CS/SB 210 by **CF, Gibson**; (Similar to CS/H 0119) Licensing of Facilities that Offer Health and Human Services

CS/SB 640 by **HP, Detert**; (Similar to CS/H 0243) Vital Statistics

CS/SB 940 by **CF, Detert (CO-INTRODUCERS) Sachs**; Continuum of Care for Children

CS/SB 758 by **HP, Evers**; (Similar to H 0155) Prescription and Use of Opioid Antagonists for Emergency Treatment of Opioid Overdoses

CS/SB 1052 by **HP, Brandes**; (Compare to CS/CS/H 0269) Florida Right to Try Act

748902	A	S	RCS	AHS, Grimsley	btw L.237 - 238:	04/06 03:33 PM

CS/SB 382 by **HP, Sobel (CO-INTRODUCERS) Gaetz**; (Similar to CS/CS/H 1001) Assisted Living Facilities

CS/SB 792 by **HP, Bean**; (Similar to CS/H 0279) Pharmacy

748994	A	S	WD	AHS, Bean	btw L.47 - 48:	04/02 11:04 AM

CS/SB 904 by **HP, Bean**; (Similar to CS/CS/H 1039) Home Health Services

SB 996 by **Richter**; (Identical to H 1305) Home Medical Equipment

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

APPROPRIATIONS SUBCOMMITTEE ON HEALTH AND HUMAN SERVICES
Senator Garcia, Chair
Senator Smith, Vice Chair

MEETING DATE: Thursday, April 2, 2015
TIME: 9:00 —11:00 a.m.
PLACE: *James E. "Jim" King, Jr. Committee Room,* 401 Senate Office Building

MEMBERS: Senator Garcia, Chair; Senator Smith, Vice Chair; Senators Abruzzo, Bean, Benacquisto, Grimsley, Richter, and Sobel

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**CS/SB 210** Children, Families, and Elder Affairs / Gibson (Similar CS/H 119)	Licensing of Facilities that Offer Health and Human Services; Requiring a family day care home to conspicuously display its license or registration in the common area of the home, to provide proof of a written plan that identifies a designated substitute for the operator, and to provide proof of screening and background checks for certain individuals; prohibiting certain persons from advertising a child care facility, a family day care home, or a large family child care home without including the facility's or home's license number, registration number, or exemption number in such advertisement; providing penalties, etc. CF 03/05/2015 Fav/CS AHS 04/02/2015 Favorable AP	Favorable Yeas 8 Nays 0
2	**CS/SB 640** Health Policy / Detert (Similar CS/H 243)	Vital Statistics; Authorizing the Department of Health to produce and maintain paper death certificates and fetal death certificates and issue burial-transit permits; requiring electronic filing of death and fetal death certificates with the department or local registrar on a prescribed form; authorizing the department, rather than the local registrar, to grant an extension of time for providing certain information regarding a death or a fetal death; requiring the department to electronically notify the United States Social Security Administration of deaths in the state, etc. HP 03/10/2015 Fav/CS AHS 04/02/2015 Favorable FP	Favorable Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
3	**CS/SB 940** Children, Families, and Elder Affairs / Detert	Continuum of Care for Children; Removing a requirement that the Department of Children and Families submit a report annually to the Legislature on the placement of children in licensed residential group care; creating the Continuum of Care Advisory Council within the department for specified purposes; authorizing the advisory council to work with certain individuals and providing limitations on the involvement of those individuals; requiring that the advisory council have access to specified information; prohibiting certain data from including information that would identify specific individuals, etc. CF 03/12/2015 Fav/CS AHS 04/02/2015 Favorable AP	Favorable Yeas 7 Nays 0
4	**CS/SB 758** Health Policy / Evers (Similar H 155, CS/H 751)	Prescription and Use of Opioid Antagonists for Emergency Treatment of Opioid Overdoses; Citing this act as the "Florida Opioid Overdose Prevention Act"; providing the purposes of the act; providing for the prescribing of opioid antagonists to, and the use of them by, patients and caregivers who have received emergency overdose treatment information; providing for the prescribing of opioid antagonists to, and the use of them by, first responders; providing immunities from liability. etc. HP 03/04/2015 Fav/CS AHS 04/02/2015 Favorable AP	Favorable Yeas 7 Nays 0
5	**CS/SB 1052** Health Policy / Brandes (Compare CS/CS/H 269, Link S 1626)	Florida Right to Try Act; Citing this act as the "Florida Right to Try Act"; authorizing a manufacturer of an investigational drug, biological product, or device to make such drug, product, or device available to certain eligible patients with a terminal illness without charge or for a specified cost; authorizing hospital personnel, nursing home facility staff, and home health agency personnel, respectively, to withhold or withdraw cardiopulmonary resuscitation if an individual has a Physician Order for Life-Sustaining Treatment (POLST); authorizing a health care surrogate to provide written consent for a POLST, etc. HP 03/17/2015 Fav/CS AHS 04/02/2015 Fav/CS FP	Fav/CS Yeas 8 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
6	**CS/SB 382** Health Policy / Sobel (Similar CS/H 1001, Compare CS/CS/H 293, S 654, S 7018)	Assisted Living Facilities; Providing that Medicaid managed care plans are responsible for mental health residents enrolled in Medicaid; specifying that managing entities under contract with the Department of Children and Families are responsible for mental health residents who are not enrolled in a Medicaid managed care plan; providing notice requirements for informing facility residents that the name and identity of the resident and complainant in any complaint made to the State Long-Term Care Ombudsman Program or a local long-term care ombudsman council is confidential and that retaliatory action may not be taken against a resident for presenting grievances or for exercising any other resident right, etc. HP 02/03/2015 Fav/CS AHS 04/02/2015 Favorable AP	Favorable Yeas 7 Nays 0
7	**CS/SB 792** Health Policy / Bean (Similar CS/H 279)	Pharmacy; Authorizing a registered intern under the supervision of a pharmacist to administer specified vaccines to an adult; revising which vaccines may be administered by a pharmacist or a registered intern under the supervision of a pharmacist, etc. HP 03/10/2015 Fav/CS AHS 04/02/2015 Favorable FP	Favorable Yeas 7 Nays 0
8	**CS/SB 904** Health Policy / Bean (Similar CS/CS/H 1039)	Home Health Services; Allowing home health agencies to operate related offices inside of the main office's geographic service area without an additional license; providing for the licensure of more than one nurse registry operational site within the same geographic service area; authorizing a licensed nurse registry to operate a satellite office; requiring a nurse registry operational site to keep all original records; requiring a nurse registry to provide notice and certain evidence before it relocates an operational site or opens a satellite office, etc. HP 03/17/2015 Fav/CS AHS 04/02/2015 Favorable FP	Favorable Yeas 7 Nays 0
9	**SB 996** Richter (Identical H 1305)	Home Medical Equipment; Exempting allopathic, osteopathic, and chiropractic physicians who sell or rent electrostimulation medical equipment and supplies to their patients in the course of their practice from licensure as home medical equipment providers, etc. HP 03/10/2015 Favorable AHS 04/02/2015 Favorable FP	Favorable Yeas 7 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 210
INTRODUCER:	Children, Families, and Elder Affairs Committee and Senator Gibson
SUBJECT:	Licensing of Facilities that Offer Health and Human Services
DATE:	April 1, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Crosier	Hendon	CF	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 210 revises regulation of child care services and the settings for those services. The bill creates a definition of "advertise" relating to child care services and revises the definition of "family day care home."

The bill requires a family day care home to conspicuously display its license or registration in the common area of the home. A large family child care home is required to permanently post its license in a conspicuous location visible to parents, guardians, and the Department of Children and Families (DCF).

Family day care homes subject to registration with the DCF must provide proof of a written plan to identity a competent adult who has met statutory screening and training requirements and serves as a designated substitute for the operator of the home in an emergency. Additionally, family day care homes subject to registration must provide proof of screening and background checks for the operator, household members, and the designated substitute.

Under the bill, certain restrictions on the advertising of child care facilities which are currently applied to licensed or registered facilities, family day care homes, and large family child care homes, are also applied to facilities that are exempt from licensure under s. 402.316, F.S.

The bill's fiscal impact is indeterminate.

The effective date of the bill is July 1, 2015.

II. Present Situation:

Child care can be provided in many different settings in exchange for payment. There are also settings that allow for the provision of child care services without payment, such as public and nonpublic schools, summer camps with children as full-time residents, summer day camps, Bible schools, and care offered at a public lodging establishment solely for guests of the public lodging establishment. Statutory provisions governing child care and child care facilities are found in ss. 402.301-402.319, F.S.

According to the U.S. Department of Health & Human Services, in 2011, licenses were issued to approximately 6,750 child care facilities, 3,327 family child care homes, and 412 group child care homes in Florida.[1] The definition of "child care" is the care, protection, and supervision of a child for a period of less than 24 hours a day on a regular basis that supplements parental care, enrichment, and health supervision for the child, in accordance with the child's needs, in exchange for a payment, fee, or grant.[2]

Types of Facilities

"Child care facility" is defined as a child care center or child care arrangement for providing child care for more than five children unrelated to the operator in exchange for a payment, fee, or grant for any of the children receiving care, regardless of where the facility is operated and whether or not it is operated for profit.[3] The terms "child care center" and "child care arrangement" are not defined, and the statutory definition of "child care facility" does not specify whether a home or residence may qualify as a child care facility. Child care facilities are required to be licensed or registered, subject to annual renewal,[4] except for those exempted from licensure and registration under s. 402.316, F.S.

The bill deals with child care facilities and the following types of "homes:"

- Family day care homes: A family day care home is an occupied residence in which child care is regularly provided for children from at least two unrelated families and which receives a payment, fee, or grant for any of the children receiving care, regardless of whether or not it is operated for profit. A family day care home is restricted to providing care for a specified capacity of children depending on their ages.[5] A family day care home is required to obtain a license from the Department of Children and Families (DCF) only if the home is required to be licensed by the county in which the home is situated. Homes that are not required to be licensed are required to register annually with the DCF and provide certain information, including proof of screening and background checks.[6] However, the statute does not identify who is subject to the screenings or background checks.

[1] U.S. Department of Health & Human Services, *Administration for Children, available at* https://childcare.gov/resource/number-licensed-child-care-facilities-2011 (follow attachment Number of Child Care Facilities in 2011) (last visited Feb. 24, 2015).
[2] Section 402.302(1), F.S.
[3] Section 402.302(2), F.S.
[4] Section 402.308(1), F.S.
[5] Section 402.302(8), F.S.
[6] Section 402.313(1), F.S.

- Large family child care homes: A large family child care home is an occupied residence in which child care is regularly provided for children from at least two unrelated families, which receives a payment, fee, or grant for any of the children receiving care, regardless of whether or not it is operated for profit, and which has at least two full-time child care personnel on the premises during the hours of operation, one of whom must be the owner or an occupant of the residence. In order to become a large family child care home, a home must first have operated as a licensed family day care home for two years, with an operator who has had a child development associate credential or its equivalent for one year. A large family child care home is restricted to providing care for a specified capacity of children depending on their ages,[7] and is required to obtain licensure from the DCF.[8]

Licensure and Registration Fees

The DCF must collect a fee for any license it issues for a child care facility, family day care home, or large family child care home.[9] The fee for a child care facility licensed under s. 402.305, F.S., is $1 per child based on the licensed capacity of the facility, with a minimum fee of $25 per facility and a maximum fee of $100 per facility. The fee is $25 for a family day care home subject to registration, and the fee is $50 for a family day care home subject to licensure. The fee is $60 for a licensed large family child care home.

Restrictions on Advertising

Section 402.318, F.S., provides that a person[10] is prohibited from advertising a child care facility, a family day care home, or a large family child care home unless the advertisement includes the state or local agency license number or registration number of the facility or home. A violation of this provision is a misdemeanor of the first degree, punishable as provided in ss. 775.082 or 775.083, F.S.[11]

Exemptions

Section 402.316, F.S., provides that certain child care facilities are exempt from ss. 402.301-402.319, F.S., except for the requirements regarding screening of child care personnel.[12] An exempt facility is a child care facility that is an integral part of a church school or parochial school conducting regularly scheduled classes, courses of study, or educational programs accredited by, or by a member of, an organization that publishes and requires compliance with its standards for health, safety, and sanitation.

[7] Section 402.302(11), F.S.
[8] Section 402.3131(1), F.S.
[9] Section 402.315(3), F.S.
[10] Section 402.318, F.S., specifies that "person" is defined the same as in s. 1.01(3), F.S., which provides that "person" includes individuals, children, firms, associations, joint adventures, partnerships, estates, trusts, business trusts, syndicates, fiduciaries, corporations, and all other groups or combinations.
[11] Section 775.082, F.S., provides that a person convicted of a misdemeanor of the first degree may be sentenced to a term of imprisonment not exceeding one year. Section 775.083(1)(d), F.S., provides that a person convicted of a misdemeanor of the first degree may be sentenced to pay a fine not to exceed $1,000, in addition to any punishment described in s. 775.082, F.S.
[12] Section 402.305(2)(a), F.S., provides minimum standards regarding child care personnel for licensed child care facilities, including good moral character based upon screening. The required screening must be conducted using level 2 standards as provided in ch. 435, F.S.

III. Effect of Proposed Changes:

Section 1 amends s. 402.302, F.S., relating to definitions used in ch. 402, F.S., to add a new definition and revise an existing definition.

The definition of "advertise" in relation to child care services is created under s. 402.302(1), F.S. Under the bill, "advertise" means to market child care services through any means, including, but not limited to, online message boards, motor vehicle signs, newspaper advertisements, roadside signs, flyers and posters, and radio and television announcements.

The bill also amends the definition of "family day care home" under s. 402.302(9), F.S., by creating a multi-faceted test for meeting the definition. Under the bill, the stipulation in current law that a family day care home is a residence that provides "child care" under certain conditions is replaced with the stipulation that a family day care home is a residence that provides "care, protection, and supervision of a child, for a period of less than 24 hours a day on a regular basis, which supplements parental care, enrichment, and health supervision for the child, in accordance with his or her individual needs" under certain conditions. If a residence satisfies those conditions, it must also engage in either of the following activities in order to meet the definition:

- Receive a payment, fee, or grant for any of the children receiving care, regardless of profit; or
- Advertise the availability of its services, regardless of whether it receives a payment, fee, or grant for any of the children receiving care and regardless of profit.

Under the bill's definition of "family day care home," it is possible for a residence to not be considered a family day care home unless and until it begins advertising, at which point it will become a family day care home without making any other changes to its services or operations.

Section 402.302, F.S., provides four definitions of facilities and homes relating to the provision of child care services. Under the bill, only the definition of "family day care home" contains a provision under which a facility or home may meet the definition depending on whether it advertises its services.

Section 2 amends s. 402.313(1), F.S., to require that each licensed or registered family day care home must conspicuously display its license or registration in the common area of the home. Under the bill, a family day care home that is required to register must provide – in addition to the currently required information – proof of a written plan to identify a competent adult who has met the DCF's screening and training requirements to serve as a designated substitute for the operator of the home in an emergency. The bill also specifies that the proof of screening and background checks required of family day care homes in the registration process must pertain to the operator, each household member, and the designated substitute.

Section 3 amends s. 402.3131, F.S., to require a large family child care home to permanently post its license in a conspicuous location that is visible by all parents and guardians and the DCF.

Section 4 amends s. 402.318, F.S., to provide that a person[13] advertising a child care facility that is exempt under s. 402.316, F.S., from the licensure requirements of ss. 402.301-402.319, F.S., must include the facility's "exemption number" within the advertisement. Under the bill, this restriction is added to similar restrictions on licensed or registered child care facilities, and violation of these restrictions continues to be a misdemeanor of the first degree, punishable as provided in ss. 775.082 or 775.083, F.S.[14]

Section 5 amends s. 402.317, F.S., to conform cross-references.

Section 6 amends s. 1002.88, F.S., to conform cross-references.

Section 7 of the bill provides an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Under CS/SB 210, a family day care home not subject to licensure may incur the costs of screening and background checks for the operator, each household member, and the designated substitute, if the home is not already conducting the screenings.

C. Government Sector Impact:

State Government

The Department of Children and Families advises that some unknown number of residences may currently be operating illegally as family day care homes by receiving

[13] *Supra*, note 10.
[14] *Supra*, note 11.

payment for child care services without becoming licensed or registered.[15] Under the bill, if such residences publicize their services in ways that meet the bill's definition of "advertise," those residences might be compelled to become licensed or registered. Such an increase in licenses or registrations would positively impact DCF revenue due to the receipt of formerly uncollected licensure and registration fees, and the DCF may also experience an increase in workload demands. The extent of these potential impacts is indeterminate.

Local Government

Counties that license family day care homes could see an increase in the number of homes licensed and licensure fees collected under the bill. The impact is indeterminate.

VI. Technical Deficiencies:

Section 4 of the bill contains two notable technical issues relating to the advertising of child care facilities that are exempt from certain regulatory provisions:

- Under current law, certain child care facilities are exempt from the regulatory provisions of ss. 402.301-402.319, F.S., except for requirements regarding the screening of child care personnel.[16] Section 4 of the bill, however, creates a requirement in s. 402.318, F.S., pertaining to a person who advertises an exempt child care facility. In this way, because a child care facility is included in the definition of "person,"[17] the bill seeks to create a regulatory requirement for exempt facilities within a portion of the Florida Statutes from which those facilities are expressly exempted. It is unclear how this conflict created under the bill would be resolved.
- Section 4 of the bill seeks to prohibit a person from advertising a child care facility that is exempt from licensing requirements unless the facility's "exemption number" is included in the advertisement. However, there is no provision for an exempt facility to be issued an "exemption number," in current law or in the bill. An exempt facility is not statutorily required to notify the DCF that it is operating under the exemption. The DCF reports that some exempt facilities have voluntarily provided notification that they are operating under the exemption, and, under those conditions, the DCF has issued exemption numbers on its own volition. However, the DCF is neither required nor authorized by law to do so. Section 4 of the bill requires that before an exempt facility may legally advertise, the facility must (1) notify the DCF that it is operating under the exemption and (2) be granted an exemption number that the DCF is neither required nor authorized by law to issue. Under the bill, these regulatory requirements on exempt facilities pertain only to those facilities that choose to advertise, and exempt facilities that choose not to advertise are not affected.

VII. Related Issues:

Under the bill's definition of "family day care home" and the definition's reliance on whether a residence advertises the availability of its services, the parameters under which a residence will

[15] Department of Children and Families, *2015 Agency Legislative Bill Analysis, CS/SB 210,* March 10, 2015, on file with staff of the Senate Appropriations Subcommittee on Health and Human Services.
[16] *See* s. 402.316, F.S.
[17] *Supra,* note 10.

be considered one that "advertises" are unclear. For example, a residence might run an advertisement on the website of a local newspaper or on a billboard and therefore be considered a residence that "advertises the availability of its services." However, if the advertisement is displayed on the website or billboard for only a certain period of time, it is unclear whether the residence will cease to be considered a residence that "advertises the availability of its services" after the advertisement is no longer displayed.

Also, under the bill's definition of "family day care home," a residence advertises the availability of its services only if the residence itself engages in activity that meets the definition of "advertise." If a party other than the residence markets the residence's child care services on an online message board, thereby advertising those services as defined in the bill, such marketing might not cause the residence itself to be considered a residence that advertises the availability of its services.

The bill requires proof of screening and background checks for the operator, each household member, and the designated substitute for family day care homes that are required to register with the DCF. However, the bill does not include a definition of "household member." Section 402.3131(2), F.S., provides a definition of "child care personnel" required to be screened for large family day care homes which includes specified household members. Including the same or similar stipulations for household members required to be screened for registered family day care homes may reduce confusion about who is subject to the screenings.

VIII. Statutes Affected:

This bill substantially amends sections 402.302, 402.313, 402.3131, 402.317, 402.318 and 1002.88 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Children, Families, & Elder Affairs on March 5, 2015:
The CS:

- Provides a definition of "advertising" relating to the provision of child care services;
- Revises the definition of "family day care home;"
- Removes the underlying bill's provisions to revise the licensure and registration fees under s. 402.315, F.S.; and
- Conforms cross-references found in ss. 402.317 and 1002.88, F.S.

B. Amendments:

None.

By the Committee on Children, Families, and Elder Affairs; and Senator Gibson

586-01952-15 2015210c1

A bill to be entitled

An act relating to the licensing of facilities that offer health and human services; amending s. 402.302, F.S.; defining the term "advertise"; redefining the term "family day care home" to include homes that advertise the availability of services whether or not they receive a payment, fee, or grant for any of the children receiving care and whether or not they are operated for profit; amending s. 402.313, F.S.; requiring a family day care home to conspicuously display its license or registration in the common area of the home, to provide proof of a written plan that identifies a designated substitute for the operator, and to provide proof of screening and background checks for certain individuals; amending s. 402.3131, F.S.; requiring a large family child care home to permanently post its license in a conspicuous location that is visible by all parents and guardians and the Department of Children and Families; amending s. 402.318, F.S.; prohibiting certain persons from advertising a child care facility, a family day care home, or a large family child care home without including the facility's or home's license number, registration number, or exemption number in such advertisement; providing penalties; amending ss. 402.317 and 1002.88, F.S.; conforming cross-references; providing an effective date.

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

586-01952-15 2015210c1

Section 1. Present subsections (1) through (7) and (9) through (18) of section 402.302, Florida Statutes, are redesignated as subsections (2) through (8) and (10) through (19), respectively, present subsection (8) is amended, and a new subsection (1) is added to that section, to read:

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

(1) "Advertise" means to market child care services through any means, including, but not limited to, online message boards, motor vehicle signs, newspaper advertisements, roadside signs, flyers and posters, and radio and television announcements.

(9)~~(8)~~ "Family day care home" means an occupied residence in which care, protection, and supervision of a child, for a period of less than 24 hours a day on a regular basis, which supplements parental care, enrichment, and health supervision for the child, in accordance with his or her individual needs, ~~child care~~ is regularly provided for children from at least two unrelated families and which either receives a payment, fee, or grant for any of the children receiving care, whether or not operated for profit, or advertises the availability of its services, whether or not it receives a payment, fee, or grant for any of the children receiving care, and whether or not operated for profit. Household children under 13 years of age, when on the premises of the family day care home or on a field trip with children enrolled in child care, shall be included in the overall capacity of the licensed home. A family day care home shall be allowed to provide care for one of the following groups of children, which shall include household children under 13 years of age:

(a) A maximum of four children from birth to 12 months of age.

(b) A maximum of three children from birth to 12 months of age, and other children, for a maximum total of six children.

(c) A maximum of six preschool children if all are older than 12 months of age.

(d) A maximum of 10 children if no more than 5 are preschool age and, of those 5, no more than 2 are under 12 months of age.

Section 2. Subsection (1) of section 402.313, Florida Statutes, is amended to read:

402.313 Family day care homes.—

(1) A family day care home must ~~homes shall~~ be licensed under this section ~~act~~ if it is ~~they are~~ presently being licensed under an existing county licensing ordinance or if the board of county commissioners passes a resolution that family day care homes be licensed. Each licensed or registered family day care home must conspicuously display its license or registration in the common area of the home.

(a) If not subject to license, a family day care home must ~~homes shall~~ register annually with the department and provide~~,~~ ~~providing~~ the following information:

1. The name and address of the home.

2. The name of the operator.

3. The number of children served.

4. Proof of a written plan to identify a ~~provide at least one other~~ competent adult who has met the screening and training requirements of the department to serve as a designated substitute ~~to be available to substitute~~ for the operator in an

emergency. This plan must ~~shall~~ include the name, address, and telephone number of the designated substitute.

5. Proof of screening and background checks for the operator, each household member, and the designated substitute.

6. Proof of successful completion of the 30-hour training course, as evidenced by passage of a competency examination, which must ~~shall~~ include:

a. State and local rules and regulations that govern child care.

b. Health, safety, and nutrition.

c. Identifying and reporting child abuse and neglect.

d. Child development, including typical and atypical language development; and cognitive, motor, social, and self-help skills development.

e. Observation of developmental behaviors, including using a checklist or other similar observation tools and techniques to determine a child's developmental level.

f. Specialized areas, including early literacy and language development of children from birth to 5 years of age, as determined by the department, for owner-operators of family day care homes.

7. Proof that immunization records are kept current.

8. Proof of completion of the required continuing education units or clock hours.

(b) A family day care home may volunteer to be licensed ~~under this act~~.

(c) The department may provide technical assistance to counties and family day care home providers to enable counties and family day care providers to achieve compliance with family

day care homes standards.

Section 3. Subsection (1) of section 402.3131, Florida Statutes, is amended to read:

402.3131 Large family child care homes.—

(1) A large family child care home must ~~homes shall~~ be licensed under this section and permanently post its license in a conspicuous location that is visible by all parents and guardians and the department.

(a) A licensed family day care home must first have operated for a minimum of 2 consecutive years, with an operator who has had a child development associate credential or its equivalent for 1 year, before seeking licensure as a large family child care home.

(b) The department may provide technical assistance to counties and family day care home providers to enable the counties and providers to achieve compliance with minimum standards for large family child care homes.

Section 4. Section 402.318, Florida Statutes, is amended to read:

402.318 Advertisement.—A person, as defined in s. 1.01 ~~s. 1.01(3)~~, may not advertise a child care facility as defined in s. 402.302, a child care facility that is exempt from licensing requirements pursuant to s. 402.316, a family day care home as defined in s. 402.302, or a large family child care home as defined in s. 402.302 without including within such advertisement the state or local agency license number, exemption number, or registration number of the ~~such~~ facility or home. A person who violates ~~Violation of~~ this section commits ~~is~~ a misdemeanor of the first degree, punishable as provided in s.

775.082 or s. 775.083.

Section 5. Section 402.317, Florida Statutes, is amended to read:

402.317 Prolonged child care.—Notwithstanding the time restriction specified in s. 402.302(2) ~~402.302(1)~~, child care may be provided for 24 hours or longer for a child whose parent or legal guardian works a shift of 24 hours or more. The requirement that a parent or legal guardian work a shift of 24 hours or more must be certified in writing by the employer, and the written certification shall be maintained in the facility by the child care provider and made available to the licensing agency. The time that a child remains in child care, however, may not exceed 72 consecutive hours in any 7-day period. During a declared state of emergency, the child care licensing agency may temporarily waive the time limitations provided in this section.

Section 6. Paragraph (d) of subsection (1) of section 1002.88, Florida Statutes, is amended to read:

1002.88 School readiness program provider standards; eligibility to deliver the school readiness program.—

(1) To be eligible to deliver the school readiness program, a school readiness program provider must:

(d) Provide an appropriate staff-to-children ratio, pursuant to s. 402.305(4) or s. 402.302(9) ~~s. 402.302(8)~~ or s. 402.302(12) ~~(11)~~, as applicable, and as verified pursuant to s. 402.311.

Section 7. This act shall take effect July 1, 2015.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 11, 2015

I respectfully request that **Senate Bill #640**, relating to Vital Statistics, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Nancy C. Detert
Florida Senate, District 28

File signed original with committee office

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 640
INTRODUCER:	Health Policy Committee and Senator Detert
SUBJECT:	Vital Statistics
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 640 amends several sections of ch. 382, F.S., to facilitate the electronic generation and filing of burial-transit permits and death certificates with the Department of Health through the electronic death registration system.

The bill could have a positive fiscal impact on county health departments.

The bill has an effective date of July 1, 2015.

II. Present Situation:

Vital Statistics in Florida

The Bureau of Vital Statistics (BVS), housed within the Department of Health (DOH) and under the direction of a state registrar, is responsible for the uniform and efficient registration, completion, storage, and preservation of all vital records in the state.[1] The registration of birth, death, and fetal death records is both a state and local function. Each local registration district is coextensive with the district for that county health department, and the county health department's director or administrator traditionally serves as the local registrar for that county or

[1] Section 382.003, F.S.

those counties.[2] The registration of death certificates is the responsibility of the funeral director or direct disposer[3] who first assumes custody of the decedent.[4]

Subregistrars

In addition to the local registrar, the state registrar may also appoint one or more subregistrars for each licensed funeral home or registered direct disposal establishment. In order to be appointed as a subregistrar, a licensed funeral director or registered direct disposer must be a notary public, attend a training class, and sign an acceptance form. Subregistrars have the authority to issue burial-transit permits and should review all death records to prevent errors and omissions and to accept or reject records accordingly.[5]

The Electronic Death Registration System

For most deaths, death records are filed with the Electronic Death Registration System (EDRS) which is an online, electronic filing and storage system for death records including death certificates, burial-transit permits, and medical information related to the death. The EDRS is designed to allow the Florida funeral directors to electronically enter the demographic information on a decedent and send that record to the certifying physician who completes the record and sends it to the EDRS for recording.[6]

In 2014, 99.6 percent of the 187,856 death certificates were filed online through the EDRS.[7] However, fetal death certificates are not filed through the EDRS and a few funeral establishments still file hard copy death records with the local registrar in the district where the death occurred.[8] Such paper records are sent to the DOH by the local registrar, reviewed for errors and omissions, keyed into the EDRS, and scanned for archival storage.

Burial-Transit Permits

The funeral director or direct disposer who first assumes custody of a decedent must obtain a burial-transit permit within five days after death or before final disposition of the body.[9] A permit is either generated by the EDRS or produced by a local registrar or subregistrar. To obtain the permit when paper death records were filed, the funeral director or direct disposer must complete and sign the application for burial transit permit and present it to either the local registrar of the county in which the death occurred or to a subregistrar. A funeral director or direct disposer cannot issue a burial transit permit to himself and the permit must be filed with

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[2] Bureau of Vital Statistics, *Vital Records Registration Handbook*, p. 8 (December 2012) *available at* http://www.floridahealth.gov/certificates/certificates/EDRS/_documents/HB2012Final.pdf, (last visited on Mar. 5, 2015).
[3] A direct disposer is someone who is in charge of the final disposition of a body without funeral services, burial services, memorial services, visitation services, or viewings. See s. 497.601(2), F.S.
[4] Supra note 2, at 59.
[5] Supra note 2, at 63.
[6] Id. p. 60.
[7] Florida House of Representatives, *CS/HB 243 Staff Analysis*, p. 3, *available at* http://www.flsenate.gov/Session/Bill/2015/0243/Analyses/h0243c.HHSC.PDF, (last visited on Mar. 5, 2015).
[8] Supra note 2, at 7.
[9] Section 382.006(1), F.S.

the local registrar within 10 days of final disposition. Burial-transit permits are retained by the local registrar for three years after they are filed.[10]

III. Effect of Proposed Changes:

The bill amends several sections of ch. 382, F.S., to allow for the electronic generation and filing of burial-transit permits and death certificates with the DOH through the EDRS.

The bill authorizes the DOH to assume responsibility for death certificates and burial-transit permits in order to use the EDRS.

- The bill defines "burial-transit permit," as a permit issued by the DOH that authorizes the final disposition of a dead body and requires the funeral director who first assumes custody of a dead body or fetus to provide a manually produced or electronic burial-transit permit from the EDRS to the person in charge of final disposition;
- The bill removes language requiring the local registrar to keep burial-transit permits for three years;
- The bill makes DOH-appointed subregistrars, rather than the local registrar, responsible for producing and maintaining paper death certificates and burial-transit permits and allows the DOH to adopt rules to implement these changes;
- The bill requires all certificates of death or fetal death to be filed electronically with the EDRS and makes the funeral director in charge responsible for filing such certificates with the DOH; however, such certificates may still be filed with the local registrar on a form prescribed by the DOH; and
- If a funeral director is unable to provide the medical certification of cause of death within 72 hours, the bill allows the DOH, rather than the local registrar, to grant the funeral director an extension of time.

The bill amends several provisions in order to facilitate the transition from paper death records to electronic records.

- The bill removes requirements necessary when submitting an application for a burial-transit permit including the funeral director's signature, license number, and attestation that he or she has contacted the medical examiner's office to ensure that the medical examiner will be providing medical certification of the cause of death;
- The bill removes a provision allowing aliases to be written on the backs of paper death certificates;
- The bill requires that the Social Security Administration be notified electronically of deaths through the EDRS; and
- The bill allows any person in charge of a premises where final dispositions are made to use the burial-transit permit on file to satisfy record keeping requirements for all deceased persons disposed of under his or her charge. When disposing of a dead body in a cemetery with no person in charge, the funeral director must enter the date of final disposition, mark the burial-transit permit with "no person in charge," and keep it on file for at least three years after final disposition.

[10] See supra note 2, at 64 and ss. 382.006 and 382.007, F.S.

The bill replaces "next of kin" with "legally authorized person," as defined in the Funeral, Cemetery, and Consumer Services Act. By this change, the person completing a death certificate may acquire personal information from any of the following persons:

- The decedent, if directions are provided on a will;
- The person designated by the decedent on the United States Department of Defense Record of Emergency Data, if the decedent died while in military service;
- The surviving spouse, unless the spouse has been arrested for committing an act of violence against the decedent;
- A son or daughter who is 18 years of age or older;
- A parent;
- A brother or sister who is 18 years of age or older;
- A grandparent; or
- Any person in the next degree of kinship.

The bill also makes numerous clarifying and technical changes such as: using the term "disposition," or "final disposition," in place of more specific types of disposition; adding "entombment" to the definition of "final disposition;" and correcting cross references and conforming other provisions as necessary due to changes made in the bill.

The bill has an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Under CS/SB 640, county health departments may see a positive fiscal impact by not having to print and store paper burial-transit permits.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 382.002, 382.003, 382.006, 382.007, 382.008, 382.0085, 382.011, and 382.0135 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 10, 2015:
The CS allows funeral directors to provide manually produced, as well as electronic, burial-transit permits, to the person in charge of final disposition of a dead body or fetus.

B. Amendments:

None.

By the Committee on Health Policy; and Senator Detert

588-02131-15 2015640c1

A bill to be entitled

An act relating to vital statistics; amending s. 382.002, F.S.; providing and revising definitions; amending s. 382.003, F.S.; authorizing the Department of Health to produce and maintain paper death certificates and fetal death certificates and issue burial-transit permits; amending s. 382.006, F.S.; requiring a funeral director to provide burial-transit permits to certain persons; assigning responsibility for manually filed paper death records to the subregistrar; authorizing the department to adopt rules; amending s. 382.007, F.S.; revising provisions relating to records of final dispositions of dead bodies; requiring maintenance of records for a specified period; amending s. 382.008, F.S.; requiring electronic filing of death and fetal death certificates with the department or local registrar on a prescribed form; authorizing certain legally authorized persons to provide personal data about the deceased; authorizing the department, rather than the local registrar, to grant an extension of time for providing certain information regarding a death or a fetal death; amending s. 382.0085, F.S.; conforming a cross-reference; amending s. 382.011, F.S.; retaining a funeral director's responsibility to file a death or fetal death certificate with the department, rather than with the local registrar; amending s. 382.0135, F.S.; requiring the department to electronically notify the United States Social Security

588-02131-15 2015640c1

Administration of deaths in the state; providing an effective date.

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

Section 1. Present subsections (1) through (17) of section 382.002, Florida Statutes, are redesignated as subsections (2) through (18), respectively, present subsections (8) and (9) are amended, and a new subsection (1) is added to that section, to read:

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

(1) "Burial-transit permit" means a permit issued by the department that authorizes the final disposition of a dead body.

(9)~~(8)~~ "Final disposition" means the burial, interment, entombment, cremation, removal from the state, anatomical donation, or other authorized disposition of a dead body or a fetus as described in subsection (8) ~~(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.

(10)~~(9)~~ "Funeral director" means a licensed funeral director or direct disposer licensed pursuant to chapter 497 who first assumes custody of or effects the final disposition of a dead body or a fetus as described in subsection (8) ~~(7)~~.

Section 2. Subsection (9) of section 382.003, Florida Statutes, is amended to read:

382.003 Powers and duties of the department.—The department

shall:

(9) Appoint one or more suitable persons to act as subregistrars, who shall be authorized to produce and maintain paper ~~receive~~ death certificates and fetal death certificates and to issue burial-transit ~~burial~~ permits in and for such portions of one or more districts as may be designated. A subregistrar may be removed from office by the department for neglect of or failure to perform his or her duty in accordance with this chapter.

Section 3. Subsections (1) and (6) of section 382.006, Florida Statutes, are amended, and subsection (7) is added to that section, to read:

382.006 Burial-transit permit.—

(1) The funeral director who first assumes custody of a dead body or fetus must obtain a burial-transit permit before ~~prior to~~ final disposition and within 5 days after death. The funeral director shall provide the manually produced or electronic burial-transit permit generated from the electronic death registration system to the person in charge of the place of final disposition. ~~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 must 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.~~

(6) For manually filed paper death records, the

subregistrar in the licensed funeral or direct disposal establishment is responsible for producing and maintaining death and fetal death certificates and burial-transit permits in accordance with this chapter. ~~Burial-transit permits filed with the local registrar under the provisions of this chapter may be destroyed after the expiration of 3 years from the date of filing.~~

(7) The department may adopt rules to implement this section.

Section 4. Section 382.007, Florida Statutes, is amended to read:

382.007 Final dispositions prohibited without burial-transit permit; records of dead bodies disposed.—A person in charge of any premises on which final dispositions are made shall not dispose ~~inter~~ or permit the ~~interment or other~~ disposition of any dead body unless it is accompanied by a burial-transit permit. ~~Any~~ Such person shall enter ~~endorse~~ upon the permit the date of final ~~interment, or other~~ disposition~~,~~ ~~over his or her signature, and shall return all permits so endorsed to the local registrar of the district where the place of final disposition is located within 10 days from the date of interment or other disposition~~. He or she shall keep a record of all dead bodies ~~interred or otherwise~~ disposed of on the premises under his or her charge, in each case stating the name of each deceased person, place of death, date of final ~~burial or other~~ disposition, and name and address of the funeral director, which record shall at all times be open to official inspection. The burial-transit permit on file may satisfy this requirement. The funeral director, when disposing of ~~burying~~ a dead body in a

cemetery having no person in charge, shall enter the date of final disposition on ~~sign~~ the ~~burial-transit~~ permit, ~~giving the date of burial, and shall~~ write ~~across the face of the permit the words~~ "No person in charge~~,~~" on the permit, and keep the permit on file for at least 3 years after the date of final disposition ~~and file the permit within 10 days after burial with the local registrar of the district in which the cemetery is located~~.

Section 5. Subsection (1), paragraph (a) of subsection (2), and paragraph (a) of subsection (3) of section 382.008, Florida Statutes, are amended to read:

382.008 Death and fetal death registration.—

(1) A certificate for each death and fetal death which occurs in this state shall be filed electronically on the department electronic death registration system or ~~on a form prescribed by the department~~ with the department or local registrar of the district in which the death occurred on a form prescribed by the department. A certificate shall be filed within 5 days after ~~such~~ death and prior to final disposition, and shall be registered by the department ~~such registrar~~ if it has been completed and filed in accordance with this chapter ~~or adopted rules~~. The certificate shall include the decedent's social security number, if available. In addition, each certificate of death or fetal death:

(a) If requested by the informant, shall include aliases or "also known as" (AKA) names of a decedent in addition to the decedent's name of record. Aliases shall be entered on the face of the death certificate in the space provided for name if there is sufficient space~~. If there is not sufficient space, aliases~~

~~may be recorded on the back of the certificate and shall be considered part of the official record of death~~;

(b) If the place of death is unknown, shall be registered in the registration district in which the dead body or fetus was ~~is~~ found within 5 days after such occurrence; and

(c) If death occurs in a moving conveyance, shall be registered in the registration district in which the dead body was first removed from such conveyance.

(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 a legally authorized person as defined in s. 497.005 ~~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 or, if s. 382.011 applies, the district medical examiner of the county in which the death occurred or the body was found. 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 department ~~local registrar~~ may grant the funeral director an extension of time if ~~upon a good and sufficient showing of~~ any of the following conditions exist:

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.

Section 6. Subsection (9) of section 382.0085, Florida Statutes, is amended to read:

382.0085 Stillbirth registration.—

(9) This section or s. 382.002(16) ~~s. 382.002(15)~~ may not be used to establish, bring, or support a civil cause of action seeking damages against any person or entity for bodily injury, personal injury, or wrongful death for a stillbirth.

Section 7. Subsection (3) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.—

(3) The funeral director shall retain the responsibility for preparation of the death or fetal death certificate,

obtaining the necessary signatures, filing with the department ~~local registrar~~ in a timely manner, and arranging for final disposition of the body when ~~disposing of the remains when the remains are~~ released by the medical examiner.

Section 8. Section 382.0135, Florida Statutes, is amended to read:

382.0135 Social security numbers; electronic notification of deaths; enumeration-at-birth program.—The department shall make arrangements with the United States Social Security Administration to provide electronic notification of deaths that occur in the state and to participate in the voluntary enumeration-at-birth program. The State Registrar is authorized to take any actions necessary to administer the program in this state, including modifying the procedures and forms used in the birth registration process.

Section 9. This act shall take effect July 1, 2015.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 17, 2015

I respectfully request that **Senate Bill #940**, relating to Children In Out-of-Home Care, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Nancy C. Detert
Florida Senate, District 28

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-2-15
Meeting Date

940
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Continuum of Care for Children

Name Kenisha Anthony

Job Title

Address
Street

Phone

City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Youth SHINE

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-2-15
Meeting Date

940
Bill Number (if applicable)

Topic Continuum of Care for Children

Amendment Barcode (if applicable)

Name Christina Spudeas

Job Title Executive Director

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Email Christina.Spudeas@floridaschildrenfirst.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida's Children First

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 940
INTRODUCER:	Children, Families, and Elder Affairs Committee and Senator Detert and others
SUBJECT:	Continuum of Care for Children
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Preston	Hendon	CF	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 940 makes numerous changes to statutes related to residential group home placements for children in out-of-home care within the child welfare system.

The bill creates the Continuum of Care Advisory Council to address the placement and service needs of children in out-of-home care. The bill requires the advisory council to consider specific issues, requires the appointment of specified members, requires the Department of Children and Families (DCF) to provide administrative support to the council, and requires a report.

The bill requires the DCF to collect and compile data and information that will be used by the newly created Continuum of Care Advisory Council and specifies the types of data to be collected.

The bill removes obsolete provisions from current law related to reporting and funding mechanisms.

The bill is anticipated to have an insignificant fiscal impact.

The bill has an effective date of July 1, 2015.

II. Present Situation:

Residential group care for children in the child welfare system has many forms and purposes, including serving as a child placement component and as a treatment component of the children's mental health system of care. The multiple roles of group care make an analysis of its effectiveness difficult and complex.[1]

Some working in child welfare contend that all residential group care is potentially harmful and that its use should be eliminated. Others support the position that such placements are beneficial for some children in certain situations. Other stakeholders favor the wholesale use of group care as an alternative to the shortage of family placements or reliance on family placements that may expose children to further risk. Both positive and negative claims about the effectiveness of residential group care and its alternatives are often made without sufficient evidence.[2]

There appears to be a growing consensus within the child-welfare community that residential group home settings for children in out-of-home care are sometimes necessary but should be used sparingly. While some states have been more successful than others, most states have tried to decrease reliance on group home care.[3]

KVC Health Systems, a private company hired to provide child-welfare services in eastern Kansas, has been very successful in effort to reduce the number of children in residential group care, reporting that only three percent of the 3,100 children it oversees are in group settings, primarily for short-term psychiatric treatment, while virtually all the others are placed with foster families. That's a dramatic change from 1997, when 30 percent of KVC's children were in group care placements.[4]

Several advocacy groups are also pushing for an overhaul of the federal funding system for child welfare, with a goal of shifting funding from residential group home settings to alternatives such as family-based care. One proposal by the Annie E. Casey Foundation and one of its partners, the Jim Casey Youth Opportunities Initiative, indicates federal reimbursement should be eliminated for shelters and group care for children under 13 years of age while federal reimbursement should be allowed for older children's group care only for short periods when necessary for

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[1] Barth, R. (2002). *Institutions vs. foster homes: The empirical basis for the second century of debate.* Chapel Hill, NC: University of North Carolina, School of Social Work, Jordan Institute for Families, *available at*: http://resourcecentre.savethechildren.se/sites/default/files/documents/2344.pdf. (last visited February 13, 2015).

[2] Child Welfare League of America. (2008). *Residential Transitions Project Phase One Final Report*, *available at*: http://rbsreform.org/materials/Residential%20Transitions%20Project%20-%204%2030%2008%20_2_.pdf. (last visited February 13, 2015).

[3] *Id*. Also see California Health and Human Services Agency. California's Child Welfare Continuum of Care Reform, January 2015, Children's Rights, *What Works in Child Welfare Reform: Reducing Reliance on Congregate Care in Tennessee,* July 2011, and The Annie E. Casey Foundation, *Rightsizing Congregate Care, A Powerful First Step in Transforming Child Welfare System*, 2010.

[4] Crary, D. *Foster care: U.S. Moves to phase out group care for foster kids*, Christian Science Monitor. May 17, 2014, *available at*: http://www.csmonitor.com/The-Culture/Family/2014/0517/Foster-care-US-moves-to-phase-out-group-care-for-foster-kids. (last visited February 16, 2015).

psychiatric treatment or other specialized care.[5] Sen. Orrin Hatch (R-Utah), recently proposed a bill that would cut off federal funding for long-term placements in group homes.[6]

Nationally, according to the Adoption and Foster Care Analysis and Reporting System (AFCARS) data, in 2012, nearly half (47 percent) of all children in care lived in the foster family homes of non-relatives. Just over one-quarter (28 percent) lived in family foster homes with relatives, often referred to as "kinship care." Six percent of foster children lived in group homes, eight percent lived in institutions, four percent lived in pre-adoptive families, and the rest lived in other types of facilities.[7] These are not substantially different from the proportions at the beginning of the decade, though there has been a slight decrease in the number of foster children in group homes and institutions, and a corresponding increase of those in home care.[8]

In Florida, 11 percent of children in foster care are in residential group care and 83 percent of the children in group care are 11 years of age and older, compared to 17 percent in family care settings.[9]

Residential group homes are one of the most expensive placement options for children in the child welfare system. The costs of group home care far exceed those for foster care or treatment foster care. The difference in monthly cost can be between six and 10 times higher than foster care and between two and three times higher than treatment foster care. Since there is virtually no evidence that these additional expenditures result in better outcomes for children, there is no cost benefit justification for group care, when other placements are available.[10]

In Florida, community-based care lead agencies annually negotiate rates for residential group home placements with providers. In Fiscal Year 2013-2014, the average per diem rate for the shift-care group home model was $124, with costs ranging from $52 to $283. The average per diem rate for a family group home model was $97, with costs ranging from $17 to $175. Family foster home care pays an average daily rate of $15.[11] The cost of group home care in Florida for Fiscal Year 2013-2014 was $81.7 million.[12]

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[5] *Id*.
[6] Senate Bill 1518 (2013) proposed eliminating federal matching funds for non-family foster homes for all children age 12 and under and for youth age 13 and older after 1 year of consecutive time spent in a non- family foster home or 18 months non-consecutive care spent in a non-family foster home, whichever comes first.
[7] U.S. Department of Health and Human Services Administration for Children and Families, Children's Bureau. The AFCARS Report (2013) available at: http://www.acf.hhs.gov/sites/default/files/cb/afcarsreport19.pdf. (last visited March 2, 2015).
[8] Child Trends Data Bank, Foster Care Indicators on Children and Youth (2014) *available at*: http://www.childtrends.org/wp-content/uploads/2014/07/12_Foster_Care.pdf. (last visited February 16, 2015).
[9] Office of Program Policy and Government Accountability. Research Memorandum. *Florida's Residential Group Care Program for Children in the Child Welfare System*. December 2014.
[10] Barth, R. (2002). *Institutions vs. foster homes: The empirical basis for the second century of debate.* Chapel Hill, NC: University of North Carolina, School of Social Work, Jordan Institute for Families, *available at*: http://resourcecentre.savethechildren.se/sites/default/files/documents/2344.pdf. (last visited February 13, 2015).
[11] Office of Program Policy and Government Accountability. Research Memorandum. *Florida's Residential Group Care Program for Children in the Child Welfare System* (December 2014).
[12] *Id*.

III. Effect of Proposed Changes:

Section 1 amends s. 39.523, F.S., related to the placement of children in residential group care, to remove provisions related to reporting and funding mechanisms that are now obsolete as a result of privatizing foster care and related services.

Section 2 creates s. 409.144, F.S., related to a continuum of care for children in out-of-home care and residential group home care. The bill provides legislative intent and findings related to the placement of children in out-of-home care into residential group home care. Under the bill, the Legislature intends to reform the current system of using group home care into a continuum of care that reflects current research and best practices.

The bill requires the DCF to collect compile data that will be used by the Continuum of Care Advisory Council. These data are related to assessments of children coming into care, service needs of those children, licensure of facilities, rates and rate setting, performance measures, and quality improvement.

The bill creates the Continuum of Care Advisory Council for the purpose of recommending a plan to address the placement and service needs of children who are in out-of-home care by creating a continuum of care consisting of recruiting, training, and supporting an adequate supply of home-based family care; providing needed services and supports in those family care settings; and limiting congregate care to only those situations in which adequate services cannot be safely provided while a child lives with a family, and then for only the minimum amount of time required for stabilization.

The bill requires the appointment of members representing specified entities and provides for the manner of appointment. The bill requires the advisory council to propose a timeline and work plan for reform and an estimate of associated costs and to submit the proposal and estimate of costs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 31, 2016. At a minimum the proposal must address the following:

- The impact of group care on children by age and history based on current research;
- Criteria for admission to residential group care and necessary assessments;
- Policies and procedures needed to ensure that placement in residential group care is appropriate for each child and lasts only as long as necessary to resolve the issue that required the placement;
- Services that are currently available for children in group placements;
- The need to develop a classification system for group care;
- Requirements needed in plans for children in group care to transition to family-based placement;
- The role of licensure in determining the quality of care and the need for a new licensing category or categories;
- The value of requiring group home accreditation by a national accrediting body;
- The need to plan for any change in federal funding for long-term residential group care;
- Current practices related to the use of residential group home care in order to develop a framework that can be used to transition residential group homes into short-term, specialized,

and intensive treatment providers used for the minority of children who cannot safely be served in home-based family care settings;
- Age limitations that should be placed on group care based on developmental research;
- Comparison of cost of group care placement and family-based care and economic and other incentives that exist for placement of children in group care;
- Alternate funding mechanisms for children placed in residential group home care;
- Adjustments in funding to encourage placement in home-based family care settings; and
- Standards to ensure that group home staff have adequate training, experience, and supervision to provide therapeutic care to children in group home facilities.

Section 3 provides an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Under CS/SB 940, the staffing and travel reimbursement of members of the Continuum of Care Council would have an insignificant fiscal impact on the Department of Children and Families.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 39.523 of the Florida Statutes.

This bill creates section 409.144 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Children, Families, and Elder Affairs on March 12, 2015:

- Removes provisions from current law related to reporting and funding mechanisms that are now obsolete,
- Requires the Department of Children and Families to collect data related to children in out-of-home care who are living in residential group home settings to be used by the Continuum of Care Advisory Council;
- Creates a Continuum of Care Advisory Council for the purpose of recommending a plan to address the placement and service needs of children who are in out-of-home care; and
- Specifies the duties of the advisory council and provides for council membership.

B. Amendments:

None.

By the Committee on Children, Families, and Elder Affairs; and Senators Detert and Sachs

586-02204-15 2015940c1

A bill to be entitled

An act relating to continuum of care for children; amending s. 39.523, F.S.; removing a requirement that the Department of Children and Families submit a report annually to the Legislature on the placement of children in licensed residential group care; removing a provision requiring the department to provide a detailed account of certain expenditures; removing provisions regarding implementation and specified annual funding; creating s. 409.144, F.S.; providing legislative findings and intent; requiring the department to collect and compile specified data and information; creating the Continuum of Care Advisory Council within the department for specified purposes; providing duties of the council; requiring the members of the advisory council to be appointed in specified manners; authorizing the advisory council to work with certain individuals and providing limitations on the involvement of those individuals; providing per diem and travel expenses for certain members; requiring the advisory council to submit specified information to the Governor and the Legislature by a certain date; requiring the department to provide administrative support to the advisory council; requiring that the advisory council have access to specified information; prohibiting certain data from including information that would identify specific individuals; providing an effective date.

586-02204-15 2015940c1

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

Section 1. Section 39.523, Florida Statutes, is amended to read:

39.523 Placement in residential group care.—

(1) Except as provided in s. 39.407, any dependent child 11 years of age or older who has been in licensed family foster care for 6 months or longer and who is then moved more than once and who is a child with extraordinary needs as defined in s. 409.1676 must be assessed for placement in licensed residential group care. The assessment procedures shall be conducted by the department or its agent and shall incorporate and address current and historical information from any psychological testing or evaluation that has occurred; current and historical information from the guardian ad litem, if one has been assigned; current and historical information from any current therapist, teacher, or other professional who has knowledge of the child and has worked with the child; information regarding the placement of any siblings of the child and the impact of the child's placement in residential group care on the child's siblings; the circumstances necessitating the moves of the child while in family foster care and the recommendations of the former foster families, if available; the status of the child's case plan and a determination as to the impact of placing the child in residential group care on the goals of the case plan; the age, maturity, and desires of the child concerning placement; the availability of any less restrictive, more family-like setting for the child in which the foster parents have the necessary training and skills for providing a suitable

placement for the child; and any other information concerning the availability of suitable residential group care. If such placement is determined to be appropriate as a result of this procedure, the child must be placed in residential group care, if available.

(2) The results of the assessment described in subsection (1) and the actions taken as a result of the assessment must be included in the next judicial review of the child. At each subsequent judicial review, the court must be advised in writing of the status of the child's placement, with special reference regarding the stability of the placement and the permanency planning for the child.

(3) Any residential group care facility that receives children under the provisions of this subsection shall establish special permanency teams dedicated to overcoming the special permanency challenges presented by this population of children. Each facility shall report to the department its success in achieving permanency for children placed by the department in its care at intervals that allow the current information to be provided to the court at each judicial review for the child.

(4) This section does not prohibit the department from assessing and placing children who do not meet the criteria in subsection (1) in residential group care if such placement is the most appropriate placement for such children.

~~(5)(a) By December 1 of each year, the department shall report to the Legislature on the placement of children in licensed residential group care during the year, including the criteria used to determine the placement of children, the number of children who were evaluated for placement, the number of~~

~~children who were placed based upon the evaluation, and the number of children who were not placed. The department shall maintain data specifying the number of children who were referred to licensed residential child care for whom placement was unavailable and the counties in which such placement was unavailable. The department shall include this data in its report to the Legislature due on December 1, so that the Legislature may consider this information in developing the General Appropriations Act.~~

~~(b) As part of the report required in paragraph (a), the department shall also provide a detailed account of the expenditures incurred for "Special Categories: Grants and Aids-Specialized Residential Group Care Services" for the fiscal year immediately preceding the date of the report. This section of the report must include whatever supporting data is necessary to demonstrate full compliance with paragraph (6)(c). The document must present the information by district and must specify, at a minimum, the number of additional beds, the average rate per bed, the number of additional persons served, and a description of the enhanced and expanded services provided.~~

~~(6)(a) The provisions of this section shall be implemented to the extent of available appropriations contained in the annual General Appropriations Act for such purpose.~~

~~(b) Each year, funds included in the General Appropriations Act for Enhanced Residential Group Care as provided for in s. 409.1676 shall be appropriated in a separately identified special category that is designated in the act as "Special Categories: Grants and Aids Specialized Residential Group Care Services."~~

~~(c) Each fiscal year, all funding increases for Enhanced Residential Group Care as provided in s. 409.1676 which are included in the General Appropriations Act shall be appropriated in a lump-sum category as defined in s. 216.011(1)(aa). In accordance with s. 216.181(6)(a), the Executive Office of the Governor shall require the department to submit a spending plan that identifies the residential group care bed capacity shortage throughout the state and proposes a distribution formula by district which addresses the reported deficiencies. The spending plan must have as its first priority the reduction or elimination of any bed shortage identified and must also provide for program enhancements to ensure that residential group care programs meet a minimum level of expected performance and provide for expansion of the comprehensive residential group care services described in s. 409.1676. Annual appropriation increases appropriated in the lump-sum appropriation must be used in accordance with the provisions of the spending plan.~~

~~(d) Funds from "Special Categories: Grants and Aids-Specialized Residential Group Care Services" may be used as one-time startup funding for residential group care purposes that include, but are not limited to, remodeling or renovation of existing facilities, construction costs, leasing costs, purchase of equipment and furniture, site development, and other necessary and reasonable costs associated with the startup of facilities or programs upon the recommendation of the lead community-based provider if one exists and upon specific approval of the terms and conditions by the secretary of the department.~~

Section 2. Section 409.144, Florida Statutes, is created to

read:

409.144 Continuum of care; residential group home care.—

(1) LEGISLATIVE FINDINGS AND INTENT.—

(a) The Legislature finds that children in out-of-home care should live in their communities in home-based family care settings and that the need to recruit, train, and support an adequate number of families to provide home-based family care is an essential part of any initiative to reform out-of-home care for children.

(b) The Legislature also finds that children who initially cannot be safely placed in home-based family care may be still placed into residential group home care, but for only the minimum time required for stabilization and with specific short time-limited plans for their care. When needed, residential group home care should be considered a short-term, specialized, and intensive intervention that is just one part of a continuum of care available for children.

(c) The Legislature further finds that, once stabilized, most children should transition from residential group home care into home-based family care with their services following them.

(d) Therefore, it is the intent of the Legislature to support an effort to reform the current system of using residential group home care that reflects current research findings and the appropriate place of residential group home care in the child welfare system continuum of care. It is further the intent of the Legislature that the reform effort provides for improved assessments of children and families to make more informed and appropriate initial placement decisions, an emphasis on home-based family care placements for children,

appropriate support for those placements with available services, a change in goals for residential group home care placements, and increased transparency and accountability for child outcomes.

(2) DUTIES OF THE DEPARTMENT.—The department shall collect and compile data and information necessary to inform the development of a work plan to be used by the Continuum of Care Advisory Council created in subsection (3) to address the placement and services needs of children who are cared for in out-of-home care. At a minimum, the collected and compiled data and information must include current data and information related to all of the following:

(a) Methods of assessing children coming into care for their initial placement.

(b) Definitions and characteristics of types of placements in use.

(c) Service needs of children in out-of-home care.

(d) Program design and quality standards.

(e) Licensing categories and accreditation requirements for types of out-of-home placements.

(f) Rates and procedures used for payment rate setting.

(g) Outcomes, outcome indicators and performance measures.

(h) Impact of existing performance measures.

(i) Mechanisms that ensure continuous quality improvement and transition strategies from group care to other levels of care.

(3) CONTINUUM OF CARE ADVISORY COUNCIL.—The Continuum of Care Advisory Council is created within the department for the purpose of recommending a plan to address the placement and

service needs of children who are cared for outside their own homes by creating a continuum of care which consists of recruiting, training, and supporting an adequate supply of home-based family care; providing needed services and supports in those family care settings; and limiting congregate care to only those situations in which adequate services cannot be safely provided while a child lives with a family, and for only the minimum amount of time required for stabilization. The work of the advisory council shall be conducted in collaboration with the primary stakeholders and shall be based on empirical research and best practices data. The process must include gathering research data, holding public meetings, and entering into partnerships with academia and other stakeholders to complete the task. The advisory council shall function as specified in this subsection until the Legislature determines that the advisory council can no longer provide a valuable contribution to the department's efforts to create a continuum of care.

(a) The 25 members of the advisory council must be appointed in the following manner:

1. Three members from the headquarters and regional offices of the department, to be appointed by the secretary.

2. One member with recognized expertise in developmental psychology, to be appointed by the secretary.

3. One member with expertise in children's mental health, to be appointed by the secretary.

4. One member with expertise in children's health issues, to be appointed by the secretary.

5. One member who is an economist with expertise in

behavioral economics, to be appointed by the secretary.

6. Two members from the community-based care lead agencies, one from the lead agency with the lowest rate and one from the lead agency with the highest rate of residential group home placement, to be appointed by the secretary.

7. One member with experience working with children with special needs in residential group home settings, to be appointed by the secretary.

8. Two members who are foster parents, to be appointed by the executive director of the Florida State Foster/Adoptive Parent Association.

9. Two members who are kinship caregivers, to be appointed by the secretary.

10. One member from the Quality Parenting Initiative, to be appointed by the secretary.

11. Three members who are residential group home providers, representing different models of residential group home care and who are involved in daily operation of the facilities, to be appointed by the secretary.

12. Two members from Florida Youth SHINE, to be appointed by the secretary.

13. One member from Florida's Children First, to be appointed by the secretary.

14. One member from the Agency for Persons with Disabilities, to be appointed by the director of the agency.

15. One member from the Department of Juvenile Justice, to be appointed by the Secretary of Juvenile Justice.

16. One member from the Department of Education, to be appointed by the Commissioner of Education.

17. One member from the Florida Institute for Child Welfare, to be appointed by the secretary.

(b) The advisory council is encouraged to work with any additional individuals who are knowledgeable in the subject areas; however, those additional individuals may not become members of the council and may not vote on the final report and recommendations of the council, but may submit reports and recommendations for review by the council and may be invited to speak to the council by a member of the council.

(c) Nongovernmental members of the advisory council shall serve without compensation but are entitled to receive per diem and travel expenses in accordance with s. 112.061 while in performance of their duties.

(d) The advisory council shall propose a timeline and work plan for reform and an estimate of associated costs and shall submit the proposal and estimate of costs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 31, 2016. At a minimum, the proposal must consider the following:

1. The impact of group care on children based on their age and history based on an impartial compilation of research related to residential group care.

2. Criteria for admission to residential group care and the types of assessments that should be performed to determine whether the admission criteria are being met and who should perform the assessments.

3. Policies and procedures needed to ensure that placement in a residential group care is appropriate for each specific child and lasts only as long as necessary to resolve the issue

that required the placement.

4. Services that are currently available for children in group placements and the types of services that could be provided to eliminate the need for group care.

5. The need to develop a classification system for group care.

6. Requirements needed in plans for children in group care to transition to family placement.

7. The role of state licensing in determining the quality of care and the need for a new licensing category or categories to better meet the needs of the children in out-of-home care.

8. The value of requiring group home accreditation by a national accrediting body.

9. The need to plan for any change in federal funding for long-term residential group care.

10. Current practices related to the use of residential group home care in order to develop a framework that can be used to transition residential group homes into short-term, specialized, and intensive treatment providers used for the minority of children who cannot safely be served in home-based family care settings.

11. Age limitations that should be placed on group care based on developmental research.

12. Comparison of cost of group care placement and family based care, and what economic and other incentives exist for placement of children in group care.

13. Alternate funding mechanisms for children placed in residential group home care.

14. Adjustments to funding to encourage placement in home-

based family care settings.

15. Standards that should be in effect to ensure that group home staff has adequate training, experience, and supervision to provide therapeutic care to children and youth in the facilities.

(e) The department shall provide administrative support to the advisory council to accomplish its assigned tasks. The advisory council shall have access to all appropriate data from the department, each community-based care lead agency, and other relevant agencies in order to accomplish the tasks set forth in this section. The data collected by the advisory council may not include information that would identify a specific child or young adult.

Section 3. This act shall take effect July 1, 2015.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

758
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title _____

Address 1000 Riverside Avenue
Street

Jacksonville, FL 32204
City *State* *Zip*

Phone 904-233-3051

Email nulandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Public Health Association
Florida Chapter, American College of Physicians

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

SB 758
Bill Number (if applicable)

Topic SB 758

Amendment Barcode (if applicable)

Name Lenys Klumpp

Job Title Gov't + Community Relations Poison Control

Address 1611 NW 12 Ave - Annex Bldg
Street

Phone 305 4913473

Miami FL 33136
City *State* *Zip*

Email LKlumpp@med.miami.edu

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL. Poison Control

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2 April 2015
Meeting Date

758
Bill Number (if applicable)

Topic Naloxone / Over-dose / Opioid Antagonist *Amendment Barcode (if applicable)*

Name Jill Gran

Job Title

Address 2808 Mahan Dr *Street*
Tallahassee FL 32308
City *State* *Zip*

Phone 878-2196

Email jill@fadaa.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL Alcohol & Drug Abuse Assoc

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/2015
Meeting Date

SB 758
Bill Number (if applicable)

Topic Opioid Antagonists for Emergency Treatment of Opioid Overdose

Amendment Barcode (if applicable)

Name Kelly Corredor

Job Title President & CEO

Address 1405 Fryston Street
Street

Phone 904-657-6371

Saint Johns FL 32259
City *State* *Zip*

Email kelly@skeeterhawk.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing The Skeeterhawk Experiment

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/2015
Meeting Date

SB 758
Bill Number (if applicable)

Topic Opioid Antagonists for Emergency Treatment of Opioid Overdose

Amendment Barcode (if applicable)

Name Jill Maliszewski

Job Title Vice-President

Address 750 Huffner Hill Circle
Street

Phone 904-509-2450

St. Augustine FL 32092
City *State* *Zip*

Email playworkstx@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing The Skeeterhawk Experiment

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

April 2, 2015
Meeting Date

758
Bill Number (if applicable)

Topic Prescription and Use of Opioid Antagonists for Emergency Treatment of Opioid Overdose

Amendment Barcode (if applicable)

Name Jesse Fry

Job Title Policy Analyst

Address 641 E College Ave Unit 2
Street

Phone (850) 339-6395

Tallahassee — *City* | FL — *State* | 32301 — *Zip*

Email jfry@theaidsinstitute.org

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing The AIDS Institute

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date	Bill Number (if applicable)
	758

Topic Prescription Use of Opioid

Amendment Barcode (if applicable)

Name Beth LABASKY

Job Title Consultant

Address 1400 Village Square Blvd (Street)

Tallahassee Fla 32312 (City / State / Zip)

Phone 850-3227335

Email bethlabasky@aol.com

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing Informed Families of Florida

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/2015
Meeting Date

758
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Brian Jogerst

Job Title _____

Address 215 South Monroe Street, Suite 703
Street

Phone 850-222-0191

Tallahassee FL 32301
City *State* *Zip*

Email brian@bhandassociates.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Shatterproof

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

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9.00

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-2-2015
Meeting Date

SB 758
Bill Number (if applicable)

Topic PRESCRIPTION AND USE OF OPIOID ANTAGONISTS

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

Job Title EXECUTIVE DIRECTOR

Address 2007 APALACHEE PARKWAY
Street

Phone 878-7364

TALLAHASSEE FL 32301
City *State* *Zip*

Email

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

CS/SB 758
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic RLT OPIOID ANTAGONISTS

Name CHRISTIAN MINOR

Job Title DIRECTOR OF GOV. AFFAIRS

Address 204 S. MONROE ST. 201
Street

Phone (321) 223-4232

TALLAHASSEE FL 32304
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing THE FLORIDA SMART JUSTICE ALLIANCE

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

0758
Bill Number (if applicable)

Topic PRESCRIPTION & USE OF OPIOID ANTAGONIST

Amendment Barcode (if applicable)

Name KURT VROMAN

Job Title 9TH DISTRICT VICE PRESIDENT

Address 345 W. MADISON ST
Street

Phone 386-235-6765

TALLAHASSEE FL 32301
City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA PROFESSIONAL FIREFIGHTERS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 758
INTRODUCER:	Health Policy Committee and Senator Evers
SUBJECT:	Prescription and Use of Opioid Antagonists for Emergency Treatment of Opioid Overdoses
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 758 establishes the "Florida Opioid Overdose Prevention Act." The bill encourages the administration of opioid antagonists for the emergency treatment of known or suspected opioid overdoses when a health care practitioner is not available.

The bill authorizes health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers, and first responders. Each patient and caregiver to whom an opioid antagonist is prescribed or dispensed must receive emergency overdose treatment information from the prescribing health care practitioner or his or her agent.

Pharmacists are authorized to dispense an appropriately labeled opioid antagonist based on a prescription that has been issued in the name of a patient or caregiver. The patient or caregiver may store and possess a dispensed opioid antagonist for later administration to a person he or she believes in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an opioid antagonist.

Civil liability protection is extended to any person, including health care practitioners, pharmacists, and first responders who possess, administer, or store an approved opioid antagonist under the bill. A health care practitioner acting in good faith and exercising reasonable care is not subject to discipline under the applicable professional licensure statute and is also immune from civil or criminal liability for prescribing or dispensing an opioid antagonist under the bill.

The bill has no fiscal impact.

The bill takes effect upon becoming law.

II. Present Situation:

An opioid can be a prescription medication or an illegal drug, such as heroin, and is used to treat pain. Opioids work by binding to certain receptors in the brain, spinal cord, and gastrointestinal tract to minimize the body's perception of pain. A variety of effects can occur after a person ingests opioids, ranging from pleasure to nausea, vomiting, severe allergic reactions (anaphylaxis), and overdose, in which breathing and heartbeat slow or even stop.[1] Opioid antagonists have been developed to reverse the effects of opioid overdoses and have been available for decades.

Opioid Deaths Nationwide

From 1999 through 2012, the age-adjusted drug-poisoning (drug overdose) death rate nationwide more than doubled, from 6.1 per 100,000 of the population in 1999 to 13.1 in 2012, while death from opioid analgesics alone more than tripled, from 1.4 per 100,000 to 5.1 during the same time period.[2] The 2012 total deaths due to drug poisoning was over 41,000, with opioid analgesics involved in 16,007 of that number and heroin involved in 5,925.[3] On January 12, 2015, the White House Office of National Drug Control Policy announced that drug deaths related to prescription opioids for 2013 had remained stable since 2012, with a one-percent increase in deaths, while deaths associated with heroin and cocaine had increased 39 percent and 12 percent, respectively.[4]

Drug poisoning deaths involving opioids for the time period of 2009-2010 nationally shows that the highest death rate occurs in the 35-to-54 age bracket at 9.9 deaths per 100,000 and was more prevalent in males at 8.1 compared to 5.1 for females and for white, non-Hispanic individuals.[5]

Opioid Deaths in Florida

Drug overdose deaths in Florida rose 61 percent from 1,804 to 2,905 during 2003-2009, with especially large increases in deaths related to opioid pain relievers and benzodiazepine.[6] After implementing several laws and enforcement actions relating to prescription drugs and pain management clinics, death rates for prescription drugs decreased 16.7 percent from 3,201 to

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[1] U.S. Department of Health and Human Services, *SAMSHA Opioid Overdose Toolkit*, p. 4, http://store.samhsa.gov/shin/content//SMA14-4742/Overdose_Toolkit.pdf (last visited Feb. 28, 2015).
[2] Centers for Disease Control and Prevention, *Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012* http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning_deaths_1999-2012.pdf (last visited Feb. 28, 2015).
[3] *Id.*
[4] Press Release, Centers for Disease Control and Prevention, *2013 Drug Overdose Mortality Data Announced*, (Jan. 20, 2015) http://www.cdc.gov/media/releases/2015/p0114-drug-overdose.html (last visited Feb. 28, 2015).
[5] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States 2013 with Special Feature on Prescription Drugs*, p. 29, (on file with the Senate Committee on Health Policy).
[6] Centers for Disease Control and Prevention, *Decline in Drug Overdose Deaths After State Policy Changes - Florida 2010-2012* (July 4, 2014) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm (last visited Feb. 28, 2015).

2,666, representing a 16.7 percent decrease from 2010-2012.[7] However, reports of increasing deaths from heroin overdose, sometimes attributed to the crackdown on "pill mills" and the overprescribing of controlled substances for the treatment of pain, is being termed an epidemic.[8]

For Florida, the 2013 total year data from the U.S. Centers for Disease Control and Prevention (CDC), shows over 2,600 individuals died from a drug-induced cause. The CDC number is not limited to opioid deaths, but the partial-year data from the Florida Medical Examiners Commission indicate that prescription drugs such as opioids continue to be found more often than illicit drugs, both as the cause of death and present at death.[9] These drugs are often prescribed for medical conditions such as muscle relaxation, anxiety, insomnia, and panic attacks. Opioids include:

Opioid Drug Occurrences in Florida: January-June 2013[10]			
Opioid	**Present at Death**	**Cause of Death**	**Total Occurrences**
Buprenorphine	10	7	17
Codeine	38	50	88
Fentanyl	85	52	137
Heroin	68	2	70
Hydrocodone	158	273	431
Hydromorphone	89	131	220
Meperidine	2	6	8
Methadone	221	103	324
Morphine	268	189	457
Oxycodone	279	262	541
Oxymorphone	24	100	124
Tramadol	51	177	228
TOTAL:	**1,293**	**1,352**	**2,645**

Naloxone: An Opioid Antagonist

Naloxone injection is in a class of medications called opiate antagonists. It works by blocking the effects of opiates to relieve dangerous symptoms caused by high levels of opiates in the blood.[11] Naloxone displaces opiates from receptor sites in the brain and reverses respiratory depression

[7] *Id*.
[8] *See* for example: National Institute on Drug Abuse, *What Can We Do About the Heroine Overdoes Epidemic?* (June 24, 2014) http://www.drugabuse.gov/about-nida/noras-blog/2014/06/what-can-we-do-about-heroin-overdose-epidemic (last visited Feb 28, 2015); National Institute on Drug Abuse, *Drug Abuse Patterns and Trends in Miami-Dade and Broward Counties, Florida—Update: January 2014* (February 2014) http://www.drugabuse.gov/about-nida/organization/workgroups-interest-groups-consortia/community-epidemiology-work-group-cewg/meeting-reports/highlights-summaries-january-2014/miami (last visited Feb. 28, 2015); Reuters, *Heroin Abuse at 'Epidemic' Level in South Florida – Drug Report*, (January 30, 2014) http://www.reuters.com/article/2014/01/30/us-usa-florida-heroin-idUSBREA0T24D20140130 (last visited Feb. 28, 2015), and 8WFLA.com, *Heroin Deaths on the Rise in Tampa Bay* (February 10, 2015) http://www.wfla.com/story/28073721/heroin-deaths-on-the-rise-in-tampa-bay (last visited Feb. 28, 2015).
[9] Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners*, p. ii (Interim Report 2013) (May 2014) http://www.fdle.state.fl.us/Content/getdoc/5de77741-a6bd-4a88-8000-ce9431321a6c/2013-Interim-Report-Final-(1).aspx (last visited Feb. 28, 2015).
[10] *Id* at p. 3.
[11] *Supra* note 1.

that usually is the cause of overdose deaths. During the period of time when an overdose can become fatal, respiratory depression can be reversed by giving the individual naloxone.[12] Naloxone injection and naloxone pre-filled auto-injection devices are used along with emergency medical treatment to reverse the life-threatening effects of opiate overdose. Naloxone injection is also used after surgery to reverse the effects of opiates given during surgery and is given to newborns to decrease the effects of opiates received by the pregnant mother prior to delivery.[13]

Naloxone can be used when someone believes an individual is suffering either an opioid or a heroin overdose. Naloxone injection comes as a solution (liquid) to be injected intravenously (into a vein), intramuscularly (into a muscle), or subcutaneously (just under the skin) and as a pre-filled auto-injection device.[14] It is usually given as needed to treat opiate overdoses. However, it does not work on benzodiazepine overdoses.[15,16] Naloxone is also known by its brand names of Narcan or Evzio.

First responders have been regularly carrying the drug for 40 years and the CDC reports that many law enforcement agencies across the nation have also been equipped with naxolone.[17] The federal government has made a tool kit available through a Department of Justice grantee website on the use of naloxone that is geared toward the law enforcement community.[18] One version of the product comes with a trainer that talks the caregiver through the drug administration.

As of December 31, 2014, 24 states authorize health care practitioners to prescribe opioid antagonists to third parties.[19]

Regulatory Landscape

Barriers may exist to the access to and the administration of the opioid antagonist where state health care practice laws prevent a non-patient from being issued a prescription as a caregiver or a friend and a dispenser from filling such a prescription, or where prescribers or dispensers have liability concerns.

The Florida Board of Medicine reviewed this issue at its December 5, 2014, meeting. A health care practitioner had raised the issue whether he could prescribe an opioid antagonist to his patient for administration by a third party at a later date and to teach overdose prevention and

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[12] *Supra* note, 1 at 5.
[13] Medline Plus, *Naloxone Injection* (May 15, 2014) http://www.nlm.nih.gov/medlineplus/druginfo/meds/a612022.html (last visited Feb. 28, 2015)
[14] *Id*.
[15] *Supra* note 12.
[16] Examples of benzodiazepines include: Valium, Xanax, or Klonopin.
[17] *Supra* note 4 and note 12.
[18] *Infra* note 29.
[19] These states are: California, Colorado, Georgia, Illinois, Kentucky, Massachusetts, Maryland, Maine, Michigan, North Carolina, New Jersey, New Mexico, new York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Virginia, Vermont, Washington, and Wisconsin. *See* Law Atlas, The Policy Surveillance Portal, Public Health law Research, Robert Wood Johnson Foundation, http://lawatlas.org/query?dataset=laws-regulating-administration-of-naloxone (last visited Feb. 28, 2015).

response education without violating certain provisions of the practice act.[20] The areas of concern covered by those provisions are:[21]

- Aiding or assisting an unlicensed person to practice medicine;
- Failing to perform any statutory or legal obligation placed on a licensed physician;
- Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of the physician's practice;
- Committing medical malpractice; and
- Delegating professional responsibilities to a person when the licensee delegating those responsibilities knows or has reason to know that such a person is not qualified to perform them.

The board granted the practitioner's request noting that its approval was specific only to his petition and suggested that a legislative change be sought.[22]

A pharmacist is subject to discipline for dispensing a drug pursuant to a prescription when the pharmacist knows or has reason to believe that the prescription is not based on a valid practitioner-patient relationship.[23]

The Florida Legislature and the federal government have already enacted legislation allowing third parties to receive prescriptions for the benefit of others relating to a variety of other health care services. For example:

- The Emergency Allergy Treatment Act authorizes a variety of entities – including individuals such as camp counselors, scout leaders, and tour guides – to possess and store epinephrine auto-injectors for later use on a person who is believed in good faith to be experiencing a severe allergic reaction.[24]
- Pharmacists may administer, in the event of an allergic reaction, epinephrine using an auto-injection delivery system within the framework of an established protocol with a physician when providing immunizations.[25]
- School personnel may purchase and maintain a supply of epinephrine auto-injectors in a secure, locked location on its premises for use if a student has an anaphylactic reaction.[26]

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[20] The specific practice acts include ss. 458.331(1)(f), (g), (q), (t) or (w), F.S., or any other rule of the board. *See* Florida Bd. of Medicine, Florida Dep't of Health, *Final Order on Petition for Declaratory Statement (p.144 of the Public Book Addendum)* (February 6, 2015) http://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Books/2015/February/02062015_FBAddendum_PublicBook.pdf (last visited Feb. 27, 2015).

[21] Florida Bd. of Medicine, Florida Dep't of Health, *Final Order on Petition for Declaratory Statement (p.144 of the Public Book Addendum)* (February 6, 2015) http://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Books/2015/February/02062015_FBAddendum_PublicBook.pdf (last visited Feb. 27, 2015).

[22] Florida Bd. of Medicine, Florida Dep't of Health, *Minutes for December 5, 2015 Meeting*, p. 20, *http://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Public_Minutes/2015/February/02062015_FB_Minutes.pdf* (last visited Feb. 27, 2015).

[23] Section 465.016(1)(s), F.S.

[24] Chapter 2014-141, Laws of Fla.

[25] Chapter Law 2012-60, s. 1, Laws of Fla.

[26] Chapter Law 2013-63, ss. 1 and 3, Laws of Fla.

- The federal *School Access to Emergency Epinephrine Act* provides a financial incentive to schools to maintain a supply of the epinephrine medication and to permit trained personnel to administer it. [27]

The Emergency Allergy Treatment Act (EATA) also authorizes a health care practitioner to prescribe epinephrine auto-injectors in the name of an authorized entity and pharmacists to dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity. Under the EATA, immunity from liability is provided to persons, authorized entities, and health care practitioners when acting in accordance with authorizations in the act.

Good Samaritan Act

Florida's Good Samaritan Act, found in s. 768.13, F.S., provides, in part:

> (2)(a) Any person, including those licensed to practice medicine, who gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situations related to and arising out of a public health emergency …, a state of emergency …, or at the scene of an emergency outside of a hospital, doctor's office, or other place having proper medical equipment, without objection of the injured victim or victims thereof, shall not be held liable for any civil damages as a result of such care or treatment or as a result of any act or failure to act in providing or arranging further medical treatment where the person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.

III. Effect of Proposed Changes:

The bill creates the "Florida Opioid Overdose Prevention Act" as s. 381.887, F.S., and provides definitions. The following definitions are created:

- Administer or administration means the introduction of an opioid antagonist approved by the United States Food and Drug Administration (FDA) into the body of a person;
- Authorized health care practitioner means a Florida-licensed practitioner authorized to prescribe drugs;
- Caregiver means a family member, friend, or any other person who may assist a person at risk of an opioid overdose; and
- Emergency overdose treatment information means information relating to:
  - Recognition of an opioid overdose and prevention;
  - How to perform rescue breathing;
  - Opioid antagonist dosage and administration;
  - The importance of calling 911; and
  - How to care for an overdose victim after an opioid antagonist administration;
- Opioid antagonist means naloxone hydrochloride or any similar acting drug that blocks the effects of opioids that is administered outside of the body and is approved by the FDA for treatment of opioid overdose; and

[27] Pub. Law 113-48, H.R. 2094, 113th Cong. (Nov. 13, 2013)

- Patient means a person at risk of experiencing an opioid overdose.

The bill authorizes the prescription of an opioid antagonist to a patient or a caregiver and to encourage the administration of that antagonist for the emergency treatment of a known or expected opioid overdose when a physician or other authorized health care practitioner is not available.

The bill authorizes health care providers to prescribe and dispense the opioid antagonist and requires the health care practitioner or his or her agent to provide the recipient of the prescription with the emergency overdose information.

A pharmacist is authorized to dispense an opioid antagonist based on a prescription that is issued to patient or caregiver. The bill requires the prescription to be appropriately labeled with instructions for use and to be issued in the name of the patient or the caregiver.

The bill permits the patient or caregiver who has an opioid antagonist prescription to store and possess the drug. The patient or caregiver is also permitted to administer the drug to a person whom he or she believes in good faith may be experiencing an opioid overdose, regardless of whether that person has his or her own prescription for an opioid antagonist.

An authorized health care practitioner may directly or through a standing order, prescribe and dispense an opioid antagonist to first responders. The bill identifies first responders as those defined under s. 112.1815, F.S.:

- Law enforcement officers as defined in s. 943.10, F.S.;
- Firefighters as defined in s. 633.102, F.S.;
- Emergency medical technicians or paramedics as defined in s. 401.23, F.S., employed by state or local government; and
- Volunteer law enforcement officers, firefighters, emergency medical technicians, or paramedics engaged by the state or local governments.

First responders are authorized to administer an approved opioid antagonist in accordance with his or her employers' policies.

Civil liability immunity protection is extended under the Good Samaritan Act to any person, an authorized or dispensing health care practitioner, or a first responder who possesses, administers, or stores an approved opioid antagonist under the bill.

The bill also provides civil and criminal liability and protection from professional licensure action or other adverse action for any licensed health care practitioner or pharmacist, acting in good faith and exercising reasonable care as a result of prescribing or dispensing an opioid antagonist under the provisions of this bill.

The bill does not limit any immunities that currently exist for first responders and others that are provided under statute or rule. Also, the bill does not create a duty or standard of care for a person to prescribe or to administer an opioid antagonist.

The bill is effective upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Under CS/SB 758, caregivers or other persons in a position to help someone at risk of an opioid overdose who have received emergency overdose treatment information would be eligible to acquire a prescription for an opioid antagonist. Individuals choosing to participate in this process would incur costs to acquire the opioid antagonist after receiving the required information.

C. Government Sector Impact:

The Bureau of Health Care Practitioner Regulation at the Department of Health reports no fiscal impact under the bill.[28]

The bill creates no fiscal impact on local governments; however, to the extent that local governments choose to stock a supply of opioid antagonists to address drug overdoses for their emergency medical services, police, fire departments, or other first responders, there could be a cost incurred to acquire the drugs.

According to the Bureau of Justice Assistance, the cost of a single rescue kit ranges from $22 to $60.[29]

[28] Department of Health, Bureau of Health Care Practitioner Regulation, *Senate Bill 758 Analysis,* p. 4 (Feb. 11, 2015) (on file with the Senate Committee on Health Policy).
[29] This information is provided by the Bureau of Justice Assistance, a contractor of the Office of Justice Programs, U.S. Department of Justice whose mission is to support state, local and tribal justice professionals to achieve safer communities. The Bureau has a Law Enforcement Naloxone Toolkit available at: https://www.bjatraining.org/tools/naloxone/Naloxone%2BBackground (last visited Feb. 26, 2015).

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 381.887 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 4, 2015:
The committee substitute makes the prescribing health care practitioner or his or her agent responsible for providing the emergency overdose treatment information to the patient or caregiver receiving the opioid antagonist prescription rather a third party organization. The committee substitute also provides a statutory cross reference for the term "first responder."

B. Amendments:

None.

By the Committee on Health Policy; and Senator Evers

588-01937-15 2015758c1

A bill to be entitled

An act relating to the prescription and use of opioid antagonists for emergency treatment of opioid overdoses; providing a short title; creating s. 381.887, F.S.; defining terms; providing the purposes of the act; providing for the prescribing of opioid antagonists to, and the use of them by, patients and caregivers who have received emergency overdose treatment information; providing for the prescribing of opioid antagonists to, and the use of them by, first responders; providing immunities from liability; providing applicability; providing an effective date.

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

Section 1. This act may be cited as the "Florida Opioid Overdose Prevention Act."

Section 2. Section 381.887, Florida Statutes, is created to read:

381.887 Prescription for and dispensing of opioid antagonists.—

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

(a) "Administer" or "administration" means to introduce an opioid antagonist into the body of a person by using a formulation approved by the United States Food and Drug Administration.

(b) "Authorized health care practitioner" means a licensed practitioner authorized by the laws of this state to prescribe drugs.

588-01937-15 2015758c1

(c) "Caregiver" means a family member, a friend, or any other person in a position to assist a person at risk of experiencing an opioid overdose.

(d) "Emergency overdose treatment information" means information regarding issues that include, but are not limited to, opioid overdose prevention and recognition, how to perform rescue breathing, opioid antagonist dosage and administration, the importance of calling 911 for assistance with an opioid overdose, and care for an overdose victim after administration of an opioid antagonist.

(e) "Opioid antagonist" means naloxone hydrochloride or any similarly acting drug that blocks the effects of opioids that have been administered from outside the body and that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

(f) "Patient" means a person at risk of experiencing an opioid overdose.

(2) The purpose of this section is to provide for the prescription of an opioid antagonist to patients and caregivers and to encourage the administration of opioid antagonists for emergency treatment of known or suspected opioid overdoses when a physician or other authorized health care practitioner is not immediately available.

(3) An authorized health care practitioner may prescribe an opioid antagonist for use in accordance with this section to a patient or caregiver who has received emergency overdose treatment information. A dispensing health care practitioner or pharmacist may dispense an opioid antagonist, appropriately labeled with instructions for use, pursuant to a prescription

which has been issued in the name of a patient or caregiver. In order to fulfill the requirement that a patient or caregiver receive emergency overdose treatment information, such information may be provided to a patient or caregiver by the prescribing authorized health care practitioner or his or her agent. The patient or caregiver who has an opioid antagonist prescription may store and possess an approved opioid antagonist. In an emergency situation when a physician or other authorized health care practitioner is not immediately available, any patient or caregiver who has received emergency overdose treatment information may administer the opioid antagonist to a person believed in good faith to be experiencing an opioid overdose, regardless of whether that person has a prescription for an opioid antagonist.

(4) An authorized health care practitioner may, directly or by standing order, prescribe and dispense opioid antagonists to first responders, as defined in s. 112.1815, and such first responders may possess, store, and administer approved opioid antagonists as prescribed and clinically indicated, and in accordance with the policies of the employer of such first responders.

(5) Any person, including an authorized health care practitioner, a dispensing health care practitioner, a pharmacist, or a first responder, as defined in s. 112.1815, who possesses, administers, or stores an approved opioid antagonist in compliance with this section and with s. 768.13 is afforded the civil liability immunity protection provided under s. 768.13.

(6) Any authorized health care practitioner, acting in good

faith and exercising reasonable care, is not subject to discipline or other adverse action under any professional licensure statute or rule and is immune from any civil or criminal liability as a result of prescribing an opioid antagonist in accordance with this section. Any dispensing healthcare practitioner or pharmacist, acting in good faith and exercising reasonable care, is not subject to discipline or other adverse action under any professional licensure statute or rule and is immune from any civil or criminal liability as a result of dispensing an opioid antagonist in accordance with this section.

(7) This section does not limit any existing immunities for first responders and others provided under any other applicable statute or rule. This section does not create a duty or standard of care for a person to prescribe or administer an opioid antagonist.

Section 3. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 17, 2015

I respectfully request that **Senate Bill #1052**, relating to **Florida Right to Try Act**, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Jeff Brandes
Florida Senate, District 22

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/2015
Meeting Date

1052
Bill Number (if applicable)

Topic POLST AMENDMENT TO 1052

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA RIGHT TO LIFE, INC.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/21/15
Meeting Date

1052
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic FL Right to Try Act

Name Laura Cantwell

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St. Pete FL 33716
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Phone 850-570-2110

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing AARP

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

02 APRIL 2015
Meeting Date

1052
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic RIGHT-TO-TRY

Name MICHAEL MCQUONE (MCCUE-ONE)

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Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA CONFERENCE OF CATHOLIC BISHOPS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

WAIVE TIME IN SUPPORT

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4-2-2015
Meeting Date

SB 1052
Bill Number (if applicable)

Topic FLORIDA RIGHT TO TRY ACT

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

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City *State* *Zip*

Email

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

1052
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Mand

Job Title _____

Address 1000 Riverside Ave
Street
Jacksonville FL 32204
City *State* *Zip*

Phone 904-233-3051

Email cmandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	PCS/CS/SB 1052 (592332)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Brandes
SUBJECT:	Florida Right to Try Act
DATE:	April 6, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Recommend: Fav/CS**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1052 creates the "Florida Right to Try Act," which provides a framework in which an eligible patient with a terminal illness may access investigational drugs, biological products, and devices from the manufacturer after phase-one clinical trials.

The bill prohibits actions against a physician's license based solely on his or her recommendation regarding access to or treatment with an investigational drug, product, or device under the bill. Action also may not be taken against a health care institution's state license or its Medicare certification based on its participation in the treatment in or with investigational drugs, biological products, or devices under the bill.

The bill establishes a Clearinghouse for Compassionate and Palliative Care Plans for state residents. The Agency for Health Care Administration (AHCA) is directed to establish and maintain the site, either independently or through a national or private clearinghouse. The AHCA is also directed to disseminate information about the clearinghouse once available.

Lastly, the bill recognizes a Physician Order for Life Sustaining Treatment (POLST) in law and directs the Department of Health to develop the form by rule.

The bill's provisions relating to the Clearinghouse for Compassionate and Palliative Care Plans represent a cost to the AHCA of $350,000 general revenue for the 2015-2016 fiscal year and a

recurring cost of $140,000 general revenue, but implementation of the clearinghouse is subject to a specific appropriation in the General Appropriations Act.

The bill takes effect July 1, 2015.

II. Present Situation:

The U.S. Food and Drug Administration (FDA) has wide regulatory authority over what drugs are marketed and sold within the United States. Prescription drugs and over-the-counter drugs are regulated by the FDA's Center for Drug Evaluation and Research.[1] If a drug company wants approval to sell a new prescription drug in the United States, it must be tested in several steps. The first step is testing in the laboratory and on animals.[2] Next, the drug is tested for safety and efficacy when used to treat or diagnose a disease in humans.[3]

Clinical trials are part of clinical research which look at new ways to prevent, detect, or treat disease through new combinations of drugs, new surgical procedures, or devices, or new ways to use existing treatments.[4] Clinical trials are part of clinical research which is conducted as part of protocol. A protocol describes:

- Who is eligible to participate in the trial;
- Details about tests, procedures, medications, and dosages; and
- The length of the study and what information will be gathered.[5]

Clinical trials are typically run by a principal investigator, usually a medical doctor, and are approved and monitored by an Institutional Review Board (IRB), an independent committee of experts usually consisting of physicians and non-physicians in hospitals and research institutions.[6] The IRB's role is to ensure that the safety and rights of the participants are protected and to periodically review the research.[7]

Informed consent is a critical component of the clinical research and trial process as it provides participants with important information about the trial before they decide to participate. The informed consent form includes information on the expected benefits and risks of participation and that as a volunteer, the participant may withdraw at any time. Withdrawal of too many participants, however, may make the research team ineligible to continue the study.[8]

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[1] U.S. Food and Drug Administration, *What is the approval process for a new prescription drug?* (last updated August 12, 2013) http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192696.htm (last visited Mar. 14, 2015).
[2] U.S. Food and Drug Administration, *What is the approval process for a new prescription drug?* (last updated April 11, 2014) http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm (last visited Mar. 14, 2015).
[3] Id.
[4] U.S. Department of Health and Human Services, National Institutes of Health, *NIH Clinical Research Trials and You*, (last reviewed February 5, 2015) http://www.nih.gov/health/clinicaltrials/basics.htm (last visited Mar. 14, 2015).
[5] Id.
[6] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, (last updated November 6, 2014) http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last viewed Mar. 14, 2015).
[7] U.S. Department of Health and Human Services, National Institutes of Health, *NIH Clinical Research Trials and You*, (last reviewed February 5, 2014) http://www.nih.gov/health/clinicaltrials/basics.htm (last visited Mar. 15, 2015).
[8] Id.

When testing is complete, the company sends an application to the FDA called a New Drug Application (NDA). If a drug is made out of biologic materials, a company submits a different application, a Biologics License Application (BLA). Regardless of the type of application used, both require similar elements:

- The drug's test results;
- Manufacturing information to demonstrate the company can properly manufacture the drug; and
- The company's proposed label for the drug which must provide necessary information about the drug, including the conditions for which it has shown to be useful.[9]

There are different types of clinical trials, and the National Institutes of Health (NIH) classifies them into these categories:

- Natural history studies, which provide valuable information about how disease and health progress;
- Prevention trials, which look for better ways to prevent disease in people who have never had the disease or to prevent the disease from returning;
- Screening trials, which test the best way to detect certain diseases or health conditions;
- Diagnostic trials, which determine better tests or procedures for diagnosing a particular disease or condition;
- Treatment trials, which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy; and
- Quality of Life trials, which explore and measure ways to improve the comfort and quality of life of people with chronic illness.

All clinical trials are conducted in phases. Prior to receiving the FDA's approval for human testing, the organization must show the FDA results of pre-clinical testing in laboratory animals and their proposal for human testing. The FDA must decide if it is reasonably safe for the organization to begin testing the drug in humans.[10] This approval process is based on an investigational new drug (IND) application. Most drugs that undergo pre-clinical (animal) testing never make it to human testing and review by the FDA.[11]

When an IND application is approved, an IRB established, the protocol approved, and the consent received from study participants, the organization can begin the process:

[9] U.S. Food and Drug Administration, *What is the approval process for a new prescription drug?* (last updated April 11, 2014) http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm (last visited Mar. 14, 2015).
[10] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, (last updated November 6, 2014) http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last viewed Mar. 14, 2015).
[11] Id.

Clinical Trial Phases[12]			
Phase	**Activities**	**Approx. Time[13]**	**# of Participants**
One	Test drug with healthy human volunteers. Determine drug's most frequent side effects. Determine how the drug is metabolized and excreted. Determine the correct dosing. Move to Phase Two if drug does not show unacceptable toxicity.	1 year	20-80
Two	Test drug with small number of targeted patients. Test drug is compared with those receiving a placebo, or a different drug (if a controlled trial). Evaluate safety and short-term side effects. Decide scope of Phase Three with FDA; drug must have shown effectiveness to move to Phase Three.	2 years	100-300
Three	Implement large scale study for effectiveness and safety. Study different populations and different dosages and using the drug in combination with other drugs. Review logistics of creating a large supply. Once complete, can complete New Drug Application (NDA).	3 years	300-3,000
Four	Post-market requirement and commitment studies must be agreed to by the sponsoring organization and are conducted after a product has been approved for sale. Information used to gather additional data about product's safety, efficacy, or optimal use.	n/a	n/a

When an NDA is received by the FDA, the FDA has 60 days to decide whether to file so it can be reviewed.[14] The FDA can refuse to file an application if it is incomplete. If the FDA determines that the drug's benefits outweighs its risks and the drug can be manufactured in a manner that ensures a quality product, the drug can be approved for marketing in the United States.[15] The company receiving approval must continue, under Phase Four, to monitor short-term and long-term results of the drug and submit those findings to the FDA. If the company wants the drug approved for another purpose, it must also receive FDA approval.[16]

[12] Id.
[13] FierceBiotech, *FDA Approval Process* http://www.fiercebiotech.com/topics/fda_approval_process.asp (last visited Mar. 14, 2015).
[14] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, (updated November 6, 2014) http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last viewed Mar. 14, 2015).
[15] Id.
[16] FierceBiotech, *FDA Approval Process*, http://www.fiercebiotech.com/topics/fda_approval_process.asp (last visited Mar. 14, 2015).

Accelerated approval is granted by the FDA to some new drugs for serious and life-threatening illnesses that lack other treatment options.[17] This option allows drugs to be approved without measures of effectiveness that are usually required ahead of time.

The FDA established regulations allowing expanded access to, or "compassionate use" of, experimental drugs, biological products, or devices in 1987, and individual patient "emergency use" expanded access in 1997. These regulations provide access to:

- Individuals on a case-by-case basis, known as "individual patient access";[18]
- Intermediate-sized groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial;[19] and
- Large groups of patients who do not have other treatment options available.[20]

Compassionate Use

"Expanded access" or "compassionate use" refers to the use of an investigational medical product outside of a clinical trial, meaning that the medical product has not yet been approved by the FDA.[21] The FDA prefers that patients seek out the use of an investigational medical product through clinical trials.[22] Clinical trials help generate the necessary data to support approval or disapproval of medical products, investigational drugs, and devices. However, under the federal Food, Drug, and Cosmetic Act, an individual may seek individual patient access to investigational products if the following conditions are met:

- The individual's physician determines that there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the person's disease or condition, and the probable risk to the person from the investigational product is not greater than the risk from the disease or condition;
- The FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support its use in the particular circumstance;
- The FDA determines that providing the investigational product will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval;
- The sponsor or the clinical investigator submits a clinical protocol that is consistent with FDA's statute and applicable regulations for INDs or investigational device exemption applications, describing the use of the investigational product.[23]

Additionally, in order for the expanded access or compassionate use request to move forward:

- Both the patient and his or her licensed physician must be willing to participate;
- The patient must have a serious or immediately life-threatening disease or condition;

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[17] U.S. Food and Drug Administration, *FDA's Drug Review Process: Continued, Accelerated Approval*, (updated November 6, 2014) http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm#accelerated (last visited Mar. 15, 2015).
[18] U.S. Food and Drug Administration, *Expanded Access Coverage for Drugs*, (last updated February 18, 2015) http://www.fda.gov/ForPatients/Other/default.htm (last visited Mar. 15, 2015)
[19] 21 U.S.C. §312.315
[20] 21 U.S.C. §312.320
[21] U.S. Food and Drug Administration, *Expanded Access (Compassionate Use)* (last updated February 18, 2015) http://www.fda.gov/newsevents/publichealthfocus/expandedaccesscompassionateuse/default.htm (last visited Mar. 15, 2015).
[22] Id.
[23] Id.

- The patient must have no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; and
- The patient must be unable to obtain the investigational drug under another IND or to participate in a clinical trial.[24]

To apply for expanded access or compassionate use under a single patient IND, the application must be made by the physician.[25] The physician must also have his patient's informed consent. If applicable, the physician should also ask the medical product company for a Letter of Authorization (LOA). The LOA allows the physician to satisfy some of the requirements for submission by relying on information that the medical product company has already submitted to the FDA.

For non-emergency requests, treatment may begin 30 days after the FDA receives the request if the treating physician fails to hear from the FDA. For emergencies, once authorization is received from the FDA, the physician may begin treatment within five working days.[26]

On February 10, 2015, the FDA released draft guidance for comment that would revise the expanded access process. The federal Office of Management and Budget (OMB) estimates that the current process takes physician approximately eight hours to request for non-emergency situations and 16 hours for emergency cases. For the new process, OMB estimates the process for both emergent and non-emergent situations will take 45 minutes.[27]

Once the FDA has approved a patient for expanded access, the drug manufacturer must still agree to provide the product. There may also be only a limited amount of a drug available under a company's expanded access programs.[28] Generally, under expanded access, the drug is provided free of charge, but not always. However, the other costs associated with care related to the patient's disease and condition would be the responsibility of the patient and any available insurance coverage.

Right to Try

Several states have implemented "Right to Try" laws that allow terminally ill patients access to investigational drugs that have completed basic safety testing. More than 60 percent of

[24] Id.
[25] The form's questions include whether the request is an emergency, the patient's clinical history, a proposed treatment plan, the informed consent form. *See U.S. Food and Drug Administration, How to Complete Form FDA 1571 and Form FDA 1572*, (last updated February 3, 2015) http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm432757.htm (last visited Mar. 15, 2015).
[26] *Supra* note 21.
[27] Individual Patient Expanded Access Applications: Form FDA 3926; Draft Guidance for Industry; Availability, 80 Fed. Reg. 7318 (proposed Feb. 10, 2015) (to be codified at 21 CFR pt. 312).
[28] American Cancer Society, *Compassionate Drug Use*, (last medical review July 9, 2013) http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/compassionate-drug-use (last visited Mar. 15, 2015).

investigational drugs in Phase I testing are deemed safe enough to move on to Phase II.[29] More than 30 percent then move on from Phase II testing to Phase III.

Federal legislation to change the expanded access policy has not been successful. Since 2008, at least four bills have been introduced in Congress, but none have had a committee or floor vote.[30] The Right to Try model legislation allows a patient access to investigational medication that have passed basic safety tests without governmental interference when the following conditions are met:

- The patient has been diagnosed with a terminal disease;
- The patient has considered all available treatment options;
- The patient's doctor has recommended that the investigational drug, device, or biological product represents the patient's best chance at survival;
- The patient or the patient's guardian has provided informed consent; and
- The sponsoring company chooses to make the investigational drug available to patients outside of the clinical trial.

As of March 15, 2015, seven states have Right to Try laws: Arkansas, Michigan, Colorado, Missouri, Louisiana, and Wyoming.[31]

End of Life Decision-Making

There are a number of different advanced decision making documents an individual may use to express his or her end of life health care decisions. In Florida, state law defines advance directives as witnessed, oral statements or written instructions that express a person's desires about any aspect of his or her future health care, including the designation of a health care surrogate, a living will, or an anatomical gift.[32]

Resuscitation may also be withheld from an individual if a "do not resuscitate" order (DNRO) by the patient's physician is presented to the health care professional treating the patient. For the DNRO to be valid, it must be on the form adopted by the DOH, signed by the patient's physician and by the patient, or if the patient is incapacitated, the patient's health care surrogate or proxy, court-appointed guardian, or attorney in fact under a durable power of attorney.[33] Florida's form is printed on yellow paper.[34] It is the responsibility of the Emergency Medical Services provider to ensure that the DNRO form or the patient identification device, which is a miniature version of the form, accompanies the patient.[35] A DNRO may be revoked by the patient at any time, if

[29] Michael Hay, et al, *Clinical development success rates for investigational drugs* (January 2014), Nature Biotechnology (see Figure 1- Phase success and LOA rates), http://www.nature.com/nbt/journal/v32/n1/abs/nbt.2786.html (last visited Mar. 15, 2015).
[30] Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of their Treatment*, pg. 20, Goldwater Institute (February 11, 2014).
[31] Goldwater Institute, *Arkansas Governor Asa Hutchinson Signs "Right to Try" Bill Into Law* (2014) http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/arkansas-governor-asa-hutchinson-signs-right-to-tr (last visited Mar. 15, 2015).
[32] *see* s. 765.101, F.S.
[33] *see* ss.395.1041, F.S., 400.142, F.S., 400.487, F.S., 400.605, F.S., 400.6095, F.S.; 401.35, F.S.; 401.45, F.S. , 429.255; 429.73; F.S.; 7665.205, F.S.
[34] Rule 64J-2.018, F.A.C.
[35] Id.

signed by the patient, or the patient's health care surrogate, or proxy, or court appointed guardian or a person acting under a durable power of attorney.[36]

A Physician Order for Life-Sustaining Treatment (POLST) documents a patient's health care wishes in the form of a physician order for a variety of end of life measures, including cardiopulmonary resuscitation (CPR).[37] A DNRO is limited to the withholding of CPR. The POLST form can only be completed by a physician and is then provided to the patient to be kept secured in a visible location for emergency personnel.[38] It is suggested that the form be completed when an individual has a serious illness, regardless of age, as the POLST serves as a medical order for a current illness.[39]

Some questions asked on other states' POLST forms include what level of care is wanted for CPR (attempt or do not attempt); medical intervention (comfort only, limited additional intervention, or full treatment); and artificially administered nutrition (none, trial, or long-term).

III. Effect of Proposed Changes:

Florida Right to Try Act

This bill creates the "Florida Right to Try Act" under s. 385.213, F.S., and provides definitions.

An *eligible patient* is defined as an individual who:

- Has a terminal illness determined by the individual's physician and a consulting physician;
- Does not have any comparable or satisfactory Food and Drug Administration (FDA) - approved options available, as determined by his or her physician, and the probable risk from an investigational drug, biological product, or device is not greater than the disease or condition;
- Has received a prescription or recommendation from his or her physician for the investigational drug, biological product, or device;
- Has provided written, informed consent for the use of the investigational drug, biological product, or device, or if a minor or lacks the capacity to provide informed consent, a parent's or legal guardian's written, informed consent on the individual's behalf; and
- Has documentation from the individual's physician indicating that the individual has met all of the applicable requirements.

An *investigational drug, biological product, or device* is defined as a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the FDA.

Physician means a physician licensed under ch. 458, F.S., or ch. 459, F.S., who provides the medical health treatment to the eligible patient for the terminal illness.

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[36] Id.
[37] POLST.ORG, *About the National POLST Paradigm, http://www.polst.org/about-the-national-polst-paradigm/ (last visited: Mar. 17, 2015).*
[38] POLST.ORG, *FAQ, http://www.polst.org/advance-care-planning/faq/* (last visited: Mar. 17, 2015).
[39] POLST.ORG, *POLST v. Advance Directives, http://www.polst.org/advance-care-planning/polst-and-advance-directives/* (last visited: Mar. 17, 2015).

Terminal illness means a disease or condition that, without life-sustaining procedures, will result in the patient's death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

A manufacturer of an investigational drug, biological product, or device has the option to make an investigational drug, biological product, or device available to an eligible patient under the bill. Relating to the investigation drug, biological product, or device, a manufacturer may also:

- Provide without charge or require the eligible patient to pay the cost of, or the costs associated with, its manufacture; and
- Require an eligible patient to participate in data collection relating to the eligible patient's use.

The bill does not require an insurer, health plan, or government health care program to provide coverage for the cost of an investigational drug, biological product, or device, or the care or treatment that may be needed as result of an eligible patient's participation, unless it is part of a clinical trial. However, an insurer, health plan, or government health care program may elect to provide such coverage, if not part of a clinical trial.

The Department of Corrections and the Department of Juvenile Justice are not required to provide coverage for an investigational drug, biological product, or device for individuals in their custody.

Notwithstanding any other law, a state regulatory board or agency may not take any action against a physician's license based solely on the practitioner's recommendation regarding access to or treatment with an investigational drug, biological product, or device.

For health care institutions licensed in this state, a state regulatory board or agency may not take any action against an institution's license or its Medicare certification based solely on the institution's participation in or any other use or treatment with an investigational drug, biological product, or device.

If a clinical trial of an investigational drug, biological product, or device is not effective for a certain patient or condition and the trial is closed due to lack of efficacy, the manufacturer may continue to offer the investigational drug, biological product, or device for a different condition to the same patient or to new patients under the bill.

If the FDA or the safety committee for a clinical trial provides notice of information for an investigational drug, biological product, or device that is being taken by a patient outside of a clinical trial, the manufacturer or the patient's physician is required to notify the patient about the information. For example, the FDA may advise the public of a previously unknown side effect or hidden ingredient of a particular drug that is on the market for another condition or disease, but the drug is also part of a clinical trial for another purpose. The side effect or hidden ingredient could affect those patients taking the drug for another condition outside of a clinical trial.

Under the bill, a private cause of action is not created against a manufacturer of an investigational drug, biological product, or device or against an entity or individual involved in the care of an eligible patient for any harm to the patient resulting from use of the investigational

drug, biological product, or device, if the manufacturer, entity, or individual complied with the requirements of the bill in good faith, unless the manufacturer, entity or individual failed to exercise reasonable care.

An official, employee, or agent of the state may not block an eligible patient's access to an investigational drug, biological product, or device that has been recommended by his or her physician unless it has been banned or removed from a clinical trial as unsafe by the FDA. If a person does block access, he or she commits a misdemeanor of the second degree.

Clearinghouse for Compassionate and Palliative Care Plans

The bill creates s. 408.064, F.S., and the Clearinghouse for Compassionate and Palliative Care Plans. The Agency for Health Care Administration (AHCA) is responsible for establishing and maintaining a reliable and secure database that will allow Florida residents to electronically submit their individual plans for compassionate and palliative care. This database is a clearinghouse of plan information that may be accessed by a health care provider who is treating the resident.

The AHCA is directed to seek input on the clearinghouse from state residents, compassionate and palliative care providers, and health care facilities for its development and implementation. The AHCA may also subscribe to or participate in a national or private clearinghouse that will accomplish the same goals in lieu of establishing an independent clearinghouse. Once clearinghouse information is available, the AHCA is required to publish and disseminate information regarding the availability of the clearinghouse to Floridians. The AHCA must also provide training to health care providers and health care facilities on how to access plans.

The bill provides that implementation of the bill's provisions relating to the clearinghouse is subject to a specific appropriation provided to the AHCA under the General Appropriations Act.

Physician Orders for Life-Sustaining Treatment (POLST)

Provisions in statute requiring health professional staff to honor "do not resuscitate" orders (DNROs) are revised to include recognition of a POLST document in the same manner. Under s. 404.45, F.S., a valid POLST is described as one completed on the form adopted by the Department of Health by rule, signed by the patient's physician, and based on a consultation with the patient's guardian or legally authorized proxy or surrogate.

The table below reflects the statutes impacted by these revisions.

Statutory Revisions - Addition of POLTS Language	
F.S. Citation	**Description**
§395.1041	Hospital Licensing and Regulation: Access to emergency services and care
§400.142	Nursing Homes; Emergency medication kits; DNROs
§400.487	Home Health Service Agreements; DNROs
§400.605	Hospices; Administration; forms; fees

§400.6095	Hospice; patient admission; assessment; plan of care; discharge; death
§401.35	Medical Transportation Services: Rules
§401.45	Denial of emergency treatment; civil liability
§429.255	Assisted Living Facilities; Use of personnel; emergency care
§429.73	Rules and standards relating to adult family-care homes

Effective Date

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

A separate public records exemption may be needed to keep the Compassionate and Palliative Care plans held by the Agency for Health Care Administration exempt from public records requests under ch. 119, F.S.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

PCS/CS/SB 1052 may increase the number of Floridians who have access to investigational drugs, biological products, and devices, but, under the bill, insurers are not required to cover these products or the treatment resulting from an insured's participation, unless the patient is part of a clinical trial.

C. Government Sector Impact:

The Agency for Health Care Administration (AHCA) estimates the costs for the Clearinghouse for Compassionate and Palliative Care Plans to be $350,000 for the first year of implementation and $140,000 per year for maintenance costs to participate in a national or private clearinghouse.[40] Under the bill, these costs relating to the

[40] Agency for Health Care Administration, *Senate Bill 1052 Analysis* (February 20, 2015), pg. 4, (on file with the Senate Committee on Health Policy).

clearinghouse will not be incurred without a specific appropriation provided to the AHCA under the General Appropriations Act.

The Department of Health will incur nonrecurring costs for rulemaking but reports it has sufficient current budget authority to absorb those expected costs.[41] Additionally, indeterminate costs may be incurred for an increase in workload related to additional complaints, but these costs are likely to be absorbed within existing resources.[42]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Agency for Health Care Administration (AHCA) notes a potential conflict with federal law and regulations. The bill prohibits the AHCA from taking action against a health care institution's Medicare certification based solely on a health care provider's recommendation to an eligible patient regarding access to an investigational drug, biological product, or device; however, the federal Centers for Medicare & Medicaid Services (CMS) could direct the AHCA to conduct a complaint investigation regarding such as an issue. The AHCA would be required to report its finding to federal CMS.[43]

The Department of Health (DOH) observed that the bill extends regulatory protection to a physician's *recommendation* of an investigational drug, biological product, or device, but not to the health care provider's *administration* of an investigational drug, biological product, or device. The DOH also advises that while the bill may provide protections to physicians and health care institutions from state regulatory actions, the bill cannot shield such providers from federal regulatory actions,[44] even though such federal actions are unlikely under the bill's constructs.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 385.213 and 408.064.

This bill substantially amends the following sections of the Florida Statutes: 395.1041, 400.142, 400.487, 400.605, 400.6095, 401.35, 401.45, 429.255, 429.73, and 765.205.

[41] Department of Health, Florida Board of Medicine, *Senate Bill 1052 Analysis* (February 25, 2015), pg. 5, (on file with the Senate Committee on Health Policy).
[42] Id.
[43] *Supra* note 40, at 5.
[44] *Supra* note 41, at 3.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS by Appropriations Subcommittee on Health and Human Services on April 2, 2015:
The proposed committee substitute provides that implementation of the Clearinghouse for Compassionate and Palliative Care Plans is subject to a specific appropriation under the General Appropriations Act.

CS by Health Policy - March 17, 2015
The committee substitute:

- Recognizes Physician Orders for Life Sustaining Treatment (POLST) as evidence of a patient's health care wishes in the same circumstances as "do not resuscitate" orders when presented to a health care professional; and
- Requires a POLST document, in order to be considered valid, to be on a form adopted by the Department of Health and signed by the patient's physician based on a consultation with the patient, the patient's guardian, or a legally authorized proxy or surrogate.

B. Amendments:

None.

748902

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/06/2015	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Between lines 237 and 238
insert:
(4) Implementation of this section is subject to a specific appropriation provided to the agency under the General Appropriations Act.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:

748902

Delete line 59

and insert:

training relating to the clearinghouse; providing that implementation is subject to specific appropriation; amending ss.

By the Committee on Health Policy; and Senator Brandes

588-02380A-15 20151052c1

A bill to be entitled

An act relating to the Florida Right to Try Act; providing a short title; creating s. 385.213, F.S.; defining terms; authorizing a manufacturer of an investigational drug, biological product, or device to make such drug, product, or device available to certain eligible patients with a terminal illness without charge or for a specified cost; authorizing the manufacturer to require eligible patients to participate in certain data collection; specifying that an insurer, a health plan, or a government health care program is not required to provide coverage for the cost of such drug, product, or device; authorizing such entities to provide coverage under specified circumstances; specifying that such entities are not required to cover care or treatment needed as the result of the use of such drug, product, or device except under certain circumstances; specifying that the Department of Corrections and the Department of Juvenile Justice are not required to provide coverage for such drugs, products, or devices for individuals in the departments' custody; prohibiting a state regulatory board or agency from taking action against the licenses of certain health care providers or against the licenses or Medicare certifications of certain health care institutions for specified actions with respect to an eligible patient's access to, treatment with, or use of investigational drugs, biological products, or devices; specifying when an

588-02380A-15 20151052c1

investigational drug, biological product, or device may continue to be offered by the manufacturer if the drug, product, or device is found to be ineffective under certain circumstances; requiring certain information relating to clinical trials to be provided to a patient taking an investigational drug, biological product, or device outside of the clinical trial; providing that the section does not create a private cause of action against certain manufacturers, entities, and individuals for any harm to an eligible patient which results from the use of an investigational drug, biological product, or device under certain circumstances; providing a criminal penalty for an official, employee, or agent of the state who blocks or attempts to block the access of an eligible patient to certain investigational drugs, biological products, or devices; creating s. 408.064, F.S.; requiring the Agency for Health Care Administration to establish and maintain a database that allows a state resident to electronically submit a plan that indicates his or her directives for compassionate and palliative care; requiring the database to serve as a clearinghouse of plan information that is accessible by certain health care providers; authorizing the agency to subscribe to or participate in a national or private clearinghouse in lieu of establishing and maintaining an independent clearinghouse; requiring the agency to publish and disseminate certain information and provide certain

training relating to the clearinghouse; amending ss. 395.1041, 400.142, and 400.487, F.S.; authorizing hospital personnel, nursing home facility staff, and home health agency personnel, respectively, to withhold or withdraw cardiopulmonary resuscitation if an individual has a Physician Order for Life-Sustaining Treatment (POLST); amending s. 400.605, F.S.; requiring the Department of Elder Affairs in consultation with the Agency for Health Care Administration to adopt by rule procedures for the implementation of POLSTs in hospice care; amending s. 400.6095, F.S.; authorizing a hospice care team to withhold or withdraw cardiopulmonary resuscitation if an individual has a POLST; amending s. 401.35, F.S.; requiring the Department of Health to establish circumstances and procedures for honoring a POLST; amending s. 401.45, F.S.; authorizing emergency medical transportation providers to withhold or withdraw cardiopulmonary resuscitation or other medical interventions if an individual has a POLST; providing requirements for a POLST to be valid; amending s. 429.255, F.S.; authorizing assisted living facility staff to withhold or withdraw cardiopulmonary resuscitation if an individual has a POLST; amending s. 429.73, F.S.; requiring the Department of Elder Affairs to adopt rules for the implementation of POLSTs in adult family-care homes; authorizing a provider of such home to withhold or withdraw cardiopulmonary resuscitation if an individual has a

POLST; providing immunity from civil and criminal liability to a provider for such actions; amending s. 765.205, F.S.; authorizing a health care surrogate to provide written consent for a POLST; providing an effective date.

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

Section 1. This act may be cited as the "Florida Right to Try Act."

Section 2. Section 385.213, Florida Statutes, is created to read:

385.213 Compassionate treatment; access to experimental treatments.—

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

(a) "Eligible patient" means an individual who:

1. Has a terminal illness, as determined by the individual's physician and consulting physician;

2. As determined by the individual's physician, does not have any comparable or satisfactory United States Food and Drug Administration-approved option available to be diagnosed, monitored, or treated for the individual's disease or condition, and the probable risk to the individual from the investigational drug, biological product, or device is not greater than the risk from the disease or condition;

3. Has received a prescription or recommendation from the individual's physician for an investigational drug, biological product, or device;

4. Has provided written, informed consent in accordance

with s. 766.103 for the use of an investigational drug, biological product, or device or, if the individual is a minor or lacks the mental capacity to provide informed consent, a parent's or legal guardian's written, informed consent on the individual's behalf; and

5. Has documentation from the individual's physician indicating that the individual has met all the requirements of this section.

(b) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration.

(c) "Physician" means the physician licensed under chapter 458 or chapter 459 who provides medical care or treatment to the eligible patient for the terminal illness.

(d) "Terminal illness" means a disease or condition that, without life-sustaining procedures, will result in the patient's death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

(2) AVAILABILITY OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.—

(a) A manufacturer of an investigational drug, biological product, or device may make the investigational drug, biological product, or device, available to an eligible patient. A manufacturer may:

1. Provide the investigational drug, biological product, or device to an eligible patient without charge or require the eligible patient to pay the cost of, or the cost associated

with, the manufacture of the investigational drug, biological product, or device.

2. Require an eligible patient to participate in data collection relating to the eligible patient's use of the investigational drug, biological product, or device.

(b) This section does not require:

1. An insurer, a health plan, or a government health care program to provide coverage for:

a. The cost of an investigational drug, biological product, or device provided to an eligible patient. An insurer, a health plan, or a government health care program may elect to provide coverage for an investigational drug, biological product, or device that is not part of a clinical trial.

b. Care or treatment needed as a result of an eligible patient's use of an investigational drug, biological product, or device unless the use is part of an approved clinical trial.

2. The Department of Corrections or the Department of Juvenile Justice to provide coverage for an investigational drug, biological product, or device for individuals in the custody of the Department of Corrections or the Department of Juvenile Justice.

(3) ACTION AGAINST PROVIDER LICENSURE PROHIBITED.—Notwithstanding any other law, a state regulatory board or agency:

(a) May not take any action against a health care provider's license issued under chapter 458 or chapter 459 based solely on the health care provider's recommendation to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device.

(b) May not, with respect to a health care institution licensed in this state, take any action against the institution's:

1. License based solely on the institution's participation in the treatment with, or in any other use of, an investigational drug, biological product, or device.

2. Medicare certification based solely on a health care provider's recommendation to an eligible patient regarding access to an investigational drug, biological product, or device.

(4) CLINICAL TRIALS.—

(a) If a clinical trial of an investigational drug, biological product, or device is not effective for a certain patient or condition and the trial is closed due to lack of efficacy, the manufacturer or health care provider may continue to offer the investigational drug, biological product, or device for a different condition to the patient or to new patients.

(b) If the United States Food and Drug Administration or the safety committee for a clinical trial provides notice of information for an investigational drug, biological product, or device that is being taken by a patient outside of the clinical trial, the manufacturer of such drug, product, or device or the patient's physician shall notify the patient of the information.

(5) NO CAUSE OF ACTION.—This section does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device or against an entity or individual involved in the care of an eligible patient for any harm to the eligible patient which results from the use of the investigational drug, biological product, or

device if the manufacturer, entity, or individual is complying in good faith with this section, unless the manufacturer, entity, or individual failed to exercise reasonable care.

(6) PENALTY.—An official, employee, or agent of the state who blocks or attempts to block the access of an eligible patient to an investigational drug, biological product, or device that has been recommended to the eligible patient by his or her physician and that has not been banned or removed from a clinical trial as unsafe by the United States Food and Drug Administration commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 3. Section 408.064, Florida Statutes, is created to read:

408.064 Clearinghouse for compassionate and palliative care plans.—

(1) The agency shall establish and maintain a reliable and secure database that allows a resident of this state to electronically submit a plan that indicates his or her directives for compassionate and palliative care. The database shall serve as a clearinghouse of plan information that may be accessed by a health care provider who is treating the resident. The agency shall seek advice from residents, compassionate and palliative care providers, and health care facilities for the development and implementation of the clearinghouse.

(2) The agency may subscribe to or otherwise participate in a national or private clearinghouse that will accomplish the requirements under subsection (1) in lieu of establishing and maintaining an independent clearinghouse for this state's residents.

(3) The agency shall publish and disseminate information to the residents of this state regarding the availability of the clearinghouse. The agency must also provide training to health care providers and health care facilities in this state on how to access plans through the clearinghouse.

Section 4. Paragraph (l) of subsection (3) of section 395.1041, Florida Statutes, is amended to read:

395.1041 Access to emergency services and care.—

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—

(l) Hospital personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a Physician Order for Life-Sustaining Treatment (POLST). Facility staff and facilities shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to either ~~such an~~ order. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 5. Subsection (3) of section 400.142, Florida Statutes, is amended to read

400.142 Emergency medication kits; orders not to resuscitate.—

(3) Facility staff may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a Physician Order for Life-

Sustaining Treatment (POLST). Facility staff and facilities are not subject to criminal prosecution or civil liability, or considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to either ~~such~~ order. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 6. Section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate; physician orders for life-sustaining treatment.—

(1) Services provided by a home health agency must be covered by an agreement between the home health agency and the patient or the patient's legal representative specifying the home health services to be provided, the rates or charges for services paid with private funds, and the sources of payment, which may include Medicare, Medicaid, private insurance, personal funds, or a combination thereof. A home health agency providing skilled care must make an assessment of the patient's needs within 48 hours after the start of services.

(2) If ~~When~~ required by ~~the provisions of~~ chapter 464, ~~,~~ part I, part III, or part V of chapter 468, ~~,~~ or chapter 486, the attending physician, physician assistant, or advanced registered

nurse practitioner, acting within his or her respective scope of practice, shall establish treatment orders for a patient who is to receive skilled care. The treatment orders must be signed by the physician, physician assistant, or advanced registered nurse practitioner before a claim for payment for the skilled services is submitted by the home health agency. If the claim is submitted to a managed care organization, the treatment orders must be signed within the time allowed under the provider agreement. The treatment orders shall be reviewed, as frequently as the patient's illness requires, by the physician, physician assistant, or advanced registered nurse practitioner in consultation with the home health agency.

(3) A home health agency shall arrange for supervisory visits by a registered nurse to the home of a patient receiving home health aide services in accordance with the patient's direction, approval, and agreement to pay the charge for the visits.

(4) Each patient has the right to be informed of and to participate in the planning of his or her care. Each patient must be provided, upon request, a copy of the plan of care established and maintained for that patient by the home health agency.

(5) If ~~When~~ nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation visits, and the discharge visit by a direct employee. Services provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully

responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with this part and applicable rules.

(6) The skilled care services provided by a home health agency, directly or under contract, must be supervised and coordinated in accordance with the plan of care.

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a Physician Order for Life-Sustaining Treatment (POLST). The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such orders ~~an order~~ and rules adopted by the agency.

Section 7. Paragraph (e) of subsection (1) of section 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.—

(1) The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter 408. The department, in consultation with the agency, shall by rule establish minimum standards and procedures for a hospice pursuant to this part. The rules must include:

(e) Procedures relating to the implementation of advanced directives; physician orders for life-sustaining treatment; and do-not-resuscitate orders.

Section 8. Subsection (8) of section 400.6095, Florida

Statutes, is amended to read:

400.6095 Patient admission; assessment; plan of care; discharge; death.—

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a Physician Order for Life-Sustaining Treatment (POLST). The department shall adopt rules providing for the implementation of such orders. Hospice staff shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 or a POLST does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 9. Subsection (4) of section 401.35, Florida Statutes, is amended to read:

401.35 Rules.—The department shall adopt rules, including definitions of terms, necessary to carry out the purposes of this part.

(4) The rules must establish circumstances and procedures under which emergency medical technicians and paramedics may honor orders by the patient's physician not to resuscitate and a Physician Order for Life-Sustaining Treatment (POLST) and the documentation and reporting requirements for handling such requests.

Section 10. Paragraph (a) of subsection (3) of section 401.45, Florida Statutes, are amended to read:

401.45 Denial of emergency treatment; civil liability.—

(3)(a) Resuscitation or other forms of medical intervention may be withheld or withdrawn from a patient by an emergency medical technician, ~~or~~ paramedic, or other health care professional if evidence of a Physician Order for Life-Sustaining Treatment (POLST) or an order not to resuscitate is presented to that professional. To be valid, a POLST must be on the form adopted by rule of the department and signed by the patient's physician after consultation with the patient, patient's guardian, or legally authorized proxy or surrogate ~~by the patient's physician is presented to the emergency medical technician or paramedic~~. To be valid, an order not to resuscitate~~, to be valid,~~ must be on the form adopted by rule of the department. The form must be signed by the patient's physician and by the patient or, if the patient is incapacitated, the patient's health care surrogate or proxy as provided in chapter 765, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

Section 11. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45 or a Physician Order for Life-Sustaining Treatment (POLST). The department shall adopt rules providing for the

implementation of such orders. Facility staff and facilities shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator pursuant to such orders ~~an order~~ and rules adopted by the department. The absence of an order to resuscitate executed pursuant to s. 401.45 or a POLST does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator as otherwise permitted by law.

Section 12. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) The department shall adopt rules providing for the implementation of orders not to resuscitate and Physician Orders for Life-Sustaining Treatment (POLST). The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a POLST. The provider shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such orders ~~an order~~ and applicable rules.

Section 13. Paragraph (c) of subsection (1) of section 765.205, Florida Statutes, is amended to read:

765.205 Responsibility of the surrogate.—

(1) The surrogate, in accordance with the principal's

instructions, unless such authority has been expressly limited by the principal, shall:

(c) Provide written consent using an appropriate form whenever consent is required, including a physician's order not to resuscitate or a Physician Order for Life-Sustaining Treatment (POLST).

Section 14. This act shall take effect July 1, 2015.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Children, Families, and Elder Affairs, *Chair*
Health Policy, *Vice Chair*
Agriculture
Education Pre-K-12
Appropriations Subcommittee on Health and Human Services

SENATOR ELEANOR SOBEL
33rd District

February 12, 2015

Senator Rene Garcia
Chair of Appropriations Subcommittee on Health and Human Services
310 Senate Office Building
404 South Monroe Street
Tallahassee, Florida 32399

Dear Chair Garcia,

This letter is to request that **SB 382** relating to **Assisted Living Facilities** be placed on the agenda of the next scheduled meeting of the Appropriations Subcommittee on Health and Human Services.

Thank you for your consideration of this request.

Respectfully,

Eleanor Sobel
State Senator, 33rd District

Cc: Scarlett Pigott, Robin Auber

REPLY TO:
❒ The "Old" Library, First Floor, 2600 Hollywood Blvd., Hollywood, Florida 33020 (954) 924-3693 FAX: (954) 924-3695
❒ 410 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5033

Senate's Website: *www.flsenate.gov*

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore

APPEARANCE RECORD

April 2, 2015 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 382

Meeting Date *Bill Number (if applicable)*

Topic SB 382 *Amendment Barcode (if applicable)*

Name James McFaddin

Job Title

Address 1235 S. Adams St Phone 850-671-4401

Street

Tallahassee FL 32301 Email mcfaddin@gostrategy.com

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information Waive Speaking: ☒ In Support ☐ Against

(The Chair will read this information into the record.)

Representing Florida ALFA

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

382
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic ALFs

Name Bob Asztalos

Job Title Chief Lobbyist

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TLH FL 32302
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Phone 850-224-3907

Email basztalos@fhca.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Health Care Assoc

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/21/15
Meeting Date

382
Bill Number (if applicable)

Topic Assisted Living Facilities

Amendment Barcode (if applicable)

Name Laura Cantwell

Job Title

Address 400 Carillon Pkwy, Suite 100
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St. Pete FL 33716
City *State* *Zip*

Phone 850-570-2110

Email

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing AARP

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 382
INTRODUCER:	Health Policy Committee and Senator Sobel and others
SUBJECT:	Assisted Living Facilities
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 382 strengthens the enforcement of current regulations for assisted living facilities (ALFs) by revising fines imposed for licensure violations, clarifying existing enforcement tools, and requiring an additional inspection for ALFs having significant violations. Among other provisions, the bill:

- Clarifies the criteria under which the Agency for Health Care Administration (AHCA) must revoke or deny a facility's license;
- Adds certain responsible parties and AHCA personnel to the list of people who must report abuse or neglect to the Department of Children and Families' (DCF) central abuse hotline; and
- Requires the AHCA to implement an ALF rating system by March 1, 2016, and to add certain content to its website by November 1, 2015, to help consumers select an ALF.

The bill is expected to result in a positive net fiscal impact to the AHCA's Health Care Trust Fund of approximately $1.1 million in Fiscal Year 2015-2016. The bill appropriates $156,943 in recurring funds, $7,546 in nonrecurring funds, and two full-time equivalent positions from the AHCA's Health Care Trust Fund for implementing the bill's regulatory provisions.

II. Present Situation:

An assisted living facility (ALF) is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period

exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[1] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[2] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[3]

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[4] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[5] If, as determined by the facility administrator or health care provider, a resident no longer meets the criteria for continued residency or the facility is unable to meet the resident's needs, the resident must be discharged in accordance with the Resident Bill of Rights.[6]

As of December 1, 2014, there were 3,027 licensed ALFs in Florida having a total of 88,306 beds.[7] An ALF must have a standard license issued by the Agency for Health Care Administration (AHCA) under part I of ch. 429, F.S., and part II of ch. 408, F.S. In addition to a standard license, an ALF may have one or more specialty licenses that allow an ALF to provide additional care. These specialty licenses include limited nursing services (LNS),[8] limited mental health services (LMH),[9] and extended congregate care services (ECC).[10] There are 826 ALFs with LNS specialty licenses, 260 with ECC licenses, and 955 with LMH specialty licenses.[11]

Limited Nursing Services Specialty License

An LNS specialty license enables an ALF to provide, directly or through contract, a select number of nursing services in addition to the personal services that are authorized under the standard license. The nursing services are limited to acts specified in administrative rules, may only be provided as authorized by a health care provider's order, and must be conducted and supervised in accordance with ch. 464, F.S., relating to nursing and the prevailing standard of practice in the nursing community.

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[1] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[2] Section 429.02(16), F.S.
[3] Section 429.02(1), F.S.
[4] For specific minimum standards see Fla. Admin. Code R 58A-5.0182.
[5] Section 429.26, F.S., and Fla. Admin. Code R 58A-5.0181.
[6] Section 429.28, F.S.
[7] Agency for Health Care Administration, *Assisted Living Facility Directory* (December 1, 2014), http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF.pdf (last visited Jan. 26, 2015).
[8] Section 429.07(3)(c), F.S.
[9] Section 429.075, F.S.
[10] Section 429.07(3)(b), F.S.
[11] *See* Agency for Health Care Administration, *Assisted Living Facility*, http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/alf.shtml (follow the hyperlinks for the ALF directories found under the "Notices/Updates" heading) (last visited Jan. 26, 2015).

Extended Congregate Care Specialty License

An ECC specialty license enables an ALF to provide, directly or through contract, services performed by licensed nurses and supportive services[12] to persons who otherwise would be disqualified from continued residence in an ALF.[13] The primary purpose of ECC services is to allow residents to remain in a familiar setting as they become more impaired with physical or mental limitations. An ALF licensed to provide ECC services may also admit an individual who exceeds the admission criteria for an ALF having a standard license, if the individual is determined appropriate for admission to the ECC facility. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, an ALF with an ECC license still may not serve residents who require 24-hour nursing supervision.[14]

Limited Mental Health Specialty License

An ALF that serves three or more mental health residents must obtain an LMH specialty license.[15] A mental health resident is an individual who receives social security disability income (SSDI) or supplemental security income (SSI) due to a mental disorder and who receives optional state supplementation (OSS).[16]

The administrator of an LMH facility must consult with a mental health resident and the resident's case manager to develop and help execute a community living support plan for the resident detailing the specific needs and services the resident requires.[17] The LMH licensee must also execute a cooperative agreement with the mental health care services provider. The cooperative agreement specifies, among other things, directions for the ALF accessing emergency and after-hours care for the mental health resident.

ALF Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established in rule by the Department of Elder Affairs (DOEA),[18] that are intended to assist

[12] Supportive services include social service needs, counseling, emotional support, networking, assistance with securing social and leisure services, shopping service, escort service, companionship, family support, information and referral, assistance in developing and implementing self-directed activities, and volunteer services. Fla. Admin. Code R. 58A-5.030(8)(a).
[13] An ECC program must provide additional services as required by the resident's service plan including: total help with bathing, dressing, grooming, and toileting; nursing assessments conducted more frequently than monthly; measuring and recording basic vital functions and weight; dietary management; assisting with self-administered medications or administering medications and treatments pursuant to a health care provider's order; supervising residents with dementia and cognitive impairments; health education, counseling, and implementing health-promoting programs; rehabilitative services; and escort services related to health-related appointments. Section 429.07(3)(b), F.S., and Fla. Admin. Code R. 58A-5.030.
[14] Section 429.07(3)(b), F.S.
[15] Section 429.075, F.S.
[16] Section 429.02(15), F.S. Optional State Supplementation is a cash assistance program. Its purpose is to supplement a person's income to help pay for costs in an assisted living facility, mental health residential treatment facility, or adult family care home, but it is not a Medicaid program. Department of Elder Affairs, *Florida Affordable Assisted Living: Optional State Supplementation (OSS)*, http://elderaffairs.state.fl.us/faal/statesupp.php (last visited Jan. 26, 2015).
[17] Fla. Admin. Code R. 58A-5.029(2)(c)3.
[18] Fla. Admin. Code R. 58A-5.0191.

ALFs in appropriately responding to the needs of residents, maintaining resident care and facility standards, and meeting licensure requirements.[19]

The current ALF core training requirements established by the DOEA consist of a minimum of 26 hours of training and passing a competency test. Administrators and managers must successfully complete the core training requirements within three months after becoming an ALF administrator or manager. The minimum passing score for the competency test is 75 percent.[20]

Administrators and managers must participate in 12 hours of continuing education in topics related to assisted living every two years.[21] A newly-hired administrator or manager, who has successfully completed the ALF core training and continuing education requirements, is not required to retake the core training. An administrator or manager who has successfully completed the core training but has not maintained the continuing education requirements, must retake the ALF core training and retake the competency test.[22]

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for six hours of in-service training for facility staff who provide direct care to residents.[23] Staff training requirements must generally be met within 30 days after staff begin employment at the facility; however, staff must have at least one hour of infection control training before providing direct care to residents. Nurses, certified nursing assistants, and home health aides who are on staff with an ALF are exempt from many of the training requirements. In addition to the standard six hours of in-service training, staff must complete one hour of elopement training and one hour of training on "do not resuscitate" orders. The staff may be required to complete training on special topics such as self-administration of medication and Alzheimer's disease, if applicable.

ECC Specific Training

The administrator and the ECC supervisor, if different from the administrator, must complete four hours of initial training in extended congregate care, either prior to the facility receiving its ECC license or within three months after beginning employment in the facility as an administrator or ECC supervisor. The administrator and ECC supervisor must also complete a minimum of four hours of continuing education every two years in topics relating to the physical, psychological, or social needs of frail elderly and disabled persons, or persons having Alzheimer's disease or related disorders.[24]

All direct-care staff providing care to residents in an ECC program must complete at least two hours of in-service training, provided by the facility administrator or ECC supervisor, within six months after beginning employment in the facility. The training must address ECC concepts

[19] Section 429.52(1), F.S.
[20] Administrators who have attended core training prior to July 1, 1997, and managers who attended the core training program prior to April 20, 1998, are not required to take the competency test. Administrators licensed as nursing home administrators in accordance with part II of chapter 468, F.S., are exempt from this requirement.
[21] Fla. Admin. Code R. 58A-5.0191(1)(c).
[22] Fla. Admin. Code R. 58A-5.0191.
[23] *Id*
[24] Fla. Admin. Code R. 58A-5.0191(7)(a) and (b).

and requirements, including statutory and rule requirements, and the delivery of personal care and supportive services in an ECC facility.[25]

LMH Specific Training

Administrators, managers, and staff who have direct contact with mental health residents in a licensed LMH facility must receive a minimum of six hours of specialized training in working with individuals having mental health diagnoses and a minimum of three hours of continuing education dealing with mental health diagnoses or mental health treatment every two years.[26]

Inspections and Surveys

The AHCA is required to conduct a survey, investigation, or monitoring visit of an ALF:

- Prior to the issuance of a license;
- Prior to biennial renewal of a license;
- When there is a change of ownership;
- To monitor ALFs licensed to provide LNS or ECC services;
- To monitor ALFs cited in the previous year for a class I or class II violation or for four or more uncorrected class III violations;[27]
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents;
- If the AHCA has reason to believe an ALF is violating a provision of part III of ch. 429, F.S., relating to adult day care centers or an administrative rule;
- To determine if cited deficiencies have been corrected; or
- To determine if an ALF is operating without a license.[28]

Abbreviated Surveys

An applicant for licensure renewal is eligible for an abbreviated biennial survey by the AHCA if the applicant does not have any:

- Class I, class II, or uncorrected class III violations;
- Confirmed complaints from the long-term care ombudsman council which were reported to the AHCA by the council; or
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.[29]

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items the AHCA must inspect.[30] The AHCA must expand an abbreviated survey or conduct a full survey if violations that threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.[31]

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[25] Fla. Admin. Code R. 58A-5.0191(7)(c).
[26] Section 429.075(1), F.S. and Fla. Admin. Code R. 58A-5.0191(8).
[27] *See* "Violations and Penalties" subheading below for a description of the violations.
[28] Section 429.34, F.S.
[29] Fla. Admin. Code R. 58A-5.033(1)(a).
[30] Fla. Admin. Code R. 58A-5.033(1)(b).
[31] Fla. Admin. Code R. 58A-5.033(1)(c).

Monitoring Visits

ALFs with LNS or ECC licenses are subject to monitoring visits in which the AHCA inspects the facility for compliance with the requirements of the specialty license. An LNS licensee is subject to monitoring inspections at least twice a year. At least one registered nurse must be included in the inspection team to monitor residents receiving services and to determine if the facility is complying with applicable regulatory requirements.[32] An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. The AHCA may waive one of the required yearly monitoring visits for an ECC facility that has been licensed for at least 24 months, if the registered nurse who participated in the monitoring inspections determines that the ECC services are being provided appropriately and there are no serious violations or substantiated complaints about the quality of service or care.[33]

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all ALFs regulated by the AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by the AHCA for certain types of violations. Violations are categorized into four classes according to the nature of the violation and the gravity of its probable effect on residents:

- **Class I violations** are those conditions that the AHCA determines present an imminent danger to residents or a substantial probability of death or serious physical or emotional harm.
  - Examples include resident death due to medical neglect, risk of resident death due to inability to exit in an emergency, and the suicide of a mental health resident in an ALF licensed for limited mental health.
  - The AHCA must fine an ALF between $5,000 and $10,000 for each class I violation.
  - During fiscal years 2011-2012 and 2012-2013, the AHCA entered 115 final orders for class I violations with an average fine amount of $6,585 for ALFs having fewer than 100 beds and $7,454 for ALFs having 100 or more beds.[34]
- **Class II violations** are those conditions that the AHCA determines directly threaten the physical or emotional health, safety, or security of the clients.
  - Examples include no qualified staff in the facility, the failure to call 911 in a timely manner for a resident in a semi-comatose state, and vermin in a food storage area.
  - The AHCA must fine an ALF between $1,000 and $5,000 for each violation.
  - During fiscal years 2011-2012 and 2012-2013, the AHCA entered 749 final orders for class II violations with an average fine amount of $1,542 for ALFs having fewer than 100 beds and $1,843 for ALFs having 100 or more beds.
- **Class III violations** are those conditions that the AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients.
  - Examples include missing or incomplete resident assessments, erroneous documentation of medication administration, and failure to correct unsatisfactory DOH food service inspection findings in a timely manner.

[32] Section 429.07(3)(c)2., F.S.
[33] Section 429.07(3)(b)2., F.S.
[34] Agency for Health Care Administration, *Senate Bill 248 Analysis* (Nov. 26, 2013) (on file with the Senate Committee on Health Policy).

- The AHCA must fine an ALF between $500 and $1,000 for each violation, but no fine may be imposed if the facility corrects the violation.
- During fiscal years 2011-2012 and 2012-2013, the AHCA entered 507 final orders for uncorrected class III violations with an average fine amount of $766 for ALFs having fewer than 100 beds and $614 for ALFs having 100 or more beds.

- **Class IV violations** are those conditions that do not have the potential of negatively affecting clients.
  - Examples include failure to file an adverse incident report, incorrect phone numbers posted for advocacy resources, and failure to post current menus.
  - The AHCA may fine an ALF between $100 and $200 for each violation but only if the problem is not corrected.
  - During fiscal years 2011-2012 and 2012-2013, the AHCA entered 18 final orders for uncorrected class IV violations with an average fine amount of $165 for ALFs having fewer than 100 beds and $100 for ALFs having 100 or more beds.[35,36,37]

In addition to financial penalties, the AHCA can take other actions against an ALF. The AHCA may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. The AHCA is required to deny or revoke the license of an ALF that has two or more class I violations that are similar to violations identified during a survey, inspection, monitoring visit, or complaint investigation occurring within the two previous years.[38] The AHCA may also impose an immediate moratorium or emergency suspension on any provider if it finds any condition that presents a threat to the health, safety, or welfare of a client.[39] The AHCA is required to publicly post notification of a license suspension, revocation, or denial of a license renewal, at the facility.[40] Finally, ch. 825, F.S., Florida's Criminal Code, provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[41] and disabled adults.[42]

Central Abuse Hotline

The Department of Children and Families (DCF) is required under s. 415.103, F.S., to establish and maintain a central abuse hotline to receive reports, in writing or through a single statewide toll-free telephone number, of known or suspected abuse, neglect, or exploitation of a vulnerable

[35] When fixing the amount of the fine, AHCA must consider the following factors: the gravity of the violation and the extent to which any laws or rules were violated, actions taken to correct the violations, any previous violations, the financial benefit of committing or continuing the violation, and the licensed capacity of the facility. Section 429.19(3), F.S.
[36] Section 429.19(2), F.S.
[37] Agency for Health Care Administration, *Senate Bill 248 Analysis* (Nov. 26, 2013) (on file with the Senate Committee on Health Policy)
[38] Section 429.14(4), F.S.
[39] Section 408.814, F.S.
[40] Section 429.14(7), F.S.
[41] "Elderly person" means a person 60 years of age or older who is suffering from the infirmities of aging as manifested by advanced age or organic brain damage, or other physical, mental, or emotional dysfunction, to the extent that the ability of the person to provide adequately for the person's own care or protection is impaired. Section 825.101(5), F.S. It does not constitute a defense to a prosecution for any violation of this chapter that the accused did not know the age of the victim. Section 825.104, F.S.
[42] "Disabled adult" means a person 18 years of age or older who suffers from a condition of physical or mental incapacitation due to a developmental disability, organic brain damage, or mental illness, or who has one or more physical or mental limitations that restrict the person's ability to perform the normal activities of daily living. Section 825.101(4), F.S.

adult[43] at any hour of the day or night, any day of the week.[44] Persons listed in s. 415.1034, F.S., who know, or have reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited are required to immediately report such knowledge or suspicion to the central abuse hotline.[45]

Florida's Long-Term Care Ombudsman Program

The federal Older Americans Act (OAA) requires each state to create a Long-Term Care Ombudsman Program to be eligible to receive funding associated with programs under the OAA.[46] In Florida, the program is a statewide, volunteer-based system of district councils that protect, defend, and advocate on behalf of long-term care facility residents, including residents of nursing homes, ALFs, and adult family-care homes. The ombudsman program is administratively housed in the DOEA and is headed by the State Long-Term Care Ombudsman, who is appointed by the DOEA Secretary.[47]

The ombudsman program is required to establish a statewide toll-free telephone number for receiving complaints concerning matters adversely affecting the health, safety, welfare, or rights of residents of ALFs, nursing homes, and adult family care homes. Every resident or representative of a resident must receive, upon admission to a long-term care facility, information regarding the program and the statewide toll-free telephone number for receiving complaints.[48] The names and identities of the complainants or residents involved in a complaint, including any problem identified by an ombudsman council as a result of an investigation, are confidential and exempt from Florida's public records laws, unless the complainant or resident, or the legal representative of the complainant or resident, consents to the disclosure, or the disclosure is required by court order.[49] In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in ALFs, referred to as administrative assessments.

Consumer Information

Section 400.191, F.S., requires the AHCA to provide information to the public about all licensed nursing homes in the state. The information must be provided in a consumer-friendly, electronic format to assist consumers and their families in comparing and evaluating nursing homes. Under s. 400.191(2), F.S., the AHCA must provide an Internet site that includes information such as a list of names and addresses of all nursing homes in the state, the total number of beds in each

[43] "Vulnerable adult" means a person 18 years of age or older whose ability to perform the normal activities of daily living or to provide for his or her own care or protection is impaired due to a mental, emotional, sensory, long-term physical, or developmental disability or dysfunction, or brain damage, or the infirmities of aging. Section 415.102(27), F.S.
[44] The central abuse hotline is operated by the DCF to accept reports for investigation when there is a reasonable cause to suspect that a vulnerable adult has been or is being abused, neglected, or exploited; determine whether the allegations require an immediate, 24-hour, or next-working-day response priority; when appropriate, refer calls that do not allege the abuse, neglect, or exploitation of a vulnerable adult to other organizations that might better resolve the reporter's concerns; and immediately identify and locate prior reports of abuse, neglect, or exploitation through the central abuse hotline. Section 415.103(1), F.S.
[45] Section 415.1034, F.S.
[46] 42 U.S.C. 3058, et. seq. *See also* s. 400.0061(1), F.S.
[47] Section 400.0063, F.S.
[48] Section 400.0078(2), F.S.
[49] Section 400.0077(1)(b), F.S.

nursing home, and survey and deficiency information. Additional information that the AHCA may provide on the site includes the licensure status history, the rating history, and the regulatory history of each nursing home.

There is no similar requirement in law to provide certain consumer information to the public on licensed ALFs in the state.

***The Miami Herald* Articles and the Governor's Assisted Living Workgroup**

Beginning on April 30, 2011, *The Miami Herald* published a four-part series, entitled "Neglected to Death," which detailed abuses occurring in ALFs and the state regulatory responses to such cases. The newspaper spent a year examining thousands of state inspections, police reports, court cases, autopsy files, emails, and death certificates and conducted dozens of interviews with operators and residents throughout Florida. The series detailed examples of abuses, neglect, and deaths that took place in ALFs.[50] The series also examined the state's regulatory and law enforcement agencies' responses to the problems. The newspaper concluded that the state's agencies, and in particular the AHCA, failed to enforce existing laws designed to protect Florida's citizens who reside in ALFs.[51]

Soon after *The Miami Herald* series, Governor Rick Scott vetoed HB 4045,[52] which reduced regulatory requirements on ALFs. The Governor then directed the AHCA to form a task force for the purpose of examining current assisted living regulations and oversight. The task force, referred to as the Assisted Living Workgroup, held meetings and produced two reports, one in August of 2011 and another in October of 2012. In addition to public testimony and presentations, the Assisted Living Workgroup focused on assisted living regulation, consumer information and choice, and long term care services and access. The workgroup made numerous recommendations in its two reports.[53]

III. Effect of Proposed Changes:

Section 1 amends s. 394.4574, F.S., to clarify that Medicaid managed care plans are responsible for state-supported mental health residents enrolled in their plans and that managing entities[54] under contract with the Department of Children and Families (DCF) are responsible for mental

[50] Rob Barry, Michael Sallah and Carol Marbin Miller, *Neglected to Death, Parts 1-3*, THE MIAMI HERALD, April 30, 2011 *available at* http://www.miamiherald.com/2011/04/30/2194842/once-pride-of-florida-now-scenes.html and http://www.miamiherald.com/2011/05/03/2199747/key-medical-logs-doctored-missing.html (see left side of article to access web links to the three-part series) (Last visited on Jan. 27, 2015).
[51] *Id.*
[52] House Bill 4045 (2011) repealed a requirement for the annual dissemination of a list of ALFs that had been sanctioned or fined, a requirement for an ALF to report monthly any liability claims filed against it, a requirement to disseminate the results of the inspection of each ALF, provisions concerning rule promulgation for ALFs by the DOEA, provisions concerning the collection of information regarding the cost of care in ALFs, and the authority for local governments or organizations to contribute to the cost of care of local facility residents.
[53] Agency for Health Care Administration, *Assisted Living Workgroup*, found at http://ahca.myflorida.com/SCHS/ALWG/wgmembers.shtml (last visited Jan. 27, 2015).
[54] *See* s. 394.9082, F.S. A managing entity is a not-for-profit corporation organized in Florida which is under contract with the DCF on a regional basis to manage the day-to-day operational delivery of behavioral health services through an organized system of care and a network of providers who are contracted with the managing entity to provide a comprehensive array of emergency, acute care, residential, outpatient, recovery support, and consumer support services related to behavioral health.

health residents who are not enrolled with a Medicaid managed care plan. The bill requires a mental health resident's community living support plan to be updated when there is a significant change to the resident's behavioral health status. The resident's case manager must keep a two-year record of any face-to-face interaction with the resident. The bill charges the entity responsible for a mental health resident with ensuring that there is adequate and consistent monitoring of the community living support plan and to report any concerns about a regulated provider failing to provide services or otherwise acting in a manner with the potential to cause harm to the resident.

Section 2 amends s. 400.0074, F.S., to require the Long-Term Care Ombudsman Program's administrative assessments of assisted living facilities (ALF) be comprehensive in nature. The bill also requires ombudsmen to conduct an exit consultation with a facility administrator to discuss issues and concerns from the visit.

Section 3 amends s. 400.0078, F.S., to require an ALF to include a statement that retaliatory action cannot be taken against a resident for presenting grievances when that ALF provides the required information to new residents upon admission to the facility about the purpose of the Long-Term Care Ombudsman Program.

Section 4 amends s. 429.07, F.S., to revise regulations of ALFs with extended congregate care services (ECC) and limited nursing services (LNS) specialty licenses. These revisions include:

- Requiring that an ALF be licensed for two or more years before being issued a full ECC license;
- Clarifying under what circumstances the Agency for Health Care Administration (AHCA) may deny or revoke an ALF's ECC license;
- Reducing monitoring visits for ALFs with ECC licenses from quarterly to twice a year, and for ALFs with LNS licenses, from twice a year to once a year; and
- Clarifying under what circumstances the AHCA may waive one of the required monitoring visits for ALFs with ECC licenses and also authorizing the AHCA to waive the required monitoring visit for ALFs with an LNS license under the same conditions.

The bill also creates a provisional ECC license for ALFs that have been licensed for less than two years.

- The provisional license lasts for a period of six months.
- The facility must inform the AHCA when it has admitted one or more residents requiring ECC services, after which the AHCA must inspect the facility for compliance with the requirements of the ECC license.
- If the licensee demonstrates compliance with the requirements of an ECC license, the AHCA must grant the facility a full ECC license.
- If the licensee fails to demonstrate compliance with the requirements of an ECC license or fails to admit an ECC resident within three months, the provisional ECC license expires.

Section 5 amends s. 429.075, F.S., to require ALFs having one or more state-supported mental health residents to obtain a limited mental health services (LMH) license. Current law requires an ALF to obtain an LMH license only if it has three or more state-supported mental health residents.

Section 6 amends s. 429.14, F.S., to clarify the use of administrative penalties, to:

- Allow the AHCA to immediately revoke, rather than only deny,[55] an ALF's or a controlling interest's license if that facility or controlling interest has, or had, a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or was the subject of other specified administrative sanctions;
- Add additional criteria under which the AHCA must deny or revoke an ALF's license; and
- Require that the AHCA impose an immediate moratorium on an ALF that fails to provide the AHCA with access to the facility, prohibits a regulatory inspection, denies access to records, or prohibits the confidential interview of facility staff or residents.

The bill also clarifies that if an ALF is required to relocate its residents due to AHCA action, the facility does not have to give residents 45 days' notice as required under s. 429.28(1)(k), F.S.

Section 7 amends s. 429.178, F.S., to make technical changes and to conform to changes elsewhere in the bill.

Section 8 amends s. 429.19, F.S., relating to the impositions of fines, as follows:

- The dollar amount of fines for ALFs having fewer than 100 beds is set at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. These figures represent the midpoint of the ranges for fines in current law.
- The dollar amount of fines for ALFs having 100 or more beds is set at $11,250 for class I violations, $4,500 for class II violations, $1,125 for class III violations, and $225 for class IV violations. These fines are 1.5 times the amount of the fines for ALFs having fewer than 100 beds under the bill.
- The bill requires the AHCA to impose a fine on an ALF for a class I violation, even if the facility corrects the violation before the AHCA conducts an investigation. ALFs can still challenge such fines through an administrative hearing under ch. 120, F.S.
- The bill doubles the fines for ALFs with repeat class I and class II violations.
- The bill imposes a fine on ALFs with repeat class III and class IV violations stemming from the same regulation, regardless of correction. Current law prohibits the AHCA from assessing fines for corrected class III and class IV violations.
- The bill doubles the fines for class III or class IV violations if an ALF is cited three or more times for one or more such violations stemming from the same regulation over the course of three licensure inspections.
- The bill provides for a fine of $500 which will be imposed in place of other fine amounts, regardless of the class of the violation cited, if a facility is found not to be in compliance with background screening requirements.

Section 9 amends s. 429.256, F.S., to allow unlicensed staff to assist with several additional services that fall under the category of assistance with self-administration of medication. Specifically, unlicensed staff will be allowed to assist with:

- Taking a prefilled insulin syringe to a resident;

[55] Denial of a license occurs when the AHCA refuses to renew the facility's license at the end of the 2-year licensure period.

- The resident's use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose into the dispensing cup;
- The resident's use of a glucometer to perform blood-glucose level checks;
- Putting on and taking off anti-embolism stockings;
- Applying and removing an oxygen cannula, but not titrating the oxygen levels;
- The resident's use of a continuous positive airway pressure device, but not titrating the device;
- Measuring vital signs; and
- The resident's use of colostomy bags.

Section 10 amends s. 429.28, F.S., to require the posted notice of a resident's rights, obligations, and prohibitions, and to specify that complaints made to the ombudsman program, as well as the names and identities of the complainant and any residents involved, are confidential. The bill also creates a fine of $2,500 to be imposed if an ALF cannot show good cause in state court for terminating the residency of an individual who has exercised an enumerated right.

Section 11 amends s. 429.34, F.S., to require certain state officials, such as Medicaid fraud investigators and state or local fire marshals, to report to the DCF central abuse hotline any knowledge or reasonable suspicion that a vulnerable adult has been or is being abused, neglected, or exploited. The bill provides that an ALF having one or more class I violations, two or more class II violations arising from separate surveys within a 60-day period, or two or more unrelated class II violations cited during one survey, must be inspected again within six months. The licensee must pay a fee to the AHCA to cover the cost of the additional inspection.

Section 12 amends s. 429.41, F.S., to provide that if a continuing care facility or a retirement community licenses part of a building for ALF services, the staffing requirements established in rule apply only to the residents receiving assisted living services.

Section 13 amends s. 429.52, F.S., to require that ALFs provide a two-hour, pre-service orientation for all new facility employees who have not previously completed core training. The pre-service orientation must cover topics that help new employees provide responsible care and respond to the needs of residents. A new employee and the facility's administrator must sign a statement that the new ALF staff member has completed the pre-service orientation. The signed statement must be kept in that staff member's file. The bill clarifies that the pre-service orientation can be provided by the ALF instead of requiring that it be provided by a trainer registered with the Department of Elder Affairs (DOEA).

The bill also increases the training requirements for staff who assist residents with medication from four to six hours.

Section 14 creates an undesignated section of law which finds that consumers need additional information in order to select an ALF. The bill requires the AHCA to implement a rating system for ALFs by March 1, 2016, and requires the AHCA to create a consumer guide website with information on ALFs no later than November 1, 2015. At a minimum, the website must include:

- Information on each licensed ALF, such as the number and type of licensed beds, the types of licenses held by the facility, and the expiration date(s) of the facility's license(s);
- A list of the facility's violations, if any, including a summary of the violations, any sanctions imposed, and the date of any corrective action taken by the facility; and
- Links to inspection reports.

Section 15 appropriates $156,943 in recurring funds and $7,546 in nonrecurring funds from the AHCA's Health Care Trust Fund for two full-time equivalent senior attorney positions, including associated salary rate, for the AHCA for the purpose of implementing the bill's regulatory provisions.

Section 16 provides an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

CS/SB 382 requires the Agency for Health Care Administration (AHCA) to conduct a new survey of an assisted living facility (ALF) within six months after finding a class I violation or two or more class II violations. ALFs that require the additional survey will be charged a fee to cover the cost of the additional survey. According to the AHCA, fees and fines from ALFs under current law do not cover the cost of regulating such ALFs statewide.

B. Private Sector Impact:

The bill revises the fine amounts for each of the four classes of violations. The bill sets the dollar amount of fines for ALFs having fewer than 100 beds at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations. The bill fixes these fines at the mid-point of the range for fine amounts provided under current law. For example, an ALF cited for a class I violation may be fined between $5,000 and $10,000 under current law. For ALFs having 100 or more beds, fines are multiplied under the bill by 1.5 to help resolve an inequity in penalties whereby small ALFs can pay the same fine amount as much larger ALFs.

Fixing the fine amounts at the mid-point of each range will provide for more predictable outcomes for ALFs that are cited for violations.

Additionally, the bill provides for the following changes to the fine amounts:

- A $2,500 fine if an ALF removes a resident without cause, as determined by a state court;
- A doubling of fines for class I or II violations if the facility was previously cited for one or more class I or II violations during the last licensure inspection; and
- An imposition of a fine for class I violations regardless of whether they were corrected prior to being cited by the AHCA.

The AHCA estimates that the new fine structure will initially cost ALFs cited for violations a total of approximately $1.3 million per year. However, these increased costs could be reduced by increased compliance with ALF regulations and a corresponding reduction in the number of cited violations.[56] All fines are subject to challenge through an administrative hearing under ch. 120, F.S.

ALFs having significant uncorrected violations will be more likely to see their licenses suspended or revoked under the bill.

ALFs having any state-supported mental health residents will need to meet limited mental health licensure requirements. ALFs that currently have fewer than three state-supported mental health residents and do not meet these requirements may see increased costs to comply.

ALFs with specialty licenses that meet licensure standards will have fewer monitoring visits from the AHCA. This will positively impact the ALFs as they will have less interruption of staff time due to such visits.

The bill requires ALFs to provide all new employees who have not already gone through the ALF core training program with a two-hour, pre-service training session before they work with residents. Additionally, the bill increases the training requirements for staff who assist residents with medication from four to six hours. The cost of both of these training requirements is not expected to be significant.

C. Government Sector Impact:

The bill will generate approximately $1.1 million of additional net revenues for the AHCA per year when accounting for revenue generated and expenditures incurred as a result of the bill. The bill appropriates $156,943 in recurring funds, $7,546 in nonrecurring funds, and two full-time equivalent positions, including associated salary rate, from the AHCA's Health Care Trust Fund for implementing the bill's regulatory provisions. These costs will likely be offset, and additional revenue will likely be generated, through the increased fines directed to the Health Care Trust Fund. The

[56] Agency for Health Care Administration, *Senate Bill 248 Analysis* (Nov. 26, 2013) (on file with the Senate Committee on Health Policy).

AHCA estimates, based on the number of violations cited over the past two years, that the new fine structure in the bill will generate approximately $1.3 million additional revenue per year. However, this amount could decrease if the new fine amounts result in increased compliance and fewer cited violations.[57]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 394.4574, 400.0074, 400.0078, 429.07, 429.075, 429.14, 429.178, 429.19, 429.256, 429.28, 429.34, 429.41, and 429.52 of the Florida Statutes.

This bill creates an undesignated section of Florida law.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 3, 2015:
The CS amends SB 382 to remove the requirement that the Office of Program Policy Analysis and Governmental Accountability conduct a study of ALF inter-surveyor reliability and to remove the requirement that the AHCA create a monitored ALF public comment page as well as the appropriations required to create and maintain the comment page.

B. Amendments:

None.

[57] See Supra note 56

By the Committee on Health Policy; and Senators Sobel and Gaetz

588-01478-15 2015382c1

A bill to be entitled

An act relating to assisted living facilities; amending s. 394.4574, F.S.; providing that Medicaid managed care plans are responsible for mental health residents enrolled in Medicaid; specifying that managing entities under contract with the Department of Children and Families are responsible for mental health residents who are not enrolled in a Medicaid managed care plan; deleting a provision to conform to changes made by the act; requiring that the community living support plan be completed and provided to the administrator of a facility upon the mental health resident's admission; requiring the community living support plan to be updated when there is a significant change to the mental health resident's behavioral health status; requiring the case manager assigned to a mental health resident for whom the mental health services provider is responsible to keep a record of the date and time of face-to-face interactions with the resident and to make the record available to the entity responsible for inspection; requiring that the record be maintained for a specified time; requiring the responsible entity to ensure that there is adequate and consistent monitoring and enforcement of community living support plans and cooperative agreements and that concerns are reported to the appropriate regulatory oversight organization under certain circumstances; amending s. 400.0074, F.S.; requiring that an administrative assessment conducted

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by a local council be comprehensive in nature; requiring a local council to conduct an exit consultation with the facility administrator or administrator designee to discuss issues and concerns in areas affecting residents' rights, health, safety, and welfare and make recommendations for any needed improvements; amending s. 400.0078, F.S.; requiring that a resident of a long-term care facility, or his or her representative, be informed that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right; amending s. 429.07, F.S.; revising the requirement that an extended congregate care license be issued to certain facilities that have been licensed as assisted living facilities under certain circumstances and authorizing the issuance of such license if a specified condition is met; providing the purpose of an extended congregate care license; specifying that the initial extended congregate care license of an assisted living facility is provisional under certain circumstances; requiring a licensee to notify the Agency for Health Care Administration if it accepts a resident who qualifies for extended congregate care services; requiring the agency to inspect the facility for compliance with the requirements of an extended congregate care license; requiring the issuance of an extended congregate care license under certain circumstances; requiring the licensee to immediately suspend extended congregate

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

care services under certain circumstances; requiring a registered nurse representing the agency to visit the facility at least twice a year, rather than quarterly, to monitor residents who are receiving extended congregate care services; authorizing the agency to waive one of the required yearly monitoring visits under certain circumstances; authorizing the agency to deny or revoke a facility's extended congregate care license; requiring a registered nurse representing the agency to visit the facility at least annually, rather than twice a year, to monitor residents who are receiving limited nursing services; providing that such monitoring visits may be conducted in conjunction with other inspections by the agency; authorizing the agency to waive the required yearly monitoring visit for a facility that is licensed to provide limited nursing services under certain circumstances; amending s. 429.075, F.S.; requiring that an assisted living facility that serves one or more mental health residents, rather than three or more such residents, obtain a limited mental health license; amending s. 429.14, F.S.; revising the circumstances under which the agency may deny, revoke, or suspend the license of an assisted living facility and impose an administrative fine; requiring the agency to deny or revoke the license of an assisted living facility under certain circumstances; requiring the agency to impose an immediate moratorium on the license of an assisted living facility under certain circumstances;

prohibiting a licensee from restricting agency staff from accessing and copying certain records or conducting certain interviews; deleting a provision requiring the agency to provide a list of facilities with denied, suspended, or revoked licenses to the Department of Business and Professional Regulation; exempting a facility from the 45-day notice requirement if it is required to relocate some or all of its residents; specifying that the exemption does not exempt a facility from any deadlines for corrective action set by the agency; amending s. 429.178, F.S.; conforming cross-references; amending s. 429.19, F.S.; revising the amounts and uses of administrative fines; requiring the agency to levy a fine for violations that are corrected before an inspection if noncompliance occurred within a specified period of time; deleting factors that the agency is required to consider in determining penalties and fines; amending s. 429.256, F.S.; revising the term "assistance with self-administration of medication" as it relates to the Assisted Living Facilities Act; amending s. 429.28, F.S.; providing notice requirements for informing facility residents that the name and identity of the resident and complainant in any complaint made to the State Long-Term Care Ombudsman Program or a local long-term care ombudsman council is confidential and that retaliatory action may not be taken against a resident for presenting grievances or for exercising any other

resident right; requiring that a facility that terminates an individual's residency after the filing of a complaint be fined if good cause is not shown for the termination; amending s. 429.34, F.S.; requiring certain persons to report elder abuse in assisted living facilities; requiring the agency to regularly inspect each licensed assisted living facility; requiring the agency to conduct more frequent inspections under certain circumstances; requiring the licensee to pay a fee for the cost of additional inspections; requiring the agency to annually adjust the fee; amending s. 429.41, F.S.; providing that certain staffing requirements apply only to residents in continuing care facilities who are receiving relevant services; amending s. 429.52, F.S.; requiring each newly hired employee of an assisted living facility to attend a preservice orientation provided by the assisted living facility; requiring the employee and administrator to sign a statement that the employee completed the required preservice orientation and keep the signed statement in the employee's personnel record; requiring 2 additional hours of training for assistance with medication; conforming a cross-reference; requiring the agency to implement a rating system for assisted living facilities by a specified date, adopt rules, and create content for the agency's website by a specified date which provides consumers information regarding assisted living facilities; providing criteria for the

content; providing appropriations; providing an effective date.

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

Section 1. Section 394.4574, Florida Statutes, is amended to read:

394.4574 ~~Department~~ Responsibilities for coordination of services for a mental health resident who resides in an assisted living facility that holds a limited mental health license.—

(1) As used in this section, the term "mental health resident" ~~"mental health resident," for purposes of this section,~~ means an individual who receives social security disability income due to a mental disorder as determined by the Social Security Administration or receives supplemental security income due to a mental disorder as determined by the Social Security Administration and receives optional state supplementation.

(2) Medicaid managed care plans are responsible for Medicaid-enrolled mental health residents, and managing entities under contract with the department are responsible for mental health residents who are not enrolled in a Medicaid health plan. A Medicaid managed care plan or a managing entity, as appropriate, shall ~~The department must~~ ensure that:

(a) A mental health resident has been assessed by a psychiatrist, clinical psychologist, clinical social worker, or psychiatric nurse, or an individual who is supervised by one of these professionals, and determined to be appropriate to reside in an assisted living facility. The documentation must be

provided to the administrator of the facility within 30 days after the mental health resident has been admitted to the facility. An evaluation completed upon discharge from a state mental hospital meets the requirements of this subsection related to appropriateness for placement as a mental health resident if it was completed within 90 days before ~~prior to~~ admission to the facility.

(b) A cooperative agreement, as required in s. 429.075, is developed by ~~between~~ the mental health care services provider that serves a mental health resident and the administrator of the assisted living facility with a limited mental health license in which the mental health resident is living. ~~Any entity that provides Medicaid prepaid health plan services shall ensure the appropriate coordination of health care services with an assisted living facility in cases where a Medicaid recipient is both a member of the entity's prepaid health plan and a resident of the assisted living facility. If the entity is at risk for Medicaid targeted case management and behavioral health services, the entity shall inform the assisted living facility of the procedures to follow should an emergent condition arise.~~

(c) The community living support plan, as defined in s. 429.02, has been prepared by a mental health resident and his or her ~~a~~ mental health case manager ~~of that resident~~ in consultation with the administrator of the facility or the administrator's designee. The plan must be completed and provided to the administrator of the assisted living facility with a limited mental health license in which the mental health resident lives upon the resident's admission. The support plan and the agreement may be in one document.

(d) The assisted living facility with a limited mental health license is provided with documentation that the individual meets the definition of a mental health resident.

(e) The mental health services provider assigns a case manager to each mental health resident for whom the entity is responsible ~~who lives in an assisted living facility with a limited mental health license~~. The case manager shall coordinate ~~is responsible for coordinating~~ the development ~~of~~ and implementation of the community living support plan defined in s. 429.02. The plan must be updated at least annually, or when there is a significant change in the resident's behavioral health status, such as an inpatient admission or a change in medication, level of service, or residence. Each case manager shall keep a record of the date and time of any face-to-face interaction with the resident and make the record available to the responsible entity for inspection. The record must be retained for at least 2 years after the date of the most recent interaction.

(f) Adequate and consistent monitoring and enforcement of community living support plans and cooperative agreements are conducted by the resident's case manager.

(g) Concerns are reported to the appropriate regulatory oversight organization if a regulated provider fails to deliver appropriate services or otherwise acts in a manner that has the potential to result in harm to the resident.

(3) The Secretary of Children and Families, in consultation with the Agency for Health Care Administration, shall ~~annually~~ require each district administrator to develop, with community input, a detailed annual plan that demonstrates ~~detailed plans~~

~~that demonstrate~~ how the district will ensure the provision of state-funded mental health and substance abuse treatment services to residents of assisted living facilities that hold a limited mental health license. This plan ~~These plans~~ must be consistent with the substance abuse and mental health district plan developed pursuant to s. 394.75 and must address case management services; access to consumer-operated drop-in centers; access to services during evenings, weekends, and holidays; supervision of the clinical needs of the residents; and access to emergency psychiatric care.

Section 2. Subsection (1) of section 400.0074, Florida Statutes, is amended, and paragraph (h) is added to subsection (2) of that section, to read:

400.0074 Local ombudsman council onsite administrative assessments.—

(1) In addition to any specific investigation conducted pursuant to a complaint, the local council shall conduct, at least annually, an onsite administrative assessment of each nursing home, assisted living facility, and adult family-care home within its jurisdiction. This administrative assessment must be comprehensive in nature and must ~~shall~~ focus on factors affecting residents' ~~the~~ rights, health, safety, and welfare ~~of the residents~~. Each local council is encouraged to conduct a similar onsite administrative assessment of each additional long-term care facility within its jurisdiction.

(2) An onsite administrative assessment conducted by a local council shall be subject to the following conditions:

(h) The local council shall conduct an exit consultation with the facility administrator or administrator's designee to

discuss issues and concerns in areas affecting residents' rights, health, safety, and welfare and, if needed, make recommendations for improvement.

Section 3. Subsection (2) of section 400.0078, Florida Statutes, is amended to read:

400.0078 Citizen access to State Long-Term Care Ombudsman Program services.—

(2) ~~Every resident or representative of a resident shall receive,~~ Upon admission to a long-term care facility, each resident or representative of a resident must receive information regarding the purpose of the State Long-Term Care Ombudsman Program, the statewide toll-free telephone number for receiving complaints, information that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right, and other relevant information regarding how to contact the program. Each resident or his or her representative ~~Residents or their representatives~~ must be furnished additional copies of this information upon request.

Section 4. Paragraphs (b) and (c) of subsection (3) of section 429.07, Florida Statutes, are amended to read:

429.07 License required; fee.—

(3) In addition to the requirements of s. 408.806, each license granted by the agency must state the type of care for which the license is granted. Licenses shall be issued for one or more of the following categories of care: standard, extended congregate care, limited nursing services, or limited mental health.

(b) An extended congregate care license shall be issued to

each facility that has been licensed as an assisted living facility for 2 or more years and that provides services ~~facilities providing~~, directly or through contract, ~~services~~ beyond those authorized in paragraph (a), including services performed by persons licensed under part I of chapter 464 and supportive services, as defined by rule, to persons who would otherwise be disqualified from continued residence in a facility licensed under this part. An extended congregate care license may be issued to a facility that has a provisional extended congregate care license and meets the requirements for licensure under subparagraph 2. The primary purpose of extended congregate care services is to allow residents the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency as they become more impaired. A facility licensed to provide extended congregate care services may also admit an individual who exceeds the admission criteria for a facility with a standard license if the individual is determined appropriate for admission to the extended congregate care facility.

1. In order for extended congregate care services to be provided, the agency must first determine that all requirements established in law and rule are met and must specifically designate~~,~~ on the facility's license~~,~~ that such services may be provided and whether the designation applies to all or part of the facility. This ~~Such~~ designation may be made at the time of initial licensure or licensure renewal ~~relicensure~~, or upon request in writing by a licensee under this part and part II of chapter 408. The notification of approval or the denial of the request shall be made in accordance with part II of chapter 408.

Each existing facility that qualifies ~~facilities qualifying~~ to provide extended congregate care services must have maintained a standard license and may not have been subject to administrative sanctions during the previous 2 years, or since initial licensure if the facility has been licensed for less than 2 years, for any of the following reasons:

a. A class I or class II violation;

b. Three or more repeat or recurring class III violations of identical or similar resident care standards from which a pattern of noncompliance is found by the agency;

c. Three or more class III violations that were not corrected in accordance with the corrective action plan approved by the agency;

d. Violation of resident care standards which results in requiring the facility to employ the services of a consultant pharmacist or consultant dietitian;

e. Denial, suspension, or revocation of a license for another facility licensed under this part in which the applicant for an extended congregate care license has at least 25 percent ownership interest; or

f. Imposition of a moratorium pursuant to this part or part II of chapter 408 or initiation of injunctive proceedings.

The agency may deny or revoke a facility's extended congregate care license if it fails to meet the criteria for an extended congregate care license as provided in this subparagraph.

2. If an assisted living facility has been licensed for less than 2 years, the initial extended congregate care license must be provisional and may not exceed 6 months. Within the

first 3 months after the provisional license is issued, the licensee shall notify the agency, in writing, when it admits at least one extended congregate care resident, after which an unannounced inspection shall be made to determine compliance with requirements of an extended congregate care license. Failure to admit an extended congregate care resident within the first 3 months renders the extended congregate care license void. A licensee that has a provisional extended congregate care license which demonstrates compliance with all of the requirements of an extended congregate care license during the inspection shall be issued an extended congregate care license. In addition to sanctions authorized under this part, if violations are found during the inspection and the licensee fails to demonstrate compliance with all assisted living requirements during a followup inspection, the licensee shall immediately suspend extended congregate care services, and the provisional extended congregate care license expires. The agency may extend the provisional license for not more than 1 month in order to complete a followup visit.

3.~~2.~~ A facility that is licensed to provide extended congregate care services shall maintain a written progress report on each person who receives services which describes the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A registered nurse, or appropriate designee, representing the agency shall visit the facility at least twice a year ~~quarterly~~ to monitor residents who are receiving extended congregate care services and to determine if the facility is in compliance with this part, part II of chapter 408, and relevant rules. One of

the visits may be in conjunction with the regular survey. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall serve as part of the team that inspects the facility. The agency may waive one of the required yearly monitoring visits for a facility that has:

a. Held an extended congregate care license for at least 24 months; ~~been licensed for at least 24 months to provide extended congregate care services, if, during the inspection, the registered nurse determines that extended congregate care services are being provided appropriately, and if the facility has~~

b. No class I or class II violations and no uncorrected class III violations; and~~.~~

c. No ombudsman council complaints that resulted in a citation for licensure ~~The agency must first consult with the long-term care ombudsman council for the area in which the facility is located to determine if any complaints have been made and substantiated about the quality of services or care. The agency may not waive one of the required yearly monitoring visits if complaints have been made and substantiated.~~

4.~~3.~~ A facility that is licensed to provide extended congregate care services must:

a. Demonstrate the capability to meet unanticipated resident service needs.

b. Offer a physical environment that promotes a homelike setting, provides for resident privacy, promotes resident independence, and allows sufficient congregate space as defined by rule.

c. Have sufficient staff available, taking into account the physical plant and firesafety features of the building, to assist with the evacuation of residents in an emergency.

d. Adopt and follow policies and procedures that maximize resident independence, dignity, choice, and decisionmaking to permit residents to age in place, so that moves due to changes in functional status are minimized or avoided.

e. Allow residents or, if applicable, a resident's representative, designee, surrogate, guardian, or attorney in fact to make a variety of personal choices, participate in developing service plans, and share responsibility in decisionmaking.

f. Implement the concept of managed risk.

g. Provide, directly or through contract, the services of a person licensed under part I of chapter 464.

h. In addition to the training mandated in s. 429.52, provide specialized training as defined by rule for facility staff.

5.~~4.~~ A facility that is licensed to provide extended congregate care services is exempt from the criteria for continued residency set forth in rules adopted under s. 429.41. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, the facility may not serve residents who require 24-hour nursing supervision. A licensed facility that provides extended congregate care services must also provide each resident with a written copy of facility policies governing admission and retention.

~~5. The primary purpose of extended congregate care services~~

~~is to allow residents, as they become more impaired, the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency. A facility licensed to provide extended congregate care services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the extended congregate care facility.~~

6. Before the admission of an individual to a facility licensed to provide extended congregate care services, the individual must undergo a medical examination as provided in s. 429.26(4) and the facility must develop a preliminary service plan for the individual.

7. If ~~When~~ a facility can no longer provide or arrange for services in accordance with the resident's service plan and needs and the facility's policy, the facility must ~~shall~~ make arrangements for relocating the person in accordance with s. 429.28(1)(k).

~~8. Failure to provide extended congregate care services may result in denial of extended congregate care license renewal.~~

(c) A limited nursing services license shall be issued to a facility that provides services beyond those authorized in paragraph (a) and as specified in this paragraph.

1. In order for limited nursing services to be provided in a facility licensed under this part, the agency must first determine that all requirements established in law and rule are met and must specifically designate, on the facility's license, that such services may be provided. This ~~Such~~ designation may be made at the time of initial licensure or licensure renewal

~~relicensure~~, or upon request in writing by a licensee under this part and part II of chapter 408. Notification of approval or denial of such request shall be made in accordance with part II of chapter 408. An existing facility that qualifies ~~facilities qualifying~~ to provide limited nursing services must ~~shall~~ have maintained a standard license and may not have been subject to administrative sanctions that affect the health, safety, and welfare of residents for the previous 2 years or since initial licensure if the facility has been licensed for less than 2 years.

2. A facility ~~Facilities~~ that is ~~are~~ licensed to provide limited nursing services shall maintain a written progress report on each person who receives such nursing services. The~~,~~ ~~which~~ report must describe ~~describes~~ the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A registered nurse representing the agency shall visit the facility ~~such facilities~~ at least annually ~~twice a year~~ to monitor residents who are receiving limited nursing services and to determine if the facility is in compliance with applicable provisions of this part, part II of chapter 408, and related rules. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall also serve as part of the team that inspects such facility. Visits may be in conjunction with other agency inspections. The agency may waive the required yearly monitoring visit for a facility that has:

a. Had a limited nursing services license for at least 24 months;

b. No class I or class II violations and no uncorrected

class III violations; and

c. No ombudsman council complaints that resulted in a citation for licensure.

3. A person who receives limited nursing services under this part must meet the admission criteria established by the agency for assisted living facilities. When a resident no longer meets the admission criteria for a facility licensed under this part, arrangements for relocating the person shall be made in accordance with s. 429.28(1)(k), unless the facility is licensed to provide extended congregate care services.

Section 5. Section 429.075, Florida Statutes, is amended to read:

429.075 Limited mental health license.—An assisted living facility that serves one ~~three~~ or more mental health residents must obtain a limited mental health license.

(1) To obtain a limited mental health license, a facility must hold a standard license as an assisted living facility, must not have any current uncorrected ~~deficiencies or~~ violations, and must ensure that, within 6 months after receiving a limited mental health license, the facility administrator and the staff of the facility who are in direct contact with mental health residents must complete training of no less than 6 hours related to their duties. This ~~Such~~ designation may be made at the time of initial licensure or licensure renewal ~~relicensure~~ or upon request in writing by a licensee under this part and part II of chapter 408. Notification of approval or denial of such request shall be made in accordance with this part, part II of chapter 408, and applicable rules. This training must ~~will~~ be provided by or

approved by the Department of Children and Families.

(2) A facility that is ~~Facilities~~ licensed to provide services to mental health residents must ~~shall~~ provide appropriate supervision and staffing to provide for the health, safety, and welfare of such residents.

(3) A facility that has a limited mental health license must:

(a) Have a copy of each mental health resident's community living support plan and the cooperative agreement with the mental health care services provider. The support plan and the agreement may be combined.

(b) Have documentation ~~that is~~ provided by the Department of Children and Families that each mental health resident has been assessed and determined to be able to live in the community in an assisted living facility that has ~~with~~ a limited mental health license.

(c) Make the community living support plan available for inspection by the resident, the resident's legal guardian or~~,~~ ~~the resident's~~ health care surrogate, and other individuals who have a lawful basis for reviewing this document.

(d) Assist the mental health resident in carrying out the activities identified in the individual's community living support plan.

(4) A facility that has ~~with~~ a limited mental health license may enter into a cooperative agreement with a private mental health provider. For purposes of the limited mental health license, the private mental health provider may act as the case manager.

Section 6. Section 429.14, Florida Statutes, is amended to

read:

429.14 Administrative penalties.—

(1) In addition to the requirements of part II of chapter 408, the agency may deny, revoke, and suspend any license issued under this part and impose an administrative fine in the manner provided in chapter 120 against a licensee for a violation of ~~any provision of~~ this part, part II of chapter 408, or applicable rules, or for any of the following actions by a licensee, ~~for the actions of~~ any person subject to level 2 background screening under s. 408.809, or ~~for the actions of~~ any facility staff ~~employee~~:

(a) An intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility.

(b) A ~~The~~ determination by the agency that the owner lacks the financial ability to provide continuing adequate care to residents.

(c) Misappropriation or conversion of the property of a resident of the facility.

(d) Failure to follow the criteria and procedures provided under part I of chapter 394 relating to the transportation, voluntary admission, and involuntary examination of a facility resident.

(e) A citation for ~~of~~ any of the following violations ~~deficiencies~~ as specified in s. 429.19:

1. One or more cited class I violations ~~deficiencies~~.

2. Three or more cited class II violations ~~deficiencies~~.

3. Five or more cited class III violations ~~deficiencies~~ that have been cited on a single survey and have not been corrected within the times specified.

(f) Failure to comply with the background screening standards of this part, s. 408.809(1), or chapter 435.

(g) Violation of a moratorium.

(h) Failure of the license applicant, the licensee during licensure renewal ~~relicensure~~, or a licensee that holds a provisional license to meet the minimum license requirements of this part, or related rules, at the time of license application or renewal.

(i) An intentional or negligent life-threatening act in violation of the uniform firesafety standards for assisted living facilities or other firesafety standards which ~~that~~ threatens the health, safety, or welfare of a resident of a facility, as communicated to the agency by the local authority having jurisdiction or the State Fire Marshal.

(j) Knowingly operating any unlicensed facility or providing without a license any service that must be licensed under this chapter or chapter 400.

(k) Any act constituting a ground upon which application for a license may be denied.

(2) Upon notification by the local authority having jurisdiction or by the State Fire Marshal, the agency may deny or revoke the license of an assisted living facility that fails to correct cited fire code violations that affect or threaten the health, safety, or welfare of a resident of a facility.

(3) The agency may deny or revoke a license of an ~~to any~~ applicant or controlling interest as defined in part II of chapter 408 which has or had a 25 percent ~~25 percent~~ or greater financial or ownership interest in any other facility that is licensed under this part, or in any entity licensed by this

state or another state to provide health or residential care, if that ~~which~~ facility or entity during the 5 years before ~~prior to~~ the application for a license closed due to financial inability to operate; had a receiver appointed or a license denied, suspended, or revoked; was subject to a moratorium; or had an injunctive proceeding initiated against it.

(4) The agency shall deny or revoke the license of an assisted living facility if any of the following apply:

(a) There are two moratoria, issued pursuant to this part or part II of chapter 408, within a 2-year period which are imposed by final order.

(b) The facility is cited for two or more class I violations arising from unrelated circumstances during the same survey or investigation.

(c) The facility is cited for two or more class I violations arising from separate surveys or investigations within a 2-year period ~~that has two or more class I violations that are similar or identical to violations identified by the agency during a survey, inspection, monitoring visit, or complaint investigation occurring within the previous 2 years~~.

(5) An action taken by the agency to suspend, deny, or revoke a facility's license under this part or part II of chapter 408, in which the agency claims that the facility owner or an employee of the facility has threatened the health, safety, or welfare of a resident of the facility, shall be heard by the Division of Administrative Hearings of the Department of Management Services within 120 days after receipt of the facility's request for a hearing, unless that time limitation is waived by both parties. The administrative law judge shall ~~must~~

render a decision within 30 days after receipt of a proposed recommended order.

(6) As provided under s. 408.814, the agency shall impose an immediate moratorium on an assisted living facility that fails to provide the agency access to the facility or prohibits the agency from conducting a regulatory inspection. The licensee may not restrict agency staff in accessing and copying records or in conducting confidential interviews with facility staff or any individual who receives services from the facility ~~provide to the Division of Hotels and Restaurants of the Department of Business and Professional Regulation, on a monthly basis, a list of those assisted living facilities that have had their licenses denied, suspended, or revoked or that are involved in an appellate proceeding pursuant to s. 120.60 related to the denial, suspension, or revocation of a license~~.

(7) Agency notification of a license suspension or revocation, or denial of a license renewal, shall be posted and visible to the public at the facility.

(8) If a facility is required to relocate some or all of its residents due to agency action, that facility is exempt from the 45 days' notice requirement imposed under s. 429.28(1)(k). This subsection does not exempt the facility from any deadline for corrective action set by the agency.

Section 7. Paragraphs (a) and (b) of subsection (2) of section 429.178, Florida Statutes, are amended to read:

429.178 Special care for persons with Alzheimer's disease or other related disorders.—

(2)(a) An individual who is employed by a facility that provides special care for residents who have ~~with~~ Alzheimer's

disease or other related disorders, and who has regular contact with such residents, must complete up to 4 hours of initial dementia-specific training developed or approved by the department. The training must ~~shall~~ be completed within 3 months after beginning employment and ~~shall~~ satisfy the core training requirements of s. 429.52(3)(g) ~~s. 429.52(2)(g)~~.

(b) A direct caregiver who is employed by a facility that provides special care for residents who have ~~with~~ Alzheimer's disease or other related disorders, and who provides direct care to such residents, must complete the required initial training and 4 additional hours of training developed or approved by the department. The training must ~~shall~~ be completed within 9 months after beginning employment and ~~shall~~ satisfy the core training requirements of s. 429.52(3)(g) ~~s. 429.52(2)(g)~~.

Section 8. Section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

(1) In addition to the requirements of part II of chapter 408, the agency shall impose an administrative fine in the manner provided in chapter 120 for the violation of any provision of this part, part II of chapter 408, and applicable rules by an assisted living facility, for the actions of any person subject to level 2 background screening under s. 408.809, for the actions of any facility employee, or for an intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility.

(2) Each violation of this part and adopted rules shall be classified according to the nature of the violation and the

gravity of its probable effect on facility residents.

(a) The agency shall indicate the classification on the written notice of the violation as follows:

1.~~(a)~~ Class "I" violations are defined in s. 408.813. The agency shall impose an administrative fine of $7,500 for each ~~a~~ cited class I violation in a facility that is licensed for fewer than 100 beds at the time of the ~~in an amount not less than $5,000 and not exceeding $10,000 for each~~ violation. The agency shall impose an administrative fine of $11,250 for each cited class I violation in a facility that is licensed for 100 or more beds at the time of the violation. If the agency has knowledge of a class I violation that occurred within 12 months before an inspection, a fine must be levied for that violation regardless of whether the noncompliance was corrected before the inspection.

2.~~(b)~~ Class "II" violations are defined in s. 408.813. The agency shall impose an administrative fine of $3,000 for each ~~a~~ cited class II violation in a facility that is licensed for fewer than 100 beds at the time of the ~~in an amount not less than $1,000 and not exceeding $5,000 for each~~ violation. The agency shall impose an administrative fine of $4,500 for each cited class II violation in a facility that is licensed for 100 or more beds at the time of the violation.

3.~~(c)~~ Class "III" violations are defined in s. 408.813. The agency shall impose an administrative fine of $750 for each ~~a~~ cited class III violation in a facility that is licensed for fewer than 100 beds at the time of the ~~in an amount not less than $500 and not exceeding $1,000 for each~~ violation. The agency shall impose an administrative fine of $1,125 for each

cited class III violation in a facility that is licensed for 100 or more beds at the time of the violation.

4.~~(d)~~ Class "IV" violations are defined in s. 408.813. The agency shall impose an administrative fine of $150 for each ~~a~~ cited class IV violation in a facility that is licensed for fewer than 100 beds at the time of the ~~in an amount not less than $100 and not exceeding $200 for each~~ violation. The agency shall impose an administrative fine of $225 for each cited class IV violation in a facility that is licensed for 100 or more beds at the time of the violation.

(b) Any fine imposed for a class I violation or a class II violation must be doubled if a facility was previously cited for one or more class I or class II violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection.

(c) Notwithstanding s. 408.813(2)(c) and (d) and s. 408.832, a fine must be imposed for each class III or class IV violation, regardless of correction, if a facility was previously cited for one or more class III or class IV violations during the agency's last licensure inspection or any inspection or complaint investigation since the last licensure inspection for the same regulatory violation. A fine imposed for a class III or a class IV violation must be doubled if a facility was previously cited for one or more class III or class IV violations during the agency's last two licensure inspections for the same regulatory violation.

(d) Regardless of the class of violation cited, instead of the fine amounts listed in subparagraphs (a)1.-4., the agency shall impose an administrative fine of $500 if a facility is

found not to be in compliance with the background screening requirements as provided in s. 408.809.

~~(3) For purposes of this section, in determining if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the following factors:~~

~~(a) The gravity of the violation, including the probability that death or serious physical or emotional harm to a resident will result or has resulted, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.~~

~~(b) Actions taken by the owner or administrator to correct violations.~~

~~(c) Any previous violations.~~

~~(d) The financial benefit to the facility of committing or continuing the violation.~~

~~(e) The licensed capacity of the facility.~~

(3) ~~(4)~~ Each day of continuing violation after the date established by the agency ~~fixed~~ for correction ~~termination~~ of the violation~~, as ordered by the agency,~~ constitutes an additional, separate, and distinct violation.

(4) ~~(5)~~ An ~~Any~~ action taken to correct a violation shall be documented in writing by the owner or administrator of the facility and verified through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated facility, revoke or deny a facility's license when a facility administrator fraudulently misrepresents action taken to correct a violation.

(5) ~~(6)~~ A ~~Any~~ facility whose owner fails to apply for a change-of-ownership license in accordance with part II of

chapter 408 and operates the facility under the new ownership is subject to a fine of $5,000.

(6) ~~(7)~~ In addition to any administrative fines imposed, the agency may assess a survey fee, equal to the lesser of one half of the facility's biennial license and bed fee or $500, to cover the cost of conducting initial complaint investigations that result in the finding of a violation that was the subject of the complaint or monitoring visits conducted under s. 429.28(3)(c) to verify the correction of the violations.

(7) ~~(8)~~ During an inspection, the agency shall make a reasonable attempt to discuss each violation with the owner or administrator of the facility, before ~~prior to~~ written notification.

(8) ~~(9)~~ The agency shall develop and disseminate an annual list of all facilities sanctioned or fined for violations of state standards, the number and class of violations involved, the penalties imposed, and the current status of cases. The list shall be disseminated, at no charge, to the Department of Elderly Affairs, the Department of Health, the Department of Children and Families, the Agency for Persons with Disabilities, the area agencies on aging, the Florida Statewide Advocacy Council, and the state and local ombudsman councils. The Department of Children and Families shall disseminate the list to service providers under contract to the department who are responsible for referring persons to a facility for residency. The agency may charge a fee commensurate with the cost of printing and postage to other interested parties requesting a copy of this list. This information may be provided electronically or through the agency's website ~~Internet site~~.

Section 9. Subsection (3) and paragraph (c) of subsection (4) of section 429.256, Florida Statutes, are amended to read:

429.256 Assistance with self-administration of medication.—

(3) Assistance with self-administration of medication includes:

(a) Taking the medication, in its previously dispensed, properly labeled container, including an insulin syringe that is prefilled with the proper dosage by a pharmacist and an insulin pen that is prefilled by the manufacturer, from where it is stored, and bringing it to the resident.

(b) In the presence of the resident, reading the label, opening the container, removing a prescribed amount of medication from the container, and closing the container.

(c) Placing an oral dosage in the resident's hand or placing the dosage in another container and helping the resident by lifting the container to his or her mouth.

(d) Applying topical medications.

(e) Returning the medication container to proper storage.

(f) Keeping a record of when a resident receives assistance with self-administration under this section.

(g) Assisting with the use of a nebulizer, including removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the prescribed premeasured dose of medication into the dispensing cup of the nebulizer.

(h) Using a glucometer to perform blood-glucose level checks.

(i) Assisting with putting on and taking off antiembolism stockings.

(j) Assisting with applying and removing an oxygen cannula,

but not with titrating the prescribed oxygen settings.

(k) Assisting with the use of a continuous positive airway pressure (CPAP) device, but not with titrating the prescribed setting of the device.

(l) Assisting with measuring vital signs.

(m) Assisting with colostomy bags.

(4) Assistance with self-administration does not include:

~~(c) Administration of medications through intermittent positive pressure breathing machines or a nebulizer.~~

Section 10. Subsections (2), (5), and (6) of section 429.28, Florida Statutes, are amended to read:

429.28 Resident bill of rights.—

(2) The administrator of a facility shall ensure that a written notice of the rights, obligations, and prohibitions set forth in this part is posted in a prominent place in each facility and read or explained to residents who cannot read. The ~~This~~ notice must ~~shall~~ include the name, address, and telephone numbers of the local ombudsman council, the ~~and~~ central abuse hotline, and, if ~~when~~ applicable, Disability Rights Florida ~~the Advocacy Center for Persons with Disabilities, Inc., and the Florida local advocacy council~~, where complaints may be lodged. The notice must state that a complaint made to the Office of State Long-Term Care Ombudsman or a local long-term care ombudsman council, the names and identities of the residents involved in the complaint, and the identity of complainants are kept confidential pursuant to s. 400.0077 and that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right. The facility must ensure a resident's access to a telephone to call

the local ombudsman council, central abuse hotline, and Disability Rights Florida ~~Advocacy Center for Persons with Disabilities, Inc., and the Florida local advocacy council~~.

(5) A ~~No~~ facility or employee of a facility may not serve notice upon a resident to leave the premises or take any other retaliatory action against any person who:

(a) Exercises any right set forth in this section.

(b) Appears as a witness in any hearing, inside or outside the facility.

(c) Files a civil action alleging a violation of the provisions of this part or notifies a state attorney or the Attorney General of a possible violation of such provisions.

(6) A ~~Any~~ facility that ~~which~~ terminates the residency of an individual who participated in activities specified in subsection (5) must ~~shall~~ show good cause in a court of competent jurisdiction. If good cause is not shown, the agency shall impose a fine of $2,500 in addition to any other penalty assessed against the facility.

Section 11. Section 429.34, Florida Statutes, is amended to read:

429.34 Right of entry and inspection.—

(1) In addition to the requirements of s. 408.811, any duly designated officer or employee of the department, the Department of Children and Families, the Medicaid Fraud Control Unit of the Office of the Attorney General, the state or local fire marshal, or a member of the state or local long-term care ombudsman council has ~~shall have~~ the right to enter unannounced upon and into the premises of any facility licensed pursuant to this part in order to determine the state of compliance with ~~the~~

~~provisions of~~ this part, part II of chapter 408, and applicable rules. Data collected by the state or local long-term care ombudsman councils or the state or local advocacy councils may be used by the agency in investigations involving violations of regulatory standards. A person specified in this section who knows or has reasonable cause to suspect that a vulnerable adult has been or is being abused, neglected, or exploited shall immediately report such knowledge or suspicion to the central abuse hotline pursuant to chapter 415.

(2) The agency shall inspect each licensed assisted living facility at least once every 24 months to determine compliance with this chapter and related rules. If an assisted living facility is cited for one or more class I violations or two or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, the agency must conduct an additional licensure inspection within 6 months. In addition to any fine imposed on the facility under s. 429.19, the licensee shall pay a fee for the cost of the additional inspection equivalent to the standard assisted living facility license and per-bed fees, without exception for beds designated for recipients of optional state supplementation. The agency shall adjust the fee in accordance with s. 408.805.

Section 12. Subsection (2) of section 429.41, Florida Statutes, is amended to read:

429.41 Rules establishing standards.—

(2) In adopting any rules pursuant to this part, the department, in conjunction with the agency, shall make distinct standards for facilities based upon facility size; the types of

care provided; the physical and mental capabilities and needs of residents; the type, frequency, and amount of services and care offered; and the staffing characteristics of the facility. Rules developed pursuant to this section may ~~shall~~ not restrict the use of shared staffing and shared programming in facilities that are part of retirement communities that provide multiple levels of care and otherwise meet the requirements of law and rule. If a continuing care facility licensed under chapter 651 or a retirement community offering multiple levels of care obtains a license pursuant to this chapter for a building or part of a building designated for independent living, staffing requirements established in rule apply only to residents who receive personal services, limited nursing services, or extended congregate care services under this part. Such facilities shall retain a log listing the names and unit number for residents receiving these services. The log must be available to surveyors upon request. Except for uniform firesafety standards, the department shall adopt by rule separate and distinct standards for facilities with 16 or fewer beds and for facilities with 17 or more beds. The standards for facilities with 16 or fewer beds must ~~shall~~ be appropriate for a noninstitutional residential environment; however, ~~provided that~~ the structure may not be ~~is no~~ more than two stories in height and all persons who cannot exit the facility unassisted in an emergency must reside on the first floor. The department, in conjunction with the agency, may make other distinctions among types of facilities as necessary to enforce the provisions of this part. Where appropriate, the agency shall offer alternate solutions for complying with established standards, based on distinctions made by the

department and the agency relative to the physical characteristics of facilities and the types of care offered ~~therein~~.

Section 13. Present subsections (1) through (11) of section 429.52, Florida Statutes, are redesignated as subsections (2) through (12), respectively, a new subsection (1) is added to that section, and present subsections (5) and (9) of that section are amended, to read:

429.52 Staff training and educational programs; core educational requirement.—

(1) Effective October 1, 2015, each new assisted living facility employee who has not previously completed core training must attend a preservice orientation provided by the facility before interacting with residents. The preservice orientation must be at least 2 hours in duration and cover topics that help the employee provide responsible care and respond to the needs of facility residents. Upon completion, the employee and the administrator of the facility must sign a statement that the employee completed the required preservice orientation. The facility must keep the signed statement in the employee's personnel record.

(6)~~(5)~~ Staff involved with the management of medications and assisting with the self-administration of medications under s. 429.256 must complete a minimum of 6 ~~4~~ additional hours of training provided by a registered nurse, licensed pharmacist, or department staff. The department shall establish by rule the minimum requirements of this additional training.

(10)~~(9)~~ The training required by this section other than the preservice orientation must ~~shall~~ be conducted by persons

registered with the department as having the requisite experience and credentials to conduct the training. A person seeking to register as a trainer must provide the department with proof of completion of the minimum core training education requirements, successful passage of the competency test established under this section, and proof of compliance with the continuing education requirement in subsection (5) ~~(4)~~.

Section 14. The Legislature finds that consumers need additional information on the quality of care and service in assisted living facilities in order to select the best facility for themselves or their loved ones. Therefore, the Agency for Health Care Administration shall:

(1) Implement a rating system for assisted living facilities by March 1, 2016. The agency shall adopt rules to administer this subsection.

(2) By November 1, 2015, create content that is easily accessible through the front page of the agency's website. At a minimum, the content must include:

(a) Information on each licensed assisted living facility, including, but not limited to:

1. The name and address of the facility.

2. The number and type of licensed beds in the facility.

3. The types of licenses held by the facility.

4. The facility's license expiration date and status.

5. Other relevant information that the agency currently collects.

(b) A list of the facility's violations, including, for each violation:

1. A summary of the violation which is presented in a

manner understandable by the general public;

2. Any sanctions imposed by final order; and

3. The date the corrective action was confirmed by the agency.

(c) Links to inspection reports that the agency has on file.

Section 15. For the 2015-2016 fiscal year, the sums of $156,943 in recurring funds and $7,546 in nonrecurring funds are appropriated from the Health Care Trust Fund and two full-time equivalent senior attorney positions with associated salary rate of 103,652 are authorized in the Agency for Health Care Administration for the purpose of implementing the regulatory provisions of this act.

Section 16. This act shall take effect July 1, 2015.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 11, 2015

I respectfully request that **Senate Bill # 792**, relating to Pharmacy, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Aaron Bean

Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

April 2, 2015
Meeting Date

CS/SB792
Bill Number (if applicable)

Topic Pharmacist Immunizations

Amendment Barcode (if applicable)

Name Michael Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street
Street

Tallahassee Florida 32301
City *State* *Zip*

Phone (850) 222-2400

Email mjackson@pharmview.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Pharmacy Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/12
Meeting Date

792
Bill Number (if applicable)

Topic Pharmacy - Support Bean Bill

Amendment Barcode (if applicable)

Name Sally West

Job Title Gov Affairs Director - Walgreens

Address _____ Phone (224) 723-2650
Street

Tallahassee FL 32312 Email Sally.West@walgreens.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Walgreens

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

792
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Pharmacy

Name Melissa Ramba

Job Title Director of Gov't Affairs

Address 227 S Adams
Street

Tallahassee FL. 32311
City *State* *Zip*

Phone 850 570-0269

Email Melissa@FRF.org

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Retail Federation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

4/2/15
Meeting Date

SB 792
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Immunizations

Name Larry Gonzalez

Job Title General Counsel

Address 223 S. Gadsden St. (*Street*)
Tallahassee FL 32301 (*City / State / Zip*)

Phone 570-6307

Email lawgonz@earthlink.net

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Society of Health-System Pharmacists

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 792
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Pharmacy
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 792 authorizes a registered pharmacy intern to administer certain immunizations or vaccines to adults under the supervision of a pharmacist who is certified to administer vaccines and within the framework of a protocol under a supervising physician. The bill requires a ratio of one pharmacist to one intern when a registered intern is administering vaccines. Prior to administering vaccines, a pharmacy intern will need to obtain certification based on at least 20 hours of coursework that has been approved by the Board of Pharmacy.

The bill also expands the specified list of vaccines that a pharmacist may administer, which may also be administered by a registered intern, to include immunizations or vaccines listed in schedules established by the U.S. Centers for Disease Control and Prevention, any additional updates to those lists which are authorized by rules of the Board of Pharmacy, and immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor.

The Medical Quality Assurance Trust Fund within the Department of Health will receive estimated revenues of approximately $259,820 and will incur estimated costs of approximately $36,328 over the first two years of the bill's implementation.

The bill has an effective date of July 1, 2015.

II. Present Situation:

Pharmacists and Pharmacy Interns

Pharmacists and pharmacy interns are regulated under ch. 465, F.S., the Florida Pharmacy Act (Act), by the Board of Pharmacy (board) within the Department of Health (DOH). A "pharmacist" is a person licensed under the Act to practice the profession of pharmacy.[1] A "pharmacy intern" is a person who is currently registered in and attending an accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is registered as a pharmacy intern with the DOH.[2]

The practice of the profession of pharmacy includes:

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy, assisting the patient in managing his or her drug therapy, and reviewing the patient's drug therapy and communicating with the patient's prescribing health care provider or the provider's agent or other persons as specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients; and
- Administering vaccines to adults.[3]

To be licensed in Florida, a pharmacist must:[4]

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Have received a degree from an accredited and approved school or college of pharmacy; or is a graduate of a four-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English, has passed the board-approved Foreign Pharmacy Graduate Equivalency Examination, and has completed a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a pharmacist licensed by the DOH, which program is approved by the board;
- Have completed an internship program of 2,080 hours, approved by the board; and
- Successfully completed the board-approved examination.

The internship experience for the purposes of qualifying for the examination must be obtained in a community pharmacy, institutional pharmacy, or any board-approved pharmacy practice which includes significant aspects of the practice of pharmacy.[5] One of many requirements for a pharmacy in which an approved internship may occur is that the pharmacy establish that it fills,

[1] Section 465.003(10), F.S.
[2] Section 465.003(12), F.S.
[3] Section 465.003(13), F.S.
[4] Section 465.007, F.S. The department may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements that are set forth in law and rule. *See* s. 465.0075, F.S.
[5] Fla. Admin. Code R. 64B16-26.2032(5).

compounds, and dispenses a sufficient number, kind, and variety of prescriptions during the course of a year so as to afford an intern with a broad experience in the filling, compounding, and dispensing of prescription drugs.[6]

An intern may not perform any acts relating to filing, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in Florida.[7] Neither the Act nor the board's rules limit the number of interns a pharmacist may supervise. A pharmacy student or graduate is required to be registered by the DOH before being employed as an intern in a pharmacy in Florida. In Fiscal Year 2013-2014, there were 10,914 registered pharmacy interns actively practicing in the state.[8]

Vaccines and Immunizations

A vaccine is a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but some can also be administered by mouth or sprayed into the nose. Immunization is a process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.[9]

Authorization in Florida

Currently, a pharmacist licensed in Florida may administer vaccines for influenza, pneumococcal, meningococcal, and shingles to an adult in accordance with a protocol under a supervising physician and guidelines of the U.S. Centers for Disease Control and Prevention (CDC). A pharmacist may also administer epinephrine using an auto-injector delivery system to address any unforeseen allergic reaction to an administered vaccine.[10]

Prior to administering vaccines, a pharmacist must be certified to administer the vaccines pursuant to a 20-hour certification program approved by the board in consultation with the boards of medicine and osteopathic medicine.[11] Additionally, the pharmacist must submit to the board a copy of his or her protocol. A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability insurance. A pharmacist who administers vaccines must also maintain applicable patient records. Approximately 11,323 or 37 percent of the actively licensed pharmacists are certified to administer vaccines.[12]

The Legislature has acted three times since 2007 to address the authorization for pharmacists to administer vaccines. Chapter 2007-152, L.O.F., established the framework for pharmacists to administer vaccines. At that time, the only vaccination authorized was influenza. In 2012, the Legislature authorized the administration of the pneumococcal vaccine, the administration of the shingles vaccine pursuant to a physician's prescription, and the use of epinephrine for an allergic

[6] Fla. Admin. Code R. 64B16-26.2032(6)(c).
[7] Fla. Admin. Code R. 64B16-26.2032(4).
[8] Department of Health, *Senate Bill 792 Analysis* (Feb. 11, 2015) (on file with the Senate Committee on Health Policy).
[9] *See* U.S. Centers for Disease Control and Prevention, *Immunizations: The Basics*, (updated Sept. 25, 2014) *available at* http://www.cdc.gov/vaccines/vac-gen/imz-basics.htm, (last visited Mar. 6, 2015)
[10] Section 465.189, F.S.
[11] Section 465.189, F.S., and Fla. Admin. Code. R. 64B16-26.1031
[12] *Supra* note 8.

reaction.[13] In 2014, the Legislature added meningococcal to the list of vaccines and eliminated the requirement for a physician's prescription as the basis for a pharmacist to administer the shingles vaccine.[14]

Authorizations in Other States

Forty-four states or territories currently authorize pharmacy interns to administer vaccines. Most commonly, the intern must be trained, such as having completed a certificate training program, and must operate under the supervision of a trained pharmacist.[15] Florida is one of a handful of states that do not authorize pharmacists to administer a more expansive list of vaccines, including Td/Tdap and HPV.[16]

Recommended Adult Immunization Schedule

Annually, the CDC publishes a recommended schedule of immunizations for adults (anyone 19 years of age or older).[17] The schedule includes the recommended age groups, number of doses, and medical indications for which administration of the currently licensed and listed vaccine is commonly indicated. Prior to being published each year, the Advisory Committee on Immunization Practices (ACIP) reviews the recommended adult immunization schedule to ensure that the schedule reflects current recommendations for the listed vaccines.[18]

The recommended adult immunization schedule is also approved by the ACIP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American College of Physicians, and the American College of Nurse-Midwives.[19]

The adult immunization schedule as of February 2015, lists the following vaccines:[20]

- Influenza (flu)*
- Tetanus, diphtheria, pertussis (Td/Tdap)
- Varicella (chickenpox)
- Human papillomavirus (HPV) Female
- Human papillomavirus (HPV) Male
- Zoster (shingles)*
- Measles, mumps, rubella (MMR)
- Pneumococcal 13-valent conjugate (PCV13)*
- Pneumococcal polysaccharide (PPSV23)*
- Meningococcal*

[13] Ch. 2012-60, Laws of Florida.
[14] Ch. 2014-113, Laws of Florida.
[15] American Pharmacists Association, *Pharmacist Administered Vaccines*, slide 6 (updated January 31, 2015), *available at* http://www.pharmacist.com/sites/default/files/files/Pharmacist_IZ_Authority_1_31_15.pdf, (last visited Mar. 6, 2015).
[16] *Id.* slides 1, 9, and 11.
[17] The most current recommended adult immunization schedule for 2015, *is available at* http://www.cdc.gov/vaccines/schedules/hcp/adult.html, (last visited Mar. 6, 2015). For past immunization schedules *see* http://www.cdc.gov/vaccines/schedules/past.html, (last visited Mar. 6, 2015).
[18] U.S. Centers for Disease Control and Prevention, *Adult Immunization Schedules* (2015) *available at* http://www.cdc.gov/vaccines/schedules/hcp/adult.html, (last visited Mar. 11, 2015).
[19] *Id.*
[20] *Id.*

- Hepatitis A
- Hepatitis B
- Haemophilus influenza type b (Hib)

* Currently authorized in Florida.

International Travel

Some types of international travel, especially to developing countries and rural areas, have higher health risks. These risks depend on a number of factors including where one is traveling, activities while traveling, current health status, and vaccination history. Vaccine-preventable diseases that are rarely seen in the United States, like polio, can still be found in other parts of the world.[21]

The CDC recommends seeing one's healthcare professional or visiting a travel clinic at least four-to-six weeks prior to any international travel, since not all primary care physicians stock travel vaccines. This allows time to complete any vaccine series and gives the body time to build up immunity.

The CDC maintains an interactive website for both travelers and clinicians, by destination and certain traveler conditions, which provides recommendations on vaccines. Options for traveler conditions include, but are not limited to, pregnant, immune-compromised, or providing mission/disaster relief.[22]

Vaccine Information Statement and Adverse Incident Reporting

A Vaccine Information Statement (VIS) is a document, produced by the CDC, which informs vaccine recipients, or their parents or legal representatives, about the benefits and risks of a vaccine they are receiving. All vaccine providers are required by the National Vaccine Childhood Injury Act[23] to give the appropriate VIS to the patient, or parent or legal representative, prior to every dose of specified vaccines. The CDC also requires providers of other vaccines to provide a VIS under certain conditions. The VIS must be given regardless of the age of the recipient.[24]

In addition to distributing a VIS, providers are required to record specific information in the patient's medical record or in a permanent office log. The required information includes:[25]

- The edition date of the VIS, (a VIS may be updated frequently);
- The date the VIS is provided, i.e., the date of the visit when the vaccine is administered;
- The office address and name and title of the person who administers the vaccine;

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[21] U.S. Centers for Disease Control and Prevention, *Travel Smart: Get Vaccinated*, http://www.cdc.gov/Features/vaccines-travel/index.html, (last visited Mar. 6, 2015).
[22] U.S. Centers for Disease Control and Prevention, *Traveler's Health: Destinations*, http://wwwnc.cdc.gov/travel/destinations/list, (last visited Feb. 23, 2015).
[23] NCVIA - 42 U.S.C. § 300aa-26
[24] U.S. Centers for Disease Control and Prevention, *Vaccine Information Statements*, (last update June 18, 2013) (last reviewed June 13, 2014) http://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html, (last visited Mar. 6, 2015).
[25] *Id.*

- The date the vaccine is administered; and
- The vaccine manufacturer and lot number.

The Vaccine Adverse Event Reporting System (VAERS) is primarily concerned with monitoring adverse health events following vaccination but it accepts all reports, including reports of vaccination errors. Using clinical judgment, healthcare professionals can decide whether to report a medical error at their own discretion. For example, a healthcare professional may elect to report vaccination errors that do not have an associated adverse health event, especially if they think the vaccination error may pose a safety risk (e.g., administering a live vaccine to an immunocompromised patient) or that the error would be preventable with public health action or education. There are three ways to report to VAERS – online, by facsimile, or by mail.[26]

III. Effect of Proposed Changes:

The bill expands access and availability of certain immunizations for adults by expanding the list of vaccines that a pharmacist may administer and authorizing a registered pharmacy intern, once certified, to administer those same vaccines under the supervision of a pharmacist who is certified to administer vaccines.

Rather than specifying individual immunizations or vaccines that may be administered by a pharmacist or registered intern, the bill authorizes administration of the immunizations or vaccines that are listed in the adult immunization schedule as of February 2015, by the U.S. Centers for Disease Control and Prevention. Currently, the statute authorizes the administration of vaccines for influenza, pneumococcal, meningococcal and shingles to adults (19 years of age or older).[27] By referencing the CDC adult immunization schedule as of February 2015, this bill adds:

- Tetanus, diphtheria, pertussis (Td/Tdap)
- Varicella (chickenpox)
- Human papillomavirus (HPV) Female
- Human papillomavirus (HPV) Male
- Measles, mumps, rubella (MMR)
- Hepatitis A
- Hepatitis B
- Haemophilus influenza type b (Hib)

The administration of immunizations or vaccines that are recommended by the CDC for international travel as of July 1, 2015, as well as those approved by the board in response to a Governor-declared state of emergency, may also be administered in accordance with the requirements in this section of law.

The bill grants rulemaking authority for the board to authorize additional immunizations or vaccines as the CDC adds to the adult immunization schedule or the CDC recommends additional immunizations or vaccines for international travel.

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[26] *See* Vaccine Adverse Events Reporting System, http://vaers.hhs.gov/esub/index (last visited Mar. 6, 2015).

[27] Section 465.189, F.S., does not define an adult. However, this section of law authorizes administration in accordance with the guidelines of the CDC, which defines an adult as a person who is 19 years of age or older.

The bill requires a registered pharmacy intern to be certified to administer vaccines pursuant to a program approved by the board, and the boards of medicine and osteopathic medicine, which includes at least 20 hours of coursework. Additionally the bill sets a supervision ratio of one registered intern to one pharmacist when the intern is administering immunizations.

The effective date of the bill is July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Under CS/SB 792, pharmacy interns seeking certification to administer vaccinations will incur a $55 initial application fee. The public may be able to obtain applicable vaccinations at their local pharmacy, which may be more expedient and possibly less expensive than scheduling an appointment at a physician's office; however, any such savings are indeterminate.

C. Government Sector Impact:

The DOH[28] estimates potential certification fees of $259,820.[29] The DOH estimates total expenditures of $36,328 related to the costs for processing certification applications, based on the processing cost of $7.69 per application.

The DOH indicates that the increase in workload associated with application and website modifications, updates to the Licensing and Enforcement Information Database System, and rulemaking can be absorbed within existing resources.

[28] *Supra* note 8.

[29] The certification fee estimate of $259,820 is based on 4,038 currently registered interns (calculated as 10,914 total registered inters X 37%, number of certified pharmacists) + 686 newly registering interns (calculated as 1,855 new registered intern applications X 37%) for 4,724 applications for certification X $55 application fee.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.189 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 10, 2015:
The CS requires the supervising pharmacist to be certified to administer vaccines, and references a more current recommended adult immunization list which is the one in effect as of February 2015. The CS also requires a one-to-one supervision ratio when the intern administers an immunization.

B. Amendments:

None.

748994

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/02/2015	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Bean) recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 47 and 48

insert:

(3) A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability insurance and has completed training in administering vaccines authorized under this section. The professional liability insurance must provide coverage for any delegated act performed by a registered intern under this section.

748994

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:
Delete line 16
and insert:
Section 1. Subsections (1), (3), and (6) of section 465.189,

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:
Delete line 8
and insert:
one-to-one ratio for such supervision; requiring professional liability insurance coverage for certain delegated acts performed by a registered intern; requiring a

By the Committee on Health Policy; and Senator Bean

588-02138A-15 2015792c1

A bill to be entitled

An act relating to pharmacy; amending s. 465.189, F.S.; authorizing a registered intern under the supervision of a pharmacist to administer specified vaccines to an adult; revising which vaccines may be administered by a pharmacist or a registered intern under the supervision of a pharmacist; requiring a one-to-one ratio for such supervision; requiring a registered intern seeking to administer vaccines to be certified to administer such vaccines and to complete a minimum amount of coursework; providing an effective date.

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

Section 1. Subsections (1) and (6) of section 465.189, Florida Statutes, are amended to read:

465.189 Administration of vaccines and epinephrine autoinjection.—

(1) In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist who is certified under subsection (6), or a registered intern who is under the supervision of a pharmacist, if both the pharmacist and the registered intern are certified under subsection (6), may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a) Immunizations or vaccines listed in the recommended

588-02138A-15 2015792c1

adult immunization schedule as of February 2015 by the United States Centers for Disease Control and Prevention. The board may authorize, by rule, additional immunizations or vaccines as they are added to the adult immunization schedule ~~Influenza vaccine~~.

(b) Immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of July 1, 2015. The board may authorize, by rule, additional immunizations or vaccines as they are recommended by the United States Centers for Disease Control and Prevention for international travel ~~Pneumococcal vaccine~~.

(c) Immunizations or vaccines approved by the board in response to a state of emergency declared by the Governor pursuant to s. 252.36 ~~Meningococcal vaccine~~.

~~(d) Shingles vaccine.~~

When a registered intern administers an immunization under this subsection, the registered intern must be supervised by a pharmacist at a ratio of one pharmacist to one registered intern.

(6) Any pharmacist or registered intern seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board and that the registered intern complete at least 20 hours of coursework approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of

such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

Section 2. This act shall take effect July 1, 2015.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 18, 2015

I respectfully request that **Senate Bill # 904**, relating to Nurse Registries, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

S-020 (03/2004)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 904
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Home Health Services
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Favorable**
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 904 amends ss. 400.462 and 400.506, F.S., to allow a nurse registry to operate one or more satellite offices within the same geographic service area as the registry's licensed operational site. The nurse registry may store supplies and records, register and process contractors, and conduct business by telephone at the satellite site as well as advertise the location of the satellite site to the public. However, the nurse registry must use the operational site for all administrative functions and to store all original records.

The bill requires the nurse registry to notify the Agency for Health Care Administration (AHCA) of changes of address of its operational site and when opening a satellite office. Before relocating its operational site or opening a satellite office, the nurse registry must submit evidence of its legal right to use the proposed property and proof that the proposed property is in an area zoned for nurse registry use.

The bill also amends s. 400.464, F.S., to allow home health agencies (HHA) to operate a related office in the same geographic service area, rather than in the same county, as the HHA's main office without requiring an additional license for the related office.

The bill is expected to have an insignificant fiscal impact.

The bill takes effect July 1, 2015.

II. Present Situation:

Nurse Registries

A nurse registry is defined to mean "any person that procures, offers, promises, or attempts to secure health care-related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent contractors, including but not limited to, contracts for the provision of services to patients and contracts to provide private duty or staffing services to health care facilities licensed under ch. 395, F.S., ch. 400, or ch. 429, F.S., or other business entities."[1] Nurse registries operate by referring qualified health care workers to patients, health care facilities, or other business entities who hire such health care workers. Workers referred by the nurse registry are independent contractors and the nurse registry receives a fee or commission for each contractor referred.[2]

Nurse registries are regulated under the Home Health Services Act in part III of ch. 400, F.S., specifically s. 400.506, F.S., and part II of ch. 408, F.S., the general licensing provisions for health care facilities regulated by the AHCA. A license issued by the AHCA is required to operate a nurse registry.

Some of the responsibilities of a nurse registry as established in statute and rule include:

- Referring independent contractors capable of delivering services as defined in a specific medical plan of treatment for a patient or services requested by a client;[3]
- Keeping clinical records received from their independent contractors for five years following the termination of that contractor's service;[4]
- Disseminating to its independent contractors the procedures governing the administration of drugs and biologicals to patients required by ch. 464, F.S., and AHCA rules, as well as all the information required by Rule 59A-18.005(1) of the Florida Administrative Code;[5]
- Initially confirming and annually reconfirming the licensure or certification of all its applicable independent contractors;[6]
- Annually requesting performance outcome evaluations from the health care facilities where the independent contractor provided services and maintaining those evaluations in that independent contractor's file;[7]
- Establishing a system for recording a following-up on complaints involving independent contractors referred by the registry;[8]
- Informing a health care facility or other business entity that a referred independent contractor is on probation with their professional licensing board or certifying agency or has had other

[1] Section 400.462(21), F.S.
[2] AHCA, *Senate Bill 904 Analysis*, (Feb. 15, 2015) (on file with the Senate Committee on Health Policy).
[3] Rule 59A-18.010(2), F.A.C.
[4] Rule 59A-18.012(7), F.A.C.
[5] Rule 59A-18.013(1), F.A.S.
[6] Rule 59A-18.005(3) and (4), F.A.C.
[7] Rule 59A-18.017, F.A.C.
[8] Id.

restrictions placed on his or her license or certification when the nurse registry has received such information;[9]
- Preparing and maintaining a written comprehensive emergency management plan;[10] and
- Complying with the background screening requirements in s. 400.512, F.S., which requires a level II background check for all employees and contractors.[11]

Operational Sites

Each nurse registry operational site must be licensed unless it is located in a county where the nurse registry has multiple operational sites. If the nurse registry has more than one operational site in a single county, only one license is necessary for all operational sites in that county and each site must be listed on the license.[12] Rule 59A-18.004(4) of the Florida Administrative Code, requires that nurse registries apply for licensure to serve a geographic service area that is equivalent to an AHCA district. There are 11 AHCA districts which range in size from a single county, such as District 10 which includes only Broward County, to numerous counties, such as District 3 which includes 16 counties. All districts except District 10 incorporate at least two counties.[13] Each nurse registry operational site can service the entire AHCA district for which the license was granted.

As of January 8, 2015, 541 nurse registries are licensed with the AHCA with 367 different owners. A total of 62 nurse registry companies own two or more nurse registry licenses and eight nurse registry companies own two or more nurse registry licenses within the same AHCA district. Nurse registries must pay a biennial license fee of $2,000 per license and are surveyed by the AHCA on a biennial basis.[14]

Home Health Agencies

An HHA is an organization that provides home health services and staffing services.[15] Home health services provided by an HHA include health and medical services and medical equipment provided to an individual in his or her home, such as nursing care, physical and occupational therapy, and home health aide services.[16] Home health agencies are regulated by the AHCA pursuant to part III of ch. 400, F.S. An HHA must designate an AHCA district in which the HHA will operate and must reapply for licensure in order to relocate to a different AHCA district.[17] Currently, an HHA may have a main office and related offices; however, all related offices outside of the county where the main office is located must be licensed separately and each such office must be specified on the main office's license.[18]

[9] Id.
[10] Rule 59A-18.018(1), F.A.C.
[11] Section 400.506(9), F.S.
[12] Section 400.506(1), F.S.
[13] Section 408.032(5), F.S.
[14] Supra note 2
[15] Section 400.462(12), F.S.
[16] Section 400.462(14)(a)-(c), F.S.
[17] Section 400.471(9), F.S.
[18] Section 400.464(2), F.S.

III. Effect of Proposed Changes:

The bill amends ss. 400.462 and 400.506, F.S., to allow a nurse registry to operate one or more satellite offices within the same geographic service area (AHCA district) as the registry's licensed operational site. This may reduce the number of licenses some nurse registries may need since currently a license is needed in each county in which the nurse registry operates. The bill defines a satellite office.

The nurse registry may store supplies and records, register and process contractors, and conduct business by telephone at the satellite site, as well as advertise the location of the satellite site to the public. However, the nurse registry must use the operational site for all administrative functions and to store all original records.

The bill requires the nurse registry to notify the AHCA of changes of address of its operational site and when opening a satellite office. Before relocating its operational site, the nurse registry must submit evidence of its legal right to use the proposed property and proof that the proposed property is in an area zoned for nurse registry use.

The bill also amends s. 400.464, F.S., to allow an HHA to operate a related office in the same geographic service area, rather than in the same county, as the agency's main office without requiring an additional license for the related office.

The bill republishes several sections of law for the purpose of incorporating amendments made by the act.

The bill establishes an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 904 may have a positive fiscal impact on nurse registries and HHAs that operate multiple licenses within the same AHCA district. If such HHAs or registries are able to replace one or more licensed sites with unlicensed satellite or related offices, they will no longer be required to hold multiple licenses and pay multiple license fees. Additionally, HHAs and nurse registries located in AHCA districts with multiple counties may see a positive fiscal impact if an additional office allows them to reduce travel and other expenses related to having a single office serving multiple counties.

C. Government Sector Impact:

The AHCA may see a slight decline in revenue due to the loss of some licensure fees and the potential requirement to conduct additional surveys. For nurse registries, the AHCA anticipates that any costs can be absorbed within existing resources.[19]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 400.462, 400.464, and 400.506 of the Florida Statutes.

The bill reenacts sections 400.497, 400.506(3), and 817.505 of the Florida Statutes to incorporate the statutory amendments made by this bill.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 17, 2015:
The CS amends s. 400.464, F.S., to allow HHAs to operate a related office in the same geographic service area, rather than in the same county, as the agency's main office without requiring an additional license for the related office.

The CS also amends the title of bill to "an act related to home health services."

B. Amendments:

None.

[19] Supra note 2

By the Committee on Health Policy; and Senator Bean

588-02399-15 2015904c1

A bill to be entitled

An act relating to home health services; amending. s. 400.462, F.S.; defining a term; amending s. 400.464, F.S.; allowing home health agencies to operate related offices inside of the main office's geographic service area without an additional license; amending s. 400.506, F.S.; providing for the licensure of more than one nurse registry operational site within the same geographic service area; authorizing a licensed nurse registry to operate a satellite office; requiring a nurse registry operational site to keep all original records; requiring a nurse registry to provide notice and certain evidence before it relocates an operational site or opens a satellite office; reenacting ss. 400.497, 817.505(3)(h), 400.506(3), F.S., to incorporate the amendment made to s. 400.506, F.S., in references thereto; providing an effective date.

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

Section 1. Present subsections (28) and (29) of section 400.462, Florida Statues, are redesignated as subsections (29) and (30), respectively, and a new subsection (28) is added to that section, to read:

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

(28) "Satellite office" means a secondary office of a nurse registry established pursuant to s. 400.506(1) in the same geographic service area as a licensed nurse registry operational

588-02399-15 2015904c1

site.

Section 2. Subsection (2) of section 400.464, Florida Statutes, is amended to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(2) If the licensed home health agency operates related offices, each related office outside the geographic service area ~~county~~ where the main office is located must be separately licensed. The counties where the related offices are operating must be specified on the license in the main office.

Section 3. Subsection (1) of section 400.506, Florida Statutes, is amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(1)(a) A nurse registry is exempt from the licensing requirements of a home health agency but must be licensed as a nurse registry. The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 400.506-400.518 and part II of chapter 408 and to entities licensed by or applying for such license from the Agency for Health Care Administration pursuant to ss. 400.506-400.518. A license issued by the agency is required for the operation of a nurse registry. Each operational site of the nurse registry must be licensed, unless there is more than one site within the geographic service area for which a license is issued. In such case, ~~a county. If there is more than one site within a county, only one license per county is required.~~ each operational site within the geographic service area must be listed on the license.

(b) A licensed nurse registry may operate a satellite office as defined in s. 400.462. The nurse registry operational site must administer all satellite offices. A satellite office may store supplies and records, register and process contractors, and conduct business by telephone as is done at other operational sites. Nurse registries may use signs and advertisements to notify the public of the location of a satellite office. All original records must be kept at the operational site.

(c) A nurse registry must provide notice, in writing, to the agency at the state and area office levels, as required by agency rule, of a proposed change of address for an operational site or the opening of a satellite office. Before relocating an operational site or opening a satellite office, the nurse registry must submit evidence of its legal right to use the proposed property, as well as a certificate of occupancy, a certificate of use, or other evidence that the property is zoned for nurse registry use.

Section 4. Section 400.497, paragraph (h) of subsection (3) of s. 817.505, and subsection (3) of s. 400.506, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 400.506, Florida Statutes, in references thereto.

Section 5. This act shall take effect July 1, 2015.

The Florida Senate

Committee Agenda Request

To: Senator Rene Garcia
Senate Appropriations Subcommittee on Health and Human Services

Scarlet Pigott, Staff Director
Robin Auber, Committee Administrative Assistant

Subject: Committee Agenda Request

Date: March 11, 2015

Dear Chairman Garcia,

I respectfully request that **Senate Bill #996**, relating to Home Medical Equipment, be placed on the Appropriations Subcommittee on Health and Human Services agenda at your earliest possible convenience.

If you have any questions regarding this legislation, please contact me. Thank you in advance for your consideration.

Senator Garrett Richter
Florida Senate, District 23

File signed original with committee office

THE FLORIDA SENATE

APPEARANCE RECORD

4/2/15
Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

996
Bill Number (if applicable)

Topic Home Medical Equipment

Amendment Barcode (if applicable)

Name Paul Lambert

Job Title

Address 263 Rosehill Drive North
Street
Tallahassee FL 32312
City *State* *Zip*

Phone 850 597-2696

Email plambert@paullambertlaw.com

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing Florida Chiropractic Asso.

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

APPEARANCE RECORD

4-2-2015
Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB 996
Bill Number (if applicable)

Topic HOME MEDICAL EQUIPMENT

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

Job Title EXECUTIVE DIRECTOR

Address 2007 APALACHEE PARKWAY
Street
TALLAHASSEE FL 32301
City *State* *Zip*

Phone 878-7364

Email

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	SB 996
INTRODUCER:	Senator Richter
SUBJECT:	Home Medical Equipment
DATE:	April 1, 2015
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.	Brown	Pigott	AHS	**Favorable**
3.			FP	

I. Summary:

SB 996 amends s. 400.93, F.S., to exempt physicians who sell or rent electrostimulation medical equipment to their patients in the course of their practice from the requirement to be licensed as a home medical equipment provider.

The bill may have an insignificant fiscal impact to the Agency for Health Care Administration (AHCA).

The effective date of the bill is July 1, 2015.

II. Present Situation:

Home Medical Equipment Providers

Part VII of ch. 400, F.S., requires the AHCA to license and regulate any person or entity that holds itself out to the public as performing any of the following functions:

- Providing home medical equipment[1] and services;[2]
- Accepting physician orders for home medical equipment and services; or
- Providing home medical equipment that typically requires home medical services.[3]

[1] Defined in s. 400.925, F.S., as any product as defined by the federal Food and Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

[2] Defined in s. 400.925, F.S., as equipment management and consumer instruction, including selection, delivery, set-up, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's regular or temporary place of residence.

[3] Section 400.93(1) and (2), F.S.

The following are exempt from the licensure requirement for home medical equipment providers:[4]

- Providers operated by the Department of Health (DOH) or the federal government;
- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Hospices;
- Intermediate care facilities;
- Homes for special services;
- Transitional living facilities;
- Hospitals;
- Ambulatory surgical centers;
- Manufacturers and wholesale distributors that do not sell directly to the consumer;
- Licensed health care practitioners who utilize home medical equipment in the course of their practice but do not sell or rent home medical equipment to their patients; and
- Pharmacies.

Currently there are 1,003 licensed home medical equipment providers, including those providers that are located out of the state but hold a Florida license.[5]

Any person or entity applying for a license as a home medical equipment provider must provide the AHCA with:

- A report of the medical equipment that will be provided, indicating whether it will be provided directly or by contract;
- A report of the services that will provided, indicating whether the services will be provided directly or by contract;
- A list of the persons and entities with whom they contract;
- Documentation of accreditation, or an application for accreditation, from an organization recognized by the AHCA;
- Proof of liability insurance; and
- A $300 application fee and a $400 inspection fee, unless exempt from inspection.[6]

As a requirement of licensure, home medical equipment providers must comply with a number of minimum standards including, but not limited to:

- Offering and providing home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services;
- Providing at least one category of equipment directly from their own inventory;
- Responding to orders for other equipment from either their own inventory or from the inventory of other contracted companies;

[4] Section 400.93(5), F.S.
[5] *See* AHCA, Florida Health Finder, *Home Health Care in Florida*, (printed list of home medical equipment providers on file with Senate Committee on Health Policy).
[6] Section 400.931, F.S.

- Maintaining trained personnel to coordinate orders and scheduling of equipment and service deliveries;
- Ensuring that their delivery personnel are appropriately trained;
- Ensuring that patients are aware of their service hours and emergency service procedures;
- Answering any questions or complaints a consumer has about an item or the use of an item;
- Maintaining and repairing, either directly or through contract, items rented to consumers;
- Maintaining a safe premises;
- Preparing and maintaining a comprehensive emergency management plan that must be updated annually and provide for continuing home medical equipment services for life-supporting or life-sustaining equipment during an emergency;
- Maintaining a prioritized list of patients who need continued services during an emergency;[7]
- Complying with AHCA rules on minimum qualifications for personnel, including ensuring that all personnel have the necessary training and background screening;[8] and
- Maintaining a record for each patient that includes the equipment and services the provider has provided and which must contain:
  - Any physician's order or certificate of medical necessity;
  - Signed and dated delivery slips;
  - Notes reflecting all services, maintenance performed, and equipment exchanges;
  - The date on which rental equipment was retrieved; and,
  - Any other appropriate information.[9]

Licensed home medical equipment providers are subject to periodic inspections, including biennial licensure inspections, inspections directed by the federal Centers for Medicare & Medicaid Services, and licensure complaint investigations. A home medical equipment provider may submit a survey or inspection by an accrediting organization in lieu of a licensure inspection if the provider's accreditation is not provisional and the AHCA receives a report from the accrediting organization. A copy of a valid medical oxygen retail establishment permit issued by the DOH may also be submitted in lieu of a licensure inspection.[10]

Electrostimulation Medical Equipment

Devices that provide electrical stimulation can be used medically to treat a number of symptoms and conditions. Electrical stimulators can provide direct, alternating, pulsating, and pulsed waveforms of energy to the human body through electrodes that may be indwelling, implanted in the skin, or used on the surface of the skin.[11] Such devices may be used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements.[12]

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[7] Section 400.934, F.S.
[8] AHCA, Rule 59A-25.004, F.A.C. All home medical equipment provider personnel are also subject to a level 2 background screening per s. 400.953, F.S.
[9] Section 400.94, F.S.
[10] Section 400.933, F.S.
[11] United Healthcare Medical Policy, *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation*, p. 4, (December 1, 2014) https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Electrical_Stim_Tx_Pain_Muscle_Rehab.pdf, (last visited Mar. 6, 2015).
[12] Id.

Functional electrical stimulation (FES), also known as therapeutic electrical stimulation (TES), is used to prevent or reverse muscular atrophy and bone loss by stimulating paralyzed limbs. FES is designed to be used as a part of a self-administered, home-based rehabilitation program for the treatment of upper limb paralysis. An FES system consists of a custom-fitted device and control unit that allows the user to adjust the stimulation intensity and a training mode which can be gradually increased to avoid muscle fatigue.[13]

A second type of electrical stimulation is Transcutaneous Electrical Nerve Stimulation, or TENS. TENS is the application of electrical current through electrodes placed on the skin for pain control. It has been used to treat a variety of painful conditions, but there is "much controversy over which conditions to treat with TENS and the adequate parameters to use."[14] Despite this controversy, there is some clinical evidence that TENS is able to relieve certain types of pain and "experimental pain studies and clinical trials are beginning to refine parameters of stimulation to obtain the best pain relief."[15] For example, studies have shown that TENS increases the pressure and heat pain thresholds in people who are healthy and reduces mechanical and heat hyperalgesia in arthritic animals.[16]

Other types of electrical stimulation include interferential therapy (IFT) and neuromuscular electrical stimulation (NMES). IFT uses two alternating currents simultaneously applied to the affected area through electrodes and which is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. NMES involves the application of electrical currents through the skin to cause muscle contractions and is used to promote the restoration of nerve supply, prevent or slow atrophy, relax muscle spasms, and to promote voluntary control of muscles in patients who have lost muscle function.[17]

III. Effect of Proposed Changes:

The bill amends s. 400.93, F.S., to exempt physicians who sell or rent electrostimulation medical equipment to their patients in the course of their practice from the requirement to be licensed as a home medical equipment provider.

The bill establishes an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[13] Supra note 11.
[14] Effectiveness of Transcutaneous Electrical Nerve Stimulation for Treatment of Hyperalgesia and Pain, *Curr Rheumatol Rep. Dec 2008; 10(6): 492–499*, found at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746624/, (last visited Mar. 6, 2015).
[15] *Id.*
[16] Effects of Transcutaneous Electrical Nerve Stimulation on Pain, Pain Sensitivity, and Function in People With Knee Osteoarthritis: A Randomized Controlled Trial, *Physical Therapy 2012 Jul; 92(7): 898–910* found at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386514/, (last visited Mar. 6, 2015).
[17] *Supra* note 11

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Any exempted physicians may see a positive fiscal impact from SB 996 due to no longer having to pay licensure and inspection fees or meet the licensure requirements of part VII of ch. 400, F.S.

C. Government Sector Impact:

The AHCA may experience a negative, but likely insignificant, fiscal impact due to fewer licensed home medical equipment providers.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.93 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

By Senator Richter

23-01119-15 2015996__

A bill to be entitled

An act relating to home medical equipment; amending s. 400.93, F.S.; exempting allopathic, osteopathic, and chiropractic physicians who sell or rent electrostimulation medical equipment and supplies to their patients in the course of their practice from licensure as home medical equipment providers; providing an effective date.

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

Section 1. Paragraph (k) is added to subsection (5) of section 400.93, Florida Statutes, to read:

400.93 Licensure required; exemptions; unlawful acts; penalties.—

(5) The following are exempt from home medical equipment provider licensure, unless they have a separate company, corporation, or division that is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence pursuant to the provisions of this part:

(k) Physicians licensed pursuant to chapter 458, chapter 459, or chapter 460 for the sale or rental of electrostimulation medical equipment and electrostimulation medical equipment supplies to their patients in the course of their practice.

Section 2. This act shall take effect July 1, 2015.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

CourtSmart Tag Report

Room: SB 401 **Case:** **Type:**
Caption: Appropriations Subcommittee on Health and Human Services **Judge:**

Started: 4/2/2015 9:09:46 AM
Ends: 4/2/2015 9:47:29 AM Length: 00:37:44

9:09:48 AM Called to Order
9:10:09 AM Roll Call
9:10:29 AM TAB 5: CS/SB 1052
9:11:40 AM 748902- Adopted
9:12:13 AM Sen. Bean
9:15:20 AM Stephen Winn, Executive Director, Florida Osteopathic Medical Association waives in support
9:15:28 AM Michael McQuone, Associate Director for Health, Florida Conference of Catholic Bishops
9:18:22 AM Laura Cantwell, AARP waives in support
9:18:31 AM Teresa Ward, Attorney, Florida Right To Life
9:19:54 AM Sen. Bean
9:20:59 AM Sen. Sobel
9:21:54 AM Chris Nuland, Florida chapter American College of Physicians waives in support
9:23:20 AM Roll Call- FAV/CS
9:23:49 AM TAB1: CS/SB 210
9:25:31 AM Sen. Sobel
9:26:15 AM Roll Call- Favorable
9:26:36 AM TAB 4: CS/SB 758
9:26:50 AM Dave Murzin, Legislative Aid
9:27:25 AM Chris Nuland, Florida Public Health Association waives in support
9:27:45 AM Lenys Klumpp, Gov Community Relation Poison Control
9:28:21 AM Jill Gran, Florida Alcohol and Drug Abuse Association waives in support
9:28:21 AM Kelly Corredor, President and CEO, The Skeeterhawk Experiement waives in support
9:28:31 AM Jill Maliszewski, Vice-President, The Skeeterhawk Experiment waives in support
9:28:41 AM Jesse Fry, Policy Analyst, The AIDS Institute waives in support
9:28:47 AM Beth Labasky, Consultant, Informed Facilities of Florida waives in support
9:28:56 AM Brian Jogerst, Shatterproof, waives in support
9:29:02 AM Stephen Winn, Executive Director, Florida Osteopathic Medical Association waives in support
9:29:10 AM Christian Minor, Director of Government Affairs, The Florida Smart Justice Alliance waives in support
9:29:19 AM Kurt Vroman, 9th District Vice President, Florida Professional Firefighters waives in support
9:29:37 AM Roll Call- Favorable
9:29:56 AM TAB 2: CS/SB 640
9:30:07 AM Charlie Anderson, Legislative Aid
9:30:55 AM Roll Call- Favorable
9:31:13 AM TAB 3: CS/SB 940
9:31:24 AM Charlie Anderson, Legislative Aid
9:32:31 AM Christina Spudeas, Executive Director, Florida Children First waives in support
9:32:39 AM Kenisha Anthony, Florida Youth SHINE
9:36:21 AM Sen. Sobel
9:37:36 AM Roll Call- Favorable
9:37:54 AM TAB 6: CS/SB 382
9:40:10 AM James McFaddin, Florida ALFA waives in support
9:40:23 AM Bob Asztalos, Cheif Looyist, Florida Health Care Association waives in support
9:40:32 AM Laura Cantwell, AARP waives in support
9:41:14 AM Roll Call- Favorable
9:42:00 AM Sen. Abruzzo
9:42:26 AM TAB 7: CS/SB 792
9:43:24 AM 748994- Withdrawn
9:43:50 AM Larry Gonzalas, General Counsel, Florida Society of Health-System Pharmacists waives in support
9:43:58 AM Melissa Ramba, Director of Government Affairs, Florida Retail Federation waives in support
9:44:03 AM Sally West, Government Affairs Director, Walgreens waives in support
9:44:08 AM Michael Jackson, Executive Vice President and CEO, Florida Pharmacy Association
9:44:22 AM Roll Call- Favorable

9:44:59 AM TAB 8: CS/SB 904
9:45:49 AM Roll Call-Favorable
9:46:07 AM TAB 9: SB 996
9:46:31 AM Paul Lambert, Florida Chiropractic Association waives in support
9:46:39 AM Stephen Winn, Executive Director, Florida Osteopathic Medical Association waives in support
9:46:52 AM Roll Call- Favorable
9:47:22 AM Adjourn