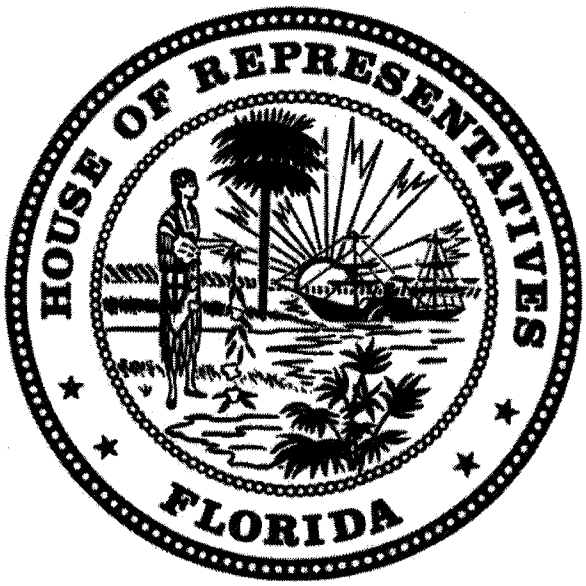

Health & Human Services Committee

Thursday, March 7, 2013
4:00 PM – 6:00 PM
Morris Hall

Will Weatherford
Speaker

Richard Corcoran
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time:	Thursday, March 07, 2013 04:00 pm
End Date and Time:	Thursday, March 07, 2013 06:00 pm
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 9 Involuntary Examinations under the Baker Act by Campbell, Rehwinkel Vasilinda
CS/HB 171 Disposition of Human Remains by Health Quality Subcommittee, Rooney
CS/HB 215 Dependent Children by Healthy Families Subcommittee, Albritton
CS/HB 239 Practice of Optometry by Health Quality Subcommittee, Caldwell
CS/HB 365 Pharmacy by Health Quality Subcommittee, Hudson
CS/HB 413 Physical Therapy by Health Quality Subcommittee, Hutson

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Wednesday, March 6, 2013.

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, March 6, 2013.

NOTICE FINALIZED on 03/05/2013 16:11 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 9 Involuntary Examinations under the Baker Act
SPONSOR(S): Campbell and others
TIED BILLS: None **IDEN./SIM. BILLS:** SB 110

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N	Guzzo	O'Callaghan
2) Civil Justice Subcommittee	12 Y, 0 N	Williams	Bond
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

In 1971, the legislature passed the Florida Mental Health Act (also known as "The Baker Act") to address mental health needs of individuals in the state. The Baker Act allows for voluntary and involuntary examination of an individual and establishes procedures for the court, law enforcement and the medical community that ensure the preservation of an individual's rights relating to medical services.

The Baker Act authorizes involuntary examination of an individual who appears to have a mental illness and who, because of mental illness, presents a substantial threat of harm to themself or others. Involuntary examination may be initiated by certain medical professionals, namely physicians, clinical psychologists, psychiatric nurses, mental health counselors, marriage and family therapists, and clinical social workers.

The bill adds Advanced Registered Nurse Practitioners and Physician Assistants to the list of medical professionals who may execute a certificate for involuntary examination of a person.

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

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Involuntary Examination (Baker Act)

In 1971, the legislature passed the Florida Mental Health Act (also known as "The Baker Act") to address mental health needs in the state.[1] Chapter 394, Part I, F.S., provides authority and process for the voluntary and involuntary examination of persons with evidence of a mental illness and the subsequent inpatient or outpatient placement of individuals for treatment. The Department of Children and Families (DCF) administers this law through receiving facilities which provide for the examination of persons with evidence of a mental illness. Receiving facilities are designated by DCF and may be public or private facilities which provide for the involuntary examination and short term treatment of persons who meet criteria under this act.[2] Subsequent to examination at a receiving facility, a person who requires further treatment may be transported to a treatment facility. Treatment facilities designated by DCF are state hospitals (e.g. Florida State Hospital) which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[3]

Current law provides that an involuntary examination may be initiated for a person if there is reason to believe the person has a mental illness and because of the illness:[4]

- The person has refused a voluntary examination after explanation of the purpose of the exam; or
- The person is unable to determine for themselves that an examination is needed and is likely to suffer from self-neglect, substantial harm to themselves, or be a danger to themselves or others.

An involuntary examination may be initiated by any of the following:[5]

- A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination.
- A law enforcement officer, as defined in s. 943.10, F.S., may take a person into custody who appears to meet the criteria for involuntary examination and transport them to a receiving facility for examination.

In addition, the following persons may issue a certificate stating that a person who has been examined within the preceding 48 hours meets the criteria for involuntary examination:[6]

- A physician licensed under ch. 458, F.S., or an osteopathic physician licensed under ch. 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders.
- A physician employed by a facility operated by the United States Department of Veterans Affairs which qualifies as a receiving or treatment facility.
- A clinical psychologist, as defined in s. 490.003(7), F.S., with 3 years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for

[1] Section 1, ch. 71-131, L.O.F.
[2] Section 394.455(26), F.S.
[3] Section 394.455(32), F.S.
[4] Section 394.463(1), F.S.
[5] Section 394.463(2)(a), F.S.
[6] *Id.*

licensure, or a psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility.
- A psychiatric nurse licensed under part I of ch. 464, F.S., who has a master's degree or a doctorate in psychiatric nursing and 2 years of post-master's clinical experience under the supervision of a physician.
- A mental health counselor licensed under ch. 491, F.S.
- A marriage and family therapist licensed under ch. 491, F.S.[7]
- A clinical social worker licensed under ch. 491, F.S.[8]

During 2011, there were 150,466 involuntary examinations initiated in the state. Law enforcement initiated almost half of the involuntary exams (49.21 percent) followed by mental health professionals (48.73 percent) and then *ex parte* orders by judges (2.06 percent).[9]

Physician Assistants (PA)

Sections 458.347(7) and 459.022(7), F.S., govern the licensure of physician assistants (PAs) in Florida. PAs are licensed by the Department of Health (DOH) and are regulated by the Florida Council on Physician Assistants (Council) and either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. Currently, there are 5,348 active licensed PAs in Florida.[10]

PAs may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship. A supervising physician may only delegate tasks and procedures to the physician assistant that are within the supervising physician's scope of practice.[11] The supervising physician is responsible and liable for any and all acts of the PA and may not supervise more than four PAs at any time.[12]

PAs are regulated through the respective physician practice acts.[13] Each of the medical practice acts has a corresponding board (i.e., the Board of Medicine and Osteopathic Board). The duty of a Board and its members is to make disciplinary decisions concerning whether a doctor or PA was practicing medicine within the confines of their practice act.[14]

To become licensed as a PA in Florida, an applicant must demonstrate to the Council:[15] passage of the National Commission on Certification of Physician Assistant exam; completion of the application; completion of a PA training program; a sworn, notarized statement of felony convictions; a sworn statement of denial or revocation of licensure in any state; letters of recommendation from physicians;[16] payment of a licensure fee; and completion of a two hour course on the prevention of

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[7] Marriage and Family Therapists use practice methods of a psychological nature to evaluate, assess, diagnose, treat and prevent emotional and mental disorders or dysfunctions. Section 491.003(8), F.S.
[8] Clinical Social Workers are required by law to have experience in providing psychotherapy and counseling. Section 491.003(3), F.S.
[9] Christy, A. (2013). *Report of Baker Act Data*. Tampa, FL; University of South Florida, Louis de la Parte Florida Mental Health Institute. Available at: http://bakeract.fmhi.usf.edu/ (last visited February 15, 2013).
[10] Florida Department of Health, Medical Quality Assurance Annual Report 2011-2012.
[11] Rule 64B8-30.012(1), F.A.C., and Rule 64B15-6.010(1), F.A.C.
[12] Section 458.347(3), F.S., and s. 459.022(3), F.S.
[13] Chapters 458 and 459, F.S.
[14] Section 458.347(12), F.S., and s. 459.022(12), F.S.
[15] Section 458.347(7), F.S., and s. 459.022(7), F.S.
[16] Rule 64B8-30.003(1), F.A.C., and Rule 64B15-6.003(1), F.A.C.

medical errors, error reduction and prevention, and patient safety.[17] Licensure renewal occurs biennially.[18]

PAs are not required by law to have experience in the diagnosis and treatment of mental and nervous disorders. However, in 2008 Attorney General Bill McCollum issued an opinion stating that:

> *A physician assistant licensed pursuant to Chapter 458 or 459, F.S., may refer a patient for involuntary evaluation pursuant to section 394.463, F.S., provided that the physician assistant has experience regarding the diagnosis and treatment of mental and nervous disorders and such tasks as are within the supervising physician's scope of practice.*[19]

Advanced Registered Nurse Practitioner (ARNP)

Part I of ch. 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by DOH and are regulated by the Board of Nursing. Licensure requirements to practice professional nursing include completion of education requirements,[20] demonstration of passage of a department-approved examination, a clean criminal background screening, and payment of applicable fees.[21] Renewal is biennial and contingent upon completion of certain continuing medical education requirements.

A nurse who holds a license to practice professional nursing may be certified as an ARNP under s. 464.012, F.S., if the nurse meets one or more of the following requirements:

- Completion of a post basic education program of at least one academic year that prepares nurses for advanced or specialized practice;
- Certification by a specialty board, such as a registered nurse anesthetist or nurse midwife; or
- Possession of a master's degree in a nursing clinical specialty area.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[22] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or a dentist.[23] ARNPs may carry out treatments as specified in statute, including:[24]

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Performing additional functions as may be determined by rule in accordance with s. 464.003(2), F.S.;[25] and
- Ordering diagnostic tests and physical and occupational therapy.

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[17] Rule 64B8-30.003(3), F.A.C., and Rule 64B-15-6.003(4), F.A.C.
[18] Section 458.347(7)(c), F.S. Rule 64B8-30.019, F.A.C., establishes the initial licensure and renewal fee schedule. Section 459.022(7)(b), F.S. Rule 64B15-6.013, F.A.C., establishes the initial licensure and renewal fee schedule.
[19] *See*, 08-31 Fla. Op. Att'y Gen. (2008).
Available at: www.dcf.state.fl.us/programs/samh/MentalHealth/laws/agopinion.pdf (last visited February 15, 2013).
[20] Rule 64B9-4.003, F.A.C., provides that an Advanced Nursing Program shall be at least one year long and shall include theory in the biological, behavioral, nursing and medical sciences relevant to the area of advanced practice in addition to clinical expertise with a qualified preceptor.
[21] Section 464.009, F.S., provides an alternative to licensure by examination for nurses through licensure by endorsement.
[22] Section 464.012(2), F.S.
[23] Section 464.012(3), F.S.
[24] *Id.*
[25] Section 464.003(2), F.S., defines "Advanced or Specialized Nursing Practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.

In addition to the above allowed acts, ARNPs may also perform other acts as authorized by statute and within his or her specialty.[26] Further, if it is within the ARNPs established protocol, the ARNP may establish behavioral problems and diagnosis and make treatment recommendations.[27]

There are 14,440 active, licensed ARNPs in Florida.[28]

Effect of Proposed Changes:

The bill amends s. 394.463, F.S., to add that a PA or an ARNP may execute a certificate stating that a person who the ARNP or PA has examined within the preceding 48 hours appears to meet the criteria for involuntary examination for mental illness.

B. SECTION DIRECTORY:

Section 1: Amends s. 394.463, F.S., relating to involuntary examination.

Section 2: Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

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

2. Expenditures:

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

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

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

2. Expenditures:

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

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

[26] Section 464.012(4), F.S.
[27] Section 464.012(4)(c)5, F.S.
[28] Florida Department of Health, Medical Quality Assurance Annual Report 2011-2012.

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

Current law provides that a physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist and clinical social worker may execute certificates for involuntary examination. These professions have been defined under The Baker Act. The bill amends current law to allow an advanced registered nurse practitioner or physician assistant to execute a certificate for involuntary examination, but does not create a definition for these professions. This would allow any advanced registered nurse practitioner or physician assistant, regardless of their specialization, to initiate an involuntary examination under the Baker Act.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

A bill to be entitled

An act relating to involuntary examinations under the Baker Act; amending s. 394.463, F.S.; authorizing physician assistants and advanced registered nurse practitioners to initiate involuntary examinations under the Baker Act of persons believed to have mental illness; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination, giving the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on sworn testimony, written or oral. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to the nearest receiving facility for involuntary examination. The order of the court shall be made a part of the patient's clinical record. No fee shall be charged for the filing of an order under this subsection. Any receiving facility

accepting the patient based on this order must send a copy of the order to the Agency for Health Care Administration on the next working day. The order shall be valid only until executed or, if not executed, for the period specified in the order itself. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to the nearest receiving facility for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, and the report shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this report must send a copy of the report to the Agency for Health Care Administration on the next working day.

3. A physician, physician assistant, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, ~~or~~ clinical social worker, or advanced registered nurse practitioner may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer shall take the person named in the certificate into custody and

deliver him or her to the nearest receiving facility for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this certificate must send a copy of the certificate to the Agency for Health Care Administration on the next working day.

Section 2. This act shall take effect July 1, 2013.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 171 Disposition of Human Remains
SPONSOR(S): Health Quality Subcommittee; Rooney, Jr. and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 370

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Holt	O'Callaghan
2) Health & Human Services Committee		Holt	Calamas

SUMMARY ANALYSIS

The disposition of human remains in Florida is regulated pursuant to part II, of ch. 406, F.S. This part of law provides authority to the Anatomical Board of the State of Florida (Board), to collect and distribute human remains for medical education and research. The bill provides:

- Revised procedures for registration of certificates of death and medical certification of causes of death;
- Modified procedures for reporting and disposition of unclaimed human remains;
- For a funeral director licensed under ch. 497, F.S., to become a legally authorized person to authorize arterial embalming and transfer unclaimed remains to the Board, without liability;
- Clarification regarding the transfer of eligible veterans, or spouses or dependents of veterans of the U.S. Armed Forces, U.S. Reserve Forces or National Guard, to national cemeteries;
- Authority for boards of county commissioners to develop policies for the final disposition of unclaimed and indigent remains;
- An exemption from approval from the Board to transmit human remains, for a non-transplant anatomical donation organization that has been accredited by the American Association of Tissue Banks (AATB);
- That non-transplant anatomical donation organizations be AATB accredited by October 1, 2014;
- For the University of Florida to audit the Board once every three years, or sooner as required, and to report the audit to the Department of Financial Services;
- For the removal of the sunset provision related to submission of affidavits to the Board by entities accredited by the American Association of Museums;
- For a written consent from an authorized person representing the decedent before the remains may be dissected, disarticulated, or segmented;
- That the Board and a non-transplant anatomical donation organization can be a donee of anatomical gifts under ch. 765, F.S.;
- Modified procedures for handling of cremated remains of a veteran;
- Repeal of s. 406.54, F.S., related to bodies claimed after delivery to the Board; and
- Numerous new definitions and conforming changes to chapters 406 and 497, F.S.

The bill has an insignificant, negative fiscal impact to the state and no fiscal impact to local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

PRESENT SITUATION

Office of Vital Statistics

The Florida Vital Statistics Act authorizes the Department of Health (DOH) to establish an Office of Vital Statistics (Office), which is responsible for the uniform and efficient registration, compilation, storage, and preservation of all vital records[1] in Florida.[2] The Office is required to:

- Procure the complete registration of all vital records in each registration district and in the Office.
- Uniformly enforce the law throughout the state.
- Establish registration districts throughout the state, which districts may be consolidated or subdivided to facilitate registration.
- Appoint a local registrar of vital statistics for each registration district in the state.
- Investigate cases of irregularity or violation of law, and all local registrars of vital statistics must assist DOH in such investigations. When necessary, DOH must report cases of violations to the state attorney in the registration district in which the violation occurs.
- Approve all forms used in registering, recording, certifying, and preserving vital records, and no other forms may be used other than those approved by DOH. DOH is responsible for the careful examination of the certificates received monthly from the local registrars and marriage certificates and dissolution of marriage reports received from the circuit and county courts.
- Prepare and publish an annual report of vital statistics.
- Appoint one or more suitable persons to act as subregistrars, who are authorized to receive death certificates and fetal death certificates and to issue burial permits.
- Accept, use, and produce all records, reports, and documents necessary in paper or electronic form, and adopt and enforce all rules necessary for the acceptance, use, production, issuance, recording, maintenance, and processing of such records, reports, and documents.
- By rule require that forms, documents, and information submitted to DOH in the creation or amendment of a vital record be under oath.

Death Certificates

Section 382.008, F.S., sets forth the requirements for certificates of death. A certificate of death is required to be filed within 5 days of the death and prior to final disposition with the local registrar of the district in which the death occurred so the death may be recorded. Final disposition means the burial, interment, cremation, removal from the state, or other authorized disposition of a dead body.[3]

Furthermore, the funeral director[4] who first assumes custody of a dead body is required to file the certificate of death. In the absence of the funeral director, the physician or other person in attendance at or after the death is required to file the certificate of death or fetal death. The physician must, within 72 hours after receipt of a death, certify the cause of death and make the certification available to the funeral director. The medical certification is completed by the physician in charge of the decedent's care for the illness or condition which resulted in death, the physician in attendance at the time of death

[1] "Vital records" or "records" are certificates or reports of birth, death, fetal death, marriage, dissolution of marriage, or name change. *See* s. 382.002(16), F.S.
[2] S. 382.003, F.S.
[3] S. 382.002(8), F.S. A "dead body" is defined as a human body or such parts of a human body from the condition of which it reasonably may be concluded that death recently occurred. *See* s. 382.002(4), F.S.
[4] "Funeral director" is a licensed funeral director or direct disposer licensed pursuant to ch. 497, F.S., or other person who first assumes custody of or effects the final disposition of a dead body. *See* s. 382.002(9), F.S.

or immediately before or after such death, or the medical examiner if cause of death determination is required.[5]

Medical Examiners and Death Investigations

Section 406.11, F.S., governs when the medical examiner must investigate the circumstances involving the death of a human being. The medical examiner of the district in which the death occurred or the body was found is required to determine the cause of death and is required to perform such examinations, investigations, and autopsies as he or she shall deem necessary or as requested by the state attorney; when any person dies in the state:

- Of criminal violence;
- By accident;
- By suicide;
- Suddenly, when in apparent good health;
- Unattended by a practicing physician or other recognized practitioner;
- In any prison or penal institution;
- In police custody;
- In any suspicious or unusual circumstance;
- By criminal abortion;
- By poison;
- By disease constituting a threat to public health; or,
- By disease, injury, or toxic agent resulting from employment.

Burial-Transit Permit and Conveyance of Anatomical Remains

Section 382.006, F.S., requires the funeral director who first assumes custody of a dead body to obtain a burial-transit permit prior to final disposition and within 5 days after death. The application for a burial-transit permit must be signed by the funeral director and include the funeral director's license number. The funeral director is required to attest on the application that he or she has contacted the physician's or medical examiner's office and has received assurance that the physician or medical examiner will provide medical certification of the cause of death within 72 hours after receipt of the death certificate from the funeral director. A burial-transit permit is issued by the local registrar or subregistrar of the registration district in which the death occurred or the body was found. The burial-transit permit is required to accompany the body to the place of final disposition. If the body is transported outside the state, the permit is required to accompany the dead body to its destination.[6]

Part II, of ch. 406, F.S., provides for the transfer of unclaimed bodies to the state Anatomical Board (Board),[7] and from the Board to Florida medical and dental schools, teaching hospitals, medical institutions and health-related teaching programs that require the use of anatomical material for study.[8] The Board is authorized to collect fees to defray expenses, can receive additional public or private moneys for expenses, and can reimburse any person who delivers anatomical remains to the Board.[9] Additionally, the Board is permitted to contract, and is annually audited by the Department of Financial Services (DFS).[10]

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[5] S. 382.011, F.S.
[6] S. 382.006(4), F.S.
[7] S. 406.50, F.S.
[8] The Board is also given the discretionary authority to provide cadavers to recognized associations of licensed embalmers or funeral directors, or the examining boards of medical and dental schools. S. 406.57, F.S.
[9] S. 406.58, F.S.
[10] *Id.*

The Board is located at the University of Florida College of Medicine Health Science Center,[11] and comprised of representatives from the medical schools in the state.[12] The Board's purpose is to provide cadavers, and parts thereof, to teaching and research programs in Florida. The Board must hold a body for at least 48 hours before it can be used for medical science.[13]

Section 406.56, F.S., provides the Board with the authority to accept a body that has been donated through a will, to be given to a Florida medical or dental school. Such an anatomical gift is provided for in part V, of ch. 765, F.S. These provisions of law outline the specific process for donation, and require that persons who wish to donate their body for transplant or anatomical study memorialize their intent by signing an organ donor card, registering with the online donor database, or completing an advance directive or other document.[14]

The selling and trading of human remains is prohibited in the state of Florida, punishable by a misdemeanor of the first degree.[15] Additionally, the transmission or conveyance of such anatomical remains outside the state is a first degree misdemeanor.[16] However, a statutory exception exists for recognized Florida medical or dental schools, which allows these institutions to transfer or convey human remains outside the state for research or other specific purposes. Human remains may be conveyed into and out of the state, for medical education or research purposes, by a person, institution, or organization that has received prior approval from the Board.[17]

The American Association of Tissue Banks and Accreditation

The American Association of Tissue Banks (AATB) is an organization that promulgates industry standards and accredits tissue banks in both the United States and Canada.[18] Membership is voluntary, and the initial accreditation fee is $3,000, with an annual fee that is determined by volume and ranges from $3,250— $75,000.[19] The AATB requires onsite inspections every three years.[20] In January 2012, the AATB developed an accreditation standard for Non-transplant Anatomical Donation Organizations (NADO).[21] A NADO stores human remains for the purposes of research, rather than transplant.

According to the AATB, an accredited NADO facilitates a Non-Transplant Anatomical Donation (NTAD) by overseeing referrals, obtaining informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of an NTAD. As of February 2013, the AATB has accredited five NADOs in the U.S. and of these, only one is located in Florida.[22] In medical research and education,

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[11] S. 406.50, F.S. The anatomical board was created by the Legislature at the University of Florida in 1996, by ch. 96-251, L.O.F. Prior to 1996, the Division of Universities of the Department of Education was responsible for these functions.
[12] Anatomical Board of the State of Florida, www.med.ufl.edu/anatbd/, last visited February 5, 2013.
[13] S. 406.52, F.S.
[14] S. 765.514, F.S.
[15] S. 406.61(1), F.S.
[16] *Id.*
[17] *Id.*
[18] Founded in 1976, the AATB has produced best practice standards for the operation of tissue banks since 1984. The association also provides an educational network for member organizations to encourage the dissemination of new practices. AATB, *About Us*, www.aatb.org/About-AATB, last visited February 5, 2013.
[19] AATB currently accredits 127 tissue banks in the U.S. There are currently 14 organizations in Florida that are accredited by the AATB. AATB, *Accredited Bank Search*, http://www.aatb.org/index.asp?bid=15 , last visited February 5, 2013.
[20] AATB, *Accreditation Policies for Transplant Tissue Banks*, www.aatb.org/Accreditation-Policies, last visited February 5, 2013.
[21] *Id.*
[22] *Supra* at note 20.

the donation of human remains is critical to the advancement of new techniques, and NADOs are a key component of this market.[23]

EFFECT OF PROPOSED CHANGES

Section One – Definition of Final Disposition

The bill amends s. 382.002, F.S., to revise the definition of final disposition. The bill adds that an anatomical donation of a dead body is considered final disposition. This clarifies that an anatomical donation is the equivalent of burying, cremating or interring a body.

Section Two – Burial Permit

The bill amends s. 382.006, F.S., to add the term department, meaning the DOH. This change clarifies the organizations that are authorized to issue a burial-transit permit to include the DOH, not just the local registrar or subregistrar.

Section Three – Death Registration

The bill amends s. 382.008, F.S., expanding the individuals who are authorized to file the certificate of death to include the district medical examiner of the county in which the death occurred or the body was found. The bill also allows the medical certification of the cause of death to be furnished to the funeral director via electronic transfer. According to DOH, this change conforms to the 2012 implementation of the Electronic Death Registration System.[24]

The bill adds the term department, meaning the DOH. This change clarifies the organizations that are authorized to issue a certificate of cause of death to include the DOH, not just the local registrar or subregistrar.

Additionally, the bill clarifies who is required to complete the certificate of cause of death by specifying how to determine a decedent's primary care physician. The bill rewords the definition of physician to include a specific definition for a "primary" or "attending physician" to mean a physician who treated the decedent through examination, medical advice, or medication during the 12 months preceding the date of death.

The bill deletes current law which states that "a physician in charge of the decedent's care for the illness or condition which resulted in death, or the physician in attendance at the time of death or immediately before or after death is required to complete the certificate of cause of death."

Section Four – Cause of Death Determination

The bill amends s. 382.011, F.S., making conforming changes by adding the terms "primary" and "attending physician." Additionally, the bill increases the timeframe by which the medical examiner must determine cause of death under suspect circumstances governed under s. 406.11, F.S., from 30 days to 12 months after the decedent was last treated. The bill also adds identical language that is currently found s. 406.11, F.S., which specifies that the medical examiner of the county in which the "death occurred or the body was found" is responsible for determining the cause of death.

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[23] *See e.g.*, National Institutes of Health, "NIH launches Genotype-Tissue Expression project," www.nih.gov/news/health/oct2010/nhgri-07.htm, last visited February 5, 2013, regarding a federal grant awarded to understand how genetic variation interacts with disease. *See also*, International Institute for the Advancement of Medicine, *Researcher Articles*, www.iiam.org/researcherArticles.php, last visited February 5, 2013, references the use of donated tissue for research.

[24] Department of Health Bill Analysis of HB 171, dated February 1, 2013, on file with the Health Quality Subcommittee staff.

The bill adds the term "nontransplant anatomical donation organization," to mean a tissue bank of other organization that facilitates nontransplant anatomical donation. The definition mirrors the AATB language.

Section Five – Definitions

The bill creates s. 406.49, F.S., a definition section for part II, of ch. 406, F.S., providing a definition of "unclaimed remains." Additionally, the bill cross-references the definitions of "anatomical board" and "indigent person" from existing sections of ch. 406, F.S., and provides that "cremated remains," "final disposition," "human remains," "remains" and "legally authorized person" have the same meaning as s. 497.005, F.S., the definition section for ch. 497, F.S., called the "Florida Funeral, Cemetery, and Consumer Services Act." Conforming changes are made throughout ch. 406, F.S., to change "disposition" to "final disposition."

Section Six – Unclaimed Remains Disposition

This section of the bill amends s. 406.50, F.S., directing any person or entity that has possession, charge, or control of unclaimed human remains that will be buried or cremated at public expense to notify the Board, unless:

- The remains are decomposed or mutilated by wounds;
- An autopsy is performed on the remains;
- The remains contain a contagious disease;
- A legally authorized person objects to use of the remains for medical education or research; or
- The deceased person was a veteran, or the spouse or dependent child of a veteran of the U.S. Armed Forces, U.S. Reserve Forces or National Guard, and eligible for burial in a national cemetery.

The bill removes the notification exception for death by a crushing injury. This is because crushed remains likely have limited utility in an educational setting.

The bill clarifies existing law requiring determination of a veteran's eligibility for burial in a national cemetery, pursuant to 38 C.F.R. s. 38.620.

The bill provides for a funeral director licensed under ch. 497, F.S., to assume the responsibility of a legally authorized person for unclaimed remains, when no family exists or is available. After 24 hours from the time of death, the funeral director may authorize arterial embalming for the purposes of storage and transfer of the unclaimed remains to the Board. The bill releases a funeral director from liability for damages, when acting in accordance with the law.

The bill clarifies that before the final disposition of unclaimed remains occurs, the person or entity in charge or control of the remains must make a reasonable effort to determine the identity of the deceased person, including contacting the National Cemetery Scheduling Office.

The bill provides that if the identity of the unclaimed remains cannot be ascertained, the remains may not be:

- Cremated;
- Donated as an anatomical gift;
- Buried at sea; or
- Removed from the state.

If the Board does not accept unclaimed remains, the county in which the remains are discovered or where the death occurred is authorized to bury or cremate the entire remains. The bill provides that a board of county commissioners may develop policies and procedures for the final disposition of unclaimed remains by resolution or ordinance.

The bill repeals existing law related to competing claims for the same unclaimed remains by legally authorized persons. Precedence for competing claims to direct disposition of remains is provided for in s. 497.005, F.S., the definition of "legally authorized person."

Section Seven – Disposition of Unclaimed Deceased Veterans

This section of the bill amends s. 406.51, F.S., to provide conforming changes to include the term "final disposition," and update a reference to the federal regulation for burial eligibility in a national cemetery.

Section Eight - Retention of Human Remains before Use; Claim after Delivery to Anatomical Board; Procedures for Unclaimed Remains or Remains of Indigent Persons

The bill substantially rewords s. 406.52, F.S., which relates to the retention of human remains, and a process for reclaiming the remains from the Board. The following changes to current law are made:

- Human remains may be embalmed by the Board when received;
- At any point prior to use for medical education or research, a legally authorized person may reclaim the remains from the Board, after payment of the Board's expenses incurred for transporting, embalming and storing the remains;
- The Board is authorized to reject unclaimed or indigent remains for any reason;
- County boards of commissioners are authorized to, by resolution or ordinance, prescribe policies and procedures for the burial or cremation of the unclaimed remains of an indigent person whose remains are found or whose death occurred in the county; and
- Funeral directors licensed under ch. 497, F.S., are relieved from liability for burying or cremating these remains, at the written direction of a county board of commissioners.

Section Nine - Unclaimed Remains of Indigent Person; Exemption from Notice to the Anatomical Board

Section 406.53, F.S., also is substantially reworded by the bill. Notification of the Board at the death of an indigent by counties is changed by removing the exceptions for instances where:

- The death was caused by crushing injuries;
- The deceased had a contagious disease; or
- A friend or representative of a fraternal organization of which the deceased was a member, or a representative of a charitable or a religious organization, or governmental agency which was providing residential care to the indigent person claims the body for burial and assumes the expense.

The bill adds new exceptions to the requirement for notification of the Board for bodies mutilated by wounds, and for notifications already made and certified by funeral directors, and clarifies that provisions relating to veterans includes the spouse or dependent child of a veteran eligible for burial in a national cemetery.

The bill also deletes current law which directs the DOH to collect burial fees for remains identified as their clients.[25] The bill also deletes a duplicative definition of "indigent," which is defined in s. 406.49, F.S.

Section Ten - Contracts for Delivery of Human Remains after Death Prohibited

The bill amends s. 406.55, F.S., changing the word "body" to "human remains" and rewording the existing statute.

[25] The Department of Health retains the capacity to assess fees for services, subject to s. 402.33, F.S.

Section Eleven - Acceptance of Human Remains under Will

Section 406.56, F.S., is amended to change "the advancement of medical science" to "medical education and research" and reword the existing statute.

Section Twelve - Distribution of Human Remains

The bill amends s. 406.57, F.S., allowing accredited colleges of mortuary science, rather than recognized associations of licensed embalmers or funeral directors, to be loaned remains for educational or research purposes.

Section Thirteen - Fees; Authority to Accept Additional Funds; Annual Audit

The bill amends s. 406.58, F.S., to reflect the changes to s. 406.57, F.S., and eliminates associations as a source of fees to be collected by the Board. The bill also limits the Board's ability to provide reimbursement for the transportation of remains to funeral establishments licensed under ch. 497, F.S.

The bill provides for the University of Florida to audit the Board every three years, or sooner as required, and to send the results of the audit to DFS.

Section Fourteen - Institutions Receiving Human Remains

This section contains rewording of s. 406.59, F.S., and removes associations from the list of entities allowed to receive human remains.

Section Fifteen - Disposition of Human Remains after Use

This section amends s. 406.60, F.S., and allows the disposal of human remains, or any part thereof, by either the Board, or a cinerator facility licensed under ch. 497, F.S., by cremation when such remains are deemed no longer of value to medical or dental education or research.

Section Sixteen - Selling, Buying, or Conveying Human Remains Outside or Within State Prohibited; Exceptions; Penalty

The bill amends s. 406.61, F.S., providing an exemption from approval from the Board, for a NADO that has been accredited by the AATB. The bill specifies that a NADO must be accredited by October 1, 2014.

The bill provides that for human remains received in this state, either by the anatomical board or a NADO, must be accompanied by burial-transit permit. The remains may not be dissected, disarticulated or segmented until approval has been given by the county medical examiner and received specific written consent from an authorized person representing the decedent. Furthermore, the consent must expressly state that the remains may undergo long-term preservation or extensive preparation, including, but not limited to, removal of the head, arms, legs, hands, feet, spine, organs, tissues, or fluids.

The bill clarifies language related to the prohibition of offering an inducement for anatomical donation. The bill defines valuable consideration, and provides that the definition does not include costs related to cremation, transportation or removal services.

The bill also removes a sunset provision regarding submission of affidavits to the Board by entities accredited by the American Association of Museums.

Section Seventeen – Final Disposition

The bill provides under s. 497.005, F.S., that anatomical donation is to be final disposition of a body. This would mean that the act of donating is the final step in process for disposing a body.

Section Eighteen – Handling of Embalmed Bodies

The bill amends s. 497.382, F.S., clarifying that funeral establishments, direct disposal establishment, cinerator facility, and centralized embalming facility must complete a prescribed monthly form that is signed by the embalmer that contains the name of the deceased and other information required by rule. The forms must be maintained on premises for inspection by the Division of Funeral, Cemetery, and Consumer Services within the DFS.

Section Nineteen – Cremation Procedure

The bill amends s. 497.607, F.S., specifying that a reasonable effort must be made prior to disposal of cremated remains to determine whether the remains are those of a veteran, spouse, or dependent child of a veteran who may be eligible for burial in a national cemetery due to military service in the U.S. Armed Forces, U.S. Reserve Forces or National Guard. If the remains are those of an eligible person, then the funeral or direct disposal establishment is required to arrange for interment of the cremated remains in a national cemetery. The bill specifies that reasonable effort includes contacting the National Cemetery Scheduling Office, the county veterans' service office, the regional office of the U.S. Department of Veterans Affairs, or a veterans' service organization. The bill defines a "veterans' service organization," as an association, corporation, or other entity that qualifies as a federally tax exempt organization that is organized for the benefit of the veterans' burial and interment and recognized by the Memorial Affairs Division of the U.S. Department of Veterans Affairs; or a member or employee of a non-profit entity that facilitates in the identification, recovery, and interment of unclaimed cremated remains of veterans.

The funeral or direct disposal establishment may use the assistance of a veterans' service organization and is not liable for any damages resulting from the release of required information to determine eligibility as long as they are acting in good faith. The bill specifies that funeral or direct disposal establishments are not required to:

- Determine whether the cremated remains are those of a veteran if a legally authorized person states that decedent was not a veteran.
- Relinquish possession of the cremated remains to a veterans' service organization if the entity is informed by a legally authorized person that the decedent did not desire any funeral, ceremony, or interment-related services recognizing the decedent's service as a veteran.

Section Twenty - Donees; Purposes for which Anatomical Gifts May be Made

The Board and a nontransplant anatomical donation organization is added to s. 765.513, F.S., as entities that can become a donee of anatomical gifts of whole bodies for medical or dental education or research.

Section Twenty-One - Bodies May be Claimed after Delivery to the Anatomical Board

The bill repeals s. 406.54, F.S., which allowed human remains to be claimed from the Board by friends, members of fraternal, charitable or religious entities, as other provisions of the law[26] provide a process for claiming remains by legally authorized persons.

[26] Ss. 406.50, 406.51, and 406.60, F.S.

B. SECTION DIRECTORY:

Section 1. Amends s. 382.002, F.S., relating to definitions.
Section 2. Amends s. 382.006, F.S., relating to burial-transit permit.
Section 3. Amends s. 382.008, F.S., relating to death and fetal death registration.
Section 4. Amends s. 382.011, F.S., relating to medical examiner determination of cause of death.
Section 5. Creates s. 406.49, F.S., relating to definitions.
Section 6. Amends s. 406.50, F.S., relating to unclaimed remains; disposition, procedure.
Section 7. Amends s. 406.51, F.S., relating to final disposition of unclaimed deceased veterans; contract requirements.
Section 8. Amends s. 406.52, F.S., relating to retention of human remains before use; claim after delivery to anatomical board; procedures for unclaimed remains of an indigent person.
Section 9. Amends s. 406.53, F.S., relating to unclaimed remains of indigent persons; exemption from notice to the anatomical board.
Section 10. Amends s. 406.55, F.S., relating to contracts for delivery of human remains after death prohibited.
Section 11. Amends s. 406.56, F.S., relating to acceptance of human remains under will.
Section 12. Amends s. 406.57, F.S., relating to distribution of human remains.
Section 13. Amends s. 406.58, F.S., relating to fees; authority to accept additional funds; annual audit.
Section 14. Amends s. 406.59, F.S., relating to institutions receiving human remains.
Section 15. Amends s. 406.60, F.S., relating to disposition of human remains after use.
Section 16. Amends s. 406.61, F.S., relating to selling, buying, or conveying human remains outside or within state prohibited; exceptions; penalty.
Section 17. Amends s. 497.005, F.S., relating to definitions.
Section 18. Amends s. 497.382, F.S., relating to reports of cases embalmed and bodies handled.
Section 19. Amends s. 497.607, F.S., relating to cremation; procedure required.
Section 20. Amends s. 765.513, F.S., relating to donees; purposes for which anatomical gifts may be made.
Section 21. Repeals s. 406.54, F.S., relating to bodies may be claimed after delivery to anatomical board.
Section 22. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

The Office of Vital Statistics within the DOH, states that the proposed language will necessitate the training of county health department staff, physicians, funeral directors, and medical examiners on the death registration process, but will not require additional staffing. Thus, DOH can absorb the increased workload within existing resources.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 7, 2013, the Health Quality Subcommittee adopted 5 amendments and reported the bill favorably as a committee substitute.

Amendment 1 – Adds "department" to clarify DOH's authority to issue extensions; the change was necessitated by the implementation of the Electronic Death Registration System, which is operated at the Central Office.

Amendment 2 – Defines "non-transplant anatomical donation organization (NADO)."

Amendment 3 – Specifies what must be included in the consent form; reflects the accrediting (AATB) organization standards.

Amendment 4 – Adds "institution" or "organization" to the list of entities that may not offer monetary inducement or other valuable considerations in exchange for a donation.

Amendment 5 – Provides that a NADO may receive a donation of the whole body to conform to other changes made in the bill.

This analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to disposition of human remains; amending s. 382.002, F.S.; revising definitions for purposes of the Florida Vital Statistics Act; amending s. 382.006, F.S.; authorizing the Department of Health to issue burial-transit permits; amending s. 382.008, F.S.; revising procedures for the registration of certificates of death or fetal death and the medical certification of causes of death; providing a definition; amending s. 382.011, F.S.; extending the time by which certain deaths must be referred to the medical examiner for investigation; creating s. 406.49, F.S.; providing definitions; amending s. 406.50, F.S.; revising procedures for the reporting and disposition of unclaimed remains; prohibiting certain uses or dispositions of the remains of deceased persons whose identities are not known; limiting the liability of licensed funeral directors who authorize the embalming of unclaimed remains under certain circumstances; amending s. 406.51, F.S.; requiring that local governmental contracts for the final disposition of unclaimed remains comply with certain federal regulations; amending s. 406.52, F.S.; revising procedures for the anatomical board's retention of human remains before their use; providing for claims by, and the release of human remains to, legally authorized persons after payment of certain expenses; authorizing county ordinances or resolutions

for the final disposition of the unclaimed remains of indigent persons; limiting the liability of certain licensed persons for cremating or burying human remains under certain circumstances; amending s. 406.53, F.S.; revising exceptions from requirements for notice to the anatomical board of the death of indigent persons; deleting a requirement that the Department of Health assess fees for the burial of certain bodies; amending ss. 406.55, 406.56, and 406.57, F.S.; conforming provisions; amending s. 406.58, F.S.; requiring audits of the financial records of the anatomical board; conforming provisions; amending s. 406.59, F.S.; conforming provisions; amending s. 406.60, F.S.; authorizing certain facilities to dispose of human remains by cremation; amending s. 406.61, F.S.; revising provisions prohibiting the selling or buying of human remains or the transmitting or conveying of such remains outside the state; providing penalties; excepting accredited nontransplant anatomical donation organizations from requirements for the notification of and approval from the anatomical board for the conveyance of human remains for specified purposes; requiring that nontransplant anatomical donation organizations be accredited by a certain date; requiring that human remains received by the anatomical board be accompanied by a burial-transit permit; requiring approval by the medical examiner and

consent of certain persons before the dissection, segmentation, or disarticulation of such remains; prohibiting the offer of any monetary inducement or other valuable consideration in exchange for human remains; providing a definition; deleting an expired provision; conforming provisions; amending s. 497.005, F.S.; revising a definition for purposes of the Florida Funeral, Cemetery, and Consumer Services Act; amending s. 497.382, F.S.; revising certain reporting requirements for funeral establishments, direct disposal establishments, cinerator facilities, and centralized embalming facilities; amending s. 497.607, F.S.; providing requirements for the disposal of unclaimed cremated remains by funeral or direct disposal establishments; limiting the liability of funeral or direct disposal establishments and veterans' service organizations related to the release of information required to determine the eligibility for interment in a national cemetery of the unclaimed cremated remains of a veteran; providing definitions; amending s. 765.513, F.S.; revising the list of donees who may accept anatomical gifts and the purposes for which such a gift may be used; repealing s. 406.54, F.S., relating to claims of bodies after delivery to the anatomical board; providing an effective date.

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

Section 1. Subsections (8) and (9) of section 382.002, Florida Statutes, are amended to read:

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

(8) "Final disposition" means the burial, interment, cremation, removal from the state, anatomical donation, or other authorized disposition of a dead body or a fetus as described in subsection (7). In the case of cremation, dispersion of ashes or cremation residue is considered to occur after final disposition; the cremation itself is considered final disposition. In the case of anatomical donation of a dead body, the donation itself is considered final disposition.

(9) "Funeral director" means a licensed funeral director or direct disposer licensed pursuant to chapter 497 ~~or other person~~ who first assumes custody of or effects the final disposition of a dead body or a fetus as described in subsection (7).

Section 2. Subsection (2) of section 382.006, Florida Statutes, is amended to read:

382.006 Burial-transit permit.—

(2) A burial-transit permit shall be issued by the department or the local registrar or subregistrar of the registration district in which the death occurred or the body was found. A burial-transit permit may ~~shall~~ not be issued:

(a) Until a complete and satisfactory certificate of death or fetal death is ~~has been~~ filed in accordance with the requirements of this chapter and adopted rules, unless the funeral director provides adequate assurance that a complete and satisfactory certificate will be so registered.

(b) Except under conditions prescribed by the department, if the death occurred from some disease that ~~which~~ is deemed ~~held~~ by the department to be infectious, contagious, or communicable and dangerous to the public health.

Section 3. Paragraph (a) of subsection (2) and subsections (3), (4), and (5) of section 382.008, Florida Statutes, are amended to read:

382.008 Death and fetal death registration.—

(2)(a) The funeral director who first assumes custody of a dead body or fetus shall file the certificate of death or fetal death. In the absence of the funeral director, the physician or other person in attendance at or after the death or the district medical examiner of the county in which the death occurred or the body was found shall file the certificate of death or fetal death. The person who files the certificate shall obtain personal data from the next of kin or the best qualified person or source available. The medical certification of cause of death shall be furnished to the funeral director, either in person or via certified mail or electronic transfer, by the physician or medical examiner responsible for furnishing such information. For fetal deaths, the physician, midwife, or hospital administrator shall provide any medical or health information to the funeral director within 72 hours after expulsion or extraction.

(3) Within 72 hours after receipt of a death or fetal death certificate from the funeral director, the medical certification of cause of death shall be completed and made available to the funeral director by the decedent's primary or

attending physician ~~in charge of the decedent's care for the illness or condition which resulted in death, the physician in attendance at the time of death or fetal death or immediately before or after such death or fetal death,~~ or, if s. 382.011 applies, the district medical examiner of the county in which the death occurred or the body was found ~~if the provisions of s. 382.011 apply~~. The primary or attending physician or medical examiner shall certify over his or her signature the cause of death to the best of his or her knowledge and belief. As used in this section, the term "primary or attending physician" means a physician who treated the decedent through examination, medical advice, or medication during the 12 months preceding the date of death.

(a) The local registrar may grant the funeral director an extension of time upon a good and sufficient showing of any of the following conditions:

1. An autopsy is pending.

2. Toxicology, laboratory, or other diagnostic reports have not been completed.

3. The identity of the decedent is unknown and further investigation or identification is required.

(b) If the decedent's primary or attending physician or district medical examiner of the county in which the death occurred or the body was found indicates ~~has indicated~~ that he or she will sign and complete the medical certification of cause of death~~,~~ but will not be available until after the 5-day registration deadline, the local registrar may grant an extension of 5 days. If a further extension is required, the

funeral director must provide written justification to the registrar.

(4) If the department or local registrar grants ~~has granted~~ an extension of time to provide the medical certification of cause of death, the funeral director shall file a temporary certificate of death or fetal death which shall contain all available information, including the fact that the cause of death is pending. The decedent's primary or attending physician or the district medical examiner of the county in which the death occurred or the body was found shall provide an estimated date for completion of the permanent certificate.

(5) A permanent certificate of death or fetal death, containing the cause of death and any other information that ~~which~~ was previously unavailable, shall be registered as a replacement for the temporary certificate. The permanent certificate may also include corrected information if the items being corrected are noted on the back of the certificate and dated and signed by the funeral director, physician, or district medical examiner of the county in which the death occurred or the body was found, as appropriate.

Section 4. Subsection (1) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.—

(1) In the case of any death or fetal death due to causes or conditions listed in s. 406.11, any ~~or where the~~ death that occurred more than 12 months ~~30 days~~ after the decedent was last treated by a primary or attending physician as defined in s. 382.008(3) ~~unless the death was medically expected as certified~~

~~by an attending physician~~, or any death for which ~~where~~ there is reason to believe that the death may have been due to an unlawful act or neglect, the funeral director or other person to whose attention the death may come shall refer the case to the district medical examiner of the county ~~district~~ in which the death occurred or the body was found for investigation and determination of the cause of death.

Section 5. Section 406.49, Florida Statutes, is created in part II of chapter 406, Florida Statutes, to read:

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

(1) "Anatomical board" means the anatomical board of the state headquartered at the University of Florida Health Science Center.

(2) "Cremated remains" has the same meaning as provided in s. 497.005.

(3) "Final disposition" has the same meaning as provided in s. 497.005.

(4) "Human remains" or "remains" has the same meaning as provided in s. 497.005.

(5) "Indigent person" means a person whose family income does not exceed 100 percent of the current federal poverty guidelines prescribed for the family's household size by the United States Department of Health and Human Services.

(6) "Legally authorized person" has the same meaning as provided in s. 497.005.

(7) "Nontransplant anatomical donation organization" means a tissue bank or other organization that facilitates nontransplant anatomical donation, including referral, obtaining

informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of nontransplant anatomical donations.

(8) "Unclaimed remains" means human remains that are not claimed by a legally authorized person, other than a medical examiner or the board of county commissioners, for final disposition at the person's expense.

Section 6. Section 406.50, Florida Statutes, is amended to read:

406.50 Unclaimed ~~dead bodies or human~~ remains; disposition, procedure.—

(1) A person or entity that comes ~~All public officers, agents, or employees of every county, city, village, town, or municipality and every person in charge of any prison, morgue, hospital, funeral parlor, or mortuary and all other persons coming~~ into possession, charge, or control of unclaimed ~~any dead human body or~~ remains that ~~which are unclaimed or which~~ are required to be buried or cremated at public expense shall ~~are hereby required to notify,~~ immediately notify~~,~~ the anatomical board, unless:

(a) The unclaimed remains are decomposed or mutilated by wounds;

(b) An autopsy is performed on the remains;

(c) The remains contain ~~whenever any such body, bodies, or remains come into its possession, charge, or control. Notification of the anatomical board is not required if the~~

~~death was caused by crushing injury, the deceased had~~ a contagious disease;

(d) A legally authorized person~~, an autopsy was required to determine cause of death, the body was in a state of severe decomposition, or a family member~~ objects to use of the remains ~~body~~ for medical education or ~~and~~ research; or

(e) The deceased person was a veteran of the United States Armed Forces, United States Reserve Forces, or National Guard and is eligible for burial in a national cemetery or was the spouse or dependent child of a veteran eligible for burial in a national cemetery.

(2)~~(1)~~ Before the final disposition of unclaimed remains, the person or entity in charge or control of the ~~dead body or human~~ remains shall make a reasonable effort to ~~determine~~:

(a) Determine the identity of the deceased person and ~~shall further make a reasonable effort to~~ contact any relatives of the ~~such~~ deceased person.

(b) Determine whether ~~or not~~ the deceased person is eligible under 38 C.F.R. s. 38.620 for ~~entitled to~~ burial in a national cemetery as a veteran of the armed forces and, if eligible ~~so~~, to cause the deceased person's remains or cremated remains to be delivered to a national cemetery ~~shall make arrangements for such burial services in accordance with the provisions of 38 C.F.R~~.

For purposes of this subsection, "a reasonable effort" includes contacting the National Cemetery Scheduling Office, the county veterans service office, or the regional office of the United

States Department of Veterans Affairs.

(3) ~~(2)~~ Unclaimed remains ~~Such dead human bodies as described in this chapter~~ shall be delivered to the anatomical board as soon as possible after death. When no family exists or is available, a funeral director licensed under chapter 497 may assume the responsibility of a legally authorized person and may, after 24 hours have elapsed since the time of death, authorize arterial embalming for the purposes of storage and delivery of unclaimed remains to the anatomical board. A funeral director licensed under chapter 497 is not liable for damages under this subsection.

(4) The remains of a deceased person whose identity is not known may not be cremated, donated as an anatomical gift, buried at sea, or removed from the state.

(5) If the anatomical board does not accept the unclaimed remains, the board of county commissioners or its designated county department of the county in which the death occurred or the remains were found may authorize and arrange for the burial or cremation of the entire remains. A board of county commissioners may by resolution or ordinance, in accordance with applicable laws and rules, prescribe policies and procedures for final disposition of unclaimed remains.

(6) ~~(3)~~ This part does not ~~Nothing herein shall~~ affect the right of a medical examiner to hold human ~~such dead body or~~ remains for the purpose of investigating the cause of death or~~,~~ ~~nor shall this chapter affect~~ the right of any court of competent jurisdiction to enter an order affecting the disposition of such ~~body or~~ remains.

~~(4) In the event more than one legally authorized person claims a body for interment, the requests shall be prioritized in accordance with s. 732.103.~~

~~For purposes of this chapter, the term "anatomical board" means the anatomical board of this state located at the University of Florida Health Science Center, and the term "unclaimed" means a dead body or human remains that is not claimed by a legally authorized person, as defined in s. 497.005, for interment at that person's expense.~~

Section 7. Section 406.51, Florida Statutes, is amended to read:

406.51 Final disposition of unclaimed deceased veterans; contract requirements.—Any contract by a local governmental entity for the final disposition ~~disposal~~ of unclaimed ~~human~~ remains must provide for compliance with s. 406.50(2) ~~406.50(1)~~ and require that the procedures in 38 C.F.R. s. 38.620, relating to disposition of unclaimed deceased veterans, are ~~be~~ followed.

Section 8. Section 406.52, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 406.52, F.S., for present text.)

406.52 Retention of human remains before use; claim after delivery to anatomical board; procedures for unclaimed remains of indigent persons.—

(1) The anatomical board shall keep in storage all human remains that it receives for at least 48 hours before allowing their use for medical education or research. Human remains may

be embalmed when received. The anatomical board may, for any reason, refuse to accept unclaimed remains or the remains of an indigent person.

(2) At any time before their use for medical education or research, human remains delivered to the anatomical board may be claimed by a legally authorized person. The anatomical board shall release the remains to the legally authorized person after payment of the anatomical board's expenses incurred for transporting, embalming, and storing the remains.

(3)(a) A board of county commissioners may by resolution or ordinance, in accordance with applicable laws and rules, prescribe policies and procedures for the burial or cremation of the entire unclaimed remains of an indigent person whose death occurred, or whose remains were found, in the county.

(b) A person licensed under chapter 497 is not liable for any damages resulting from cremating or burying such human remains at the written direction of the board of county commissioners or its designee.

Section 9. Section 406.53, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 406.53, F.S., for present text.)

406.53 Unclaimed remains of indigent person; exemption from notice to the anatomical board.—A board of county commissioners or its designated county department that receives a report of the unclaimed remains of an indigent person, notwithstanding s. 406.50(1), is not required to notify the anatomical board of the remains if:

(1) The indigent person's remains are decomposed or mutilated by wounds or if an autopsy is performed on the remains;

(2) A legally authorized person or a relative by blood or marriage claims the remains for final disposition at his or her expense or, if such relative or legally authorized person is also an indigent person, in a manner consistent with the policies and procedures of the board of county commissioners of the county in which the death occurred or the remains were found;

(3) The deceased person was a veteran of the United States Armed Forces, United States Reserve Forces, or National Guard and is eligible for burial in a national cemetery or was the spouse or dependent child of a veteran eligible for burial in a national cemetery; or

(4) A funeral director licensed under chapter 497 certifies that the anatomical board has been notified and either accepted or declined the remains.

Section 10. Section 406.55, Florida Statutes, is amended to read:

406.55 Contracts for delivery of human remains ~~body~~ after death prohibited.—The anatomical board may not enter ~~is specifically prohibited from entering~~ into any contract, oral or written, that provides for ~~whereby~~ any sum of money to ~~shall~~ be paid to any living person in exchange for ~~which~~ the delivery of that person's remains ~~body of said person shall be delivered~~ to the anatomical board when the ~~such living~~ person dies.

Section 11. Section 406.56, Florida Statutes, is amended

to read:

406.56 Acceptance of human remains ~~bodies~~ under will.—If any person ~~being~~ of sound mind executes ~~shall execute~~ a will leaving his or her remains ~~body~~ to the anatomical board for ~~the advancement of~~ medical education or research ~~science~~ and the ~~such~~ person dies within the geographical limits of the state, the anatomical board may ~~is hereby empowered to~~ accept and receive the person's remains ~~such body~~.

Section 12. Section 406.57, Florida Statutes, is amended to read:

406.57 Distribution of human remains ~~dead bodies~~.—The anatomical board or its duly authorized agent shall take and receive human remains ~~the bodies~~ delivered to it as provided in ~~under the provisions of~~ this chapter and shall:

(1) Distribute the remains ~~them~~ equitably ~~to and~~ among the medical and dental schools, teaching hospitals, medical institutions, and health-related teaching programs that require cadaveric material for study; or

(2) Loan the remains ~~same may be loaned for examination or study purposes~~ to accredited colleges of mortuary science ~~recognized associations of licensed embalmers or funeral directors,~~ or medical or dental examining boards for educational or research purposes ~~at the discretion of the anatomical board~~.

Section 13. Section 406.58, Florida Statutes, is amended to read:

406.58 Fees; authority to accept additional funds; annual audit.—

(1) The anatomical board may:

(a) Adopt ~~is empowered to prescribe~~ a schedule of fees to be collected from the institutions ~~institution or association~~ to which the human remains ~~bodies, as described in this chapter,~~ are distributed or loaned to defray the costs of obtaining and preparing the remains ~~such bodies~~.

(b) ~~(2) The anatomical board is hereby empowered to~~ Receive money from public or private sources, in addition to the fees collected from the institutions ~~institution or association~~ to which human remains ~~the bodies~~ are distributed, to be used to defray the costs of embalming, handling, shipping, storing, cremating, and otherwise ~~storage, cremation, and other costs relating to the~~ obtaining and using the remains. ~~use of such bodies as described in this chapter; the anatomical board is empowered to~~

(c) Pay or reimburse the reasonable expenses, as determined by the anatomical board, incurred by a funeral establishment or removal service licensed under chapter 497 for the removal, storage, and transportation ~~any person delivering the bodies as described in this chapter~~ to the anatomical board of unclaimed human remains. ~~and is further empowered to~~

(d) Enter into contracts and perform such other acts ~~as are~~ necessary for ~~to~~ the proper performance of its duties.~~;~~

(2) The anatomical board shall keep a complete record of all fees and other financial transactions. The University of Florida shall conduct an audit of the financial records of the anatomical board at least once every 3 years or more frequently as the university deems necessary. Within 90 days after completing an audit, the university shall provide a copy of the

audit to the Department of Financial Services. The university may contract with a licensed public accounting firm to provide for the audit, which firm may be paid from the fees collected by the ~~of said~~ anatomical board ~~shall be kept and audited annually by the Department of Financial Services, and a report of such audit shall be made annually to the University of Florida~~.

Section 14. Section 406.59, Florida Statutes, is amended to read:

406.59 Institutions receiving human remains ~~bodies~~.~~—~~A ~~No~~ university, school, college, teaching hospital, or institution may not~~, or association shall be allowed or permitted to~~ receive any human remains from the anatomical board ~~such body or bodies as described in this chapter~~ until its facilities are ~~have been~~ inspected and approved by the anatomical board. Human remains ~~All such bodies~~ received by such university, school, college, teaching hospital, or institution may not~~, or association shall~~ be used for any ~~no other~~ purpose other than ~~the promotion of~~ medical education or research ~~science~~.

Section 15. Section 406.60, Florida Statutes, is amended to read:

406.60 Disposition of human remains ~~bodies~~ after use.~~—At any time~~ When human remains ~~any body or bodies or part or parts of any body or bodies, as described in this chapter, shall~~ have been used for, and are not ~~deemed~~ of any ~~no~~ further value to, medical or dental education or research ~~science~~, ~~then~~ the anatomical board or a cinerator facility licensed under chapter 497 ~~person or persons having charge of said body or parts of said body~~ may dispose of the remains or any part thereof by

cremation.

Section 16. Section 406.61, Florida Statutes, is amended to read:

406.61 Selling, buying, or conveying human remains ~~bodies~~ outside state prohibited; exceptions~~;~~ ~~,~~ penalty.—

(1)(a) The anatomical board may transport human remains outside the state for educational or scientific purposes. ~~Any person who sells or buys any body or parts of bodies as described in this chapter or any person except a recognized Florida medical or dental school who transmits or conveys or causes to be transmitted or conveyed such body or parts of bodies to any place outside this state commits a misdemeanor of the first degree, punishable as provided in ss. 775.082 and 775.083. However,~~ This chapter does not prohibit the transport of ~~anatomical board from transporting~~ human remains, any part of such remains ~~specimens outside the state for educational or scientific purposes or prohibit the transport of bodies, parts of bodies~~, or tissue specimens in furtherance of lawful examination, investigation, or autopsy conducted pursuant to s. 406.11.

(b) A ~~Any~~ person, institution, or organization that conveys human remains ~~bodies~~ or any part thereof ~~parts of bodies~~ into or outside ~~out of~~ the state for medical or dental education or research purposes must ~~shall~~ notify the anatomical board of such intent and receive approval from the board.

(c) Notwithstanding paragraph (b), a nontransplant anatomical donation organization accredited by the American Association of Tissue Banks may convey human remains or any part

thereof into or outside the state for medical or dental education or research purposes without notifying or receiving approval from the anatomical board. Effective October 1, 2014, a nontransplant anatomical donation organization must be accredited by the American Association of Tissue Banks.

(d) A person who sells or buys human remains or any part thereof, or a person who transmits or conveys or causes to be transmitted or conveyed such remains or part thereof to any place outside this state, in violation of this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. This paragraph does not apply to a recognized Florida medical or dental school.

(2)(a) Human remains received in this state by the anatomical board or a nontransplant anatomical donation organization must be accompanied by the original burial-transit permit issued pursuant to s. 382.007. The remains may not be dissected, segmented, or disarticulated until the district medical examiner of the county in which the death occurred or the remains were found grants approval pursuant to s. 406.11.

(b) A nontransplant anatomical donation organization must obtain specific written consent for the dissection, segmentation, or disarticulation of any part of the remains from a person who is authorized under s. 765.512 to give such consent. Such consent must expressly state that the remains may undergo long-term preservation or extensive preparation, including, but not limited to, removal of the head, arms, legs, hands, feet, spine, organs, tissues, or fluids.

(3) A person, institution, or organization may not offer

in exchange for human remains any monetary inducement or other valuable consideration, including goods or services, to a donor, a legally authorized person, the donor's estate, or any other third party. As used in this subsection, the term "valuable consideration" does not include, and this subsection does not prohibit, payment or reimbursement of the reasonable costs associated with the removal, storage, and transportation of human remains, including payment or reimbursement of a funeral establishment or removal service licensed under chapter 497 or the reasonable costs after use, including payment or reimbursement for the disposition of human remains pursuant to s. 406.60.

(4) ~~(2)~~ An ~~Any~~ entity accredited by the American Association of Museums may convey plastinated human remains ~~bodies~~ or any part thereof within, ~~parts of bodies~~ into, or outside ~~out of~~ the state for exhibition and public educational purposes without the consent of the anatomical board if the accredited entity:

(a) Notifies the anatomical board of the conveyance and the duration and location of the exhibition at least 30 days before the intended conveyance.

(b) Submits to the anatomical board a description of the remains ~~bodies~~ or any part thereof ~~parts of bodies~~ and the name and address of the company providing the remains ~~bodies~~ or any part thereof ~~parts of bodies~~.

(c) Submits to the anatomical board documentation that the remains or each part thereof ~~body~~ was donated by the decedent or his or her next of kin for purposes of plastination and public

exhibition, or, in lieu of such documentation, an affidavit stating that the remains or each part thereof ~~body~~ was donated directly by the decedent or his or her next of kin for such purposes to the company providing the remains ~~body~~ and that such company has a donation form on file for the remains ~~body~~.

~~(3) Notwithstanding paragraph (2)(c) and in lieu of the documentation or affidavit required under paragraph (2)(c), for a plastinated body that, before July 1, 2009, was exhibited in this state by any entity accredited by the American Association of Museums, such an accredited entity may submit an affidavit to the board stating that the body was legally acquired and that the company providing the body has acquisition documentation on file for the body. This subsection expires January 1, 2012.~~

Section 17. Subsection (32) of section 497.005, Florida Statutes, is amended to read:

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

(32) "Final disposition" means the final disposal of a dead human body by earth interment, aboveground interment, cremation, burial at sea, anatomical donation, or delivery to a medical institution for lawful dissection if the medical institution or entity receiving the anatomical donation assumes responsibility for disposition after use pursuant to s. 406.60 ~~disposal~~. The term ~~"Final disposition"~~ does not include the disposal or distribution of cremated remains and residue of cremated remains.

Section 18. Section 497.382, Florida Statutes, is amended to read:

497.382 Reports of cases embalmed and bodies handled.—

(1) Each funeral establishment, direct disposal establishment, cinerator facility, and centralized embalming facility shall record monthly ~~report~~ on a form prescribed and furnished by the licensing authority the name of the deceased and such other information as may be required by rule with respect to each dead human body embalmed or otherwise handled by the establishment or facility. Such forms shall be signed monthly by the embalmer who performs the embalming, if the body is embalmed, and the funeral director in charge of the establishment or facility or by the direct disposer who disposes of the body and shall be maintained at the business premises of the establishment or facility for inspection by division staff. The licensing authority shall prescribe by rule the procedures for preparing and retaining ~~in submitting~~ such forms ~~documentation~~. ~~Reports required by this subsection shall be filed by the 20th day of each month for final dispositions handled the preceding month.~~

(2) Funeral directors performing disinterments shall record monthly on the form specified in subsection (1) and pursuant to ~~report, using a form and~~ procedures prescribed ~~specified~~ by rule~~,~~ the name of the deceased and such other information as may be required by rule with respect to each dead human body disinterred.

Section 19. Subsection (2) of section 497.607, Florida Statutes, is amended to read:

497.607 Cremation; procedure required.—

(2)(a) With respect to any person who intends to provide for the cremation of the deceased, if, after a period of 120

days from the time of cremation the cremated remains have not been claimed, the funeral or direct disposal establishment may dispose of the cremated remains. Such disposal shall include scattering them at sea or placing them in a licensed cemetery scattering garden or pond or in a church columbarium or otherwise disposing of the remains as provided by rule.

(b) A reasonable effort shall be made before such disposal to determine whether the cremated remains are those of a veteran of the United States Armed Forces, United States Reserve Forces, or National Guard eligible for burial in a national cemetery or a spouse or dependent child of a veteran eligible for burial in a national cemetery.

(c) If the unclaimed cremated remains are those of an eligible veteran or the spouse or dependent child of an eligible veteran, the funeral or direct disposal establishment shall arrange for the interment of the cremated remains in a national cemetery. A funeral or direct disposal establishment may use the assistance of a veterans' service organization for this purpose. A funeral or direct disposal establishment or veterans' service organization acting in good faith is not liable for any damages resulting from the release of required information to determine eligibility for interment.

(d) This subsection does not require a funeral or direct disposal establishment to:

1. Determine whether the cremated remains are those of a veteran if the funeral or direct disposal establishment is informed by a legally authorized person that the decedent was not a veteran.

2. Relinquish possession of the cremated remains to a veterans' service organization if the funeral or direct disposal establishment is informed by a legally authorized person that the decedent did not desire any funeral, ceremony, or interment-related services recognizing the decedent's service as a veteran.

(e) For purposes of this subsection, the term:

1. "Reasonable effort" includes contacting the National Cemetery Scheduling Office, the county veterans service office, the regional office of the United States Department of Veterans Affairs, or a veterans' service organization.

2. "Veterans' service organization" means an association, corporation, or other entity that qualifies under s. 501(c)(3) or s. 501(c)(19) of the Internal Revenue Code as a tax-exempt organization, that is organized for the benefit of veterans' burial and interment, and that is recognized by the Memorial Affairs Division of the United States Department of Veterans Affairs. The term includes a member or employee of an eligible nonprofit veterans' corporation, association, or entity that specifically assists in facilitating the identification, recovery, and interment of the unclaimed cremated remains of veterans.

Section 20. Subsection (1) of section 765.513, Florida Statutes, is amended to read:

765.513 Donees; purposes for which anatomical gifts may be made.—

(1) The following persons or entities may become donees of anatomical gifts of bodies or parts of them for the purposes

stated:

(a) Any procurement organization or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.

(b) Any individual specified by name for therapy or transplantation needed by him or her.

(c) The anatomical board or a nontransplant anatomical donation organization, as defined in s. 406.49, for donation of the whole body for medical or dental education or research.

Section 21. Section 406.54, Florida Statutes, is repealed.

Section 22. This act shall take effect July 1, 2013.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 215 Dependent Children
SPONSOR(S): Healthy Families Subcommittee; Albritton
TIED BILLS: **IDEN./SIM. BILLS:** SB 164

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	13 Y, 0 N, As CS	Poche	Schoolfield
2) Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

House Bill 215 promotes the concept that all dependent children in out-of-home care should have an opportunity to engage in normal childhood activities and experience a normal family-like upbringing.

The bill removes the "safety and normalcy balance" standard of decision making for licensed caregivers in considering participation of children in out-of-home care in age-appropriate activities. In its place, the bill imposes a "reasonable and prudent parent" standard for decision making. The standard is characterized by careful and sensible parental decisions that maintain the child's health, safety, and best interests while encouraging emotional and developmental growth. A caregiver will not be held liable for injury to a child in out-of-home care resulting from a decision to permit the child to engage in an activity if the decision was made pursuant to the "reasonable and prudent parent" standard.

The bill removes the requirement that a written plan, outlining the age-appropriate activities in which a child in out-of-home care may participate and the authority of the licensed caregiver to approve such participation, be developed and signed by the caregiver, the child, and the case manager. Instead, the bill requires the caregiver to approve participation in age-appropriate activities using the "reasonable and prudent parent" standard. The bill requires goals and objectives for participation in age-appropriate activities and information reflecting the child's progress in reaching the goals and objectives to be included in the judicial social study report to be reviewed by the court at each hearing held pursuant to s. 39.701, F.S.

The bill amends s. 39.522, F.S., to clarify the standard for placement of a child in a postdisposition change of custody. In cases in which a court is determining reunification with a parent who has substantially completed the goals and objectives of an approved case plan, the statute and case law requires the court to reunify the child with the parent if reunification does not endanger the safety, well-being, and physical, mental, and emotional health of the child. The bill requires the court to also consider whether reunification is in the best interest of the child.

The bill does not appear to have a fiscal impact.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Dependency and Dependent Children in Florida

Chapter 39, F.S., establishes legislative intent to provide for the care, safety, and protection of dependent children in an environment that fosters healthy social, emotional, intellectual, and physical development; to recognize that most families desire to be competent caregivers and providers for their children; to ensure permanency for dependent children within one year, and to ensure that the health and safety of dependent children served shall be of paramount concern.[1] Chapter 39, F.S., provides the process and procedures for the following:

- Reporting child abuse and neglect;
- Protective investigations;
- Taking children into custody and shelter hearings;
- Petition, arraignment, and adjudication of dependency;
- Disposition of the dependent child;
- Postdisposition change of custody;
- Case plans;
- Permanency;
- Judicial reviews; and
- Termination of parental rights.

Many of the provisions and time-frames in chapter 39, F.S., are required by federal law in order to be eligible for federal funding.[2]

The dependency process in Florida begins with an investigation of an allegation of child abuse, abandonment, and/or neglect.[3] A child protection investigator conducts an on-site investigation of the home where the abuse, abandonment, and/or neglect was alleged to have occurred.[4] Following the investigation, the investigator recommends that no further action be taken (indicating that the allegations are unfounded), offers voluntary services to address identified issues in the home, or recommends judicial intervention and/or removal of the child from the home.[5]

If a child is removed from the home as a result of an investigation into child abuse, abandonment, and/or neglect allegations, a shelter hearing is held within 24 hours of removal.[6] An Intervention Staffing is held to identify the service needs of the child and the family and a dependency petition is filed with the court.[7] The dependency petition contains the allegations that led to the removal of the child from the home.[8] The parent admits to, consents to, or denies the allegations contained in the dependency petition. In the meantime, the court determines the most appropriate placement for the

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[1] S. 39.001, F.S.
[2] Including, but not limited to, the Fostering Connections to Success and Increasing Adoptions Act (P.L. 110-351); the Keeping Children and Families Safe Act (P.L. 108-36); the Adoption and Safe Families Act (P.L. 105-89); the Child Abuse Prevention and Treatment Act (P.L. 93-247); and the Adoption Assistance and Child Welfare Act (P.L. 96-242).
[3] S. 39.301(1), F.S.
[4] Id.
[5] S. 39.301(14) and (15), F.S.
[6] S. 39.402(8)(a) and (c), F.S.
[7] S. 39.501, F.S.
[8] S. 39.501(3)(c), F.S.

child at the shelter hearing with an approved adult relative, with a licensed shelter or foster home, or with an approved non-relative.

If the parent admits or consents to the allegations in the dependency petition, the court adjudicates the child dependent and a Guardian ad Litem is appointed to represent the child's best interests. A disposition hearing is held to determine appropriate services and placement setting for the child. A case plan determining permanency of the child, culminating in reunification of the family or another outcome, is also approved by the court.

In determining placement of the child following the disposition hearing, the court is faced with different standards depending on available placement options. If Department of Children and Families (DCF) prevention or reunification efforts allow the child to remain in or return to the home, the court allows such placement after making a specific finding that the reasons for removal from the home have been remedied to an extent that the child's safety, well-being, and physical, mental and emotional health will not be endangered.[9] If the child is adjudicated dependent and the court determines the child can safely remain in the home with the parent with whom the child was residing at the time the circumstances arose which brought the child under the jurisdiction of the court, and that remaining in the home is in the best interest of the child, the court shall order such placement.[10]

If the parent denies the allegations contained in the dependency petition, the case will be set for an adjudicatory hearing. The court considers evidence and hears testimony at the hearing and if, by a preponderance of the evidence, the court finds that the child was abused, abandoned, or neglected, the child is adjudicated dependent. A disposition hearing is held to determine services and placement for the child and a case plan is approved.[11]

The court also considers postdisposition changes in custody. The standard for changing custody of the child is whether the recommended or requested change is in the best interest of the child.[12] However, when the question before the court is reunification with a parent, the court must determine if the parent substantially completed the terms of the case plan to the extent that the safety, well-being, and physical, mental, and emotional health of the child is not endangered by returning to the home.[13]

The court holds periodic judicial reviews, generally every six months until supervision is terminated, to determine the child's status, the parent's progress in following the case plan, and the goals and objectives of the case plan.[14] After twelve months, if the case plan goals have not been met, the court holds a permanency hearing to determine the child's permanency goal.[15]

There are more than 8,000 dependent children in Florida's foster care system and more than 4,000 foster parents across the state.[16] Over the past year, on any given day, there were approximately 5,000 teens between the ages of 13 and 17 residing in out-of-home care placement.[17]

Permanency

Chapter 39, F.S., provides that time is of the essence for determining permanency of a child in the dependency system.[18] A permanency hearing must be held no later than 12 months after the date the

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[9] S. 39.521(1)(e), F.S.
[10] S. 39.521(3)(a), F.S.
[11] S. 39.603(1), F.S.
[12] S. 39.522(1), F.S.
[13] S. 39.522(2), F.S.
[14] S. 39.521(1)(c), F.S.
[15] S. 39.621(1), F.S.
[16] Florida Department of Children and Families, Fostering Florida's Future, Fact Sheet, available at www.fosteringflorida.com/docs/materials/fosterbusiness.pdf (last viewed Feb. 5, 2013).
[17] Florida Department of Children and Families, Independent Living Services Advisory Council, 2012 Report of Independent Living Services for Florida's Foster Youth, page 3.

child was removed from the home or no later than 30 days after a court determines that reasonable efforts to return a child to either parent are not required, whichever occurs first.[19] The purpose of the permanency hearing is to determine when the child will achieve the permanency goal or whether modifying the current goal is in the best interest of the child.[20] A permanency hearing must be held at least every 12 months for any child who continues to receive supervision from the department or awaits adoption.[21] Available permanency goals for a child, listed in order of preference, are:

- Reunification;
- Adoption, if a petition for termination of parental rights has been or will be filed;
- Permanent guardianship of a dependent child under s. 39.6221;
- Permanent placement with a fit and willing relative under s. 39.6231; or
- Placement in another planned permanent living arrangement under s. 39.6241.[22]

If, upon a finding by the court that the current permanency placement is no longer in the best interest of the child, a parent who has not had his or her parental rights terminated makes a motion for reunification or increased contact with the child, the court must hold a hearing to determine whether the dependency case should be reopened and whether there should be a modification of the order determining permanency.[23] The parent seeking modification of the order must prove that the requested modification does not endanger the safety, well-being, and physical, mental, and emotional health of the child.[24]

Florida Courts and Standards for Reunification

The Third District Court of Appeal has identified inconsistent statutory provisions relating to reunification contained in chapter 39, F.S.[25] The court points to s. 39.522(2), F.S., relating to postdisposition change of custody, which reads:

> "In cases where the issue before the court is whether a child should be reunited with a parent, the court shall determine whether the parent has substantially complied with the terms of the case plan to the extent that the safety, well-being, and physical, mental, and emotional health of the child is not endangered by the return of the child to the home."

The court also points to s. 39.621(10), F.S., relating to permanency determination by the court, which provides:

> "The court shall base its decision concerning any motion by a parent for reunification or increased contact with a child on the effect of the decision on the safety, well-being, and physical and emotional health of the child. Factors that must be considered and addressed in the findings of fact of the order on the motion must include:
>
> (a) The compliance or noncompliance of the parent with the case plan;..."

The statute lists six factors that must be considered and addressed in the court's order on a parent's motion for reunification or increased contact with a child following a permanency placement order.[26] These factors are used to determine the "best interest" of the child.[27]

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[18] S. 39.621(1) and (5), F.S.
[19] Id.
[20] Id.
[21] Id.
[22] S. 39.621(2), F.S.
[23] S. 39.621(9), F.S.
[24] Id.
[25] *See* S.V.-R. v. Department of Children and Family Services, 77 So.3d 687, 688 (Fla. 3rd DCA 2011).
[26] S. 39.621(10)(a) through (f), F.S.
[27] *See supra* FN 25, at 689.

There appears to be a lack of clarity in statute as to which standard, "endangerment" or "best interest of the child", should be used in decisions to reunite a child with his or her parent. In *S.V.-R.*, the court confirmed the applicable standard is "endangerment"[28] in cases in which a non-offending parent seeks to become the custodial parent and the offending parent achieved her goals for reunification.[29] The court acknowledged that its approach is consistent with the analysis of the Second and Fifth District Courts of Appeal.[30] However, the court also notes that two decisions in the Fourth District Court of Appeal imply that the "best interests of the child" standard controls in reunification cases in general.[31]

Normalcy for Foster Children

DCF is statutorily required to provide children and young adults in foster care with opportunities to participate in life skills activities within their foster families and communities which are reasonable and appropriate for their respective ages.[32] DCF must also provide children and young adults in foster care with services designed to build life skills and increase their ability to live independently and self-sufficiently.[33] In order to support the provision of opportunities for participation in age-appropriate life skills activities, DCF is required to develop procedures which maximize the authority of foster parents and other authorized caregivers to approve participation in age-appropriate activities of children in their care.[34] The activities and authority of foster parents and other authorized caregivers are to be included in a written plan that is developed and signed by the authorized caregiver, the child, and the case manager.[35] Foster parents, or other authorized caregivers, will not be held responsible under rules or laws related to licensure as caregivers as a result of the actions of a child engaged in approved activities specified in the written plan.[36]

Florida rules also require the case manager and the foster parents, or other authorized caregiver, to work together to ensure opportunities for children and young adults in foster care to engage in social and extracurricular activities that promote social development and maturity.[37] Activities that promote such development and maturity include:

- School attendance and participation and educational planning[38];
- Participation in social and extracurricular activities, including employment[39];
- Efforts to learn to drive a car and obtain a learner's permit and driver's license, as appropriate[40];
- Attendance at overnight or planned outings, if deemed safe and appropriate[41];
- Experience in circumstances and events without direct supervision to facilitate the ability to make appropriate decisions[42]; and
- Receipt of an allowance.[43]

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[28] S. 39.522(2), F.S.
[29] *See supra,* FN 25 at 690.
[30] *See id.; see also* In re A.F., 39 So.3d 1288 (Fla. 2nd DCA 2010) *and* M.M. v. Department of Children and Families, 29 So.3d 1200 (Fla. 5th DCA 2010).
[31] *See supra,* FN 28; *see also* C.S. v. Department of Children and Families, 12 So.3d 309 (Fla. 4th DCA 2009) *and* E.I. v. Department of Children and Families, 979 So.2d 378 (Fla. 4th DCA 2008).
[32] S. 409.1451(3)(a), F.S.
[33] Id.
[34] S. 409.1451(3)(a)3., F.S.
[35] Id.
[36] Id.
[37] Rule 65C-30.007(10), F.A.C.
[38] Rule 65C-30.007(10)(a), F.A.C. and Rule 65C-13.029(2)(p), F.A.C.
[39] Rule 65C-30.007(10)(c), F.A.C. and Rule 65C-13.029(2)(o), F.A.C.
[40] Rule 65C-30.007(10)(d), F.A.C. and Rule 65C-13.029(2)(s), F.A.C.
[41] Rule 65C-30.007(10)(g), F.A.C.
[42] Rule 65C-20.007(10)(h), F.A.C.
[43] Rule 65C-30.007(10)(k), F.A.C.

Despite efforts to normalize the life and experiences of Florida's foster children, the Independent Living Services Advisory Council reports that foster teens find these efforts lagging:

> "The percentage of teens that reported that they have a written approved activities plan has not changed substantially over the past three years and remains in the 60% range. In 2012, slightly more than half (53%) of the foster care youth reported that they receive the statutorily required weekly allowance. Teens that reported that they have a Florida Identification (39%), Learners Permit (10%), or Drivers' License (3%) were also low."[44]

Reasonable and Prudent Parent Standard

In 2005, the state of California passed legislation regarding the "reasonable and prudent parent standard".[45] The standard is characterized by careful and sensible parental decisions, which maintain the child's health, safety, and best interests, that an administrator or facility manager, or his or her responsible designee, shall use when determining whether to allow a child in care to participate in extracurricular, enrichment and social activities.[46] The concept behind the standard is that a foster parent or a caregiver for a child in out-of-home care, including group home facilities, should be allowed to make decisions regarding the children in their care to the best of their ability. In essence, the law is aimed at allowing foster parents, or other authorized caregivers, to use their best judgment in determining what activities a child may or may not be able to participate in. The goal of this law is to provide youth in out-of-home care with a normal life experience and to encourage the caregiver to engage youth in extracurricular activities.

The current legal standard for foster parent decision-making in Florida is to balance safety and normalcy.[47] Prospective foster parents receive training in decision-making that balances normalcy for children in their care with safety.[48] Licensed foster parents are tasked with promoting opportunities for foster children to develop interests and skills through participation in school and community activities.[49] This includes permitting children to engage in age-appropriate social, school, and employment related activities as detailed in the written plan for appropriate activities.[50] In addition, children in licensed out-of-home care shall be afforded every opportunity for social development, recreation, and normalization of their lives.[51] Many providers equate safety with liability, and make decisions accordingly.

Effect of Proposed Changes

The bill, entitled the "Quality Parenting for Children in Foster Care Act", creates s. 39.4091, F.S., regarding participation in childhood activities. In legislative findings and intent, the bill recognizes the importance of normalizing the lives of children in out-of-home care and empowering caregivers to make decisions regarding children participating in age-appropriate activities, using their own assessments as caregivers based on a reasonable and prudent parent standard. The bill clarifies that each child coming into out-of-home care is entitled to participate in age-appropriate activities.

The bill defines "reasonable and prudent parent standard" as a standard, characterized by careful and sensible parental decisions that maintain the health, safety, and best interests of the child while encouraging the child's emotional and developmental growth, that a caregiver must use when

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[44] *See supra,* FN 17 at page 9.
[45] CAL. WIC s. 362.05
[46] CAL.WIC s. 362.04
[47] S. 409.1451(10), F.S.
[48] Rule 65C-13.024(2), F.A.C.
[49] Rule 65C-13.029(1)(f)3., F.A.C.
[50] Rule 65C-13.029(2)(o), F.A.C.
[51] Rule 65C-13.029(1)(g)7., F.A.C.

determining whether to permit a child in out-of-home care to participate in extracurricular, enrichment, and social activities. The standard closely mirrors the standard established in California in 2005.[52]

The bill further requires a caregiver to use the "reasonable and prudent parent" standard, and make the following specific considerations, when determining whether to permit any child in out-of-home care to participate in an activity:

- The child's age, maturity, and developmental level;
- Potential risk factors and the appropriateness of the activity;
- The best interest of the child, based on the information known to the caregiver;
- The importance of encouraging the child's emotional and developmental growth;
- The importance of providing the most family-like living experience to the child as possible; and
- The behavioral history of the child and the child's ability to safely participate in the activity.

DCF and the community-based care lead agencies are required to ensure that private agencies are implementing policies that are consistent with employing the "reasonable and prudent parent" standard and are promoting and protecting the child's ability to participate in age-appropriate activities.

The bill protects a caregiver from liability for harm caused to a child resulting from participation in an age-appropriate activity that was approved by the caregiver, if the caregiver acted as a reasonable and prudent parent in approving participation in that activity. The protection from liability for caregivers in these situations may lead to children in out-of-home care engaging in more age-appropriate activities designed to facilitate their emotional and developmental growth. While caregivers are currently liable for their decisions that result in injury to children in care, it is not clear whether the application of the "reasonable and prudent parent" standard will reduce liability further than what is currently experienced by caregivers.

The bill amends s. 39.522, F.S., related to postdisposition change of custody, to clarify that, in cases in which a court is deciding whether to reunite a child, who is in the custody of one parent, with a non-custodial parent who has substantially completed a reunification plan, the standard to be applied is whether the child is endangered by placement with the non-custodial parent and whether reunification with the non-custodial parent is in the best interest of the child when compared to the existing custody arrangement. The change in legal standard should eliminate future confusion by the courts and ensure that the custody decision is in the best interest of the child. The change in legal standard is also consistent with the overall principle of chapter 39, F.S., which is the ultimate welfare of the child.

The bill amends s. 409.1451, F.S., related to independent living transition services, by eliminating the requirement that the caregiver, the child in out-of-home care, and the case manager develop and sign a written plan that outlines the age-appropriate activities in which the child may participate and the authority of the caregiver to permit participation in the activities. The written plan is replaced by imposition of the "reasonable and prudent parent" standard on any decision made by the caregiver regarding the child's participation in age-appropriate activities.

The bill requires written goals and objectives for a child's participation in activities and specific information related to the child's progress in reaching the goals and objectives to be included in the written judicial study report that is provided to the dependency court. The court is to review the study report at each hearing held pursuant to s. 39.701, F.S., until the child reaches permanency status.

Lastly, the bill removes the requirement that any rules adopted by DCF pursuant to s. 409.1451, F.S., balance normalcy and safety. Instead, the bill requires that rules provide as much flexibility to caregivers to ensure that children are able to participate in normal life experiences. The bill reiterates that the standard for decision making is the "reasonable and prudent parent" standard.

[52] See supra, FN 45 and 46.

B. SECTION DIRECTORY:

Section 1: Provides for citation to the act as the "Quality Parenting for Children in Foster Care Act".
Section 2: Creates s. 39.4091, F.S., relating to participation in childhood activities.
Section 3: Amends s. 39.522, F.S., relating to postdisposition change of custody.
Section 4: Amends s. 409.1451, F.S., relating to independent living transition services.
Section 5: Provides an effective date of July 1, 2013.

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 offers protection from liability for a caregiver if a child in out-of-home care is injured as a result of a decision to allow the child to participate in an age-appropriate activity, if the caregiver made the decision under the "reasonable and prudent parent" standard. The liability protection may positively impact liability insurance premiums for licensed caregivers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to DCF to implement the provisions of the act.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 13, 2013, the Healthy Families Subcommittee adopted three amendments for House Bill 215. The amendments made the following changes to the bill:

- Removed a citation to the Florida Administrative Code and replaced it with a citation to the relevant and applicable statute.
- Clarified the legal standard to be applied in cases where the court is determining reunification of a child with a parent who has substantially completed the terms of a case plan to include consideration of the best interests of the child.
- Removed a repetitive definition of "reasonable and prudent parent" standard and replaced it with a reference to the applicable statute.

The bill was reported favorably as a committee substitute. The analysis reflects the committee substitute.

A bill to be entitled

An act relating to dependent children; providing a short title; creating s. 39.4091, F.S.; providing legislative findings and intent; providing definitions; providing for participation in age-appropriate extracurricular, enrichment, and social activities by children in out-of-home care; providing for use of a reasonable and prudent parent standard for decisionmaking about such activities; providing rulemaking authority; amending s. 39.522, F.S.; clarifying the standard for reunification and for changing custody; amending s. 409.1451, F.S.; providing for use of reasonable and prudent parent standard in certain decisionmaking; requiring submission of plan for judicial review; providing a definition; providing rulemaking authority; providing an effective date.

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

Section 1. This act may be cited as the "Quality Parenting for Children in Foster Care Act."

Section 2. Section 39.4091, Florida Statutes, is created to read:

39.4091 Participation in childhood activities.—

(1) FINDINGS AND INTENT.—

(a) The Legislature finds that every day parents make important decisions about their child's participation in

activities and that caregivers for children in out-of-home care are faced with making the same decisions for a child in their care.

(b) The Legislature also finds that when a caregiver makes decisions, he or she must consider applicable laws, rules, and regulations to safeguard the health and safety of a child in out-of-home care and that those rules and regulations have commonly been interpreted to prohibit children in out-of-home care from participating in extracurricular activities.

(c) The Legislature further finds that participation in these types of activities is important to the child's well-being, not only emotionally, but in developing valuable life-coping skills.

(d) It is the intent of the Legislature to recognize the importance of making every effort to normalize the lives of children in out-of-home care and to empower a caregiver to approve or disapprove a child's participation in activities based on the caregiver's own assessment using a reasonable and prudent parent standard, without prior approval of the department, the caseworker, or the court.

(2) DEFINITIONS.—When used in this section, the term:

(a) "Age-appropriate" means activities or items that are generally accepted as suitable for children of the same chronological age or level of maturity. Age appropriateness is based on the development of cognitive, emotional, physical, and behavioral capacity that is typical for an age or age group.

(b) "Caregiver" means a person with whom the child is placed in out-of-home care, or a designated official for group

care facilities licensed by the Department of Children and Families pursuant to s. 409.175.

(c) "Reasonable and prudent parent standard" means the standard characterized by careful and sensible parental decisions that maintain the child's health, safety, and best interests while at the same time encouraging the child's emotional and developmental growth, that a caregiver shall use when determining whether to allow a child in out-of-home care to participate in extracurricular, enrichment, and social activities.

(3) REQUIREMENTS FOR DECISIONMAKING.—

(a) Each child who comes into care under this chapter is entitled to participate in age-appropriate extracurricular, enrichment, and social activities.

(b) Caregivers must use a reasonable and prudent parent standard in determining whether to give permission for a child in out-of-home care to participate in extracurricular, enrichment, and social activities. When using the reasonable and prudent parent standard, the caregiver shall consider:

1. The child's age, maturity, and developmental level to maintain the overall health and safety of the child.

2. The potential risk factors and the appropriateness of the extracurricular, enrichment, and social activity.

3. The best interest of the child based on information known by the caregiver.

4. The importance of encouraging the child's emotional and developmental growth.

5. The importance of providing the child with the most

family-like living experience possible.

6. The behavioral history of the child and the child's ability to safely participate in the proposed activity, as with any other child.

(c) The department and community-based care lead agencies are required to verify that private agencies providing out-of-home services to dependent children have policies consistent with this section and that those agencies promote and protect the ability of dependent children to participate in age-appropriate extracurricular, enrichment, and social activities.

(d) A caregiver as defined in this section is not liable for harm caused to a child in care who participates in an activity approved by the caregiver, provided that the caregiver has acted as a reasonable and prudent parent. This section does not remove or limit any existing liability protection afforded by statute.

(4) RULEMAKING.—The department shall adopt by rule procedures to administer this section.

Section 3. Subsection (3) is added to section 39.522, Florida Statutes, to read:

39.522 Postdisposition change of custody.—The court may change the temporary legal custody or the conditions of protective supervision at a postdisposition hearing, without the necessity of another adjudicatory hearing.

(3) In cases where the issue before the court is whether a child who is placed in the custody of a parent should be reunited with the other parent upon a finding of substantial compliance with the terms of the case plan, the standard shall

be that the safety, well-being, and physical, mental, and emotional health of the child would not be endangered by reunification and that reunification would be in the best interest of the child.

Section 4. Paragraph (a) of subsection (3) and subsection (10) of section 409.1451, Florida Statutes, are amended to read:

409.1451 Independent living transition services.—

(3) PREPARATION FOR INDEPENDENT LIVING.—

(a) It is the intent of the Legislature for the Department of Children and Families ~~Family Services~~ to assist older children in foster care and young adults who exit foster care at age 18 in making the transition to independent living and self-sufficiency as adults. The department shall provide such children and young adults with opportunities to participate in life skills activities in their foster families and communities which are reasonable and appropriate for their respective ages or for any special needs they may have and shall provide them with services to build life skills and increase their ability to live independently and become self-sufficient. To support the provision of opportunities for participation in age-appropriate life skills activities, the department shall:

1. Develop a list of age-appropriate activities and responsibilities to be offered to all children involved in independent living transition services and their foster parents.

2. Provide training for staff and foster parents to address the issues of older children in foster care in transitioning to adulthood, which shall include information on high school completion, grant applications, vocational school

opportunities, supporting education and employment opportunities, and opportunities to participate in appropriate daily activities.

3. Establish ~~Develop procedures to maximize~~ the authority of foster parents, family foster homes, residential child-caring agencies, or other authorized caregivers to approve participation in age-appropriate activities of children in their care according to a reasonable and prudent parent standard. ~~The age-appropriate activities and the authority of the foster parent, family foster home, residential child-caring agency, or caregiver shall be developed into a written plan that the foster parent, family foster home, residential child-caring agency, or caregiver, the child, and the case manager all develop together, sign, and follow. This plan must include specific goals and objectives and be reviewed and updated no less than quarterly.~~ Foster parents, family foster homes, residential child-caring agencies, or other authorized caregivers employing the reasonable and prudent parent standard in their decisionmaking ~~who have developed a written plan as described in this subparagraph~~ shall not be held responsible under administrative rules or laws pertaining to state licensure or have their licensure status in any manner jeopardized as a result of the actions of a child engaged in the approved age-appropriate activities ~~specified in the written plan~~. Goals and objectives for participation in extracurricular, enrichment, and social activities, as well as specific information on the child's progress toward meeting those objectives, shall be incorporated into the agency's written judicial social study report and shall

be reviewed by the court at each hearing conducted pursuant to s. 39.701.

4. Provide opportunities for older children in foster care to interact with mentors.

5. Develop and implement procedures for older children to directly access and manage the personal allowance they receive from the department in order to learn responsibility and participate in age-appropriate life skills activities to the extent feasible.

6. Make a good faith effort to fully explain, prior to execution of any signature, if required, any document, report, form, or other record, whether written or electronic, presented to a child or young adult pursuant to this chapter and allow for the recipient to ask any appropriate questions necessary to fully understand the document. It shall be the responsibility of the person presenting the document to the child or young adult to comply with this subparagraph.

(10) RULEMAKING.—The department shall adopt rules ~~by rule procedures~~ to administer this section. The rules must provide~~, including balancing the goals of normalcy and safety for the youth and providing the~~ caregivers with as much flexibility as possible to enable the children in their care ~~youth~~ to participate in normal life experiences and must reflect the considerations listed in s. 39.4091(3)(b) in connection with the reasonable and prudent parent standard established in that section. The department shall engage in appropriate planning to prevent, to the extent possible, a reduction in awards after issuance. The department shall adopt rules to govern the

payments and conditions related to payments for services to youth or young adults provided under this section.

Section 5. This act shall take effect July 1, 2013.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 239 Practice of Optometry
SPONSOR(S): Health Quality Subcommittee; Caldwell
TIED BILLS: **IDEN./SIM. BILLS:** SB 278

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 3 N, As CS	Holt	O'Callaghan
2) Health & Human Services Committee		Holt	Calamas

SUMMARY ANALYSIS

The bill amends ch. 463, F.S., the Optometry Practice Act, authorizing certified optometrists to administer and prescribe ocular pharmaceutical agents that may be ingested orally. Currently, a certified optometrist is only permitted to administer and prescribe topical ocular pharmaceutical agents. The bill revises the definitions of "certified optometrist" and "optometry" to reflect the broader authority. The bill provides a definition of "ocular pharmaceutical agent."

The bill requires a certified optometrist and an optometry faculty certificate holder to complete additional coursework and pass an examination that is jointly developed by the Florida Medical Association and the Florida Optometric Association to be authorized to prescribe or administer oral ocular pharmaceutical agents. The first examination must be presented by July 1, 2013. Moreover, the bill states that the formulary of ocular pharmaceutical agents consists of agents that are appropriate to treat and diagnose ocular diseases and disorders. The bill amends the composition of the advisory committee requiring two optometrists to be certified optometrists and amends the Board of Optometry's rule-making authority.

The bill authorizes a certified optometrist to perform any eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions.

The bill defines "practitioner" under s. 893.02, F.S., to include certified optometrists who have obtained a federal controlled substance registry number to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. However, the bill prohibits a certified optometrist from administering or prescribing a Schedule I or Schedule II controlled substance.

The bill requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist. Finally, the bill makes conforming changes to cross-references.

The bill has an insignificant, negative fiscal impact to the state and no fiscal impact to local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Optometrists and Ophthalmologists

Optometrists are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists may prescribe certain medications, vision therapy, and corrective lenses, but may not perform surgical procedures in Florida.[1]

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrist's complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.[2]

Ophthalmologists are medical doctors who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and medications to performing eye surgery. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologist training involves an undergraduate degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[3]

Florida law requires optometrists diagnosing a patient with certain diseases to refer such patients to "physician skilled in the diseases of the eye" (ophthalmologists) or for further treatment.[4] Additionally, an optometrist is required to promptly advise a patient to seek an evaluation by an ophthalmologist for diagnosis and possible treatment whenever the optometrist is informed by the patient of the sudden onset of spots or "floaters" with loss of all or part of the visual field.[5] Optometrists are also required to maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.[6]

Administration of Medications by Optometrists in Florida

Florida is one of three states that do not authorize optometrists to prescribe oral medications for their patients. Of the 47 states that grant optometrists the authority to prescribe oral medications, 43 allow optometrists to prescribe controlled substances.[7] In Florida, licensed optometrists, if they are appropriately certified by the Board of Optometry (Board), may administer and prescribe topical ocular pharmaceutical agents. If an optometrist diagnoses a condition that would be best addressed with an oral medication, the patient must see another practitioner, such as an ophthalmologist, [or hospital

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[1] Section 463.014(4), F.S.
[2] American Optometric Association, *What is a Doctor of Optometry?*, *available at*: http://www.aoa.org/x4891.xml (last visited Feb. 5, 2013).
[3] American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s.*, *available at:* http://www.aao.org/about/eyemds.cfm (last visited Feb. 5, 2013).
[4] Diagnoses which mandate a referral to an ophthalmologist include angle closure glaucoma, congenital or infantile glaucoma, and infectious corneal diseases that are unresponsive to standard treatment. Section 463.0135, F.S.
[5] Section 463.0135(4), F.S.
[6] Section 463.0135(8), F.S.
[7] The Florida Legislature, Office of Program Policy Analysis and Government Accountability, *Expanding Scope of Practice for Advanced Registered Nurse Practitioners, Physician Assistants, Optometrists, and Dental Hygienists*, December 30, 2010, on file with the Health Quality Subcommittee.

emergency room] for treatment. If an optometrist administers or prescribes a topical pharmaceutical[8], it must be related to the diagnosis and treatment of ocular conditions and must not require surgery or other invasive techniques for administration. Medications approved for prescription by certified optometrists are listed in a formulary[9] maintained by the Board.[10]

To be certified for prescribing privileges, an optometrist must:[11]

- Complete at least 110 hours of board-approved coursework and clinical training in general and ocular pharmacology at an accredited institution which has facilities for both didactic and clinical instruction in pharmacology. Training already completed by the applicant under an optometry training program provided by a Board-approved school of optometry may be accepted by the Board toward the required coursework and training;
- Complete at least 1 year of supervised experience in differential diagnosis of eye diseases or disorders, which may occur during training or clinical practice;
- Pass part II of the National Board of Examiners in Optometry examination;[12] and
- Pay a $250 fee.[13]

For over 25 years, certification for prescribing privileges is a required component of the general licensure process for optometrists.[14] Optometrists who are not certified are only authorized to use topical anesthetics for glaucoma examinations.[15]

Prescribing Controlled Substances

The Drug Enforcement Administration (DEA) within the United States Department of Justice is tasked with monitoring controlled substances and preventing their abuse. Controlled substances fall into five categories, or schedules, depending on their addictive potential. Drug schedules are specified by the DEA in 21 C.F.R. §§ 1308.11-15 and in s. 893.03, F.S.

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, lysergic acid diethylamide (LSD), and cannabis.

Schedule II controlled substances have a high potential for abuse, which may lead to severe psychological or physical dependence, including morphine and its derivatives, amphetamines, cocaine, and pentobarbital.

Schedule III controlled substances have lower abuse potential than Schedule II substances but may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of dihydrocodeine per dose (such as Tylenol #3), ketamine, and anabolic steroids.

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[8] A topical medication is a medication that is applied to body surfaces such as the skin or mucous membranes to treat ailments via a large range of classes including but not limited to creams, foams, gels, lotions and ointments.
[9] The formulary is listed in Rule 64B13-18.002, F.A.C., and includes agents to dilate and constrict pupils, local anesthetics, antibiotics, anti-inflammatory agents, antihistamines, antivirals, and anti-glaucoma medications. All medications are for topical ocular use only.
[10] Section 463.0055, F.S.
[11] Rule 64B13-10.001, F.A.C.
[12] This examination consists of 60 simulated patient cases to assess the examinee's performance in clinical practice situations, *available at:* http://www.optometry.org/part_2_pam.cfm (last visited Feb. 5, 2013).
[13] Rule 64B13-6.001(7), F.A.C.
[14] *See* s. 463.006(1), F.S.; and Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with the Health Quality Subcommittee staff.
[15] Section 463.0055(1), F.S.

Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan).

Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[16]

Any health care professional wishing to prescribe controlled substances must apply for a Federal Controlled Substance Registry Number (DEA number). A DEA number is linked to a state license, which may be suspended or revoked upon any disciplinary action taken against the licensee. The DEA will grant DEA numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances that have been authorized to them under state law. DEA numbers must be renewed every 3 years.[17]

In Florida, only licensed physicians, dentists, veterinarians, naturopaths, and podiatrists are currently permitted to prescribe controlled substances and receive a DEA number. However, they may only prescribe medications that are within the scope of their practice.[18]

Physicians and Pugilistic Exhibitions

In Florida, the law requires at least one physician to be assigned to each boxing match to observe the physical condition of the participants and advise the commissioner or commission representative in charge of the Florida State Boxing Commission (commission) and the referee of the participants' conditions before, during, and after the match. The commission establishes a schedule of fees for the physician's services. The physician's fee is paid by the promoter of the match attended by the physician. The physician is considered an agent of the commission in determining the state insurance coverage and sovereign immunity protection applicability of ss. 284.31 and 768.28, F.S.[19]

In addition to any other required examination under law, each participant must be examined by the attending physician at the time of weigh-in. If the physician determines that a participant is physically or mentally unfit to proceed, the physician must notify any commissioner or the commission representative who must immediately cancel the match. The examination must conform to rules adopted by the commission. The result of the examination must be reported in writing signed by the physician and filed with the commission prior to completion of the weigh-in.[20]

Clinical Laboratories

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition. Clinical laboratories may be free-standing facilities, may be part of a hospital, or may be part of a private practitioner's office.[21] Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists. Clinical laboratories must be biennially licensed and inspected by the Agency for Health Care Administration to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.[22]

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[16] DEA, Office of Diversion Control, *Controlled Substance Schedules*, *available at*: http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited Feb. 5, 2013).
[17] DEA, *Questions and Answers*, *available at*: http://www.deadiversion.usdoj.gov/drugreg/faq.htm (last visited Feb. 5, 2013).
[18] Sections 893.02 and 893.05, F.S.
[19] Section 548.046, F.S.
[20] *Id.*
[21] Section 483.041, F.S.
[22] Section 483.051, F.S.

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:[23]

- Physicians
- Chiropractors
- Podiatrists
- Naturopaths
- Dentists
- Advanced registered nurse practitioners.

Results of laboratory tests must be reported directly to the requesting practitioner. The same price must be charged regardless of what type of practitioner requests the testing.

Effect of Proposed Changes

The bill revises the definition of the terms "certified optometrist" and "optometry" to authorize the administration and prescription of ocular pharmaceutical agents by a practitioner licensed pursuant to ch. 463, F.S. The bill defines "ocular pharmaceutical agents" to mean a pharmaceutical agent that is administered topically or orally for the diagnosis and treatment of ocular conditions of the human eye and its appendages. Current law only authorizes the administration and prescription of topical ocular pharmaceutical agents by certified optometrists in the practice of optometry. Numerous conforming changes are made throughout the bill to reflect this new authority.

The bill revises the Board's rule-making authority, allowing the Board to adopt rules relating to the administration and prescription of ocular pharmaceutical agents. In addition, the bill requires certified optometrists and optometric faculty certificate holders to complete certain coursework and an examination before being authorized to administer or prescribe oral ocular pharmaceutical agents. The course and subsequent examination must cover general and ocular pharmaceutical agents and the side effects of those agents. However, the bill does not require certified optometrists, who wish to administer only topical pharmaceutical agents, to complete the course and subsequent examination. For certified optometrists licensed before January 1, 1990, the course must consist of 50 contact hours and 25 of those hours are to be web-based. For certified optometrists licensed on or after January 1, 1990, the course must consist of 20 contact hours and 10 of those hours are to be web-based. The first course and examination must be available by July 1, 2013, and must be administered at least annually thereafter. The Florida Medical Association and the Florida Optometric Association are required to jointly develop and administer the course and examination and must jointly determine the site or sites for the course and examination.

The bill amends the composition of the advisory committee to require the two appointed optometrists to be certified optometrists. Additionally the advisory committee, is required to review, and provide recommendations to the Board regarding, the formulary of ocular pharmaceutical agents for administration and prescription by certified optometrists.

In addition, the bill:

- Authorizes a certified optometrist to perform any eye examination, including a dilated examination, if required or authorized under ch. 548, F.S., relating to pugilistic exhibitions, or rules adopted thereunder;
- Requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist;
- Includes certified optometrists in the definition of the term "practitioner" in s. 893.02, F.S., to regulate the prescription, administration, and dispensing of controlled substances by certified optometrists who hold a valid DEA number; and

[23] Section 483.181, F.S.

- Prohibits a certified optometrist licensed in Florida from administering or prescribing a Schedule I or Schedule II controlled substance.

The bill amends ss. 463.009 and 641.31, F.S., to update cross-references.

B. SECTION DIRECTORY:

Section 1. Amends s. 463.002, F.S., relating to definitions.
Section 2. Amends s. 463.005, F.S., relating to authority of the Board of Optometry.
Section 3. Amends s. 463.0055, F.S., relating to administration and prescription of topical ocular pharmaceutical agents; committee.
Section 4. Amends s. 463.0057, F.S., relating to optometric faculty certificate.
Section 5. Amends s. 463.006, F.S., relating to licensure and certification by examination.
Section 6. Amends s. 463.0135, F.S., relating to standards of practice.
Section 7. Amends s. 463.014, F.S., relating to certain acts prohibited.
Section 8. Amends s. 483.035, F.S., relating to clinical laboratories operated by practitioners for exclusive use; licensure and regulation.
Section 9. Amends s. 483.041, F.S., relating to definitions.
Section 10. Amends s. 483.181, F.S., relating to acceptance, collection, identification, and examination of specimens.
Section 11. Amends s. 893.02, F.S., relating to definitions.
Section 12. Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence.
Section 13. Amends s. 463.009, F.S., relating to supportive personnel.
Section 14. Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 15. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Department of Health reports that it will incur additional costs and workload to implement the provisions of the bill, but anticipates that current resources are adequate to absorb the costs and workload.[24]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[24] Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with the Health Quality Subcommittee staff.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Certified optometrists and an optometric faculty certificate holder, wanting to prescribe and administer ocular pharmaceutical agents, may incur costs associated with the coursework and examination required by the bill.[25]

Patients may experience some cost-savings if they can be treated immediately by an optometrist, without having to be referred to an ophthalmologist for treatment.[26]

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 for additional rule-making authority, which is necessary to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

It is unclear whether optometric faculty certificate holders, who do not complete the coursework and examination required to administer or prescribe oral ocular pharmaceutical agents, would still be authorized to administer or prescribe topical ocular pharmaceutical agents.

On line 120, after "administer" the words "or prescribe" should be added if the intent is to retain the prescribing authority for topical ocular pharmaceuticals provided for under current law for those who don't take a course and subsequent examination.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 7, 2013, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Defines "ocular pharmaceutical agents" to clarify the term means only those pharmaceutical agents that may be administered orally or applied topically.
- Uses the term "ocular pharmaceutical agents" consistently throughout the bill.
- Provides that if a certified optometrist does not complete a course and subsequent examination, they are only authorized to administer ocular pharmaceutical agents by topical application.
- Requires a person who is an optometric faculty certificate holder to complete a course and subsequent examination in order to administer or prescribe oral ocular pharmaceutical agents.
- Comports with the style of the definition and clarifies the application of the term "licensed practitioner" under s. 483.041, F.S., by adding "a certified optometrist licensed under."

This analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

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[25] *Id.*
[26] *Supra* Note 7.

A bill to be entitled

An act relating to the practice of optometry; amending s. 463.002, F.S.; providing a definition; authorizing a certified optometrist to administer and prescribe ocular pharmaceutical agents; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules relating to the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; requiring a certified optometrist to complete a course and examination on general and ocular pharmaceutical agents before administering or prescribing those agents; providing an exception; specifying the number of required course hours based on the date of licensure; requiring the Florida Medical Association and the Florida Optometric Association to jointly develop and administer the course and examination; revising provisions relating to the development of a formulary of ocular pharmaceutical agents; amending s. 463.0057, F.S.; prohibiting the holder of an optometric faculty certificate from administering or prescribing ocular pharmaceutical agents; amending s. 463.006, F.S.; revising provisions relating to licensure and certification of optometrists; amending s. 463.0135, F.S.; authorizing a certified optometrist to perform certain eye examinations; amending s. 463.014, F.S.; prohibiting a licensed practitioner of optometry from providing any drug for the purpose of treating a

systemic disease; amending s. 483.035, F.S.; requiring a clinical laboratory operated by a licensed practitioner of optometry to be licensed under ch. 463, F.S.; amending s. 483.041, F.S.; revising the definition of the term "licensed practitioner" to include certified optometrists; amending s. 483.181, F.S.; providing for an optometrist to accept a human specimen for examination, under certain conditions; amending s. 893.02, F.S.; redefining the term "practitioner" to include certified optometrists; amending s. 893.05, F.S.; prohibiting a certified optometrist from administering or prescribing pharmaceutical agents listed in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending ss. 463.009 and 641.31, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Paragraph (b) of subsection (3) and subsection (4) of section 463.002, Florida Statutes, are amended, subsection (5) is renumbered as subsection (6) and amended, present subsections (6) through (10) are renumbered as subsections (7) through (11), respectively, a new subsection (5) is added to that section, to read:

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

(3)

(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Ocular pharmaceutical agent" means a pharmaceutical agent that is administered topically or orally for the diagnosis and treatment of ocular conditions of the human eye and its appendages.

(6) ~~(5)~~ "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of ~~topical~~ ocular pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ~~topical~~ ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.

Section 2. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.—

(1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:

(g) Administration and prescription of ~~topical~~ ocular pharmaceutical agents.

Section 3. Section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ~~topical~~ ocular pharmaceutical agents; committee.—

(1)(a) Certified optometrists may administer and prescribe ~~topical~~ ocular pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing ~~topical~~ ocular pharmaceutical agents.

(b) Before a certified optometrist may administer or prescribe ocular pharmaceutical agents, the certified optometrist must complete a course and subsequent examination on general and ocular pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be web-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be web-based.

The first course and examination shall be presented by July 1, 2013, and shall be administered at least annually thereafter. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly determine the site or sites for the course and examination. If a certified optometrist does not complete a course and subsequent examination under this paragraph, the certified optometrist is only authorized to administer ocular pharmaceutical agents by topical application.

(2)(a) There is ~~hereby~~ created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of ~~topical~~ ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary shall consist of those ~~topical~~ ocular pharmaceutical agents which are appropriate to treat and diagnose ocular diseases and disorders and which the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule

shall become effective 60 days from the date it is filed with the Secretary of State.

(b) The formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized ~~topical~~ ocular pharmaceutical agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.

(c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

1. Does not protect the public from any significant and discernible harm or damages;

2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(d) Upon adoption of the formulary required by this section, and upon each addition, deletion, or modification to the formulary, the board shall mail a copy of the amended

formulary to each certified optometrist and to each pharmacy licensed by the state.

(3) A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for an ~~a topical~~ ocular pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 4. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.—

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section~~,~~ but may not administer or prescribe ~~topical~~ ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1)(b) and ~~s.~~ 463.006(1)(b)4. and 5.

Section 5. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

463.006 Licensure and certification by examination.—

(2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the use ~~topical application~~ and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.

(3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to

administer and prescribe ~~topical~~ ocular pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6. Subsection (10) is added to section 463.0135, Florida Statutes, to read:

463.0135 Standards of practice.—

(10) A certified optometrist is authorized to perform any eye examination, including a dilated examination, required or authorized by chapter 548 or by rules adopted to implement that chapter.

Section 7. Subsection (3) of section 463.014, Florida Statutes, is amended to read:

463.014 Certain acts prohibited.—

(3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug for the purpose of treating a systemic disease ~~systemic drugs~~ by a licensed practitioner is prohibited.

Section 8. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing,

and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 9. Subsection (7) of section 483.041, Florida Statutes, is amended to read:

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

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461; a certified optometrist licensed under chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 10. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a

specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 11. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed pursuant to chapter 463, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 12. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

893.05 Practitioners and persons administering controlled substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for

use on animals only, and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter 463 may not administer or prescribe pharmaceutical agents listed in Schedule I or Schedule II of s. 893.03.

Section 13. Section 463.009, Florida Statutes, is amended to read:

463.009 Supportive personnel.—No person other than a licensed practitioner may engage in the practice of optometry as defined in s. 463.002(6) ~~463.002(5)~~. Except as provided in this section, under no circumstances shall nonlicensed supportive personnel be delegated diagnosis or treatment duties; however, such personnel may perform data gathering, preliminary testing, prescribed visual therapy, and related duties under the direct supervision of the licensed practitioner. Nonlicensed personnel, who need not be employees of the licensed practitioner, may perform ministerial duties, tasks, and functions assigned to them by and performed under the general supervision of a licensed practitioner, including obtaining information from consumers for the purpose of making appointments for the licensed practitioner. The licensed practitioner shall be responsible for all delegated acts performed by persons under her or his direct and general supervision.

Section 14. Subsection (19) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(19) Notwithstanding any other provision of law, health maintenance policies or contracts which provide coverage,

benefits, or services as described in s. 463.002(6) ~~463.002(5)~~, shall offer to the subscriber the services of an optometrist licensed pursuant to chapter 463.

Section 15. This act shall take effect July 1, 2013.

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 Committee

Representative Caldwell offered the following:

Amendment (with title amendment)

Remove lines 49-68 and insert:

Section 1. Paragraph (b) of subsection (3) and subsection (4) of section 463.002, Florida Statutes, are amended, subsection (5) is renumbered as subsection (7) and amended, present subsection (6) through (10) are renumbered as subsections (7) through (12), respectively, new subsections (5) and (6) are added to that section, to read:

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

(3)(a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.

(b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not

a Certified Optometrist, and I am not able to prescribe ~~topical~~ ocular pharmaceutical agents."

(4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe ~~topical~~ ocular pharmaceutical agents.

(5) "Ocular pharmaceutical agent" means a pharmaceutical agent that is administered topically or orally for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques.

(6) "Surgery" means a procedure using a laser, scalpel, or needle in which human tissue is cut, burned, or vaporized.

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

Remove line 3 and insert:

s. 463.002, F.S.; providing definitions; authorizing

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 239 (2013)

Amendment No. 2

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Caldwell offered the following:

Amendment (with title amendment)

Remove lines 103-120 and insert:

(b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified optometrist must demonstrate to the department, on a format prescribed by the department, successful completion of a course and subsequent examination on general and ocular pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contract hours and 25 of those hours shall be web-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be web-based. The first course and examination shall be presented by July 1, 2013, and shall be administered at least annually thereafter. The Florida Medical Association and the Florida Optometric Association shall jointly develop and

administer a course and examination for such purpose and jointly determine the site or sites for the course and examination. A certified optometrist may not administer or prescribe pharmaceutical agents:

1. Listed in Schedule II of s. 893.03.

2. Listed in Schedule III, IV, or V, except for oral analgesics for the relief of pain due to ocular conditions of the eye and its appendages.

3. For the treatment of chronic nonmalignant pain as defined in s. 456.44(1)(e).

If a certified optometrist does not complete a course and subsequent examination under this paragraph, the certified optometrist is only authorized to administer and prescribe topical ocular pharmaceutical agents.

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

Remove line 12 and insert:

prescribing those agents; requiring a demonstration of successful completion of a course and subsequent examination; providing an exception; providing exceptions to the pharmaceutical agents a certified optometrist may administer or prescribe; providing an exception to the coursework and subsequent examination requirements;

Amendment No. 3

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 Committee

Representative Caldwell offered the following:

Amendment (with title amendment)

Remove lines 133-140 and insert:

and recommendations on such requests. The advisory opinions and recommendations must state specific findings of fact and grounds for its recommendation, and are not subject to review pursuant to ss. 120.569 and 120.57. The formulary shall consist of those ~~topical~~ ocular pharmaceutical agents that ~~which~~ are approved to treat and diagnose ocular diseases and disorders and which the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. The board is bound by the committee's advisory opinions and recommendations on oral ocular pharmaceutical agents unless competent substantial evidence is presented to the board sufficient to rebut the committee's advisory opinion and recommendation. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule

becomes ~~shall become~~ effective 60 days from the date it is filed with the Secretary of State.

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

Remove line 19 and insert:

pharmaceutical agents; providing that the committee's advisory opinions and recommendations state specific findings of fact and grounds for recommendations; providing an exception to review; providing that the board is bound by the committee's advisory opinions and recommendations unless competent substantial evidence is presented to the board to rebut; amending s. 463.0057, F.S.;

Amendment No.4

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 Committee

Representative Caldwell offered the following:

Amendment

Remove line 182 and insert:

s. 463.006(1)(b)4. and 5. If a certificateholder wishes to administer or prescribe oral ocular pharmaceutical agents, the certificateholder must also satisfy the requirements under s. 463.0055(1)(b).

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 239 (2013)

Amendment No. 5

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 Committee

Representative Caldwell offered the following:

Amendment (with title amendment)

Remove lines 198-204 and insert:

Section 6. Subsection (10) and (11) are added to section 463.0135, Florida Statutes, to read:

463.0135 Standards of practice.—

(10) A certified optometrist is authorized to perform any eye examination, including a dilated examination, required or authorized by chapter 548 or by rules adopted to implement that chapter.

(11) Co-management of postoperative care shall be conducted pursuant to a transfer of patient care letter. The patient shall be informed that either the physician who performed the surgery or the licensed practitioner will be available for emergency care throughout the postoperative period.

Amendment No. 5

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

Remove line 26 and insert:

certain eye examinations; requiring a co-management letter to transfer a patient for postoperative care; amending s. 463.014, F.S.;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 365 Pharmacy
SPONSOR(S): Health Quality Subcommittee; Hudson
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 1 N, As CS	Poche	O'Callaghan
2) Health & Human Services Committee		Poche MP	Calamas

SUMMARY ANALYSIS

A biological product is a virus, therapeutic serum, vaccine, protein, blood component, or other product used to prevent, treat, or cure a disease or condition in human beings. A biological product is made by using a living system or organism to essentially "grow" or create the product, which causes variation in composition of the biological product. This differs from the manufacture of a chemical drug, which is created by combining various chemicals in an easily replicated manner to produce the desired therapeutic effect.

A biosimilar biological product is highly similar to another biological product, known as a reference product, with minor differences in clinically inactive components. There are no clinically meaningful differences between a biosimilar biological product and its reference product that impact the safety, purity, and potency of the product. Biosimilar biological products have been approved and sold in Europe since 2006, as well as in other parts of the world. There is no biosimilar biological product market currently in the United States.

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act on March 23, 2010. The BPCIA creates a pathway for approval of biosimilar biological products by the federal Food and Drug Administration (FDA), which, if determined to be interchangeable, can be substituted for more expensive reference products and thereby lower health care costs.

House Bill 365 permits the substitution of biosimilar biological products for prescribed biological products by Florida pharmacists. Substitution is only permitted if the biological product to be substituted appears on a list developed and maintained by the FDA as biosimilar to and interchangeable with the prescribed biological product. The patient has the ability to reject substitution and request the prescribed biological product.

The bill requires a pharmacist to notify the prescribing health care provider of the substitution within a specific time frame and in a specific manner. Both the pharmacist and the prescribing health care provider are required to maintain a written record of the substitution.

The bill appears to have an undetermined, positive fiscal impact on state and local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

"Brand Name" Chemical Drugs and Generic Chemical Drugs

A "brand name" chemical drug is manufactured with simple chemical ingredients that have uniform, predictable structures which are easy to characterize and replicate. The potency of a "brand name" chemical drug is determined by a defined chemical process. A generic chemical drug has the identical active substance and biological effect as its "brand name" counterpart. A generic chemical drug differs from a "brand name" chemical drug by inactive ingredients contained in the chemical structure and the rate and extent of absorption by the human body.

The Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), established the Abbreviated New Drug Application process, creating a pathway for approval of generic medications, primarily for chemical drugs.[1] Since 1984, the federal Food and Drug Administration (FDA) has approved more than 8,000 generic drugs, which has resulted in hundreds of billions of dollars in cost savings to consumers.[2] In 2009, almost 75% of pharmaceutical prescriptions dispensed in the U.S. were generic medications.[3]

Biological Products and Biosimilar Biological Products

A biological product (biologic), in contrast to a chemical drug, is a large and complex protein, generally produced using a living system or organism.[4] It is heterogeneous and difficult to characterize. The effectiveness of a biologic is expressed in a biological system, meaning the biologic interacts with the human body, or an animal's body, to produce the desired effect. A biologic can be manufactured through a biotechnological process, derived from natural sources, or completely synthesized in a laboratory setting.[5]

A biosimilar biological product (biosimilar) has a similar, but not identical, active substance to another biologic. The biological activity of a biosimilar may vary as compared to another biologic. Because of the variable nature of a biosimilar, it is critical to identify the differences and determine which differences matter clinically. The determination of clinically meaningful differences between a biologic and its biosimilar can be exhibited through animal studies that measure toxicity, clinical studies on humans, and other scientifically accepted metrics.

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[1] The Federal Food, Drug and Cosmetic Act, s. 505(b)(2); 21 U.S.C. 355(b)(2).
[2] U.S. Dept. of Health and Human Services, Food and Drug Administration, Regulatory Information, *Fact Sheet: New "Biosimilars" User Fees Will Enhance Americans' Access to Alternatives to Biologic Drugs*, July 16, 2012, available at www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm311121.htm. (last viewed on February 14, 2013).
[3] Kozlowski, S., Woodcock, J., et al., *Developing the Nation's Biosimilar Program*, N Engl J Med 365:5, 385 (August 4, 2011).
[4] U.S. Dept. of Health and Human Services, Food and Drug Administration, Sherman, M.D., Rachel, *Biosimilar Biological Products-Biosimilar Guidance Webinar*, February 15, 2012, slide 3, available at www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm292463.pdf.
[5] Id.

In 2011, roughly 25% of the $320 billion spent on drugs in the U.S., was spent on biologics.[6] Each year, patients in the U.S. receive over 200 million vaccinations, 29 million transfusions of blood and blood components, and 1.6 million transplants of musculoskeletal tissue, all of which require the use of biologics.[7]

There is no existing market for biosimilars currently in the U.S.[8] Twelve biologics with global sales exceeding $67 billion will lose patent protection by 2020, and will be open to biosimilar competition.[9] By 2015, sales of biosimilars worldwide are expected to reach between $1.9 billion and $2.6 billion, up from $378 million in the first half of 2011.[10] The U.S. is forecast to be the largest opportunity for biosimilar sales by 2020, with a market value between $11 billion and $25 billion, which represents a 4% to 10% share of the total biologics market.[11] Biosimilars are forecast to comprise up to 50% of the off-patent biological market by 2020, with an assumed price discount between 20% and 30% when compared to biologics.[12]

The U.S. Federal Trade Commission predicts that the availability of biosimilars will significantly reduce the cost of biologics and increase their accessibility.[13]

The Biologics Price Competition and Innovation Act of 2010

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act on March 23, 2010.[14] The BPCIA amends the Public Health Service Act and other statutes to create an abbreviated licensure pathway for biologics demonstrated to be biosimilar to or interchangeable with a reference biologic.[15] The BPCIA establishes the requirements for an application for a proposed biosimilar and an application for a proposed interchangeable product.[16]

The application must include information demonstrating biosimilarity, based on data derived from, among other things, "analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components,"[17] animal studies that include an assessment of toxicity,[18] and a clinical study or studies sufficient to establish safety, purity, and potency of the biosimilar.[19] Biosimilarity means that a biologic is highly similar to the

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[6] IMS Health, *Top Therapeutic Classes by U.S. Spending-2011*, available at www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top_Therapy_Classes_by_Sales[1].pdf

[7] U.S. Dept. of Health and Human Services, Food and Drug Administration, *About FDA*, available at www.fda.gov/AboutFDA/CentersOffices/ucm193951.htm. (last viewed on Feb. 13, 2013).

[8] One product exists in the U.S. that may meet the current definition of "biosimilar" contained in the BPCIA. Omnitrope, a form of synthetic human growth hormone used to treat long-term growth failure in children and adult onset growth deficiency, and manufactured by Sandoz, was approved for sale in the U.S. under a special ruling from FDA in 2007.

[9] Genetics and Biosimilar Initiative, *US$67 billion worth of biosimilar patents expiring before 2020*, June 29, 2012 (on file with the Health Quality subcommittee staff).

[10] IMS Health, *Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape*, December 2011, page 1, available at www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Documents/Biosimilars_White_Paper.pdf.

[11] Id. at pages 3 and 6.

[12] Id. at page 6.

[13] U.S. Federal Trade Commission, *Emerging health care issues: follow-on biologic drug competition*, 2009, available at www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

[14] PPACA (Pub. L. 111-148), title VII, subtitle A, §§7001 to 7003.

[15] A reference product is an existing biological product against which another biological product is compared to determine biosimilarity and interchangeability.

[16] S. 351(k) of the PHS Act (42 U.S.C. 262(k)).

[17] 42 U.S.C. §262(k)(2)(A)(i)(I)(aa).

[18] 42 U.S.C. §262(k)(2)(A)(i)(I)(bb).

[19] 42 U.S.C. §262(k)(2)(A)(i)(I)(cc).

reference biologic, even when considering the differences in clinically inactive components, and that there are no clinically meaningful differences between the biologic and the reference biologic in terms of safety, purity, and potency.[20]

The FDA will use a totality-of-the evidence approach in reviewing biosimilar applications, meaning all available data and information submitted in support of biosimilarity and the proposed biosimilar will be evaluated before a determination is made regarding biosimilarity and interchangeability.[21] To meet the standard of interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity, and also demonstrate that the biologic can be expected to produce the same clinical result as the reference product in any given patient. In addition, an applicant must demonstrate that, if the biologic is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar and the reference product is not greater than the risk of using the reference product without an alternation or switch in products.[22]

Pending FDA Rules on Biosimilars and Interchangeability

On February 9, 2012, the FDA issued three draft guidance documents regarding biosimilars and interchangeability. The documents, referenced as *Guidance for Industry*, answered questions regarding implementation of the BPCIA[23] and detailed scientific and quality considerations to be addressed in demonstrating biosimilarity.[24] The guidance documents have not yet been finalized by the FDA.

The Federal Food, Drug, and Cosmetic Act, as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes the FDA to assess and collect fees for biosimilars from October 2012 through September 2017.[25] The FDA dedicates these fees to expediting the review process for approval of biosimilars. The FDA has determined that biosimilars represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. According to the FDA, BsUFA facilitates the development of safe and effective biosimilars for the American public.[26]

The FDA is currently meeting with sponsors of proposed biosimilars, receiving 50 requests for meetings and fulfilling 37 of those requests.[27] In addition, the FDA has approved 14 Investigative New Drug

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[20] 42 U.S.C. §262(i)(2).
[21] U.S. Dept. of Health and Human Services, Food and Drug Administration, *Biosimilars Fact Sheet: Issuance of Draft Guidances on Biosimilar Products*, available at www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm291197.htm .
[22] 42 U.S.C. §262(i)(3).
[23] U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, *Guidance for Industry, Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, February 2012, available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm259797.htm. (last viewed on February 15, 2013).
[24] U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, *Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* and *Guidance for Industry, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product*, February 2012, both documents available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm. (last viewed on February 15, 2013).
[25] Biosimilar User Fee Act of 2012, Pub. L. 112-144, title IV, ss. 401-408 (21 U.S.C. 379j-51 through 53).
[26] U.S. Dept. of Health and Human Services, Food and Drug Administration, *For Industry: Biosimilar User Fee Act (BsUFA)*, available at www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm. (last viewed on February 16, 2013).
[27] Comments of Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, at Bloomberg State of Health Care 2013 Summit, February 11, 2013 (video available at www.bloomberg.com/video/fda-sees-more-breakthrough-drugs-woodcock-says-~Obd9FUMQ7qWka0CfYq3dg.html) (last viewed on February 15, 2013).

applications (INDs) for clinical development of proposed biosimilars.[28] The FDA has also noted that they are in active discussions with many sponsors at the pre-IND stage, indicating further clinical development of biosimilars in the near future.[29] The FDA also does not expect to diverge greatly from the policies established by the European Medicines Agency for approval of biosimilars for sale in the European Union and other specific countries.[30]

Biosimilars in Europe

The European Medicines Agency (EMA) is a decentralized agency of the European Union (EU), located in London, England. It is the scientific body of the European Commission (EC).[31] The EMA's primary responsibility is the "protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use".[32]

The EMA is responsible for the scientific evaluation of applications for EU marketing authorizations for human and veterinary medicines governed by the "centralised procedure".[33] Under the "centralised procedure", pharmaceutical companies submit a single marketing-authorization application to the EMA.[34] Medicines are then approved by the EC based on the positive scientific opinion of the EMA and its expert committee, the Committee on Human Medicinal Products.[35] Once granted by the EC, a centralized marketing authorization is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway.[36] By law, a company can only market a medicine once it has received a marketing authorization.[37]

The "centralised procedure" is mandatory for:

- Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- Veterinary medicines for use as growth or yield enhancers;
- Medicines derived from biotechnology processes, such as genetic engineering;
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and
- Officially designated medicines used for rare human diseases.[38]

Biologics and biosimilars fall within the mandatory "centralised procedure" for approval and marketing within the EU and other specified European countries.

In 2003, the EMA created a new pathway for approving biosimilar medicines.[39] The central feature of the evaluation process is the comparison of the biosimilar with its reference product to show that there

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[28] Id.
[29] Id.
[30] Id.
[31] European Generic Medicines Association, *EGA FACT SHEET on generic medicines, FAQs about Biosimilar Medicines*, July 2011, available at www.egagenerics.com/index.php/biosimilar-medicines/faq-on-biosimilars. (last viewed on February 15, 2013).
[32] European Medicines Agency, *What we do*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42. (last viewed on February 15, 2013)
[33] Id.
[34] Id.
[35] *See supra*, FN 23.
[36] Id.
[37] Id.
[38] European Medicines Agency, *Central authorization of medicines*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp&mid=WC0b01ac0580028a47. (last viewed on February 15, 2013).

are no significant differences between them.[40] The EMA further explains the evaluation process to determine biosimilarity, which is very similar to the proposed pathway process in the U.S.:

> The relevant regulatory authority applies stringent criteria in their evaluation of the studies comparing the quality, safety and effectiveness of the two medicines. The studies on quality include comprehensive comparisons of the structure and biological activity of their active substances, while the studies on safety and effectiveness should show that there are no significant differences in their benefits and risks, including the risk of immune reactions.

One critical difference between the approval process established by the EMA and the proposed pathway outlined by the FDA is that the EMA does not make recommendations on whether a biosimilar can be used interchangeably with its reference product.[41] The FDA will determine interchangeability, which in turn will determine whether or not a biosimilar can be substituted for a prescription biologic by a pharmacist.

The EMA published general guidelines on biosimilars in 2005 and approved its first biosimilar in 2006.[42] As of February 2012, the EMA had approved 14 biosimilar products,[43] with reference products including filgrastim,[44] epoetin,[45] and somatropin.[46]

Pharmacist Substitution in Florida

In general, a pharmacist in Florida is required to substitute a less expensive generic medication for a prescribed brand name medication.[47] The presenter of the prescription may specifically request the brand name medication.[48] Also, the prescriber may prevent substitution by indicating the brand name medication is "medically necessary" in writing, orally, or, in the case of an electronic transmission of the prescription, by making an overt act to indicate the brand name medication is "medically necessary."[49] The pharmacist must inform the presenter of the prescription that a substitution has been made and advise the presenter that he or she may refuse the substitution and request the brand name medication.[50]

Each pharmacy is required to establish a formulary of brand name medications and generic medications which, if selected as the drug product of choice, pose no threat to patient health and safety.[51] The Board of Pharmacy and the Board of Medicine are required to establish a formulary which lists brand name medications and generic medications that are determined to be clinically different so as to be biologically and therapeutically inequivalent.[52] Substitution of the drugs included in this formulary would pose a threat to patient health and safety.[53] The boards are required to distribute

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[39] European Medicines Agency, *Questions and answers on biosimilar medicines (similar biological medicinal products)*, available at www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf. (last viewed on February 15, 2013).
[40] *See supra*, FN 38.
[41] *See supra*, FN 39.
[42] European Medicines Agency, *Guideline on similar biological medicinal products*, 2005, available at www.emea.europa.eu/pdfs/human/biosimilar/043704en.pdf .
[43] *See supra*, FN 4 at slide 23.
[44] A white blood cell booster used to reduce infection risks in persons receiving strong chemotherapy treatment.
[45] Also known as EPO, it treats anemia caused by chronic kidney disease in dialysis patients by promoting red blood cell production.
[46] Synthetic human growth hormone (hGH).
[47] S. 465.025(2), F.S.
[48] Id.
[49] Id.
[50] S. 465.025(3)(a), F.S.; *see also* Rule 64B-16-27.530, F.A.C.
[51] S. 465.025(5), F.S.; *see also* Rule 64B-16.27.520, F.A.C.
[52] S. 465.025(6), F.S.; *see also* Rule 64B-16.27.500, F.A.C.
[53] Id.

the formulary to licensed and registered pharmacies and pharmacists.[54] Each board that regulates practitioners licensed by the state to prescribe medications must incorporate the formulary into its rules.[55] No pharmacist may substitute a generic medication for a brand name medication if either medication is included in the formulary.[56]

There is no provision in Florida law regarding substitution for biosimilars.

Effect of Proposed Changes

The bill allows a pharmacist to substitute a biosimilar for a prescribed biologic if the biosimilar has been determined by the FDA to be interchangeable with the prescribed biologic and the prescribing health care provider does not express a preference against substitution in writing, orally, or electronically. The ability of a pharmacist to substitute a biosimilar for a prescription biologic is permissive; substitution of a generic chemical drug for brand name chemical drug is mandatory under Florida law.[57]

The bill requires the pharmacist to notify the person presenting the prescription that he or she has substituted a biosimilar for the prescribed biologic. The presenter has the right to reject the substitution and request the prescribed biologic. This is identical to current law regarding generic chemical drugs, which permits a presenter of a prescription for a brand name chemical drug to reject substitution and request the brand name chemical drug.

The bill requires the pharmacist, within 5 days after dispensing the substitution, to inform the prescribing health care provider that he or she substituted a biosimilar for the prescribed biologic. Notification can be made by telephone, voicemail, facsimile, e-mail, electronic medical record, or other electronic means. Both the pharmacist and the prescribing health care provider are required to retain a written record of the substitution for four years. The notification and recordkeeping requirements allow the health care provider to have an accurate record of a patient's medication history if needed to determine the source of an adverse reaction or ineffective treatment protocol. This provision would require a pharmacist to establish a communication policy with prescribing health care providers to ensure notification is made within the statutorily required time frame.

The bill directs the Board of Pharmacy to maintain a list on its website of biological products that the FDA has determined to be biosimilar to and interchangeable with other biologics. Changes to the list of biosimilar and interchangeable biologics made by the FDA would require the Board of Pharmacy to also update the list on its website.

Lastly, the bill adopts the definitions of the terms "biological product," "biosimilar," and "interchangeable" as they appear in the federal Public Health Service Act.[58]

B. SECTION DIRECTORY:

Section 1: Creates s. 465.0252, F.S., relating to substitution of interchangeable biosimilar products.
Section 2: Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

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[54] S. 465.025(6)(b), F.S.
[55] Id.
[56] Id.
[57] *See supra*, section I(A), Background, *Pharmacist Substitution in Florida*.
[58] 42 U.S.C. §262(i)(1), (2), and (3).

1. Revenues:

   None.

2. Expenditures:

   While a biosimilar market does not currently exist in the U.S., it is anticipated that once biosimilars are approved by the FDA and deemed interchangeable with prescription biologics, Medicaid and the State Group Insurance program may realize cost savings due to substitution of less expensive biosimilars for prescription biologics. The estimate of cost savings is undetermined.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   While a biosimilar market does not currently exist in the U.S., it is anticipated that once biosimilars are approved by the FDA and deemed interchangeable with prescription biologics, cities and counties that are self-insured or pay a portion of employees' prescription drug insurance coverage may realize cost savings due to substitution of less expensive biosimilars for prescription biologics. The estimate of cost savings is undetermined.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill provides a pathway to establish a market for biosimilars in Florida. Companies that manufacture biosimilars for treatment or prevention of disease or conditions will be permitted to sell such products in Florida.

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 Department of Health and the Board of Pharmacy have appropriate rule-making authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

A patient may be faced with an out-of-pocket cost to obtain a second prescribed biologic if the patient's physician rejects the substitution of the biosimilar after receiving notice of such substitution.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 19, 2013, the Health Quality Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment shortens the time period within which a pharmacist must notify a prescribing health care provider that a biosimilar has been substituted for a prescribed biologic.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to pharmacy; creating s. 465.0252, F.S.; providing definitions; providing requirements for a pharmacist to dispense a substitute biological product that is determined to be biosimilar to and interchangeable for the prescribed biological product; requiring the Board of Pharmacy to maintain a current list of interchangeable biosimilar products; providing an effective date.

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

Section 1. Section 465.0252, Florida Statutes, is created to read:

465.0252 Substitution of interchangeable biosimilar products.—

(1) As used in this section, the terms "biological product," "biosimilar," and "interchangeable" have the same meanings as defined in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(2) A pharmacist may only dispense a substitute biological product for the prescribed biological product if:

(a) The United States Food and Drug Administration has determined that the substitute biological product is biosimilar to and interchangeable for the specified indicated use of the prescribed biological product.

(b) The prescribing health care provider does not express a preference against substitution in writing, verbally, or

electronically.

(c) The pharmacist notifies the person presenting the prescription of the substitution in the same manner as provided in s. 465.025(3)(a).

(d) The pharmacist, within 5 business days after dispensing the substitute biological product in lieu of the prescribed biological product, notifies the prescribing health care provider of the substitution by facsimile, telephone, voicemail, e-mail, electronic medical record, or other electronic means.

(e) The pharmacist and the prescribing health care provider each retain a written record of the substitution for at least 4 years.

(3) The board shall maintain on its public website a current list of biological products that the United States Food and Drug Administration has determined are biosimilar and interchangeable as provided in paragraph (2)(a).

Section 2. This act shall take effect July 1, 2013.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 365 (2013)

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 Committee

Representative Hudson offered the following:

Amendment (with title amendment)

Between lines 12 and 13, insert:

Section 1. Subsection (6) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.-

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, ~~and~~ proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of

Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

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

Remove line 2 and insert:

An act relating to pharmacy; amending s. 465.019, F.S.; permitting a class II institutional pharmacy formulary to include biologics, biosimilars, and biosimilar interchangeables;

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 365 (2013)

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Hudson offered the following:

Amendment

Remove line 25 and insert:

to and interchangeable for the

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 365 (2013)

Amendment No. 3

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 Committee

Representative Hudson offered the following:

Amendment

Remove line 33 and insert:

(d) The pharmacist or the pharmacist's agent, within 5 business days after

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 365 (2013)

Amendment No. 4

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 Committee

Representative Hudson offered the following:

Amendment

Remove lines 40-41 and insert:

provider each retain a written or electronic record of the substitution for at least 2 years.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 365 (2013)

Amendment No. 5

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 Committee

Representative Hudson offered the following:

Amendment (with title amendment)

Between lines 41 and 42, insert:

A pharmacist who practices in a class II or modified class II institutional pharmacy shall comply with the notification provisions of subsections (c) and (d) by entering the substitution in the institution's written medical record system or electronic medical record system.

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

Between lines 6 and 7, insert:

providing notification requirements for a pharmacist in a class II or modified class II institutional pharmacy;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 413 Physical Therapy
SPONSOR(S): Health Quality Subcommittee; Hutson and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 536

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Holt	O'Callaghan
2) Health & Human Services Committee		Holt	Calamas

SUMMARY ANALYSIS

CS/HB 413 amends s. 486.021(11), F.S., the definition of the practice of physical therapy, to authorize a physical therapist (PT) to implement a treatment plan provided by an advanced registered nurse practitioner (ARNP). Moreover, the bill clarifies that a PT may continue to implement their own treatment plans or those provided by a practitioner of record as long as the patient's condition is within the scope of physical therapy practice and the treatment timeframe is under 21 days.

The bill makes numerous technical changes by restructuring the definition to improve organizational structure and deletes unnecessary words to improve readability.

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

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

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 works in conjunction with 22 boards and 6 councils to regulate activities of 200-plus license types in 41 health care professions and 8 types of facilities. MQA's three core business processes are the licensure of and enforcement of laws and rules governing Florida's 1,059,958 health care practitioners and facilities, as well as providing information and data to the public.[1]

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[2] 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.

Physical Therapy Practice

Physical therapy is the performance of physical therapy assessments and treatment, or prevention of any disability, injury, disease, or other health condition of human beings and rehabilitation as it relates to the use of various modalities such as electricity, exercise, massage, ultrasound, and water.[3]

Physical therapy practitioners are regulated by ch. 486, F.S., the Physical Therapy Practice Act. A physical therapy practitioner is considered either a physical therapist (PT) or a physical therapist assistant (PTA) who is licensed and who practices physical therapy.[4]

As of November 1, 2012, there are 11,596 PTs, and 6,140 PTAs who hold active, in-state licenses to practice in Florida.[5]

To be licensed as a PT, an applicant must be at least 18 years old; be of good moral character; pay $180 in fees[6]; pass the Laws and Rules Examination[7] offered by the Federation of State Boards of Physical Therapy (FSBPT) within 5 years before the date of application for licensure;[8] meet the general requirements for licensure of all health care practitioners in ch. 456, F.S.; and meet one of the following requirements:

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[1] Florida Department of Health, Division of Medical Quality Assurance, *About Medical Quality Assurance*, *available at*: http://doh.state.fl.us/mqa/wearemqa.htm (last viewed February 10, 2013).
[2] Section 456.001, F.S.
[3] Section 486.021(11), F.S.
[4] Section 486.021(7), F.S.
[5] Florida Department of Health, Division of Medical Quality Assurance, *2011-2012 MQA Annual Report*, pg. 39, *available at*: http://doh.state.fl.us/mqa/reports.htm (last viewed February 10, 2013).
[6] *See* Section 486.041, F.S., and Rule 64B17-2.001, F.A.C.
[7] A separate $25 application fee is required per Rule 64B17-2.001and Rule 64B-1.016, F.A.C., for the Laws and Rules Examination.
[8] *See* Section 486.031, F.S., and Rules 64B17-3.001, 64B17-3.002, and 64B17-3.003, F.A.C.

- Have graduated from an accredited PT training program and have passed the National Physical Therapy Examination (NPTE) for PTs offered by the FSBPT within 5 years before the date of application for licensure.
- Have graduated from a PT training program in a foreign country, have had his or her credentials deemed by the Foreign Credentialing Commission on Physical Therapy or other board-approved credentialing agency to be equivalent to those of U.S.-educated PTs and have passed the NPTE for PTs within 5 years before the date of application for licensure.
- Have passed a board-approved examination and holds an active license to practice physical therapy in another state or jurisdiction if the board determines that the standards for licensure in that state or jurisdiction are as high as those of this state.[9]

Licenses must be renewed biennially for a $75 fee.[10] Continuing education of 24 hours per biennium is also required. At least 1 hour of education must be on HIV/AIDS, and 2 hours must be on medical error prevention.[11]

Licensure requirements for PTAs are the same as those for PTs except that applicants must have graduated from an approved PTA training program, passed the NPTE for PTAs, or hold an active PTA license in another state or jurisdiction. Licensure fees and continuing education requirements are also the same.[12]

The physical therapist's professional responsibilities include:[13]

- Interpretation of the practitioner's referral.
- Delivery of the initial physical therapy assessment of the patient.
- Identification of and documentation of precautions, special problems, contraindications.
- Development of a treatment plan including the long and short term goals.
- Implementation of or directing implementation of the treatment plan.
- Delegation of appropriate tasks.
- Direction and supervision of supportive staff in a manner appropriate for the patient's individual needs.
- Reassessment of the patient in reference to goals and, when necessary, modification of the treatment plan.
- Collaboration with members of the health care team when appropriate.

A program plan, in practice referred to as a treatment plan, establishes the objectives (goals) and specific remediation techniques that a PT will use in the course of treating a patient.[14] Currently, PTs may implement a treatment plan for a patient without a written order from a practitioner of record if the recommended treatment plan is performed within a 21 day timeframe. If the treatment plan requires treatment beyond 21 days, the condition must be assessed by a practitioner of record who is required to review and sign the treatment plan.[15] Section 486.021(11), F.S., provides that a health care practitioner who is an allopathic or osteopathic physician, chiropractor, podiatrist, or dentist, that is actively engaged in practice is eligible to serve as a practitioner of record. Advanced registered nurse practitioner's (ARNP's) are not eligible to serve as a practitioner of record. However, the Nurse Practice Act authorizes ARNP's to order physical and occupational therapy.[16]

A PT is not allowed to implement any treatment plan that, in the physical therapist's judgment, is contraindicated. If the treatment plan was requested by a referring practitioner, the PT must

[9] Rule 64B17-3.003, F.A.C.
[10] Rule 64B17-2.005(1), F.A.C.
[11] Rules 64B17-8.001, and 64B17-8.002, F.A.C.
[12] Rules 64B17-4.001, 64B17-4.002, and 64B17-4.003, F.A.C.
[13] Rule 64B17-6.001, F.S.
[14] Rule 64B17-6.001, F.A.C
[15] Section 486.021, F.S.
[16] Section 464.012(4)(c)2., F.S.

immediately notify the referring practitioner that he or she is not going to follow the request and the reasons for such refusal.[17]

PTs are limited as to what treatment may be provided or what procedures may be performed for diagnosing a condition. For example, a PT may not use roentgen rays[18] and radium for diagnostic or therapeutic purposes or electricity for surgical purposes, including cauterization. In addition, a PT may not practice chiropractic medicine, including specific spinal manipulation.[19] Moreover, PTs are not authorized to implement a plan for a patient being treated in a hospital or an ambulatory surgical center licensed under ch. 395, F.S.

Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the DOH, and are regulated by the Board of Nursing.

Licensure requirements to practice professional nursing include completion of education and training requirements,[20] demonstration of passage of a department-approved examination[21], a clean criminal background screening, and payment of applicable fees.[22] Renewal is biennial and is contingent upon completion of certain continuing medical education requirements.

A nurse who holds a license to practice professional nursing may be certified as an advanced registered nurse practitioner (ARNP) under s. 464.012, F.S., if the nurse meets one or more of the following requirements:

- Completion of a post-basic education program of at least one academic year that prepares nurses for advanced or specialized practice;
- Certification by a specialty board, including boards for registered nurse anesthetists or nurse midwives; or
- Possession of a master's degree in a nursing clinical specialty area.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[23] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or a dentist.

ARNPs may carry out treatments as specified in statute, including:[24]

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Performing additional functions as may be determined by rule in accordance s. 464.003(2), F.S., which provides for such advanced or specialized nursing practices;[25] and
- Ordering diagnostic tests and physical and occupational therapy.

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[17] Rule 64B17-6.001, F.A.C.

[18] Roentgen rays can penetrate most substances and are used to investigate the integrity of certain structures, to therapeutically destroy diseased tissue, and to make radiographic images for diagnostic purposes, as in radiography and fluoroscopy. Mosby's Medical Dictionary, 8th edition, (2009).

[19] *Id.*

[20] Rule 64B9-4.003, F.A.C., provides that an Advanced Nursing Program shall be at least one year long and shall include theory in the biological, behavioral, nursing and medical sciences relevant to the area of advanced practice in addition to clinical expertise with a qualified preceptor.

[21] Section 464.008, F.S.

[22] Section 464.009, F.S., provides an alternative to licensure by examination for nurses through licensure by endorsement.

[23] Section 464.012(2), F.S.

[24] Section 464.012(3), F.S.

[25] Section 464.003(2), F.S., defines "Advanced or Specialized Nursing Practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.

In addition to the above permitted acts, ARNPs may perform other acts as permitted in statute within the specialty.[26] If it is within an established protocol, an ARNP may also diagnose behavioral problems and make treatment recommendations.[27] PTs are not expressly authorized to implement treatment plans from ARNPs.

There are 14,440 active, licensed ARNPs in Florida.[28]

Effect of Proposed Changes

The bill amends s. 486.0219(11), F.S., the definition of the practice of physical therapy, to authorize PTs to implement treatment plans provided by licensed ARNPs. Additionally, the bill clarifies that PTs may continue to implement their own treatment plans for patients or those treatment plans provided by a currently licensed and actively practicing practitioner of record[29]. As under current law, a PT will still only be able to implement a treatment plan for a patient as long as the patient's condition is within the scope of physical therapy practice and the treatment timeframe is under 21 days.

The bill makes numerous technical changes by restructuring the definition to improve organizational structure and deletes unnecessary words to improve readability.

B. SECTION DIRECTORY:

Section 1. Amends s. 486.021, F.S., relating to definitions.
Section 2. Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[26] Section 464.012(4), F.S.
[27] Section 464.012(4)(c)5, F.S.
[28] *Supra* note 5.
[29] *Supra* note 16.

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 board has sufficient authority in s. 486.025, F.S., to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 12, 2013, the Health Quality Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment restores current authority that authorizes a PT to implement his or her own treatment plans.

This analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to physical therapy; amending s. 486.021, F.S.; authorizing a physical therapist to implement physical therapy treatment plans of a specified duration which are developed by the physical therapist or provided by a practitioner of record or an advanced registered nurse practitioner; providing an effective date.

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

Section 1. Subsection (11) of section 486.021, Florida Statutes, is amended to read:

486.021 Definitions.—In this chapter, unless the context otherwise requires, the term:

(11) "Practice of physical therapy" means the performance of physical therapy assessments and the treatment of any disability, injury, disease, or other health condition of human beings, or the prevention of such disability, injury, disease, or other condition of health, and rehabilitation as related thereto by the use of the physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; water; the use of apparatus and equipment in the application of the foregoing or related thereto; the performance of tests of

neuromuscular functions as an aid to the diagnosis or treatment of any human condition; or the performance of electromyography as an aid to the diagnosis of any human condition only upon compliance with the criteria set forth by the Board of Medicine.

(a) A physical therapist may implement a plan of treatment developed by the physical therapist for a patient or provided for a patient by a practitioner of record or by an advanced registered nurse practitioner licensed under s. 464.012. The physical therapist shall refer the patient to or consult with a ~~health care~~ practitioner of record ~~licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466,~~ if the patient's condition is found to be outside the scope of physical therapy. If physical therapy treatment for a patient is required beyond 21 days for a condition not previously assessed by a practitioner of record, the physical therapist shall obtain a practitioner of record who will review and sign the plan. For purposes of this paragraph, a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466 and engaged in active practice is eligible to serve as a practitioner of record.

(b) The use of roentgen rays and radium for diagnostic and therapeutic purposes and the use of electricity for surgical purposes, including cauterization, are not ~~authorized under the term~~ "physical therapy" for purposes of ~~as used in~~ this chapter.

(c) The practice of physical therapy ~~as defined in this chapter~~ does not authorize a physical therapy practitioner to practice chiropractic medicine as defined in chapter 460, including specific spinal manipulation. For the performance of

specific chiropractic spinal manipulation, a physical therapist shall refer the patient to a health care practitioner licensed under chapter 460.

(d) ~~Nothing in~~ This subsection does not authorize ~~authorizes~~ a physical therapist to implement a plan of treatment for a patient currently being treated in a facility licensed pursuant to chapter 395.

Section 2. This act shall take effect July 1, 2013.