, technical school, or college graduate or has successfully completed the requirements for a graduate equivalency diploma (GED) or its equivalent;

(c) Is of good moral character;

(d) Has passed an examination as specified in s. 468.306 or meets the requirements specified in s. 468.3065; and

(e)1. Has successfully completed an educational program, which program may be established in a hospital licensed pursuant to chapter 395 or in an accredited postsecondary academic institution which is subject to approval by the department as maintaining a satisfactory standard; or

2.a. With respect to an applicant for a basic X-ray machine operator's certificate, has completed a course of study approved by the department with appropriate study material provided the applicant by the department;

b. With respect to an applicant for a basic X-ray machine operator-podiatric medicine certificate, has completed a course of study approved by the department, if ~~provided that~~ such course of study is ~~shall be~~ limited to the ~~that~~ information necessary to perform radiographic procedures within the scope of practice of a podiatric physician licensed pursuant to chapter 461;

c. With respect only to an applicant for a general radiographer's certificate who is a basic X-ray machine operator certificateholder, has completed an educational program or a 2-year training program that takes into account the types of

procedures and level of supervision usually and customarily practiced in a hospital, which educational or training program complies with the rules of the department;

d. With respect only to an applicant for a nuclear medicine technologist's certificate who is a general radiographer certificateholder, has completed an educational program or a 2-year training program that takes into account the types of procedures and level of supervision usually and customarily practiced in a hospital, which educational or training program complies with the rules of the department; ~~or~~

e. With respect to an applicant for a radiologist assistant's certificate, ~~who~~ demonstrates to the department that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists; or~~.~~

f. With respect to an applicant for a specialty technologist's certificate, demonstrates to the department that he or she holds a current certificate or registration granted by a national organization in a particular advanced, postprimary, or specialty area of radiologic technology, such as computed tomography or positron emission tomography.

(4) Submits complete documentation of any criminal offense in any jurisdiction of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere.

(5) Submits complete documentation of any final disciplinary action taken against the applicant by a licensing or regulatory body in any jurisdiction, by a national

organization, or by a specialty board that is recognized by the department. Disciplinary action includes revocation, suspension, probation, reprimand, or being otherwise acted against, including being denied certification or resigning from or nonrenewal of membership taken in lieu of or in settlement of a pending disciplinary case.

The department may not certify any applicant who has committed an offense that would constitute a violation of any of the provisions of s. 468.3101 or applicable ~~the~~ rules ~~adopted thereunder~~ if the applicant had been certified by the department at the time of the offense. An ~~No~~ application for a limited computed tomography certificate may not ~~shall~~ be accepted. A person ~~All persons~~ holding a valid computed tomography certificate ~~certificates~~ as of October 1, 1984, is ~~are~~ subject to ~~the provisions of~~ s. 468.309.

Section 4. Section 468.306, Florida Statutes, is amended to read:

468.306 Examinations.—An applicant ~~All applicants~~ for certification as a radiologic technologist, basic X-ray machine operator, or basic X-ray machine operator-podiatric medicine, except an applicant ~~those~~ certified pursuant to s. 468.3065, shall be required to pass an examination. An applicant for certification as a specialty technologist shall be certified only in accordance with s. 468.3065. An application for certification as a specialty technologist by examination may not be accepted. In lieu of an examination for a radiologist assistant certificate, the department shall accept a demonstration by the applicant for such a certificate that he or

she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists. The department may develop or use examinations for each type of certificate. The department may require an applicant who does not pass an examination after five attempts to complete additional remedial education, as specified by rule of the department, before admitting the applicant to subsequent examinations.

(1) The department may contract with organizations that develop such test examinations. Examinations may be administered by the department or the contracting organization.

(2) Examinations shall be given for each type of certificate at least twice a year at such times and places as the department may determine to be advantageous for applicants.

(3) All examinations must ~~shall~~ be written and must include positioning, technique, and radiation protection. The department shall ~~either~~ pass or fail each applicant on the basis of his or her final grade. The examination for a basic X-ray machine operator must ~~shall~~ include basic positioning and basic techniques directly related to the skills necessary to safely operate radiographic equipment.

(4) A nonrefundable fee not to exceed $75 plus the actual per-applicant cost for purchasing the examination from a national organization shall be charged for any subsequent examination.

Section 5. Subsection (3) is added to section 468.3065, Florida Statutes, to read:

468.3065 Certification by endorsement.—

(3) The department may issue a certificate by endorsement

to practice as a specialty technologist to an applicant who, upon applying to the department and remitting a nonrefundable fee not to exceed $100, demonstrates to the department that he or she holds a current certificate, or registration from a national organization in a particular advanced, postprimary, or specialty area of radiologic technology, such as computed tomography or positron emission tomography.

Section 6. 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

An act relating to radiological personnel; amending s. 468.301, F.S.; defining the term "specialty technologist" as it relates to the certification of radiological personnel; amending s. 468.302, F.S.; providing titles for persons who hold a certificate as a specialty technologist; authorizing a person holding a certificate as a specialty technologist to perform the specific duties allowed for a specialty technologist as defined by the Department of Health; requiring that the duties fall within the scope of practice of the specialty as set by the national organization for the particular advanced, postprimary, or specialty area; amending s. 468.304, F.S.; providing criteria for certification as a specialty technologist; amending s. 468.306, F.S.; providing for an applicant for certification as a specialty

technologist to be certified only by endorsement rather than by examination; amending s. 468.3065, F.S.; authorizing the department to issue a certificate by endorsement to practice as a specialty technologist to an applicant who meets certain criteria; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 381 Electrolysis
SPONSOR(S): Logan
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Currently, a licensed electrologist who performs laser or light-based hair removal or reduction may only practice under a formal written protocol with a supervising physician who is either a Florida licensed medical doctor or a doctor of osteopathic medicine. The provisions stating the formal supervisory relationship are located in the Medical Practice Act and the Osteopathic Medicine Practice Act, but are not in the Electrolysis Practice Act. The bill duplicates this language and places it in the Electrolysis Practice Act.

The bill decreases the level of supervision of the formal relationship from direct to indirect supervision. The bill provides a definition for "indirect supervision," such that a supervising physician must be readily available for consultation but not on the premises and practices at a location within 20 miles or 30 minutes of where the practicing licensed electrologist is located.

The bill makes conforming changes to the Medical Practice Act and the Osteopathic Medicine Practice Act by deleting references to direct supervision and the requirement that the supervising physician must be onsite when electrology services are performed.

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

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Medical Quality Assurance

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA supports licensure and disciplinary activities for 43 professions and 37 types of facilities/establishments, and works with 22 boards and 6 councils.

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[1] Boards are responsible for approving or denying applications for licensure and making disciplinary decisions on whether a practitioner practices within the authority of their practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

Electrology

Electrology is the science of permanent hair removal by inserting a very fine needle into the natural opening of the hair follicle alongside the hair shaft. A minute amount of electricity is gently applied to the base of the hair follicle destroying hair growth cells and the regenerative ability of the hair follicle.[2] The electrolysis modality was the first method used to permanently remove hair, back in 1875.[3] The term electrolysis is used to describe all methods of permanent hair removal.

According to the American Electrology Association, there are three modalities used today that fall under the heading of electrolysis: galvanic or electrolysis; thermolysis or short-wave; and the blended method.[4] The modality used is at the discretion of the professional electrologist.[5]

The galvanic or electrolysis modality is a chemical process. The current produces a chemical reaction in the hair follicle eliminating the hair growth cells. This method is widely used in the multiple needle galvanic electrolysis, utilizing up to 16 needles simultaneously.

The thermolysis or short-wave modality produces heat. When this modality is used it heats and destroys the hair growth cells in the follicle. This modality can be utilized in two ways: (1) flash method of thermolysis uses high intensity current for less time in the follicle (2) the current is used at lower intensity and longer timing.

The blend method combines galvanic current with the thermolysis current modality. Thermolysis heats up the chemical reaction in the follicle destroying hair growth cells.

Florida law provides that electrology is the permanent removal of hair by destroying the hair-producing cells of the skin and vascular system, using equipment and devices approved by the Board of Medicine which have been cleared by and registered with the United States Food and Drug Administration (FDA)

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[1] S. 456.001, F.S.
[2] American Electrology Association, Inc., Frequently Asked Questions About Permanent Hair Removal, *available at*: http://www.electrology.com/consumer/faq.html (last viewed December 14, 2011)
[3] *Ibid.*
[4] *Ibid.*
[5] *Ibid.*

and that are used pursuant to approved protocols.[6] The Board of Medicine has approved the following equipment and devices to be used by licensed electrologist for the permanent removal of hair:[7]

- Needle type epilators.[8]
- Laser and light-based hair removal or reduction devices cleared by the FDA for hair removal or reduction.

Licensure

Chapter 478, F.S., governs the practice of electrology in Florida, and is referred to as the "Electrolysis Practice Act". Section 478.44, F.S., creates the Electrolysis Council (council), which is under the supervision of the Board of Medicine (board). The practice act sets forth definitions, requirements for licensure in Florida, requirements for renewal of license, requirements for electrolysis facilities, requirements for training programs, grounds for discipline, penalties for violating the practice act, and the powers and duties of the board, with assistance from the council. Currently ss. 459.025(2) and 458.348(3), F.S., require that an electrologist, when performing laser hair removal, perform such procedure under the direct supervision and responsibility of a medical doctor or doctor of osteopathic medicine licensed under chapter 458 or 459, F.S.

The supervising physician, initially upon assuming duties as the supervisor and semiannually thereafter, is required to review and inspect the techniques, procedures, and equipment utilized by the electrologist in the performance of laser and light-based hair removal or reduction.[9] Additionally, the supervising physician is required to ensure that the electrologist has received semi-annual training in the areas of infection control, sterilization, and emergency procedures.

The supervising physician and the electrologist are required to jointly develop a written protocol regarding:[10]

- Medical condition for individuals to receive laser and light-based hair removal or reduction treatment;
- The condition and the procedure for identifying conditions that require direct evaluation or specific consultation by the physician;
- The treatment of routine minor problems resulting during or from laser and light-based hair removal or reduction;
- The procedures to be followed in the event of an emergency developing during the performance of or as a result of laser and light-based hair removal or reduction;
- The initial consultation with each patient must include an examination and assessment by a licensed physician; and
- A statement that the electrologist does and will maintain professional liability coverage that includes coverage for incidents arising from laser usage in an amount not less than $100,000.

The written protocols are to be signed, dated, and maintained in a readily available location on the premises where the electrologist practices. The supervising physician is required to maintain one copy on the premises and another copy must be submitted to the DOH. Additionally, a supervising physician must keep the Board of Medicine informed of the number of licensed electrologists under their supervision since they may not supervise more than four electrologists at any one time.[11]

To qualify for licensure, applicants must:[12]

- Be at least 18 years old;.

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[6] S. 478.42(5), F.S.
[7] 64B8-56.002, F.A.C.
[8] An epilator is an electrical device used to remove hair by mechanically grasping multiple hairs simultaneously and pulling them out at the root.
[9] 64B8-56.002, F.A.C.
[10] *Ibid.*
[11] *Ibid.*
[12] S. 478.45, F.S. and 64B8-51.002, F.A.C.

- Possess good moral character;
- Possess a high school diploma, a graduate equivalency diploma, college diploma, university diploma, or technical school diploma if such college, university, or technical school required high school or graduate equivalency diploma for admission;
- Not have committed an act in any jurisdiction which would constitute grounds for disciplining an electrologist in this state;
- Complete the requirements of an electrolysis training program consisting of 120 hours academic training and a minimum of 200 hours of practical application; and
- Pass the the International Board of Electrologist Certification national examination.

To become licensed as an electrologist, individuals must submit an application,; remit a $100 application fee, $135 examination fee, $100 initial licensure fee and a $5 fee to fund efforts to combat unlicensed practice.[13] As of June 30, 2011, there were 1,081 individuals who possessed active in-state licenses as electrologists.[14]

Effects of Proposed Changes

Currently, a licensed electrologist who performs laser or light-based hair removal or reduction may only practice under a formal written protocol with a supervising physician who is either a Florida licensed medical doctor or a doctor of osteopathic medicine. The provisions stating the formal supervisory relationship are located in the Medical Practice Act and the Osteopathic Medicine Practice Act, but are not in the Electrolysis Practice Act. The bill duplicates this language and places it in the Electrolysis Practice Act.

The bill decreases the level of supervision of the formal relationship from direct to indirect supervision. The bill provides a definition for "indirect supervision," such that a supervising physician is readily available for consultation but not on the premises and practices at a location within 20 miles or 30 minutes of where the practicing licensed electrologist is located.

The bill makes conforming changes to the Medical Practice Act and the Osteopathic Medicine Practice Act by deleting references to direct supervision and the requirement that the supervising physician must be onsite when electrology services are performed.

B. SECTION DIRECTORY:

Section 1. Amends s. 487.42, F.S., relating to definitions.
Section 2. Amends s. 487.451, F.S., relating to formal supervisory relationships.
Section 3. Amends s. 458.348, F.S., relating to formal supervisory relationships, standing orders, and established protocols.
Section 4. Amends s. 459.025, F.S., relating to formal supervisory relationships, standing orders, and established protocols.
Section 5. Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None identified.

2. Expenditures:

   None identified.

[13] 64B8-51.007, F.A.C.
[14] The Florida Department of Health, Division of Medical Quality Assurance, 2010-2011 Annual Report, *available at*: http://www.doh.state.fl.us/mqa/reports.htm (last viewed December 28, 2011).

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:

None.

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:

   None.

B. RULE-MAKING AUTHORITY:

The DOH has sufficient authority to promulgate rules 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 electrolysis; amending s. 478.42, F.S.; defining the term "indirect supervision"; creating s. 478.451, F.S.; requiring a licensed electrologist who performs hair removal or reduction using laser or light-based technology to practice under a protocol with a licensed physician or osteopathic physician, subject to specified training and supervision; amending ss. 458.348 and 459.025, F.S.; revising supervision requirements for persons performing electrolysis using laser or light-based hair removal or reduction under practice protocols who are not licensed physicians or osteopathic physicians; providing an effective date.

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

Section 1. Subsection (6) is added to section 478.42, Florida Statutes, to read:

478.42 Definitions.—As used in this chapter, the term:

(6) "Indirect supervision" means supervision of an electrologist by a physician who is not on the premises but practices at a location within 20 miles or 30 minutes of the practice location of the supervised electrologist and is readily available for consultation as needed.

Section 2. Section 478.451, Florida Statutes, is created to read:

478.451 Formal supervisory relationships.—

(1) A person licensed as an electrologist under this chapter who performs hair removal or reduction using laser or light-based technology must practice under a protocol with a physician licensed under chapter 458 or chapter 459.

(2) All protocols relating to electrolysis or electrology using laser or light-based hair removal or reduction must require the licensed electrologist to be appropriately trained and work under the indirect supervision of a physician licensed under chapter 458 or chapter 459.

Section 3. Subsection (3) of section 458.348, Florida Statutes, is amended to read:

458.348 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(3) PROTOCOLS RELATING TO LASER OR LIGHT-BASED HAIR REMOVAL OR REDUCTION ~~REQUIRING DIRECT SUPERVISION~~.—All protocols relating to electrolysis or electrology using laser or light-based hair removal or reduction by persons other than physicians licensed under this chapter or chapter 459 shall require the person performing such service to be appropriately trained and work ~~only~~ under the ~~direct~~ supervision ~~and responsibility~~ of a physician licensed under this chapter or chapter 459. The supervisory physician under the protocol is not required to be onsite when the service is performed.

Section 4. Subsection (2) of section 459.025, Florida Statutes, is amended to read:

459.025 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(2) PROTOCOLS RELATING TO LASER OR LIGHT-BASED HAIR

REMOVAL OR REDUCTION ~~REQUIRING DIRECT SUPERVISION~~.—All protocols relating to electrolysis or electrology using laser or light-based hair removal or reduction by persons other than ~~osteopathic~~ physicians licensed under this chapter or chapter 458 shall require the person performing such service to be appropriately trained and to work ~~only~~ under the ~~direct~~ supervision ~~and responsibility~~ of a ~~an osteopathic~~ physician licensed under this chapter or chapter 458. The supervisory physician under the protocol is not required to be onsite when the service is performed.

Section 5. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 475 Blood Establishments
SPONSOR(S): Eisnaugle
TIED BILLS: **IDEN./SIM. BILLS:** SB 364

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

SUMMARY ANALYSIS

Blood establishments, commonly referred to as blood banks, are regulated by ch. 381 and ch. 499, F.S., implemented by Department of Health (DOH) and the Department of Business and Professional Regulation (DBPR), respectively. The bill amends blood establishment laws to change current permitting requirements, require information disclosure, and change the use of not-for-profit blood establishments.

The bill creates a Restricted Prescription Drug Distributor Permit for blood establishments, which allows blood establishments to distribute certain prescription drugs essential to their operation. The bill authorizes blood establishments to engage in the wholesale distribution of certain drugs which are otherwise restricted from wholesale distribution. The bill eliminates the requirement of certain blood establishments to maintain a Prescription Drug Manufacturer Permit. In addition, the bill requires blood establishments to disclose certain financial and operational information, and authorizes the Department of Legal Affairs (DLA) to assess penalties for failure to do so.

The bill prohibits the for-profit or not-for-profit status from being the sole determinant of the service fee charged for the provision of blood. Similarly, the bill prohibits local governments from considering for-profit or not-for-profit status in determining use of public facilities by blood establishments.

The bill redefines the term "blood establishment" to include mobile units and defines the term "volunteer donor."

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

The bill has an indeterminate, but likely insignificant, fiscal impact to the Florida Drug, Device, and Cosmetic Trust Fund within DBPR. (See Fiscal Analysis).

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Florida law defines a "blood establishment" as "any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product."[1]

There are many types of blood establishments under federal law, including community blood banks, hospital blood banks, and hospital transfusion centers.[2] The majority of blood establishments involved in the collection of blood from volunteer donors are community blood banks.[3] Many community blood banks in Florida collect blood from volunteers, but also perform a variety of health care services, such as performing blood transfusions and apheresis procedures,[4] processing blood and blood components, product and compatibility testing, and storing and distributing blood and blood products.[5] These activities require the purchase and distribution of prescription drugs to operate.[6] For example, Albumin is used to replace fluid, Rh Immune Globulin is used to prevent incompatible maternal-fetal blood admixture, and Erthropietin is used to stimulate the production of red blood cells.[7]

Blood transfusions often occur as whole blood, but sometimes a primary component of blood may be transferred to a patient.[8] These components are red blood cells, plasma, platelets, and cryoprecipitated antihemophilic factor.[9] Since these components are transferred separate from one another, blood must be processed to separate one blood component from another and occasionally agents must be added to blood for increased safety.[10]

Regulation of Blood Establishments

In order to operate in Florida, a blood establishment must comply with state requirements and with federal regulations.[11] This requires a variety of regulations and permits regarding the prescription drugs necessary for operation.

Due to the nature of blood and the processes performed by blood establishments, federal regulation of drugs and biologics applies to blood establishments. Blood and blood components are considered "biologics" under the federal Public Health Service Act. Biologics "means a virus therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative... applicable to the prevention treatment, or cure of a disease or condition of human beings."[12]

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[1] S. 381.06014, F.S.

[2] A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on January 10, 2011).

[3] *Id.*

[4] DBPR e-mail correspondence, January 1, 2012; on file with Subcommittee Staff.

[5] The Florida Senate Committee on Health Regulation Interim Report 2010-119, Review of the Regulation of Blood Banks, *available at*: http://www.flsenate.gov/publications/2010/senate/reports/interim_reports/pdf/2010-119hr.pdf.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] S. 381.06014, F.S., requires Blood Establishments to comply with Title 21 C.F.R. § 607.7

[12] Blood component definitions from: AABB "Whole Blood and Blood Components" available at: <http://www.aabb.org/Content/About_Blood/Facts_About_Blood_and_Blood_Banking/fabloodwhole.htm> (Last visited on January 10, 2011).

Similarly, blood and blood components are also considered drugs, which applies the regulations of the Federal Food, Drug, and Cosmetic Act to blood and blood components.[13] The Food and Drug Administration (FDA) in combination with the Center for Biologics Evaluation and Research (CBER) regulate the collection of blood and blood components.[14] Blood establishments are required to register with the CBER and report every blood product manufactured, prepared, or processed for commercial distribution.[15] All registered blood establishments must also obtain a biologics license in order to distribute in interstate commerce.[16] The CBER inspects, monitors, and enforces these requirements for blood quality and safety purposes.[17] In addition, community blood centers must obtain a Clinical Laboratory Improvement Act (CLIA) License and testing laboratories must register with the FDA and obtain certification by the Centers for Medicare and Medicaid Services for infectious disease testing.[18]

In Florida, blood establishments where blood or blood products are collected are required to be licensed as clinical laboratories.[19] Blood establishments which only offer transfusions are not required to obtain this license.[20] As previously mentioned, some blood establishments perform duties in addition to transfusions, such as apheresis procedures.

In addition, to operate in Florida, a blood establishment must comply with the requirements of ch. 381, F.S., regarding public health and safety.[21] The Department of Health (DOH) may make rules regarding the general public safety and the Agency for Health Care Administration (ACHA) may bring an injunction to cease operation if a threat to public safety is found.[22] Ch. 381, F.S., also requires Florida to comply with federal law regarding blood establishments.[23]

Additional regulation, specific to blood establishments, is located in ch. 499, F.S., which regulates the purchase and distribution of prescription drugs by blood establishments. A Prescription Drug Wholesale Distributor Permit is necessary to engage in the wholesale distribution of prescription drugs,[24] which is distribution of prescription drugs to persons other than a consumer or patient, but does not include "the sale, purchase, or trade of blood and blood components intended for transfusion."[25] Many establishments need to obtain and distribute prescription drugs not covered under the exemption for blood and blood components, such as Albumin.[26] As of 2009, many community blood centers were permitted as Prescription Drug Wholesalers under ch. 499, F.S.[27] However, blood establishments are currently considered by DBPR to be "health care entities," which are ineligible for a Prescription Drug Wholesale Distributor Permit under state law.[28] Federal law allows blood establishments to engage in the wholesale distribution of drugs necessary for their operation, even when categorized as health care entities.[29]

A Restricted Prescription Drug Distributor Permit is required to engage in the distribution of prescription drugs which is not considered "wholesale distribution."[30] This permit is available to health care entities, charitable organizations, reverse distributors, government programs, and institutional researchers,

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[13] *Supra* at note 5.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] Rule 59A-7.019, F.A.C.
[20] *Id.*
[21] S. 381.06014, F.S.
[22] *Id.*
[23] *Id.*
[24] S. 499.01(2)(d), F.S.
[25] S. 499.003(54), F.S.
[26] *Supra* at note 5.
[27] *Supra* at note 4.
[28] S. 499.012 (1)(d), F.S.
[29] The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published October 9, 2008.
[30] S. 499.01 (1)(g), F.S.

which may not qualify for a Prescription Drug Wholesale Distributor Permit.[31] Currently, DBPR does not allow blood establishments to obtain a Restricted Prescription Drug Distributor Permit.[32]

Under federal law, blood establishments are considered prescription drug manufacturers.[33] Under Florida law, a Prescription Drug Manufacturer Permit "is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs."[34] The fee associated with this permit is determined by DBPR and must be between $500 and $750 annually.[35] The current fee is $1500 every two years.[36] However, blood establishments have not been permitted as Prescription Drug Manufacturers.[37]

Florida law prohibits the wholesale distribution of any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization.[38]

Certain tax-exempt organizations are required to submit to the Internal Revenue Service a form 990.[39] This form includes financial information about an organization, such as the total revenue of the organization and salaries and employee benefits.[40] These forms are submitted to the IRS and are usually available to the public.[41] Some blood establishments, such as Florida's Blood Centers currently offer governance documents on their websites.[42] While not directly financial information, these documents include policies related to conflict of interest, executive compensation and whistleblowers.[43]

Industry Issues

In 2009, a series of newspaper articles regarding Florida's Blood Centers was published. The articles addressed questionable financial management of Florida's Blood Centers, a not-for-profit blood establishment.[44] Florida Blood Centers made management changes in March 2010, including replacing the CEO.[45]

The Florida Senate conducted an interim report in 2009 to study the regulation of blood banks.[46] The report studied the service fee charged to hospitals by blood banks for blood.[47] The Senate surveyed a number of hospitals to determine the average service fee of blood.[48] According to the survey, the service fee of blood paid by for-profit and not-for-profit hospitals per unit was not identical, but similar in range.[49] The median blood fee in Florida in 2008 and 2009 was consistent with or lower than the

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[31] Rule 64F-12.018, F.A.C.
[32] Department of Business and Professional Regulation, 2012 Bill Analysis, House Bill 475 (December 22, 2011).
[33] 21 C.F.R. § 607.7 (2011)..
[34] S. 499.01(2)(a), F.S.
[35] S. 499.041(1)(a), F.S.
[36] *Supra* at note 31.
[37] *Supra* at note 32.
[38] S. 499.005(21), F.S.
[39] The Internal Revenue Service-Charitable Organizations, *available at*: http://www.irs.gov/charities/article/0,,id=152728,00.html (Last visited December 20, 2011).
[40] *Id.*
[41] *Id.*
[42] Florida's Blood Centers-Board of Directors, *available at*: http://floridasbloodcenters.org/about/board-of-directors.stml (Last visited December 20, 2011).
[43] *Id.*
[44] Dan Tracy, *Orlando blood-bank chief's pay raised to $605,000 -- then 42 jobs cut*, The Palm Beach Post, Feb. 19, 2010, *available at*: http://www.palmbeachpost.com/news/state/orlando-blood-bank-chiefs-pay-raised-to-605orlando-blood-bank-chiefs-pay-raised-to-605-253423.html.
[45] Dan Tracy, *Blood-bank chief Anne Chinoda resigns*, The Orlando Sentinel, March 10, 2010, *available at*: http://articles.orlandosentinel.com/2010-03-10/news/os-anne-chinoda-resigns-20100310_1_president-at-universal-orlando-fbc-anne-chinoda.
[46] *Supra* at note 5.
[47] *Id.*
[48] *Id.*
[49] *Id.*

national median fees.[50] The fees associated with blood vary according to geographic region and depend on the following factors:

- Cost of collecting, testing, preparing components, labeling, storing and shipping blood;
- Recruiting and educating donors; and
- Quality assurance.[51]

The Senate Interim Report cited an incident in which a for-profit blood establishment was denied access to meter rentals due to its for-profit status.[52] This lack of access was cited as a reason for the blood bank's inability to compete with not-for-profit community blood centers.[53]

The interim report recommended several changes to the regulation of blood establishments, including:

- Require disclosure information on the internet, including financial information, the process of collecting blood, and members and compensation for the board of directors;
- Prohibit the restriction of using public facilities based on the tax status of the blood establishment;
- Prohibit community blood centers from using the tax status of a hospital as the sole factor when determining the price of blood for sale; and
- Provide a method for blood establishments to engage in the distribution of prescription drugs and also act as a healthcare entity.[54]

Effect of Proposed Changes

The bill makes various regulatory changes related to financial transparency and permitting of blood establishments.

Financial Disclosure

The bill amends s. 381.06014, F.S., to require establishments that collect blood or components of blood from volunteer donors to disclose the following information on the internet:

- A description of the steps involved in collecting, processing, and distributing volunteer donations;
- The number of units of blood produced by the establishment, obtained from other sources, distributed to health care providers outside of the state, and distributed to entities which are not health care providers in the previous year; and
- Administrative policies addressing conflict-of-interest, related-party transactions, whistleblowers, and executive compensation.

The website must be updated regarding any changes to these policies by March 1 of the following year. The reports of the units of blood distributed to health care providers outside of the state and distributed to entities which are not health care providers must include the aggregate for providers within the United States and its territories and outside of the United States and its territories. An establishment does not need to report for the units of blood distributed outside of the state if the blood donations are redistributed to health care entities in the same county in which they were collected. This must be reported by March 1 of each year. These disclosure requirements do not apply to hospitals which collect blood used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity. All blood establishments within a business entity can submit this information in a single submission.

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[50] *Id.*
[51] AABB, *Blood FAQ: What fees are associated with blood, available at*: http://www.aabb.org/resources/bct/Pages/bloodfaq.aspx#a11 (Last visited December 20, 2011).
[52] *Supra* at note 5.
[53] *Id.*
[54] *Id.*

All establishments, with the exception of hospitals that collect blood from volunteers, must also disclose on the Internet the Return of Organization Exempt from Income Tax and Internal Revenue Service Form 990 (if eligible for such return) for the previous 3 years. The Income Tax and Internal Revenue Service Form 990 must be made available 60 days after it was filed. If an establishment is ineligible for the Internal Revenue Service Form 990, the establishment must disclose a balance sheet, income statement, statement of changes in cash flow, and the expression of an option by an independent public account who audited for reviewed these documents. This information must be available on the establishment's website 120 days after the end of the establishment's fiscal year, and must remain on the website for 36 months.

Establishments which fail to disclose this information are liable for a civil penalty, to be assessed by the Department of Legal Affairs (DLA), within the Office of the Attorney General. DLA may assess this penalty each day that the disclosures are not met for a maximum fine of $10,000 per year. DLA may only assess this penalty once for business entities which have multiple establishments. DLA may terminate a civil action if the establishment agrees to pay a stipulated penalty, or may waive the civil penalty if the establishment shows good cause for why the disclosures were not made. Collected civil penalties accrue to the state and are deposited into to the General Revenue Fund unallocated.

Permitting

The bill amends s. 499.01, F.S., to exclude blood establishments which manufacture only those drugs described in s. 499.003(54)(d), F.S., (blood and blood components intended for transfusion) from the requirements to obtain a Prescription Drug Manufacturer Permit and register products under s. 499.015, F.S.

The bill amends s. 499.003, F.S., to include blood establishments as health care entities which may engage in the wholesale distribution of certain prescription drugs if they obtain a Restricted Prescription Drug Distributor Permit. Establishments which collect blood only from volunteer donors (as defined in s. 381.06014, F.S.), or pursuant to an authorized practitioner's order for medical treatment or therapy, and engage in wholesale distribution of prescription drugs, other than those defined in s. 499.003(54)(d), F.S., (blood and blood components intended for transfusion), must obtain a Restricted Prescription Drug Distributor Permit.

The bill allows the following drugs to be distributed under this permit:

- Prescription drugs for a bleeding or clotting disorder or anemia;
- Blood-collection containers;
- Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;
- Prescription drugs adopted in rule by DBPR[55] which are essential to services performed by blood establishments and authorized by distribution under federal law;
- Drugs necessary to collect blood from volunteers, or for blood establishment personnel to perform therapeutic procedures; and
- Drugs necessary to diagnose, treat, manage, and prevent any reaction of a volunteer or patient undergoing a therapeutic procedure, to the extent authorized by federal law.

The therapeutic procedures requiring the prescription drugs must be related to the activities of a registered establishment or consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimen if they are tested with specimens undergoing routine donor testing.

The bill requires that the storage, handling, and recordkeeping of the drugs distributed under a Restricted Prescription Drug Distributor Permit comply with current standards for these activities in s. 499.0121, F.S. While some Restricted Prescription Drug Distributor Permits are exempt from the pedigree paper requirements of s. 499.01212, F.S., the bill excludes blood establishments from this exemption and thus blood establishments must comply with s. 499.01212, F.S. The health care entity

[55] In 2010, the legislature transferred the functions and duties of Ch. 499 from DOH to DBPR. Ch. 2010-161, L.O.F. References to "department" within 499 refer to DOH, pursuant to s. 499.003 (15), which has not yet been revised to reflect the transfer.

receiving these drugs must either be licensed as a closed pharmacy or provide health care services at the blood establishment. The bill allows DBPR to make rules regarding the distribution of prescription drugs by blood establishments as necessary.

The bill does not specify the permit fee for blood establishments to obtain a Restricted Prescription Drug Distributor Permit. Under current law, Restricted Prescription Drug Distributor Permit annual fees may range between $200 and $300, as determined by DBPR.[56] Similar permits include the Restricted Prescription Drug Distributor Permit for health care entities and for charitable organizations, both of which charge a fee of $600 every two years.[57]

Current law prohibits wholesale distribution of drugs donated or supplied at a reduced price to a charitable organization and drugs purchased by public or private hospitals.[58] The bill amends s. 499.005, F.S., to allow the wholesale distribution of the prescription drugs listed above, even when those drugs were purchased by a public or private hospital or healthcare entity or were donated or supplied at reduced price to a charitable organization.

The bill amends s. 381.06014, F.S., to redefine the term "blood establishments." The term "blood establishments" was altered to include mobile units which conduct activities of blood establishments. The term "volunteer donor" is created in the bill and defined as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion. The container of the donation must qualify for labeling with the statement "volunteer donor" under federal law.

The bill amends s. 381.06014, F.S., to prevent local governments from restricting the use of public facilities based on for-profit or not-for-profit status. The bill also prohibits establishing the service fee of blood received from volunteer donors and sold to hospitals or healthcare providers solely on for-profit or not-for-profit status.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.06014 F.S., relating to blood establishments.
Section 2: Amends s. 499.003 F.S., relating to definitions of terms used in this part.
Section 3: Amends 499.005 F.S., relating to prohibited acts.
Section 4: Amends s. 499.01 F.S., relating to permits.
Section 5: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Blood establishments required to obtain a Restricted Prescription Drug Distributor Permit would pay an annual fee between $300 and $600, to be determined by DBPR. If blood establishments do not comply with the disclosure requirements DLA could impose fines, up to $10,000 per establishment, which would be deposited into the General Revenue Fund.[59]

2. Expenditures:

   DBPR will have to create another type of Restricted Drug Distributor Permit, which may require expenditures for department processes, training for employees, and updates to the computer

[56] S. 499.041(4), F.S.
[57] *Supra* at note 31.
[58] *Supra* at note 38.
[59] Department of Legal Affairs, 2012 Bill Analysis, House Bill 475 (November 9, 2011).

systems and webpages.[60] Both DLA[61] and DBPR will have increased expenses if the bill's regulatory penalties result in increased administrative appeals.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill increases the commercial freedom of blood establishments, since blood establishments would be allowed to wholesale distribute certain prescription drugs.[62]

D. FISCAL COMMENTS:

The bill does not provide a licensure fee for blood establishments to obtain a Restricted Prescription Drug Distributor Permit. State law requires Restricted Prescription Drug Distributor permits to be between $200 and $300 annually. The Prescription Drug Wholesale Distributor Permit, which was previously used by blood establishments, but is now prohibited, cost $800 annually. Although the previous cost of a permit was more expensive, the bill will likely cause a positive fiscal impact since there are currently no permits distributed.

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:

The bill provides DLA and DBPR sufficient rulemaking authority to implement the regulations of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[60] *Id.*
[61] *Id.*
[62] *Id.*

A bill to be entitled

An act relating to blood establishments; amending s. 381.06014, F.S.; redefining the term "blood establishment" and defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund; amending s. 499.003, F.S.; redefining the term "health care entity" to clarify that a blood establishment is a health care entity that may engage in certain activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated

or supplied at a reduced price to a charitable organization, to conform to changes made by the act; amending s. 499.01, F.S.; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; requiring that certain blood establishments obtain a restricted prescription drug distributor permit under specified conditions; limiting the prescription drugs that a blood establishment may distribute under a restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments; providing an effective date.

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

Section 1. Section 381.06014, Florida Statutes, is amended to read:

381.06014 Blood establishments.—

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

(a) "Blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product. A person, entity, or

organization that uses a mobile unit to conduct such activities within the state is also a blood establishment.

(b) "Volunteer donor" means a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. s. 606.121.

(2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~ unless that blood establishment is operated in a manner consistent with the provisions of ~~Title~~ 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations~~.

(3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of ~~Title~~ 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration is ~~shall be~~ in violation of this chapter and must ~~shall~~ immediately cease all operations in the state.

(4) The operation of a blood establishment in a manner not consistent with the provisions of ~~Title~~ 21 C.F.R. parts 211 and 600-640~~, Code of Federal Regulations,~~ and in a manner that constitutes a danger to the health or well-being of blood donors or recipients as evidenced by the federal Food and Drug Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency

for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.

(5) A local government may not restrict the access to or use of any public facility or infrastructure for the collection of blood or blood components from volunteer donors based on whether the blood establishment is operating as a for-profit organization or not-for-profit organization.

(6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.

(7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. A blood establishment must disclose on its website all of the following information:

(a) A description of the steps involved in collecting, processing, and distributing volunteer donations.

(b) By March 1 of each year, the number of units of blood components which were:

1. Produced by the blood establishment during the preceding calendar year;

2. Obtained from other sources during the preceding calendar year;

3. Distributed during the preceding calendar year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and

4. Distributed during the preceding calendar year to entities that are not health care providers. Such information shall be reported in the aggregate for purchasers located within the United States and its territories or outside the United States and its territories.

(c) The blood establishment's conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change occurs to any of these documents, the revised document must be available on the blood establishment's website by the following March 1.

(d) Except for a hospital that collects blood or blood components from volunteer donors:

1. The most recent 3 years of the Return of Organization

Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 60 calendar days after it is filed with the Internal Revenue Service; or

2. If the business entity for the blood establishment is not eligible to file the Form 990 return, a balance sheet, income statement, and statement of changes in cash flow, along with the expression of an opinion thereon by an independent certified public accountant who audited or reviewed such financial statements. Such documents must be available on the blood establishment's website within 120 days after the end of the blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

(8) A blood establishment is liable for a civil penalty for failing to make the disclosures required under subsection (7). The Department of Legal Affairs may assess the civil penalty against the blood establishment for each day that it fails to make such required disclosures, but the penalty may not exceed $10,000 per year. If multiple blood establishments operated by a single business entity fail to meet such disclosure requirements, the civil penalty may be assessed against only one of the business entity's blood establishments. The Department of Legal Affairs may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. A civil penalty so collected accrues to the state and shall be deposited as received into the General Revenue Fund unallocated. The Department of Legal Affairs may terminate the action and

waive the civil penalty upon a showing of good cause by the blood establishment as to why the required disclosures were not made.

Section 2. Subsection (23) of section 499.003, Florida Statutes, is amended to read:

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

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 3. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(21) The wholesale distribution of any prescription drug that was:

(a) Purchased by a public or private hospital or other health care entity; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 4. Paragraphs (a) and (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(a) *Prescription drug manufacturer permit.*—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which ~~that~~ apply to a wholesale distributor.

2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(g) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who ~~that~~ engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.~~1.~~ Any ~~A~~ person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction ~~must obtain a permit as a restricted prescription drug distributor~~ if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(54)(d) to a health care entity. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules

adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance ~~comply~~ with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a

permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, ~~or~~ other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 621 Nursing Homes and Related Health Care Facilities
SPONSOR(S): Frishe
TIED BILLS: **IDEN./SIM. BILLS:** SB 482

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

Nursing homes and related health care facilities are regulated by the Agency for Health Care Administration (AHCA) under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S., and chapter 400, F.S. The bill streamlines regulations relating to nursing homes and related health care facilities through repeal of obsolete or duplicative provisions and reform of regulations. The bill makes the following changes to current law:

- Clarifies that nursing home residents are excluded from the landlord tenant laws of s.83.42, F.S.
- Removes language requiring the director of nursing to sign the resident care plan.
- Repeals s. 400.145, F.S., to remove the requirement for nursing home facilities to furnish copies of resident records to the spouse, guardian, surrogate, or attorney of a resident upon receipt of a written request and amends s. 400.191, F.S., to retain language from s. 400.145, F.S., defining the amount a facility may charge for copying resident's records.
- Requires the licensee to maintain clinical records on each resident in accordance with accepted professional standards.
- Repeals s. 400.148, F.S., which created the Medicaid "Up-or-Out" Pilot project to improve the quality of care for Medicaid recipients in nursing homes and assisted living facilities with poor performance records. The pilot project was subject to appropriation that was never allocated and the program was never implemented.
- Removes the requirement for nursing home licensure applicants to submit a signed affidavit disclosing financial interest of controlling interest and allows applicants to submit controlling interest information if requested by AHCA.
- Removes duplicative language requiring nursing home applicants to submit data relating to the total number of beds, copies of any civil verdict or judgment involving the applicant rendered within 10 years preceding the application, and a plan for quality assurance and risk management.
- Removes duplicative language that allows AHCA to issue an inactive license to a nursing home for all or a portion of its beds.
- Removes language requiring a facility to be awarded a Gold Seal and have no class I or class II deficiencies during the past two years in order to provide other needed services.
- Adds language that outlines detailed requirements for facilities offering respite care.
- Reduces the class II deficiency fine amount from $7,500 to $1,000 for facilities that fail to meet the minimum staffing requirements for two consecutive days.
- Adds language outlining minimum staffing requirements for facilities that provide care for persons under 21 years of age who are medically fragile or require skilled care.
- Removes the requirement for facilities to report grievance data to AHCA at the time of re-licensure and adds language allowing AHCA to review the grievance data during inspections.
- Removes the requirement for facilities to report adverse incidents to AHCA within one day of receiving an adverse incident report. The bill retains the requirement for facilities to submit a report to AHCA within 15 calendar days after an incident is determined to be an adverse incident.
- Removes the requirement for AHCA to adopt rules relating to the implementation of Do Not Resuscitate Orders for nursing home residents. These requirements are already contained in s. 401.45, F.S.
- Amends the definition of remuneration as it relates to home health agencies to allow providers to give away certain novelty items with an individual value of up to $15.

The bill does not appear to have a significant 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:

Nursing Homes

Licensure

Nursing homes are regulated by the Agency for Health Care Administration (AHCA) under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S. The Act contains uniform licensing standards for 29 provider types, including nursing homes, 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, nursing homes must comply with the requirements contained in the individual authorizing statutes of part II of chapter 400, F.S., 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. Chapter 2009-223, L.O.F., made changes to part II of chapter 408, F.S., which supersede components of the specific licensing statutes.

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.[1]
- A plan for quality assurance and risk management.[2]
- 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.[3]

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.

[1] SS. 400.071(1)(b), and 400.111, F.S.
[2] S. 400.071(5), F.S.
[3] S. 400.147(11), F.S.

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.

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.[4] 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.[5] 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.[6] Residents are entitled to a fair hearing to challenge a facility's proposed transfer or discharge.[7] 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.[8]

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.

Administration and Management

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.

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.[9] 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.[10]

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 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.

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[4] S. 83.41, F.S.
[5] S. 400.0255(7), F.S.
[6] S. 400.0255(8), F.S.
[7] S. 400.0255(10)(a), F.S.
[8] S. 400.0255(15), F.S.
[9] 42 C.F.R. 483.10(b)(2)
[10] *Id.*

Section 400.141(1)(v), F.S., requires facilities to 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. PPV is an infection that is caused by a bacterium and can result in infections of the middle ear, sinus infections, lung infections (pneumonia), blood stream infections, and meningitis.[11]

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

The bill repeals s. 400.145, F.S., relating to copies of medical records. The bill amends s. 400.191, 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.

The bill amends s. 400.141(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.[12] 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. Industry estimates indicate an annual savings of $335,000 to providers as a result of removing the requirement for facilities to secure the consultative services of Medical Records Practitioners.[13]

The bill removes obsolete language requiring facilities to vaccinate residents for PPV within 60 days after the effective date of the act which made this law. The bill retains language that requires new residents to be assessed for PPV within five working days after admission and if needed, vaccinated within 60 days.

Nursing homes are required to maintain records of all grievances, and to report to the agency, upon licensure renewal, various data regarding those grievances.[14] 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 maintain a report, subject to inspection by AHCA, of the total number of grievances handled.

Inspections and Deficiencies

Under s. 408.813, F.S., which provides the general licensure standards for all facilities regulated by AHCA, nursing homes may be subject to administrative fines imposed by the AHCA for certain types of violations. Each violation is classified according to the nature of the violation and the gravity of its probable effect on facility residents:

- Class "I" violations are those conditions or occurrences related to the operation and maintenance of a provider or to the care of clients, which AHCA determines present an imminent danger to the clients of the provider or a substantial probability that death or serious physical or emotional harm would occur. The condition or practice constituting a class I violation must be abated or eliminated within 24 hours, unless a fixed period, as determined by AHCA, is required for correction. AHCA must impose an administrative fine for a cited class I violation, notwithstanding the correction of the violation.
- Class "II" violations are those conditions or occurrences related to the operation and maintenance of a provider or to the care of clients which AHCA determines directly threaten the physical or emotional health, safety, or security of the clients, other than class I violations. AHCA must impose an administrative fine, notwithstanding the correction of the violation.

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[11] *See* Vaccines & Immunizations, Pneumococcal Disease Q&A, Department of Health and Human Services, Centers for Disease Control and Prevention, available at http://www.cdc.gov/vaccines/vpd-vac/pneumo/dis-faqs.htm (last viewed January 9, 2012).
[12] 42 C.F.R. 483.75
[13] AHCA, *Staff Analysis and Economic Impact, House Bill Number 621* (January 10, 2012).
[14] S. 400.1183(2), F.S.

- Class "III" violations are those conditions or occurrences related to the operation and maintenance of a provider or to the care of clients which AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients, other than class I or class II violations. AHCA must impose an administrative fine and a citation for a class III violation, which must specify the time within which the violation is required to be corrected. If a class III violation is corrected within the time specified, a fine may not be imposed.
- Class "IV" violations are those conditions or occurrences related to the operation and maintenance of a provider or to required reports, forms, or documents that do not have the potential of negatively affecting clients. These violations are of a type that the AHCA determines do not threaten the health, safety, or security of clients. AHCA must impose an administrative fine and a citation for a class IV violation, which must specify the time within which the violation is required to be corrected. If a class IV violation is corrected within the time specified, a fine may not be imposed.

Section 400.19(3), F.S., requires AHCA to conduct every 15 months at least one unannounced inspection of nursing home facilities to determine compliance relating to quality and adequacy of care. If a deficiency is cited, AHCA must conduct a subsequent inspection to determine if the deficiency identified during inspection has been corrected. If the cited deficiency is a class III or class IV deficiency, AHCA may verify the correction without re-inspecting the facility if adequate written documentation has been received from the facility ensuring that the deficiency has been corrected. However, the class III or class IV deficiency must be unrelated to resident rights or resident care.[15]

The bill amends s. 400.19, F.S., to remove the requirement that class III or class IV deficiencies must be unrelated to resident rights or resident care in order for AHCA to be able to verify that the deficiency has been corrected without re-inspecting the facility. As a result, this section of law will be more consistent with federal nursing home regulations, which allow facilities to submit documentation of corrected deficiencies if the existing deficiencies do not jeopardize the health and safety of patients nor limit the facility's capacity to render adequate care.[16]

Staffing Requirements

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 2011.[17]

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

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[15] S. 400.19(3), F.S.
[16] 42 C.F.R. 488.28.
[17] AHCA, *Staff Analysis and Economic Impact, House Bill Number 621* (December 20, 2011).

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.

Pediatric 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

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.[18] 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.[19]

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:[20]

- 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.
- 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.

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.

[18] S. 401.45, F.S.
[19] Id.
[20] Florida Department of Health Rule 64J-2.018, F.A.C.

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.

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.

"Up-or-Out" Program

The Medicaid "Up-or-Out" Quality of Care Contract Management Program authorized in s. 400.148, F.S., was created as a pilot program in 2001. The purpose of the program was to improve care in poor performing nursing homes and assisted living facilities by assigning trained medical personnel to facilities in select counties similar to Medicare models for managing the medical and supportive-care needs of long-term nursing home residents. The pilot was subject to appropriation; however, an appropriation was not allocated. Therefore, the program was never implemented.

Since the enactment of s. 400.148, F.S., new resources have become available to provide information relating to facility performance and to help consumers make informed choices for care. The nursing home guide is an available resource to assist consumers in finding quality care by allowing them to compare facilities' performance ratings.[21] Consumers can also view a facility's "statement of deficiencies" online, which displays violations of regulations found during an inspection or investigation.[22]

The bill repeals the Medicaid Up-or-Out Pilot Quality of Care Contract Management Program.

[21] Florida's *Nursing Home Guide* available at http://www.floridahealthfinder.gov/index.html (last viewed January 9, 2012).
[22] Agency for Health Care Administration, *Public Records Search, Statement of Deficiencies and Final Orders* available at http://apps.ahca.myflorida.com/dm_web/(S(m0lde3n51dftvokbz23ycn5p))/default.aspx (last viewed January 9, 2012).

Home Health Agencies

Section 400.174(6), F.S., requires AHCA 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 for staffing services;
- Gives remuneration to an individual who is involved in the facilities discharge planning process;
- Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary;
- Gives remuneration to a physician, member of the physician's staff, or an immediate family member of the physician without a medical director contract being in effect;

Section 400.462(27), F.S., defines "remuneration", as it relates to home health agencies, as any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. The bill amends the definition of remuneration to help clarify what is meant by remuneration as used in s. 400.474(6), F.S. The new language clarifies that the term remuneration does not apply to novelty items that have an individual value of up to $15, provided the item is intended solely for presentation or is customarily given away for promotional, recognition, or advertising purposes. According to AHCA, this language should result in fewer complaints from home health agencies relating to other home health agencies that give items of minimal cost to advertise or promote their business.[23]

B. SECTION DIRECTORY:

Section 1: Amends s. 83.42, F.S., relating to nursing home resident transfer.
Section 2: Amends s. 400.021, F.S., relating to nursing home resident care plans.
Section 3: Amends s. 400.0234, F.S. relating to availability of facility records for investigation of resident's rights violations and defenses.
Section 4: Amends s. 400.0239, F.S., relating to the quality of long-term care facility improvement trust fund.
Section 5: Amends s. 400.0255, F.S., relating to requirements for resident transfers and discharges.
Section 6: Amends s. 400.063, F.S., relating to resident protection.
Section 7: Amends s. 400.071, F.S., relating to application for licensure.
Section 8: Amends s. 400.0712, F.S., relating to inactive licensure.
Section 9: Amends s. 400.111, F.S., relating to disclosure of controlling interests.
Section 10: Amends s. 400.1183, F.S., relating to resident grievance procedures.
Section 11: Amends s. 400.141, F.S., relating to the administration and management of nursing home facilities.
Section 12: Amends s. 400.142, F.S., relating to emergency medication kits and orders not to resuscitate.
Section 13: Repeals s. 400.145, F.S., relating to records of care and treatment of residents; copies to be furnished.
Section 14: Amends s. 400.147, F.S., relating to the internal risk management and quality assurance program.
Section 15: Repeals s. 400.148, F.S., relating to Medicaid "Up-or-Out" quality of care contract management program.
Section 16: Amends s. 400.19, F.S., relating to the right of entry and inspection.
Section 17: Amends s. 400.191, F.S., relating to the availability, distribution, and posting of reports and records.
Section 18: Amends s. 400.23, F.S., relating to rules, evaluation and deficiencies and licensure status.
Section 19: Amends s. 400.462, F.S, relating to home health agency remuneration.
Section 20: Amends s. 429.294, F.S., relating to the availability of facility records for investigation of resident's rights, violations and penalties.
Section 21: Amends s. 430.80, F.S., relating to the implementation of a teaching nursing home pilot project.

[23] AHCA, *Staff Analysis and Economic Impact, House Bill Number 621* (December 20, 2011).

Section 22: Amends s. 430.81, F.S., relating to the implementation of a teaching agency for home and community based care.

Section 23: Amends s. 651.118, F.S., relating to the Agency for Health Care Administration; certificates of need; sheltered beds; and community beds.

Section 24: 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 estimated savings to providers of $335,000 annually. The savings are the result of the elimination of rules regarding securing the services of a qualified Medical Records Practitioner on a consultation basis who is eligible for certification as a Registered Record Administrator or Accredited Records Technician. This savings is based upon an estimate that approximately 335 nursing homes spend $1,000 annually to hire a consultant to meet this requirement.[24]

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 appropriate rulemaking authority to the Agency for Health Care Administration to implement the provisions of the proposed legislation.

[24] *AHCA, Staff Analysis and Economic Impact, House Bill Number 621 (January 10, 2012).*

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to nursing homes and related health care facilities; amending s. 83.42, F.S.; clarifying that the transfer and discharge of facility residents are governed by nursing home law; amending s. 400.021, F.S.; deleting a requirement that a resident care plan be signed by certain persons; amending ss. 400.0234 and 400.0239, F.S.; conforming provisions to changes made by the act; amending s. 400.0255, F.S.; revising provisions relating to hearings on resident transfer or discharge; amending s. 400.063, F.S.; deleting an obsolete cross-reference; amending s. 400.071, F.S.; deleting provisions requiring a license applicant to submit a signed affidavit relating to financial or ownership interests, the number of beds, copies of civil verdicts or judgments involving the applicant, and a plan for quality assurance and risk management; amending s. 400.0712, F.S.; revising provisions relating to the issuance of inactive licenses; amending s. 400.111, F.S.; providing that a licensee must provide certain information relating to financial or ownership interests if requested by the Agency for Health Care Administration; amending s. 400.1183, F.S.; revising requirements relating to facility grievance reports; amending s. 400.141, F.S.; revising provisions relating to the provision of respite care in a facility; deleting requirements for the submission of certain reports to the agency relating

to ownership interests, staffing ratios, and bankruptcy; deleting an obsolete provision; amending s. 400.142, F.S.; deleting the agency's authority to adopt rules relating to orders not to resuscitate; repealing s. 400.145, F.S., relating to resident records; amending s. 400.147, F.S.; revising provisions relating to incident reports; deleting certain reporting requirements; repealing s. 400.148, F.S., relating to the Medicaid "Up-or-Out" Quality of Care Contract Management Program; amending s. 400.19, F.S.; revising provisions relating to agency inspections; amending s. 400.191, F.S.; authorizing the facility to charge a fee for copies of resident records; amending s. 400.23, F.S.; specifying the content of rules relating to staffing requirements for residents under 21 years of age; amending s. 400.462, F.S.; revising the definition of "remuneration" to exclude items having a value of $10 or less; amending ss. 429.294, 430.80, 430.81, and 651.118, F.S.; conforming cross-references; providing an effective date.

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, where ~~when~~ residence or detention is incidental to the provision of medical, geriatric, educational, counseling, religious, or similar services. For residents of a facility licensed under part II of chapter 400, the procedures provided under s. 400.0255 govern all transfers or discharges from such facilities.

Section 2. Subsection (16) of section 400.021, Florida Statutes, is amended to read:

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

(16) "Resident care plan" means a written plan developed, maintained, and reviewed at least ~~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 3. 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 is ~~in accordance with s. 400.145 shall constitute~~ evidence of failure of that party to comply with good faith discovery requirements and waives ~~shall waive~~ the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 4. Paragraph (g) of subsection (2) of section 400.0239, Florida Statutes, is amended to read:

400.0239 Quality of Long-Term Care Facility Improvement Trust Fund.—

(2) Expenditures from the trust fund shall be allowable for direct support of the following:

(g) Other initiatives authorized by the Centers for Medicare and Medicaid Services for the use of federal civil monetary penalties~~, including projects recommended through the Medicaid "Up-or-Out" Quality of Care Contract Management Program pursuant to s. 400.148~~.

Section 5. 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 requested under this section.

(a) 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. The ~~These~~ procedures must ~~shall~~ be equivalent to the procedures used for ~~fair~~ hearings for other Medicaid cases brought pursuant to 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 6. 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, may establish 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 may ~~the agency is authorized to~~ disburse moneys from such account to pay obligations incurred for the purposes of this section. The agency may ~~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. A ~~Any~~ bank account established under this section need not be approved in advance of its creation as required by s. 17.58, but must ~~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 an ~~any such~~ account so established and ~~shall~~ make a quarterly accounting to the Chief Financial Officer for all moneys deposited in such account.

Section 7. 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 must ~~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.

~~(e) 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 8. 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 of ~~to~~ a nursing home facility 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) The ~~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) A facility ~~Nursing homes~~ that receives ~~receive~~ an inactive license to provide alternative services may ~~shall~~ not

be given ~~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 administer ~~implement~~ this section.

Section 9. 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, the nursing home facility, if requested by the agency, ~~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 10. Subsection (2) of section 400.1183, Florida Statutes, is amended to read:

400.1183 Resident grievance procedures.—

(2) Each nursing home facility shall maintain records of all grievances and a ~~shall~~ report, subject to agency inspection, of ~~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 11. Section 400.141, Florida Statutes, is amended to read:

400.141 Administration and management of nursing home facilities.—

(1) A nursing home facility must ~~Every licensed facility shall~~ comply with all applicable standards and rules of the agency and must ~~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 state licensed 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 any other law, a registered pharmacist licensed in this state who ~~in Florida, that~~ is under contract with a facility licensed under this chapter or chapter 429 must~~, shall~~ repackage a nursing facility resident's bulk prescription medication, which was ~~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 home facility~~.~~ if the pharmacist is requested to offer such service.

1. 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).

2. 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.

3. In order to be eligible for the repackaging, a ~~nursing facility~~ resident for whom the medication is to be repackaged must ~~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 under ~~in~~ this paragraph.

4. A pharmacist who repackages and relabels the 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 with access 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. If ~~When~~ a geriatric outpatient nurse clinic is conducted in accordance with rules adopted by the agency, outpatients attending such clinic may ~~shall~~ not be counted as part of the general resident population of the

~~nursing home~~ facility, nor may ~~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, if for each person admitted under the respite care program, the licensee:~~.~~

a. Has a contract that, at a minimum, specifies the services to be provided to the respite resident, and includes the charges for services, activities, equipment, emergency medical services, and the administration of medications. If multiple respite admissions for a single individual are anticipated, the original contract is valid for 1 year after the date of execution;

b. Has a written abbreviated plan of care that, at a minimum, includes nutritional requirements, medication orders, physician assessments and orders, nursing assessments, and dietary preferences. The physician or nursing assessments may

take the place of all other assessments required for full-time residents; and

c. Ensures that each respite resident is released to his or her caregiver or an individual designated in writing by the caregiver.

2. A person admitted under a respite care program is:

a. Covered by the residents' rights set forth in s. 400.022(1)(a)-(o) and (r)-(t). Funds or property of the respite resident are not considered trust funds subject to s. 400.022(1)(h) until the resident has been in the facility for more than 14 consecutive days;

b. 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 which must agree with the physician's order. Medications shall be released with the respite resident upon discharge in accordance with current physician's orders; and

c. Exempt from rule requirements related to discharge planning.

3. A person receiving respite care is entitled to reside in the facility for a total of 60 days within a contract year or 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.

4. The respite resident provided medical information from

a physician, physician assistant, or nurse practitioner and other information from the primary caregiver as may be required by the facility before or at the time of admission. 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.

5. A person receiving respite care resides in a licensed nursing home bed.

6. The facility assumes the duties of the primary caregiver. To ensure continuity of care and services, the respite 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 allows ~~shall allow~~ for shared programming and staff in a facility that ~~which~~ meets minimum standards and offers services pursuant to this paragraph, but, if the facility is cited for deficiencies in patient care, the agency 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 must ~~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 (c)~~, 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.

(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 adopting ~~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 resident ~~residents~~; and individual resident care plans, including, but not limited to, prescribed services,

service frequency and duration, and service goals. The records must ~~shall~~ be open to agency inspection ~~by the agency~~. The licensee shall maintain clinical records on each resident in accordance with accepted professional standards and practices, which must be 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 reasons ~~any reason~~ for termination. A ~~Any~~ facility releasing such records pursuant to this part is ~~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.~~

~~(c)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) Comply with state minimum-staffing requirements:

1.~~d.~~ A ~~nursing~~ facility that has failed to comply with state minimum-staffing requirements for 2 consecutive days is prohibited from accepting new admissions until the facility 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 by the facility 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 has failed to meet those standards on 2 consecutive days or if it 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, arrange for 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 such ~~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. The ~~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 may ~~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 administer ~~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, if ~~when~~ indicated, vaccinate such residents ~~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 may ~~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 administer ~~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 administer ~~comply with or implement~~ this paragraph.

This subsection 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 residents' needs.

(2) Facilities that have been awarded a Gold Seal under the program established in s. 400.235 may develop a plan to provide certified nursing assistant training as prescribed by federal regulations and state rules and may apply to the agency for approval of their program.

Section 12. 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, or ~~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 13. Section 400.145, Florida Statutes, is repealed.

Section 14. Subsections (7) through (10) of section 400.147, Florida Statutes, are amended, and present subsections (11) through (15) of that section are redesignated as

subsections (9) through (13), respectively, to read:

400.147 Internal risk management and quality assurance program.—

(7) The nursing home 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). The facility must complete the investigation and submit a report to the agency within 15 calendar days after an incident is determined to be an adverse incident. ~~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 the report which ~~notification~~ must include the name of the risk manager, 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 report ~~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 report ~~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.~~

(8) ~~(9)~~ Abuse, neglect, or exploitation must be reported to the agency as required by 42 C.F.R. s. 483.13(c) and to the department as required by chapters 39 and 415.

~~(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 15. Section 400.148, Florida Statutes, is repealed.

Section 16. 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 every 15 months to determine the licensee's compliance ~~by the licensee~~ with statutes~~,~~ and related ~~with~~ rules ~~promulgated under the provisions of those statutes,~~ governing minimum standards of construction, quality and adequacy of care, and rights of residents. The survey must ~~shall~~ be conducted every 6 months for the next 2-year period if the nursing home 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 under ~~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 is ~~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 at least ~~not fewer than~~ 5 working days according to the provisions of chapter 110.

Section 17. Present subsection (6) of section 400.191, Florida Statutes, is renumbered as subsection (7), and a new subsection (6) is added to that section, to read:

400.191 Availability, distribution, and posting of reports and records.—

(6) A nursing home 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 18. Subsection (5) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(5) The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, must~~,~~ ~~no later than December 31, 1993,~~ adopt rules for:

(a) 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 exempted ~~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) Minimum staffing requirements for each nursing home facility that serves persons under 21 years of age, which apply in lieu of the standards contained in subsection (3).

1. For persons under 21 years of age who require skilled care, the requirements must include a minimum combined average of 3.9 hours of direct care per resident per day provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

2. For persons under 21 years of age who are medically fragile, the requirements must include a minimum combined average of 5 hours of direct care per resident per day provided by licensed nurses, respiratory therapists, respiratory care

practitioners, and certified nursing assistants.

Section 19. 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, if the term is used in any provision of law relating to health care providers, the term does not apply to an item that has an individual value of up to $15, including, but not limited to, a plaque, a certificate, a trophy, or a novelty item that is intended solely for presentation or is customarily given away solely for promotional, recognition, or advertising purposes.

Section 20. 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, is ~~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 waives ~~shall waive~~ the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 21. Paragraph (g) of 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:

(g) Maintain insurance coverage pursuant to s. 400.141(1)(q) ~~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 which ~~that~~ has its principal place of business in this state or has a branch office that ~~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 if ~~when~~ such final judgment or settlement is a result of a liability claim against the facility.

Section 22. 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) ~~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 if ~~when~~ such final judgment or settlement is a result of a liability claim against the agency.

Section 23. 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) ~~400.141(1)(o)1.d~~.

Section 24. This act shall take effect July 1, 2012.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 711 Sale or Lease of a County, District, or Municipal Hospital
SPONSOR(S): Hooper
TIED BILLS: **IDEN./SIM. BILLS:** SB 464

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

SUMMARY ANALYSIS

County, district and municipal hospitals are created pursuant to a special enabling act, rather than a general act. The special act sets out the hospital authority's power to levy taxes to support the maintenance of the hospital, the framework for the governing board and defines the ability to issue bonds.

The process for the sale or lease of a county, district or municipal hospital is established in s. 155.40, F.S. Currently, the authority to make this decision and to negotiate such a transaction is given to the governing board that is selling the hospital. A hospital can be sold or leased to a for-profit or a not-for-profit Florida corporation, and the transaction must be in the best interest of the public.

This bill amends s. 155.40, F.S., to require that the governing board of a county, district or municipal hospital, prior to completing a proposed sale or lease of the hospital, receive approval from a majority of registered voters in the county, district or municipality, or in the alternative, from the circuit court.

The bill:

- Requires certain findings by the hospital governing board;
- Requires public notice by the hospital governing board;
- Provides for certain content for petitions to the court;
- Allows interested parties to participate in the court approval process;
- Requires certain findings by the court; and
- Allows for appeal.

The bill has an indeterminate fiscal impact on the courts. Costs associated with the petition are borne by the hospital board, unless a party contests.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

County, district[1] and municipal hospitals are created pursuant to a special enabling act, rather than a general act.[2] The special act sets out the hospital authority's power to levy taxes to support the maintenance of the hospital, the framework for the governing board and defines the ability to issue bonds.

The process for the sale or lease of a county, district or municipal hospital is established by s. 155.40, F.S. Currently, the authority to make this decision and to negotiate such a transaction is given to the governing board that is selling the hospital.[3] A hospital can be sold or leased to a for-profit or a not-for-profit Florida corporation, and must be in the best interest of the public.[4] The board must publically advertise both the meeting at which the proposed sale or lease will be discussed,[5] and the offer to accept proposals from all interested and qualified purchasers.[6] Any lease, contract or agreement must contain the following terms:

- Articles of incorporation of the corporation are subject to approval of the board.
- Qualification under s. 501(c)(3) of the U.S. Internal Revenue Code for a not-for-profit corporation.
- Orderly transition of the operation and management of the facilities must be provided for.
- On termination of the contract, lease or agreement, that the facility returns to the county, district or municipality.
- Continued treatment of indigent patients pursuant to law.[7]

For the sale or lease to be considered a complete sale of the public agency's interest in the hospital, the purchasing entity must:

- Acquire 100 per cent ownership of the hospital enterprise;
- Purchase the physical plant of the hospital facility and have complete responsibility for the operation and maintenance thereof, regardless of the underlying ownership of the real property;
- Not receive public funding, other than by contract for the payment of medical services provided to patients for which the public agency has responsibility to pay;
- Take control of decision-making or policy-making for the hospital from the public agency seller;
- Not receive substantial investment or loans from the seller;
- Not be created by the public agency seller; and
- Primarily operate for its interests and not those of the public agency seller.[8]

The State courts currently do not have a role in the sale or lease process of a county, district or municipal hospital, unless the transaction is challenged in litigation. The Office of the Attorney General (OAG) reviews the proposed transaction with regard to any anti-competitive issues.[9] The OAG has

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[1] Hospital districts are created under the statutory authority provided in s. 189.404, F.S., and a special act.
[2] S. 155.04, F.S., allows a county, upon receipt of a petition signed by at least 5 per cent of resident freeholders, to levy an ad valorem tax or issue bonds to pay for the establishment and maintenance of a hospital. Section 155.05, F.S., gives a county the ability to establish a hospital without raising bonds or an ad valorem tax, utilizing available discretionary funds. However, an ad valorem tax can be levied for the ongoing maintenance of the hospital.
[3] S. 155.40(1), F.S.
[4] *Id.*
[5] In accordance with s. 286.0105, F.S.
[6] In accordance with s. 255.0525, F.S.
[7] Specifically, the Florida Health Care Responsibility Act, ss. 154.301-154.316, F.S., and ch. 87-92, Laws of Florida. S. 155.40(2), F.S.
[8] S. 155.40(8)(a), F.S.
[9] The OAG is responsible for enforcing state and federal antitrust laws, and the anti-trust division works to stop violations that harm competition and adversely impact the citizens of Florida. Chapter 542, F.S., provides the OAG with the authority

charitable trust authority to review transactions that would implicate trusts where the public hospital entity was the beneficiary.[10]

In March 2011, the Governor issued Executive Order 11-63, creating the Commission on Review of Taxpayer Funded Hospital Districts (Commission).[11] This Commission was tasked with assessing and making recommendations as to the role of hospital districts, including what was in the public interest as to hospital operation and an effective access model for the economically disadvantaged.[12] Specifically, the Governor requested the following areas be examined:

- Quality of care;
- Cost of care;
- Access to care for the poor;
- Oversight and accountability;
- Physician employment; and
- Changes in ownership and governance.[13]

From May 23 through December 29 2011, the Commission met 14 times, and heard from 20 different individuals and organizations.[14] In a final report delivered on December 30, 2012, the Commission made the following general recommendations:

- Appointees to hospital boards should be qualified and not have conflicts of interest.
- Board members should include health care stakeholders and community members with financial expertise in running private enterprise.
- The boards of the district and the hospital should be separate, and both should be subject to appropriate oversight.
- Hospital board members should not be a part of the hospital administrative or management team.
- There should be a transition from hospital districts to indigent health care districts, which would include decoupling district owned hospitals from the district.
- Hospital boards should have flexibility with ad valorem millage rates, within their maximum allowable rate.[15]

Effect of the Proposed Changes

The bill requires the governing board of a county, district or municipal hospital to receive approval from a majority of the registered electors in the county, district or municipality, or alternatively submit a petition for approval of sale or lease to the circuit court, to be approved, prior to the completion of the proposed sale or lease of a hospital. The bill amends s. 155.40, F.S., detailing the process to determine the approval of a sale or lease.

The bill amends s. 155.40(4), F.S., requiring the hospital governing board to determine that operating the hospital is no longer in the public's interest and to ascertain whether there are any interested and qualified purchasers or lessees. The bill adds that the sale or lease must be for "fair market value."

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to bring actions against individuals or entities that commit state or federal antitrust violations, including bid-rigging, price-fixing, market or contract allocation, and monopoly-related actions. *See* ch. 542, F.S. However, s. 542.235, F.S., provides additional limitations to suit against local governments, including a limitation on criminal action, and civil and injunctive relief against both the governmental entity and agents when they are acting within the scope of their authority.

[10] The OAG may assert the rights of qualified beneficiaries with respect to charitable trusts pursuant to s. 736.0110(3), F.S., and with respect to the dissolution of not-for-profit corporations pursuant to ss. 617.1420, 617.1430, and 617.2003, F.S. The OAG notes that the review under this authority varies considerably from transaction to transaction and can be very labor intensive. This is especially the case in transactions that involve mergers of competitors within the same market. Email from the OAG on file with House Health & Human Services Quality Subcommittee staff. March 18, 2011.

[11] Fla. Exec. Order No. 11-63 (Mar. 23, 2011). The Executive Order is available at http://www.flgov.com/2011-executive-orders/ site accessed January 9, 2012.

[12] *Id.*

[13] The Commission's report is available at http://ahca.myflorida.com/mchq/FCTFH/fctfh.shtml site accessed January 5, 2012.

[14] *Id.*

[15] *Id.*

This is defined as the "price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's length transaction."[16]

The governing board is required to determine, in writing, the basis for choosing a particular proposal. This must include:

- A determination that the proposed transaction represents fair market value, or if not why the transaction is in the best interests of the public;
- A determination of whether there will be a reduction or elimination of ad valorem or other taxes used to support the hospital;
- A determination that the quality of care will not be affected, especially in relation to indigent, uninsured and underinsured;
- The details of the facilities and all parties to the transaction;
- A description of the terms of all proposed agreements;
- An estimate of the total value associated with the proposed agreement, including available valuations from the last three years of the hospital's assets;
- Any available financial or economic analysis prepared by experts that the board retained;
- An independent fairness evaluation; and
- Copies of all other proposals and bids received.

The bill requires the hospital board to publish this information not later than 120 days before the anticipated closing for the proposed transaction. Notice must be published in one or more newspapers of general circulation in the county where the majority of the hospital's assets are located. The notice must provide a mechanism for public comment about the proposed transaction to the board, for up to 20 days after the date of publication. If a statement of opposition is received, the governing board or proposed purchaser or lessee has 10 days to respond in writing.

The bill provides that the transaction is subject to the approval of a majority of the voters in the district but offers an alternative to this requirement: circuit court approval. It is unclear from the bill how a hospital board would decide between using a referendum or the circuit court as a part of the approval process. It would seem that the bill may authorize a hospital board to make such a determination, regardless of whether their charter may require a referendum.

If a hospital board elected to use the circuit court, the bill provides that no sooner than 30 days after the publication of notice, a petition for approval must be filed in the circuit court in which the majority of the hospital's assets are located. The bill directs the court to issue an order that would require all interested parties to appear at a specified date and time and show why the petition should not be granted. The order is to be published at least once a week for two consecutive weeks in one or more major newspapers, not less than 20 days prior to the hearing. Unless the petition is contested, the hospital board bears the expense.

The bill provides that any interested party may become a party to the action. The circuit court must hold a hearing to determine all questions of law and fact, rendering a final judgment that either approves or denies a proposed transaction.

The bill provides that the court shall determine that the transaction:

- Is permitted by law;
- Does not discriminate against a potential purchaser or lessee on the basis of being a for-profit or not-for-profit Florida corporation;
- Complied with the notice provisions;
- Was made with the exercise of due diligence by the board;
- Disclosed board conflicts of interest;

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[16] An arm's length transaction is negotiated by unrelated parties, each acting in his or her self interest; the basis for a fair market value determination. It is a transaction in good faith in the ordinary course of business by parties with independent interests. This is the standard under which unrelated parties, each acting in his or her own best interest, would carry out a particular transaction. Black's Law Dictionary (8th Ed. 2006).

- Reflects fair market value;
- Makes an enforceable commitment to the continuation of quality care for all residents, and especially, the indigent, uninsured and underinsured; and
- Will result in a reduction or elimination of ad valorem or other taxes used to support the hospital.

The bill provides that any party to the action has the right to seek judicial review in the appellate district where it was filed, and will be governed by the Florida Rules of Appellate Procedure. Any interested party seeking review must file an appeal within 30 days of the final judgment. The standard of review for the appellate court is that the decision is not arbitrary, capricious, or not in compliance with s. 155.40, F.S.

The bill provides that any sale or lease completed before March 9, 2011, is not subject to the requirements of these provisions. Additionally, any lease that contained, on March 9, 2011, an option to renew or extend that lease upon its expiration date is not subject to these provisions upon any renewal or extension on or after March 9, 2011.

The bill does not alter the OAG's duty in relation to charitable trusts, and the transaction must still be reviewed for anti-competitive issues pursuant to ch. 542, F.S., and s. 736.0110(3), F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 155.40, F.S., relating to sale or lease of county, district or municipal hospitals; effect of sale.
Section 2: Amends s. 395.3036, F.S., relating to confidentiality of records of meetings of corporations that lease public hospitals or other public health care facilities.
Section 3: Provides an effective date of January 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has an indeterminate fiscal impact on state courts to review proposed transactions for the sale or lease of a county, municipal or district hospital. However, the bill provides for the ability to assess costs to either the hospital board or a contesting party.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has an indeterminate fiscal impact on the private sector. Prospective purchasers or lessees may be required to pay costs if they oppose the proposed transaction. The sale or lease of a hospital could be delayed by this oversight process. However, more interested parties should be able to participate in the process of selling or leasing a public hospital creating more competition.

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:

Several terms and standards in the bill could subject the statute to judicial interpretation. These include: a "fairness evaluation," and non-discriminatory decision making.

Additionally, the bill is not clear as to the mechanism a hospital board would use to decide between a referendum or the circuit court approval process. It would seem that this may authorize a board to make such a determination, regardless of the charter.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the sale or lease of a county, district, or municipal hospital; amending s. 155.40, F.S.; providing that the sale or lease of a county, district, or municipal hospital is subject to approval by the registered voters or by the circuit court; requiring the hospital governing board to determine by certain public advertisements whether there are qualified purchasers or lessees before the sale or lease of such hospital; defining the term "fair market value"; requiring the board to state in writing specified criteria forming the basis of its acceptance of a proposal for sale or lease of the hospital; providing for publication of notice; authorizing submission of written statements of opposition to a proposed transaction, and written responses thereto, within a certain timeframe; requiring the board to file a petition for approval with the circuit court and receive approval before any transaction is finalized; specifying information to be included in such petition; providing for the circuit court to issue an order requiring all interested parties to appear before the court under certain circumstances; requiring the clerk of the court to publish the copy of the order in certain newspapers at specified times; providing that certain parties are made parties to the action by the publication of the order; granting the circuit court jurisdiction to approve the sale or

lease of a county, district, or municipal hospital based on specified criteria; providing for a party to seek judicial review; requiring that the reviewing court affirm the judgment of the circuit court unless the decision is arbitrary, capricious, or not in compliance with the act; requiring the board to pay costs associated with the petition for approval unless a party contests the action; providing an exemption for certain sale or lease transactions completed before a specified date; amending s. 395.3036, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Subsections (1) and (4) of section 155.40, Florida Statutes, are amended, present subsections (5) through (8) of that section are renumbered as subsections (14) through (17), respectively, and new subsections (5) through (13) are added to that section, to read:

155.40 Sale or lease of county, district, or municipal hospital; effect of sale.—

(1) In order for ~~that~~ citizens and residents of the state to ~~may~~ receive quality health care, any county, district, or municipal hospital organized and existing under the laws of this state, acting by and through its governing board, may ~~shall have the authority to~~ sell or lease such hospital to a for-profit or not-for-profit Florida corporation, and enter into leases or

other contracts with a for-profit or not-for-profit Florida corporation for the purpose of operating and managing such hospital and any or all of its facilities of whatsoever kind and nature. The term of any such lease, contract, or agreement and the conditions, covenants, and agreements to be contained therein shall be determined by the governing board of such ~~county, district, or municipal~~ hospital. The governing board of the hospital must find that the sale, lease, or contract is in the best interests of the public and must state the basis of such finding. The sale or lease of such hospital is subject to approval by a majority vote of the registered voters in the county, district, or municipality or, in the alternative, approval by a circuit court. ~~If the governing board of a county, district, or municipal hospital decides to lease the hospital, it must give notice in accordance with paragraph (4)(a) or paragraph (4)(b).~~

(4) If ~~In the event~~ the governing board of a county, district, or municipal hospital determines that it is no longer in the public interest to own or operate such hospital and elects to consider a sale or lease of the hospital to a third party, the governing board must first determine whether there are any qualified purchasers or lessees. In the process of evaluating any potential purchasers or lessees ~~elects to sell or lease the hospital~~, the board shall:

(a) ~~Negotiate the terms of the sale or lease with a for-profit or not-for-profit Florida corporation and~~ Publicly advertise the meeting at which the proposed sale or lease will be considered by the governing board of the hospital in

accordance with s. 286.0105; or

(b) Publicly advertise the offer to accept proposals in accordance with s. 255.0525 and receive proposals from all interested and qualified purchasers and lessees.

Any sale or lease must be for fair market value~~,~~ and ~~any sale or lease~~ must comply with all applicable state and federal antitrust laws. For the purposes of this section, the term "fair market value" means the price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arms-length transaction.

(5) A determination by a governing board to accept a proposal for sale or lease must state, in writing, the findings and basis for supporting the determination.

(a) The findings and basis for supporting the governing board's determination must include, but need not be limited to, a balanced consideration of the following factors:

1. The proposal represents fair market value, or if the proposal does not represent fair market value, a detailed explanation of why the public interest is served by the acceptance of less than fair market value.

2. Whether the proposal will result in a reduction or elimination of ad valorem or other tax revenues to support the hospital.

3. Whether the proposal includes an enforceable commitment that existing programs and services and quality health care will continue to be provided to all residents of the affected community, particularly to the indigent, the uninsured, and the

underinsured.

4. Whether the proposal is otherwise in compliance with subsections (6) and (7).

(b) The findings must be accompanied by all information and documents relevant to the governing board's determination, including, but not limited to:

1. The names and addresses of all parties to the transaction.

2. The location of the hospital and all related facilities.

3. A description of the terms of all proposed agreements.

4. A copy of the proposed sale or lease agreement and any related agreements, including, but not limited to, leases, management contracts, service contracts, and memoranda of understanding.

5. The estimated total value associated with the proposed agreement and the proposed acquisition price and other consideration.

6. Any valuations of the hospital's assets prepared during the 3 years immediately preceding the proposed transaction date.

7. Any financial or economic analysis and report from any expert or consultant retained by the governing board.

8. A fairness evaluation by an independent expert in such transactions.

9. Copies of all other proposals and bids the governing board may have received or considered in compliance with subsection (4).

(6) Within 120 days before the anticipated closing date of

the proposed transaction, the governing board shall make publicly available all findings and documents required under subsection (5) and publish a notice of the proposed transaction in one or more newspapers of general circulation in the county in which the majority of the physical assets of the hospital are located. The notice must include the names of the parties involved and the means by which a person may submit written comments about the proposed transaction to the governing board and obtain copies of the findings and documents required under subsection (5).

(7) Within 20 days after the date of publication of the public notice, any interested person may submit to the governing board a detailed written statement of opposition to the transaction. If a written statement of opposition has been submitted, the governing board or the proposed purchaser or lessee may submit a written response to the interested party within 10 days after the written statement of opposition due date.

(8) A governing board of a county, district, or municipal hospital may not enter into a sale or lease of a hospital facility without first receiving approval by a majority vote of the registered voters in the county, district, or municipality or, in the alternative, approval from a circuit court.

(a) The governing board shall file a petition in a circuit court seeking approval of the proposed transaction at least 30 days after publication of the notice of the proposed transaction. The petition must be filed in the circuit in which the majority of the physical assets of the hospital are located.

(b) The petition for approval filed by the governing board must include all findings and documents required under subsection (5) and certification by the governing board of compliance with all requirements of this section.

(c) A circuit court has jurisdiction to approve the sale or lease of a county, district, or municipal hospital.

(9) Upon the filing of a petition for approval, the court shall issue an order requiring all interested parties to appear at a designated time and place within the circuit where the petition is filed and show why the petition should not be granted. For purposes of this subsection, the term "interested parties" includes any party submitting a proposal for sale or lease of the county, district, or municipal hospital, as well as the governing board.

(a) Before the date set for the hearing, the clerk shall publish a copy of the order in one or more newspapers of general circulation in the county in which the majority of the physical assets of the hospital are located at least once each week for 2 consecutive weeks, commencing with the first publication, which must be at least 20 days before the date set for the hearing. By these publications, all interested parties are made parties defendant to the action and the court has jurisdiction of them to the same extent as if named as defendants in the petition and personally served with process.

(b) Any interested person may become a party to the action by moving against or pleading to the petition at or before the time set for the hearing. At the hearing, the court shall determine all questions of law and fact and make such orders as

will enable it to properly consider and determine the action and render a final judgment with the least possible delay.

(10) Upon conclusion of all hearings and proceedings, and upon consideration of all evidence presented, the court shall render a final judgment approving or denying the proposed transaction and shall order the governing board to accept or reject the proposal for the sale or lease of the county, district, or municipal hospital. In reaching its final judgment, the court shall determine whether:

(a) The proposed transaction is permitted by law.

(b) The proposed transaction unreasonably excludes a potential purchaser or lessee on the basis of being a for-profit or a not-for-profit Florida corporation.

(c) The governing board of the hospital publicly advertised the meeting at which the proposed transaction was considered by the board in compliance with s. 286.0105.

(d) The governing board of the hospital publicly advertised the offer to accept proposals in compliance with s. 255.0525.

(e) The governing board of the hospital exercised due diligence in deciding to dispose of hospital assets, selecting the proposed purchaser or lessee, and negotiating the terms and conditions of the disposition.

(f) Any conflict of interest was disclosed, including, but not limited to, conflicts of interest relating to members of the governing board and experts retained by the parties to the transaction.

(g) The seller or lessor will receive fair market value

for the assets, or if the sale or lease represents less than fair market value, why the public interest will be served by accepting less than fair market value.

(h) The acquiring entity has made an enforceable commitment that existing programs and services and quality health care will continue to be provided to all residents of the affected community, particularly to the indigent, the uninsured, and the underinsured.

(i) The proposed transaction will result in a reduction or elimination of ad valorem or other taxes used to support the hospital.

(11) Any party to the action has the right to seek judicial review in the appellate district where the petition for approval was filed.

(a) All proceedings shall be instituted by filing a notice of appeal or petition for review in accordance with the Florida Rules of Appellate Procedure within 30 days after the date of final judgment.

(b) In such judicial review, the reviewing court shall affirm the judgment of the circuit court, unless the decision is arbitrary, capricious, or not in compliance with this section.

(12) All costs shall be paid by the governing board, unless an interested party contests the action, in which case the court may assign costs to the parties.

(13) Any sale or lease completed before March 9, 2011, is not subject to this section. Any lease that contained, on March 9, 2011, an option to renew or extend that lease upon its expiration is not subject to this section upon renewal or

extension on or after March 9, 2011.

Section 2. 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 if ~~when~~ the public lessor complies with the public finance accountability provisions of s. 155.40(14) ~~155.40(5)~~ with respect to the transfer of any public funds to the private lessee and if ~~when~~ the private lessee meets at least three of the five following criteria:

(1) The public lessor that owns the public hospital or other public health care facility was not the incorporator of the private corporation that leases the public hospital or other health care facility.

(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 subsection (5) ~~(2)~~.

(3) Except as otherwise provided by law, the private lessee is not allowed to participate, except as a member of the public, in the decisionmaking process of the public lessor.

(4) The lease agreement does not expressly require the

lessee to comply with ~~the requirements of~~ ss. 119.07(1) and 286.011.

(5) The public lessor is not entitled to receive any revenues from the lessee, except for rental or administrative fees due under the lease, and the lessor is not responsible for the debts or other obligations of the lessee.

Section 3. 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 Hooper offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsections (1) and (4) of section 155.40, Florida Statutes, are amended, subsections (5) through (8) are renumbered as subsections (15) through (18), respectively, and new subsections (5) through (14) are added to that section, to read:

155.40 Sale or lease of county, district, or municipal hospital; effect of sale.—

(1) In order that citizens and residents of the state may receive quality health care, any county, district, or municipal hospital organized and existing under the laws of this state, acting by and through its governing board, shall have the authority to sell or lease such hospital to a for-profit or not-for-profit Florida corporation, and enter into leases or other

contracts with a for-profit or not-for-profit Florida corporation for the purpose of operating and managing such hospital and any or all of its facilities of whatsoever kind and nature. The term of any such lease, contract, or agreement and the conditions, covenants, and agreements to be contained therein shall be determined by the governing board of such county, district, or municipal hospital. The governing board of the hospital must find that the sale, lease, or contract is in the best interests of the public and must state the basis of such finding. The sale or lease of such hospital is subject to approval by a circuit court unless otherwise exempt under subsection (14) or, for those hospitals that are required by their statutory charter to seek approval by referendum for any action which would result in the termination of the direct control of such hospital by its governing board, approval by such referendum. ~~If the governing board of a county, district, or municipal hospital decides to lease the hospital, it must give notice in accordance with paragraph (4)(a) or paragraph (4)(b).~~

(4) In the event the governing board of a county, district, or municipal hospital determines that it is no longer in the public interest to own or operate such hospital and elects to consider a sale or lease to a third party, the governing board shall first determine whether there are any qualified purchasers or lessees. In the process of evaluating any potential purchasers or lessees ~~elects to sell or lease the hospital~~, the board shall:

~~(a) Negotiate the terms of the sale or lease with a for-profit or not-for-profit Florida corporation and~~ Publicly advertise the meeting at which the proposed sale or lease will be considered by the governing board of the hospital in accordance with s. 286.0105; or

(b) Publicly advertise the offer to accept proposals in accordance with s. 255.0525 and receive proposals from all interested and qualified purchasers and lessees.

Any sale or lease must be for fair market value, and any sale or lease must comply with all applicable state and federal antitrust laws. For the purposes of this section, the term "fair market value" means the price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction, which includes any benefit that the public would receive in connection with the sale or lease.

(5) A determination by a governing board to accept a proposal for sale or lease shall state, in writing, the findings and basis supporting the determination.

(a) The board shall develop findings and bases to support the determination of a balanced consideration of factors including, but not limited to, the following:

1. Whether the proposal represents fair market value, which includes an explanation of why the public interest is served by the proposed transaction.

2. Whether the proposal will result in a reduction or elimination of ad valorem or other tax revenues to support the hospital.

3. Whether the proposal includes an enforceable commitment that existing programs and services and quality health care will continue to be provided to all residents of the affected community, particularly to the indigent, the uninsured, and the underinsured.

4. Whether the proposal is otherwise in compliance with subsections (6) and (7).

(b) The findings shall be accompanied by all information and documents relevant to the governing board's determination, including, but not limited to:

1. The name and address of all parties to the transaction.

2. The location of the hospital and all related facilities.

3. A description of the terms of all proposed agreements.

4. A copy of the proposed sale or lease agreement and any related agreements, including, but not limited to, leases, management contracts, service contracts, and memoranda of understanding.

5. The estimated total value associated with the proposed agreement and the proposed acquisition price and other consideration.

6. Any valuations of the hospital's assets prepared in the 3 years immediately preceding the proposed transaction date.

7. Any financial or economic analysis and report from any expert or consultant retained by the governing board.

8. A fairness evaluation by an independent expert in such transactions.

9. Copies of all other proposals and bids the governing board may have received or considered in compliance with the procedures required under subsection (4).

(6) Not later than 120 days before the anticipated closing date of the proposed transaction, the governing board shall publish a notice of the proposed transaction in one or more newspapers of general circulation in the county in which the majority of the physical assets of the hospital are located. The notice shall include the names of the parties involved, the means by which persons may submit written comments about the proposed transaction to the governing board, and the means by which persons may obtain copies of the findings and documents required under subsection (5).

(7) Within 20 days after the date of publication of public notice, any interested person may submit to the governing board a detailed written statement of opposition to the transaction. When a written statement of opposition has been submitted, the governing board or the proposed purchaser or lessee may submit a written response to the interested party within 10 days after the written statement of opposition due date.

(8) A governing board of a county, district, or municipal hospital may not enter into a sale or lease of a hospital facility without first receiving approval from a circuit court or, for those hospitals which are required by their statutory charter to seek approval by referendum for any action which would result in the termination of the direct control of such hospital by its governing board, approval by such referendum.

(a) The governing board shall file a petition for approval in a circuit court seeking approval of the proposed transaction not sooner than 30 days after publication of notice of the proposed transaction.

(b) Any such petition for approval filed by the governing board shall include all findings and documents required under subsection (5) and certification by the governing board of compliance with all requirements of this section.

(c) Circuit courts shall have jurisdiction to approve the sale or lease of a county, district, or municipal hospital. A petition for approval shall be filed in the circuit in which the majority of the physical assets of the hospital are located.

(9) Upon the filing of a petition for approval, the court shall issue an order requiring all interested parties to appear at a designated time and place within the circuit where the petition is filed and show why the petition should or should not be granted. For purposes of this section, the term "interested party" means any party submitting a proposal for sale or lease of the county, district, or municipal hospital; any taxpayer from the county, district, or municipality in which the majority of the physical assets of the hospital are located; and the governing board.

(a) Before the date set for the hearing, the clerk shall publish a copy of the order in one or more newspapers of general circulation in the county in which the majority of the physical assets of the hospital are located at least once each week for 2 consecutive weeks, commencing with the first publication, which shall not be less than 20 days before the date set for the

hearing. By this publication, all interested parties are made parties defendant to the action and the court has jurisdiction of them to the same extent as if named as defendants in the petition and personally served with process.

(b) Any interested party may become a party to the action by moving against or pleading to the petition at or before the time set for the hearing. At the hearing, the court shall determine all questions of law and fact and make such orders as will enable it to properly consider and determine the action and render a final judgment with the least possible delay.

(10) Upon conclusion of all hearings and proceedings, and upon consideration of all evidence presented, the court shall render a final judgment as to whether the governing board complied with the process provided in this section. In reaching its final judgment, the court shall determine whether:

(a) The proposed transaction is permitted by law.

(b) The governing board reviewed all proposals.

(c) The governing board publicly advertised the meeting at which the proposed transaction was considered by the board in compliance with ss. 286.0105 and 286.011.

(d) The governing board publicly advertised the offer to accept proposals in compliance with s. 255.0525.

(e) The governing board did not act arbitrarily and capriciously in making the determination to sell or lease the hospital assets, selecting the proposed purchaser or lessee, and negotiating the terms of the sale of lease.

(f) Any conflict of interest was disclosed, including, but not limited to, conflicts of interest relating to members of the

governing board and experts retained by the parties to the transaction.

(g) The seller or lessor will receive fair market value for the assets, which includes an explanation of why the public interest is served by the proposed transaction.

(h) The governing board incorporated a provision in the sale or lease requiring the acquiring entity to continue to provide existing programs and services and quality health care to all residents of the affected community, particularly to the indigent, the uninsured, and the underinsured.

(i) The proposed transaction will result in a reduction or elimination of ad valorem or other taxes used to support the hospital.

(11) Any party to the action has the right to seek judicial review in the appellate district where the petition was filed.

(a) All proceedings shall be instituted by filing a notice of appeal or petition for review in accordance with the Florida Rules of Appellate Procedure within 30 days after the date of the final judgment.

(b) In such judicial review, the reviewing court shall affirm the judgment of the circuit court, unless the decision is arbitrary, capricious, or not in compliance with this section.

(12) All costs shall be paid by the governing board, except when an interested party contests the action, in which case the court may assign costs to the parties at its discretion.

(13) Any sale or lease completed before June 30, 2012, is not subject to the requirements of this section. Any lease that contained, on June 30, 2012, an option to renew or extend that lease upon its expiration shall not be subject to this section upon any renewal or extension on or after June 30, 2012.

(14) A county, district, or municipal hospital that has not received any tax support is exempt from the requirements of subsections (8)-(12). For the purposes of this section, the term "tax support" means ad valorem or other tax revenues paid directly from a county, district, or municipal taxing authority to a hospital without a corresponding exchange of goods or services within the 5 years before the effective date of a proposed lease or sale.

Section 2. 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(15)~~(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:

(1) The public lessor that owns the public hospital or other public health care facility was not the incorporator of the private corporation that leases the public hospital or other health care facility.

(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 subsection (5)~~(2)~~.

(3) Except as otherwise provided by law, the private lessee is not allowed to participate, except as a member of the public, in the decisionmaking process of the public lessor.

(4) The lease agreement does not expressly require the lessee to comply with the requirements of ss. 119.07(1) and 286.011.

(5) The public lessor is not entitled to receive any revenues from the lessee, except for rental or administrative fees due under the lease, and the lessor is not responsible for the debts or other obligations of the lessee.

Section 3. 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:

An act relating to

the sale or lease of a county, district, or municipal hospital; amending s. 155.40, F.S.; requiring approval from

a circuit court for the sale or lease of a county, district, or municipal hospital unless certain exemption or referendum approval applies; requiring the hospital governing board to determine by certain public advertisements whether there are qualified purchasers or lessees before the sale or lease of such hospital; defining the term "fair market value"; requiring the board to state in writing specified criteria forming the basis of its acceptance of a proposal for sale or lease of the hospital; providing for publication of notice; authorizing submission of written statements of opposition to a proposed transaction, and written responses thereto, to the hospital governing board within a certain timeframe; requiring the board to file a petition for approval with the circuit court and receive approval before any transaction is finalized; providing an exception; specifying information to be included in such petition; providing for the circuit court to issue an order requiring all interested parties to appear before the court under certain circumstances; defining the term "interested party"; granting the circuit court jurisdiction to approve sales or leases of county, district, or municipal hospitals based on specified criteria; providing for a party to seek judicial review; requiring the court to enter a final judgment; requiring the board to pay costs associated with the petition for approval unless a party contests the action; providing an exemption for certain sale or lease transactions completed before a specified date; providing an exemption for county,

district, or municipal hospitals that receive no tax support; defining the term "tax support"; amending s. 395.3036, F.S.; conforming cross-references; providing an effective date.