



Health & Human Services Committee

**Wednesday, April 1, 2015
8:30 AM – 10:30 AM
Morris Hall**

**Steve Crisafulli
Speaker**

**Jason Brodeur
Chair**

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time: Wednesday, April 01, 2015 08:30 am
End Date and Time: Wednesday, April 01, 2015 10:30 am
Location: Morris Hall (17 HOB)
Duration: 2.00 hrs

Consideration of the following bill(s):

CS/HB 141 Pub. Rec./Impaired Practitioner Consultants by Health Quality Subcommittee, Renuart, Adkins
CS/CS/HB 269 Experimental Treatments for Terminal Conditions by Insurance & Banking Subcommittee, Health Innovation Subcommittee, Pilon
CS/HB 281 Prescription Medication by Health Innovation Subcommittee, Pigman
CS/HB 309 Patient Admission Status Notification by Health Care Appropriations Subcommittee, Harrison
CS/HB 515 Physical Therapy by Health Quality Subcommittee, Cummings
HB 633 Informed Patient Consent by Sullivan
CS/HB 893 Blanket Health Insurance Eligibility by Health Innovation Subcommittee, Ingoglia
HB 935 Individuals with Disabilities by Rodrigues, R.
HB 937 Trust Funds/Florida ABLE Trust Fund/State Board of Administration by Rodrigues, R.
CS/HB 939 Pub. Rec./Florida Prepaid College Board/Florida ABLE, Inc./Florida ABLE Program by Government Operations Subcommittee, Rodrigues, R.
CS/HB 1001 Assisted Living Facilities by Health Care Appropriations Subcommittee, Ahern
CS/HB 1049 Practice of Pharmacy by Health Quality Subcommittee, Peters
HB 1305 Home Medical Equipment Providers by Eagle
HB 7045 State Veterans' Nursing Homes by Health Innovation Subcommittee, Sprowls

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Tuesday, March 31, 2015.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, March 31, 2015.

NOTICE FINALIZED on 03/30/2015 15:23 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 141 Pub. Rec./Impaired Practitioner Consultants
SPONSOR(S): Health Quality Subcommittee; Renuart and Adkins
TIED BILLS: IDEN./SIM. **BILLS:** CS/SB 144

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Castagna	O'Callaghan
2) Government Operations Subcommittee	12 Y, 0 N	Williamson	Williamson
3) Health & Human Services Committee		Castagna <i>NC</i>	Calamas <i>CC</i>

SUMMARY ANALYSIS

The Department of Health (DOH) administers a treatment program for impaired health care practitioners, and the Department of Business and Professional Regulation (DBPR) administers a treatment program for impaired pilots. These treatment programs assist DOH and DBPR in determining whether health care practitioners or pilots, who have experienced a substance abuse or mental or physical health impairment, are safe to practice their profession. Currently, two different impaired professional consultant companies provide such services in Florida.

CS/HB 141 creates a public records exemption for certain identification and location information of a current or former impaired practitioner consultant who is retained by an agency, a current or former employee of such consultant whose duties result in a determination of a person's skill and safety to practice a licensed profession, and the spouses and children of both. The exemption is subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2020, unless reviewed and saved from repeal by the Legislature.

The bill also provides a statement of public necessity as required by the Florida Constitution.

The bill may have an insignificant negative fiscal impact on state and local governments.

The bill provides that the act will take effect upon becoming a law.

Article I, s. 24(c) of the Florida Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created or expanded public records or public meetings exemption. The bill creates a public records exemption; thus, it requires a two-thirds vote for final passage.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Public Records Laws

The Florida Constitution provides that the public has the right to access government records. It guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government.¹

In addition to the Florida Constitution, the Florida Statutes specify conditions under which public access must be provided to government records. The Public Records Act² guarantees every person's right to inspect and copy any state or local government public record.³

Only the Legislature may create an exemption from public records requirements.⁴ An exemption must specifically state the public necessity justifying the exemption and must be tailored to accomplish the stated purpose of the law.⁵ A bill enacting an exemption may not contain other substantive provisions⁶ and must pass by a two-thirds vote of the members present and voting in each house of the Legislature.⁷

Open Government Sunset Review Act

The Open Government Sunset Review Act (Act) prescribes a legislative review process for newly created or substantially amended public records exemptions.⁸ The Act provides that an exemption automatically repeals on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.⁹

The Act provides that a public records exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary.¹⁰ An exemption serves an identifiable purpose if it meets one of the following criteria:

- It allows the state or its political subdivision to effectively and efficiently administer a program, and administration would be significantly impaired without the exemption;¹¹

¹ FLA. CONST., art. I, s. 24(a).

² Chapter 119, F.S.

³ Section 119.011(12), F.S., defines "public record" to mean "all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency." The Public Records Act does not apply to legislative or judicial records. *Locke v. Hawkes*, 595 So.2d 32 (Fla. 1992). The Legislature's records are public pursuant to section 11.0431, F.S.

⁴ FLA. CONST., art. I, s. 24(c). There is a difference between records the Legislature designates as exempt from public records requirements and those the Legislature designates *confidential* and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *Williams v. City of Minneola*, 575 So.2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential, such record may not be released, to anyone other than the persons or entities specifically designated in statute. *WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48 (Fla. 5th DCA 2004).

⁵ FLA. CONST., art. I, s. 24(c).

⁶ The bill, however, may contain multiple exemptions that relate to one subject.

⁷ FLA. CONST., art. I, s. 24(c).

⁸ Section 119.15, F.S. Section 119.15(4)(b), F.S. provides that an exemption is considered to be substantially amended if it is expanded to include more information or to include meetings. The act does not apply to an exemption that is required by federal law or that applies solely to the legislature or the state court system pursuant to section 119.15(2), F.S.

⁹ Section 119.15(3), F.S.

¹⁰ Section 119.15(6)(b), F.S.

¹¹ Section 119.15(6)(b)1., F.S.

- Releasing sensitive personal information would be defamatory or would jeopardize an individual's safety. If this public purpose is cited as the basis of an exemption, only personal identifying information may be made exempt;¹² or
- It protects trade or business secrets.¹³

In addition, the Legislature must find that the identifiable public purpose is compelling enough to override Florida's open government public policy and that the purpose of the exemption cannot be accomplished without the exemption.¹⁴

Public Records Exemptions

Current law provides public records exemptions for identification and location information of certain current or former public employees and their spouses and children.¹⁵ Examples of public employees covered by these exemptions include: law enforcement personnel, firefighters, local government personnel who are responsible for revenue collection and enforcement or child support enforcement, justices and judges, and local and statewide prosecuting attorneys.

Although the types of exempt information vary, the following information is exempt from public records requirements for all of the above-listed public employees:

- Home addresses and telephone numbers of the public employees;
- Home addresses, telephone numbers, and places of employment of the spouses and children of such employees; and
- Names and locations of schools and day care facilities attended by the children of such employees.

If exempt information is held by an agency that is not the employer of the public employee, the public employee must submit a written request to that agency to maintain the public records exemption.¹⁶

Department of Health- Division of Medical Quality Assurance

The Department of Health's (DOH) Division of Medical Quality Assurance (MQA) regulates health care practitioners to ensure the health, safety, and welfare of the public. There are 22 boards and eight councils under the MQA, and the MQA licenses seven types of facilities and 200-plus occupations in more than 40 health care professions.¹⁷ MQA is responsible for the licensure of health care practitioners and facilities, the enforcement of laws and rules governing practitioners and facilities, and providing information and data to the public.¹⁸

As part of its enforcement responsibilities, DOH investigates complaints against health care practitioners. It must investigate any complaint that is written, signed by the complainant, and legally sufficient, and may initiate an investigation if it believes a violation of law or rule has occurred. Such an investigation may result in an administrative case against the health care practitioner's license.¹⁹

¹² Section 119.15(6)(b)2., F.S.

¹³ Section 119.15(6)(b)3., F.S.

¹⁴ Section 119.15(6)(b), F.S.

¹⁵ Section 119.071(4)(d), F.S.

¹⁶ Section 119.071(4)(d)3., F.S.

¹⁷ Florida Department of Health, *Florida Health Source*, available at <http://www.flhealthsource.gov/> (last visited February 20, 2015).

¹⁸ *Id.*

¹⁹ Section 456.073, F.S.

Department of Business and Professional Regulation

The Department of Business and Professional Regulation (DBPR) licenses and regulates businesses and professionals.²⁰ The Division of Professions within DBPR administers 12 professional boards, five Department-regulated professions, and one council.²¹ The Division of Regulation is the enforcement authority for the professional boards, professions, and council. It monitors professions and related businesses to ensure that the laws, rules, and standards set by the Legislature and professional boards are followed.²²

Treatment Programs for Practitioners and Professionals

Impairment can result from the use or misuse of drugs or alcohol, or both, or from a mental or physical condition that could affect a person's ability to practice with skill and safety.²³ DOH administers a treatment program for impaired health care practitioners pursuant to s. 456.076, F.S., which includes veterinarians regulated by DBPR.²⁴ DBPR administers a treatment program for pilots pursuant to s. 310.102, F.S. These treatment programs ensure that licensed health care practitioners and professionals, applicants for licensure, and students enrolled in pre-licensure education programs, who are impaired and may pose a threat to the public if allowed to obtain or retain a license, are evaluated and referred for treatment.

DOH and DBPR contract with impaired practitioner consultants (IPCs) to monitor the treatment of an impaired practitioner or professional and coordinate services. DOH and DBPR contract with the Professionals Resource Network (PRN) and DOH also contracts with the Intervention Project for Nurses (IPN). An IPC must be a licensed physician, a licensed nurse, or an entity with a licensed physician or nurse as its medical director.²⁵ An IPC initiates intervention, recommends evaluation, and refers impaired persons to approved treatment providers or treatment programs and monitors the progress of impaired persons under the direction of consultants. An IPC does not provide medical services.²⁶

A practitioner or professional's participation in a treatment program is voluntary, but it requires him or her to voluntarily withdraw from practice or limit the scope of his or her practice until the impaired practitioner or professional successfully completes the treatment program.²⁷ By entering and successfully completing the impaired practitioner treatment program, a person may avoid formal disciplinary action if the impairment is the only violation of the licensing statute under which the person is regulated.²⁸

An IPC does not render decisions relating to licensure of a particular practitioner or professional. However, an IPC is required to make recommendations to the relevant practitioner or professional board's probable cause panel, or DOH when there is no board, regarding a person's ability to practice safely.²⁹

²⁰ Florida Dep't of Business and Professional Regulation, *Department of Business and Professional Regulation*, available at <http://www.myfloridalicense.com/dbpr/os/os-info.html>

²¹ Florida Dep't of Business and Professional Regulation, Division of Professions, available at <http://www.myfloridalicense.com/dbpr/pro/index.html> (last visited March 9, 2015).

²² Florida Dep't of Business and Professional Regulation, Division of Regulation, available at <http://www.myfloridalicense.com/dbpr/reg/index.html> (last visited March 9, 2015).

²³ Section 456.076(4)(a), F.S.

²⁴ The Board of Veterinarians, under the Department of Business and Professional Regulation, administers a treatment program for impaired veterinarians pursuant to s. 456.076, F.S. See s. 474.221, F.S.

²⁵ Sections 456.076(2)(a), F.S., and 310.102(2), F.S.

²⁶ Section 456.076(2), F.S.

²⁷ Sections 456.076(4), F.S., and 310.102(3), F.S.

²⁸ *Id.*

²⁹ Sections 456.076(2)(c)1., F.S., and 310.102(3)(e), F.S.

According to DOH, there are approximately 2,449 participants enrolled in the programs: 1,461 are served by IPN and 988 are served by PRN.³⁰ According to DBPR, there are currently 21 veterinarians and no pilots served by PRN.³¹

Effect of Proposed Changes

The bill creates a public records exemption for identification and location information of a current or former IPC who is retained by an agency,³² a current or former employee of an IPC whose duties result in a determination of a person's skill and safety to practice a licensed profession, and the spouses and children of both.

The bill makes the following information exempt from public records requirements:

- The home addresses, telephone numbers, dates of birth, and photographs of current or former IPCs and their employees;
- The names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such IPCs or their employees; and
- The names and locations of schools and day care facilities attended by the children of such IPCs or their employees.

The bill provides that the exemption may be maintained only if the IPC or employee has made reasonable efforts to protect such information from being accessible through other means available to the public. Additionally, the exemption is subject to an existing requirement under s. 119.071(4)(d)3., F.S., which provides that if exempt information is held by an agency that is not the employer of the protected public employee, then the protected public employee must submit to that agency a written request to maintain the public records exemption.

The bill provides for repeal of the exemption on October 2, 2020, unless reviewed and saved from repeal by the Legislature.

The bill provides a public necessity statement, which is required by the Florida Constitution. Specifically, the bill states that the exemption is needed to protect an IPC, the IPC's employees, and the spouses and children of both, from the risk of physical or emotional harm or of being stalked by a practitioner who has a hostile reaction to a recommendation, report, or conclusion of an IPC or the IPC's employee.

The bill takes effect upon becoming a law.

B. SECTION DIRECTORY:

Section 1. Amends s. 119.071, F.S., relating to general exemptions from inspection or copying of public records.

Section 2. Provides a public necessity statement.

Section 3. Provides an effective date of upon becoming a law.

³⁰ Email correspondence with DOH staff (on file with the Health Quality subcommittee).

³¹ Email correspondence with DBPR staff (on file with the Health Quality subcommittee).

³² Section 119.011(2), F.S., defines the term "agency" to mean any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of chapter 119, F.S., the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill could create a minimal fiscal impact on agencies because staff responsible for complying with public record requests could require training related to creation of the public record exemption. In addition, agencies could incur costs associated with redacting the exempt identification and location information prior to releasing a record. These costs, however, would be absorbed, as they are part of the day-to-day responsibilities of agencies.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

Vote Requirement

Article I, s. 24(c) of the Florida Constitution requires a two-thirds vote of the members present and voting in each house of the Legislature for passage of a newly-created or expanded public records or public meetings exemption. Because the bill creates a new public records exemption, it requires a two-thirds vote for passage.

Public Necessity Statement

Article I, s. 24(c) of the Florida Constitution requires a public necessity statement for a newly-created or expanded public records or public meetings exemption. The bill creates a new public records exemption and includes a public necessity statement.

Breadth of Exemption

Article I, s. 24(c) of the Florida Constitution requires a newly created public records or public meetings exemption to be no broader than necessary to accomplish the stated purpose of the law. The bill creates a public records exemption for identification and location information of a current or former IPC who is retained by an agency, a current or former employee of an IPC whose duties result in a determination of a person's skill and safety to practice a licensed profession, and the spouses and children of both. The exemption does not appear to be in conflict with the constitutional requirement that the exemption must be no broader than necessary to accomplish its purpose.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 12, 2015, the Health Quality Subcommittee adopted an amendment to the bill and reported the bill favorably as a committee substitute. The amendment:

- Expands the public records exemption to include current or former impaired practitioner consultants or employees and to exempt photographs and dates of birth of the consultants and employees;
- Limits the employees who are covered by the exemption to those employees whose duties result in a determination of a person's skill and safety to practice a licensed profession; and
- Provides additional statements of necessity.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

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A bill to be entitled
 An act relating to public records; amending s.
 119.071, F.S.; creating an exemption from public
 records requirements for certain identifying and
 location information of current or former impaired
 practitioner consultants who are retained by an agency
 or current or former employees of an impaired
 practitioner consultant whose duties result in a
 determination of a person's skill and safety to
 practice a licensed profession and the spouses and
 children of such consultants or employees, under
 specified circumstances; providing for future
 legislative review and repeal of the exemption under
 the Open Government Sunset Review Act; providing a
 statement of public necessity; providing an effective
 date.

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

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

119.071 General exemptions from inspection or copying of
 public records.—

(4) AGENCY PERSONNEL INFORMATION.—

(d)1. For purposes of this paragraph, the term "telephone
 numbers" includes home telephone numbers, personal cellular

27 telephone numbers, personal pager telephone numbers, and
 28 telephone numbers associated with personal communications
 29 devices.

30 2.a.(I) The home addresses, telephone numbers, social
 31 security numbers, dates of birth, and photographs of active or
 32 former sworn or civilian law enforcement personnel, including
 33 correctional and correctional probation officers, personnel of
 34 the Department of Children and Families whose duties include the
 35 investigation of abuse, neglect, exploitation, fraud, theft, or
 36 other criminal activities, personnel of the Department of Health
 37 whose duties are to support the investigation of child abuse or
 38 neglect, and personnel of the Department of Revenue or local
 39 governments whose responsibilities include revenue collection
 40 and enforcement or child support enforcement; the home
 41 addresses, telephone numbers, social security numbers,
 42 photographs, dates of birth, and places of employment of the
 43 spouses and children of such personnel; and the names and
 44 locations of schools and day care facilities attended by the
 45 children of such personnel are exempt from s. 119.07(1).

46 (II) The names of the spouses and children of active or
 47 former sworn or civilian law enforcement personnel and the other
 48 specified agency personnel identified in sub-sub-subparagraph
 49 (I) are exempt from s. 119.07(1) and s. 24(a), Art. I of the
 50 State Constitution.

51 (III) Sub-sub-subparagraph (II) is subject to the Open
 52 Government Sunset Review Act in accordance with s. 119.15, and

53 shall stand repealed on October 2, 2018, unless reviewed and
 54 saved from repeal through reenactment by the Legislature.

55 b. The home addresses, telephone numbers, dates of birth,
 56 and photographs of firefighters certified in compliance with s.
 57 633.408; the home addresses, telephone numbers, photographs,
 58 dates of birth, and places of employment of the spouses and
 59 children of such firefighters; and the names and locations of
 60 schools and day care facilities attended by the children of such
 61 firefighters are exempt from s. 119.07(1).

62 c. The home addresses, dates of birth, and telephone
 63 numbers of current or former justices of the Supreme Court,
 64 district court of appeal judges, circuit court judges, and
 65 county court judges; the home addresses, telephone numbers,
 66 dates of birth, and places of employment of the spouses and
 67 children of current or former justices and judges; and the names
 68 and locations of schools and day care facilities attended by the
 69 children of current or former justices and judges are exempt
 70 from s. 119.07(1).

71 d.(I) The home addresses, telephone numbers, social
 72 security numbers, dates of birth, and photographs of current or
 73 former state attorneys, assistant state attorneys, statewide
 74 prosecutors, or assistant statewide prosecutors; the home
 75 addresses, telephone numbers, social security numbers,
 76 photographs, dates of birth, and places of employment of the
 77 spouses and children of current or former state attorneys,
 78 assistant state attorneys, statewide prosecutors, or assistant

79 statewide prosecutors; and the names and locations of schools
 80 and day care facilities attended by the children of current or
 81 former state attorneys, assistant state attorneys, statewide
 82 prosecutors, or assistant statewide prosecutors are exempt from
 83 s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

84 (II) The names of the spouses and children of current or
 85 former state attorneys, assistant state attorneys, statewide
 86 prosecutors, or assistant statewide prosecutors are exempt from
 87 s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

88 (III) Sub-sub-subparagraph (II) is subject to the Open
 89 Government Sunset Review Act in accordance with s. 119.15, and
 90 shall stand repealed on October 2, 2018, unless reviewed and
 91 saved from repeal through reenactment by the Legislature.

92 e. The home addresses, dates of birth, and telephone
 93 numbers of general magistrates, special magistrates, judges of
 94 compensation claims, administrative law judges of the Division
 95 of Administrative Hearings, and child support enforcement
 96 hearing officers; the home addresses, telephone numbers, dates
 97 of birth, and places of employment of the spouses and children
 98 of general magistrates, special magistrates, judges of
 99 compensation claims, administrative law judges of the Division
 100 of Administrative Hearings, and child support enforcement
 101 hearing officers; and the names and locations of schools and day
 102 care facilities attended by the children of general magistrates,
 103 special magistrates, judges of compensation claims,
 104 administrative law judges of the Division of Administrative

105 Hearings, and child support enforcement hearing officers are
 106 exempt from s. 119.07(1) and s. 24(a), Art. I of the State
 107 Constitution if the general magistrate, special magistrate,
 108 judge of compensation claims, administrative law judge of the
 109 Division of Administrative Hearings, or child support hearing
 110 officer provides a written statement that the general
 111 magistrate, special magistrate, judge of compensation claims,
 112 administrative law judge of the Division of Administrative
 113 Hearings, or child support hearing officer has made reasonable
 114 efforts to protect such information from being accessible
 115 through other means available to the public.

116 f. The home addresses, telephone numbers, dates of birth,
 117 and photographs of current or former human resource, labor
 118 relations, or employee relations directors, assistant directors,
 119 managers, or assistant managers of any local government agency
 120 or water management district whose duties include hiring and
 121 firing employees, labor contract negotiation, administration, or
 122 other personnel-related duties; the names, home addresses,
 123 telephone numbers, dates of birth, and places of employment of
 124 the spouses and children of such personnel; and the names and
 125 locations of schools and day care facilities attended by the
 126 children of such personnel are exempt from s. 119.07(1) and s.
 127 24(a), Art. I of the State Constitution.

128 g. The home addresses, telephone numbers, dates of birth,
 129 and photographs of current or former code enforcement officers;
 130 the names, home addresses, telephone numbers, dates of birth,

131 and places of employment of the spouses and children of such
 132 personnel; and the names and locations of schools and day care
 133 facilities attended by the children of such personnel are exempt
 134 from s. 119.07(1) and s. 24(a), Art. I of the State
 135 Constitution.

136 h. The home addresses, telephone numbers, places of
 137 employment, dates of birth, and photographs of current or former
 138 guardians ad litem, as defined in s. 39.820; the names, home
 139 addresses, telephone numbers, dates of birth, and places of
 140 employment of the spouses and children of such persons; and the
 141 names and locations of schools and day care facilities attended
 142 by the children of such persons are exempt from s. 119.07(1) and
 143 s. 24(a), Art. I of the State Constitution, if the guardian ad
 144 litem provides a written statement that the guardian ad litem
 145 has made reasonable efforts to protect such information from
 146 being accessible through other means available to the public.

147 i. The home addresses, telephone numbers, dates of birth,
 148 and photographs of current or former juvenile probation
 149 officers, juvenile probation supervisors, detention
 150 superintendents, assistant detention superintendents, juvenile
 151 justice detention officers I and II, juvenile justice detention
 152 officer supervisors, juvenile justice residential officers,
 153 juvenile justice residential officer supervisors I and II,
 154 juvenile justice counselors, juvenile justice counselor
 155 supervisors, human services counselor administrators, senior
 156 human services counselor administrators, rehabilitation

157 therapists, and social services counselors of the Department of
 158 Juvenile Justice; the names, home addresses, telephone numbers,
 159 dates of birth, and places of employment of spouses and children
 160 of such personnel; and the names and locations of schools and
 161 day care facilities attended by the children of such personnel
 162 are exempt from s. 119.07(1) and s. 24(a), Art. I of the State
 163 Constitution.

164 j.(I) The home addresses, telephone numbers, dates of
 165 birth, and photographs of current or former public defenders,
 166 assistant public defenders, criminal conflict and civil regional
 167 counsel, and assistant criminal conflict and civil regional
 168 counsel; the home addresses, telephone numbers, dates of birth,
 169 and places of employment of the spouses and children of such
 170 defenders or counsel; and the names and locations of schools and
 171 day care facilities attended by the children of such defenders
 172 or counsel are exempt from s. 119.07(1) and s. 24(a), Art. I of
 173 the State Constitution.

174 (II) The names of the spouses and children of the
 175 specified agency personnel identified in sub-sub-subparagraph
 176 (I) are exempt from s. 119.07(1) and s. 24(a), Art. I of the
 177 State Constitution. This sub-sub-subparagraph is subject to the
 178 Open Government Sunset Review Act in accordance with s. 119.15
 179 and shall stand repealed on October 2, 2019, unless reviewed and
 180 saved from repeal through reenactment by the Legislature.

181 k. The home addresses, telephone numbers, and photographs
 182 of current or former investigators or inspectors of the

183 Department of Business and Professional Regulation; the names,
 184 home addresses, telephone numbers, and places of employment of
 185 the spouses and children of such current or former investigators
 186 and inspectors; and the names and locations of schools and day
 187 care facilities attended by the children of such current or
 188 former investigators and inspectors are exempt from s. 119.07(1)
 189 and s. 24(a), Art. I of the State Constitution if the
 190 investigator or inspector has made reasonable efforts to protect
 191 such information from being accessible through other means
 192 available to the public. This sub-subparagraph is subject to the
 193 Open Government Sunset Review Act in accordance with s. 119.15
 194 and shall stand repealed on October 2, 2017, unless reviewed and
 195 saved from repeal through reenactment by the Legislature.

196 1. The home addresses and telephone numbers of county tax
 197 collectors; the names, home addresses, telephone numbers, and
 198 places of employment of the spouses and children of such tax
 199 collectors; and the names and locations of schools and day care
 200 facilities attended by the children of such tax collectors are
 201 exempt from s. 119.07(1) and s. 24(a), Art. I of the State
 202 Constitution if the county tax collector has made reasonable
 203 efforts to protect such information from being accessible
 204 through other means available to the public. This sub-
 205 subparagraph is subject to the Open Government Sunset Review Act
 206 in accordance with s. 119.15 and shall stand repealed on October
 207 2, 2017, unless reviewed and saved from repeal through
 208 reenactment by the Legislature.

209 m. The home addresses, telephone numbers, dates of birth,
 210 and photographs of current or former personnel of the Department
 211 of Health whose duties include, or result in, the determination
 212 or adjudication of eligibility for social security disability
 213 benefits, the investigation or prosecution of complaints filed
 214 against health care practitioners, or the inspection of health
 215 care practitioners or health care facilities licensed by the
 216 Department of Health; the names, home addresses, telephone
 217 numbers, dates of birth, and places of employment of the spouses
 218 and children of such personnel; and the names and locations of
 219 schools and day care facilities attended by the children of such
 220 personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of
 221 the State Constitution if the personnel have made reasonable
 222 efforts to protect such information from being accessible
 223 through other means available to the public. This sub-
 224 subparagraph is subject to the Open Government Sunset Review Act
 225 in accordance with s. 119.15 and shall stand repealed on October
 226 2, 2019, unless reviewed and saved from repeal through
 227 reenactment by the Legislature.

228 n. The home addresses, telephone numbers, dates of birth,
 229 and photographs of current or former impaired practitioner
 230 consultants who are retained by an agency or of current or
 231 former employees of an impaired practitioner consultant whose
 232 duties result in a determination of a person's skill and safety
 233 to practice a licensed profession; the names, home addresses,
 234 telephone numbers, dates of birth, and places of employment of

235 the spouses and children of such consultants or employees; and
 236 the names and locations of schools and day care facilities
 237 attended by the children of such consultants or employees are
 238 exempt from s. 119.07(1) and s. 24(a), Art. I of the State
 239 Constitution if a consultant or employee has made reasonable
 240 efforts to protect such information from being accessible
 241 through other means available to the public. This sub-
 242 subparagraph is subject to the Open Government Sunset Review Act
 243 in accordance with s. 119.15 and shall stand repealed on October
 244 2, 2020, unless reviewed and saved from repeal through
 245 reenactment by the Legislature.

246 3. An agency that is the custodian of the information
 247 specified in subparagraph 2. and that is not the employer of the
 248 officer, employee, justice, judge, or other person specified in
 249 subparagraph 2. shall maintain the exempt status of that
 250 information only if the officer, employee, justice, judge, other
 251 person, or employing agency of the designated employee submits a
 252 written request for maintenance of the exemption to the
 253 custodial agency.

254 4. The exemptions in this paragraph apply to information
 255 held by an agency before, on, or after the effective date of the
 256 exemption.

257 5. Except as otherwise expressly provided in this
 258 paragraph, this paragraph is subject to the Open Government
 259 Sunset Review Act in accordance with s. 119.15, and shall stand
 260 repealed on October 2, 2017, unless reviewed and saved from

261 repeal through reenactment by the Legislature.



262 Section 2. The Legislature finds that it is a public
 263 necessity that the home addresses, telephone numbers, dates of
 264 birth, and photographs of current or former impaired
 265 practitioner consultants who are retained by an agency or of
 266 current or former employees of an impaired practitioner
 267 consultant whose duties result in a determination of a person's
 268 skill and safety to practice a licensed profession; that the
 269 names, home addresses, telephone numbers, dates of birth, and
 270 places of employment of the spouses and children of such
 271 consultants or employees; and that the names and locations of
 272 schools and day care facilities attended by the children of such
 273 consultants or employees be exempt from public records
 274 requirements if the consultant or employee has made reasonable
 275 efforts to protect such information from being accessible
 276 through other means available to the public. An impaired
 277 practitioner consultant assists the state and its regulatory
 278 boards in implementing an impaired practitioner treatment
 279 program. The consultant provides the necessary resources to
 280 evaluate and monitor program compliance of licensees, applicants
 281 for licensure, and students enrolled in prelicensure education
 282 programs who could be impaired and, as a result, unable to
 283 practice with reasonable skill and safety to the public. A
 284 person who is referred to the program but who, in the opinion of
 285 the consultant, based on treatment and compliance monitoring
 286 information, fails to successfully complete its requirements or

287 is an immediate, serious threat to public safety is at risk of
288 failing to obtain or losing the license that is necessary to
289 engage in his or her chosen profession. The Legislature finds
290 that release of identifying and location information could place
291 an impaired practitioner consultant or an employee of a
292 consultant whose duties result in a determination of a person's
293 skill and safety to practice a licensed profession, or the
294 spouses and children of such consultants or employees, in danger
295 of being physically or emotionally harmed or stalked by a person
296 who has a hostile reaction to a recommendation, report, or
297 conclusion provided by a consultant or an employee of a
298 consultant in the determination of whether the practitioner is
299 impaired. The Legislature further finds that the harm that may
300 result from the release of such identifying and location
301 information outweighs any public benefit that may be derived
302 from the disclosure of the information.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 269 Experimental Treatments for Terminal Conditions
SPONSOR(S): Insurance & Banking Subcommittee; Health Innovation Subcommittee; Pilon
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N, As CS	Tuszynski	Poche
2) Insurance & Banking Subcommittee	12 Y, 0 N, As CS	Haston	Cooper
3) Health & Human Services Committee		Tuszynski 	Calamas 

SUMMARY ANALYSIS

The Food and Drug Administration (FDA) has regulatory authority over what drugs are marketed and sold within the United States. Investigational or experimental drugs are new drugs that are not approved by the FDA and are in the process of being tested for safety and effectiveness. An investigational drug must go through a lengthy and expensive approval process requiring phased clinical trials. Approval of an investigational drug by the FDA can take as long as 11 years.

The FDA has a procedure to gain access to investigational drugs that have not yet been approved by the FDA, known as expanded access. Under the FDA's expanded access scheme, physicians can request an investigational drug for a single patient using an emergency use application. However, this process is considered burdensome, time-consuming, and confusing. In February of 2015, the FDA announced a draft application that removes many of the burdensome and time-consuming requirements of the old procedure.

The bill creates the "Right to Try Act," which establishes a framework in which a manufacturer may provide a post-phase 1 investigational drug, biological product, or device to an eligible patient with a terminal condition, bypassing the FDA's emergency use expanded access program. The bill defines an eligible patient and a terminal condition. The bill also requires certain information and attestations in a written informed consent document, which must be signed by the patient or the patient's parent, guardian, or health care surrogate and provided to the manufacturer, in order to receive a post-phase 1 investigational drug, biological product, or device.

The bill also protects the licenses of physicians who recommend investigational drugs, biological products, or devices from disciplinary action as a result of making the recommendation. The bill permits insurers to pay for investigational drugs, but does not require such payment. Lastly, the bill provides liability protection for manufacturers, persons, and entities involved in the use of the investigational drug, biological product, or device pursuant to the provisions of the bill.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Drugs

The U.S. Food and Drug Administration (FDA) has wide regulatory authority over what drugs are marketed and sold within the United States. The Pure Food and Drug Act, passed in 1906, was the genesis of the federal regulation of drugs.¹ The responsibility of enforcing this act was given to the Bureau of Chemistry, later renamed the Food and Drug Administration in 1927.² The Federal Food, Drug and Cosmetic Act (FFDCA) was passed in 1938 and gave authority to the FDA to oversee the safety of food, drugs, and cosmetics.³ In 1962, in the wake of deaths and birth defects from the tranquilizer thalidomide marketed in Europe, Congress passed the Kefauver-Harris Drug Amendments to the FFDCA, increasing safety provisions and requiring that drugs be proven effective as well as safe.⁴

Approval Process

Investigational or experimental drugs are new drugs that have yet to be approved by the FDA, or are approved drugs that have not been approved by the FDA for a new use, and are in the process of being tested for safety and effectiveness. To bring a drug to market, an investigational drug's sponsor, typically a pharmaceutical company or research entity, must go through a lengthy approval process. It can take up to 11 years⁵ from the beginning of the FDA's involvement to bring an investigational drug to market; the average time to market is 8 years.⁶ The same process applies to new biological products and devices.

The first step in the process, basic laboratory research, can take years and occurs prior to FDA involvement. Basic laboratory research, often funded by the federal government in federal labs or research universities, investigates chemical components and compounds that may have therapeutic efficacy. If research identifies a component that may be promising as an experimental drug, private industry or private research groups continue development of the drug and begin animal testing.

When the drug is ready for human trials, an investigational new drug application (IND) is submitted to the FDA,⁷ which includes details on the appropriateness of human testing.⁸ Once the IND is approved, the sponsor may begin testing to gather evidence as to the safety and effectiveness of the drug.⁹ Generally, the investigation into experimental drugs, biological products, and devices is divided into three clinical development trials, detailed in the chart below.^{10,11}

¹ Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 769 (1906) (Repealed by the Federal Food, Drug, and Cosmetic Act of 1938 [21 U.S.C. Sec 329(a)]), <http://www.fda.gov/regulatoryinformation/legislation/ucm148690.htm>; The Federal Food and Drugs Act of 1906 is called the "Wiley Act."

² Federal Food and Drugs Act of 1906, P.L. 59-384, s. 1.

³ Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. ch. 9 § 301 et seq.).

⁴ Kefauver-Harris Drug Amendments to the FFDCA, P.L. 87-781, (1962).

⁵ Christopher P. Adams & Van. V. Brantner, *New Drug Development: Estimating Entry From Human Clinical Trials* 9 (Jul. 7, 2003), available at <http://www.ftc.gov/reports/new-drug-development-estimating-entry-human-clinical-trials>

⁶ *Id.*

⁷ 21 U.S.C. § 355(i)(1); *see also* 21 C.F.R. § 312.

⁸ 21 C.F.R. § 312.23.

⁹ 21 U.S.C. § 355(d)(5).

¹⁰ Adams & Brantner, *supra* note 5.

¹¹ Phase 4 trials are post-approval clinical trials to test the long term effects of investigational drugs, biological products, and devices.

CLINICAL TRIAL PHASES			
Phase	Participants	Purpose	Average Time
Phase 1	20-80	This is the initial introduction of a new drug into humans. These studies are typically closely monitored and designed to determine the metabolism and pharmacologic action of the treatment, side effects associated with increased dosage, and if possible, to gain early evidence of effectiveness.	1.7 years
Phase 2	Several Hundred	These are the controlled clinical studies conducted to evaluate the effectiveness of the treatment for a particular indication or indications, and to determine common short-term side effects and risks.	2.4 years
Phase 3	Several Thousand	These are performed after preliminary evidence suggesting effectiveness of the treatment has been obtained from Phase 2. This phase is intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the treatment and to provide an adequate basis for physician labeling.	3.7 years

When a sponsor believes there is “substantial evidence”¹² of safety and effectiveness, the sponsor submits a new drug application (NDA) to the FDA for approval.¹³ The NDA must contain full reports of the phased clinical trials detailing the safety and effectiveness of the drug.¹⁴ During the NDA review, the FDA evaluates the clinical trial data, analyzes samples, inspects the facilities where the finished product will be made, and checks the proposed labeling for accuracy.¹⁵ Once the FDA determines that there is substantial evidence of safety and effectiveness, the NDA is approved and the sponsor is allowed to bring the drug to market.

Expanded Access

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

1. Individuals on a case-by-case basis, known as “individual patient access”;¹⁶
2. Intermediate sized groups of patients with similar treatment needs who otherwise do not qualify to participate in a clinical trial;¹⁷ and
3. Large groups of patients who do not have other treatment options available.¹⁸

The access routes for intermediate and large groups are essentially expanded clinical trials. If enough patients are outside of the geographical area of a clinical trial, or were unable to meet the criteria of the specific trial, the FDA can approve concurrent trials.

¹² 21 U.S.C. § 355(d)(5).

¹³ 21 U.S.C. § 355(a).

¹⁴ 21 U.S.C. § 355(b)(1)(a).

¹⁵ Adams & Brantner, *supra* note 5.

¹⁶ U.S. Food and Drug Administration, *Expanded Access Categories for Drugs*,

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431774.htm>. (last visited March 4, 2015).

¹⁷ 21 U.S.C. § 312.315.

¹⁸ 21 U.S.C. § 312.320.

Individual patient access includes “emergency use.” Emergency use requests can be made by phone or other means of electronic communication. A patient may start using the investigational drug, biological product, or device immediately upon FDA authorization of the request.¹⁹ The written emergency use request must be received by the FDA within 15 business days of the telephone authorization.²⁰ The written emergency use request requires physicians to submit 26 distinct fields of information and seven attachments.²¹ This process can take up to 100 hours to gather and submit the required information.²²

The FDA reviews emergency use requests and makes the determination of whether to approve the request based on the following factors:

- The patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy.²³
- The potential benefit justifies the potential risks, and that those risks are not unreasonable.²⁴
- Provision of the treatment will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the development of the expanded access use.²⁵
- A determination by the patient’s physician that the probable risk to the person is not greater than the risk of the disease or condition.²⁶
- A determination by the FDA that the patient cannot obtain the treatment under another IND or protocol.²⁷

Between October 1, 2013 and September 30, 2014, the FDA approved 1,066 of the 1,069 emergency use requests it received.²⁸

“Right to Try” Laws and FDA Response

Five states have passed laws in the past 12 months providing terminally ill patients access to experimental drugs outside of the FDA’s normal regulatory scheme: Colorado,²⁹ Louisiana,³⁰ Missouri,³¹ Arizona,³² and Michigan.³³

These state laws allow, but do not require, manufacturers of experimental treatments to make these treatments available to eligible patients with terminal illnesses. The laws also require written informed consent from patients stating that they are aware of the dangers associated with the experimental treatment. The laws also include provisions that protect the licenses of physicians who recommend or prescribe experimental treatments; exempt insurers from having to pay for experimental treatment; and provide liability protection to manufacturers and distributors of experimental treatments.

¹⁹ Peter D. Jacobson, J.D., M.P.H. & Wendy E. Parmet, J.D., *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. Von Eschenbach*, 297 JAMA 205 (2007).

²⁰ *Id.*

²¹ Peter Lurie, M.D., M.P.H., *A Big step to help the patients most in need*, FDA Voice, February 4, 2015, available at <http://blogs.fda.gov/fdavoices/index.php/tag/individual-patient-expanded-access-applications-form-fda-3926/>. (last visited February 17, 2015).

²² *Id.*

²³ 21 U.S.C. § 312.305(a)(1)

²⁴ 21 U.S.C. § 312.305(a)(2)

²⁵ 21 U.S.C. § 312.305(a)(3)

²⁶ 21 U.S.C. § 312.310(a)(1)

²⁷ 21 U.S.C. § 312.310(a)(2)

²⁸ Expanded Access Submission Receipts Report: Oct 1, 2013 - Sep 30, 2014,

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/INDActivityReports/UCM430188.pdf> (last visited February 10, 2015).

²⁹ Colo. R.S.A. §§ 25-45-101 to -108

³⁰ La. R.S. § 1300.381-386

³¹ V.A. Mo. S. § 191.480

³² Ariz. R.S.A. §§ 36-1311 to -1314

³³ Mich. C.L.A. §§ 16221, 26451

On February 4, 2015, the FDA issued new draft guidance for Individual Patient Expanded Access, or “compassionate use,” applications. The draft guidance addresses a new “compassionate use” form, a streamlined alternative for submitting an IND application for use in cases requesting individual patient expanded access to an investigational drug, biological product, or device. The old form, FDA 1571, was designed for large experimental drug sponsors and manufacturers to apply for expanded access, not physicians.³⁴ The new form, FDA 3926, is designed for physicians seeking authorization on behalf of an individual patient. The new form requires only eight distinct fields of information and one attachment.³⁵ The FDA estimates that it will take approximately 45 minutes to complete the new form.³⁶

Abigail Alliance Case

In 1999, Abigail Burroughs, a 19-year-old college student, was diagnosed with head and neck cancer. Despite undergoing chemotherapy and radiation therapy, her tumor showed increased expression of the cell surface membrane receptor EGFR.³⁷ She did not meet the inclusion criteria for either of the two clinical trials targeting EGFR at the time. Shortly after her death in 2001, her father formed the Abigail Alliance for Better Access to Developmental Drugs³⁸ and, in 2003, sued the FDA. The Abigail Alliance argued that terminal cancer patients have a constitutional right to experimental drugs, positing self-defense theories as well as 5th amendment substantive due process claims, and that the FDA should grant access to experimental drugs for use by terminally ill patients.

In 2007, after years of protracted litigation, the U.S. Court of Appeals for the District of Columbia, sitting *en banc*, upheld the previous trial court decision finding no constitutional right to unapproved drugs by terminally ill patients.³⁹ The Supreme Court of the United States declined to review the case.

Dispensing

Chapter 465, F.S., limits the dispensing of medicinal drugs to licensed pharmacists and licensed physicians.⁴⁰ The Board of Pharmacy⁴¹ regulates the practice of pharmacy and the licensure of pharmacists. Currently, manufacturers of medicinal drugs are not authorized by Florida law to dispense directly to patients.

Effect of Proposed Changes

The bill creates the “Right to Try Act” (Act), establishing a framework in which a manufacturer may provide an investigational drug, biological product, or device to an eligible patient without utilizing the FDA’s emergency use expanded access program. The bill allows manufacturers to contract with and dispense investigational drugs directly to patients, without licensure or regulation under chapter 465, F.S., by the Board of Pharmacy.

To be eligible to access such drugs, a patient must have a terminal condition that will result in death within one year of diagnosis if the condition runs its normal course. The patient’s treating physician must attest to the terminal condition, it must be confirmed by a second evaluation by a board-certified physician in an appropriate specialty, and the patient must have considered all other approved treatments. Under the bill, a terminal condition is a progressive disease or medical condition that causes significant functional impairment, is not considered reversible with available treatments, and will result in death within a year without the administration of life-sustaining procedures.

³⁴ Supra. at FN 21.

³⁵ Id.

³⁶ Id.

³⁷ Jacobson & Parnet, *supra* note 19.

³⁸ Id.

³⁹ *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

⁴⁰ S. 465.0276, F.S.

⁴¹ S. 465.004, F.S.

The bill requires the patient, a parent of a minor patient, a court-appointed guardian for the patient, or a health care surrogate designated by the patient to provide written informed consent prior to accessing an investigational drug, biological product, or device under the Act. The written informed consent must include:

- An explanation of the currently approved products and treatments for the patient's terminal condition;
- An attestation that the patient agrees with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life;
- The specific name of the investigational drug, biological product, or device;
- A realistic description of the most likely outcome, detailing the possibility of unanticipated or worse symptoms.
- A statement that death could be hastened by use of the investigational drug, biologic product, or device.
- A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for treatment consequent to the use of the investigational drug, biological product, or device, unless required to do so by law;
- A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment, and reinstated if curative treatment ends and the patient meets hospice eligibility requirements; and
- A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless negotiated otherwise.

The bill provides that there is no obligation on the part of any manufacturer to provide a requested investigational drug, biologic product, or device under the Act, but that a manufacturer may do so with or without compensation. The eligible patient may be required to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device. The bill allows a health plan, third-party administrator, or governmental agency to cover the cost of an investigational drug, biological product, or device. The bill does not mandate insurance coverage for an investigational drug, biological product, or device, nor does it affect any mandatory coverage for participation in clinical trials. The bill exempts a patient's heirs from any outstanding debt associated with the patient's use of the investigational drug, biological product, or device.

The bill states that health care facilities are not required to provide new or additional services associated with a patient's use of an investigational drug, biologic product, or device under the Act, unless it is approved by the health care facility.

The bill prohibits the Board of Medicine or Board of Osteopathic Medicine from revoking, suspending, or denying renewal of a physician's license based solely on the physician's recommendation to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. The bill also prohibits action against a physician's Medicare certification for the same reason.

The bill provides liability protection for a manufacturer, person, or entity involved in the use of an investigational drug, biological product, or device in good faith compliance with the provisions of the bill and exercising reasonable care.

The bill provides an effective date of July 1, 2015

B. SECTION DIRECTORY:

- Section 1:** Creates s. 499.0295, F.S., relating to experimental treatments for terminal conditions.
Section 2: Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill permits manufacturers of investigational drugs, biologic products, and devices to provide such drugs, products, and devices to patients with a terminal condition without the approval of the FDA. A manufacturer can track the safety and effectiveness of the drug, biological product, or device on a human subject much earlier than through the traditional FDA approval process, which may quicken the development process and the shorten the amount of time it takes for a drug, biological product, or device to get to market.

The bill also permits a manufacturer to charge an eligible patient for use of the investigational drug, biological product, or device.

The bill provides liability protection to manufacturers, persons, and entities involved with the use of an investigational drug, biological product, or device in good faith compliance with the provisions of the bill and exercising reasonable care.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

Access to and the use of investigational drugs is controlled by the FDA through the "expanded access" provisions of 21 U.S.C. § 360bbb and 21 C.F.R. § 312. The language of this bill creates a framework that bypasses this federal regulatory scheme.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill language protects a physician's license and Medicare certification from action for recommending an investigational drug, biological product, or device, but not for administering the same investigational drug, biological product, or device.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 10, 2015, the Health Innovation Subcommittee adopted a strike-all amendment and reported the bill favorable as a committee substitute. The amendment made the following changes:

- Changed "terminal illness" to "terminal condition."
- Required confirmation of a patient's terminal condition by a second, board-certified physician in an appropriate specialty for that condition.
- Clarified that a terminal condition is a condition that will result in death within one year of diagnosis if the condition runs its normal course.
- Replaced "health care provider" with "physician."
- Removed the explicit exemption for a governmental agency from paying the costs associated with providing an investigational drug, biological product or device.
- Removed the section that prohibited an official, employee, or agent of the state from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device.
- Strengthened the liability protection for a manufacturer, person, and entity involved in the use of the investigational drug, biological product, or device, except for willful torts.

On March 25, 2015, the Insurance & Banking Subcommittee adopted one amendment and reported the bill favorable as a committee substitute. The amendment returned the language from the original filed version of the bill relating to liability protection for a manufacturer, person, and entity involved in the use of the investigational drug, biological product, or device. The amendment requires a manufacturer, person, and entity involved in the use of the investigational drug, biological product, or device to comply in good faith with the terms of the section and to exercise reasonable care.

The analysis is drafted to the committee substitute as passed by the Insurance & Banking Subcommittee.

1 A bill to be entitled
 2 An act relating to experimental treatments for
 3 terminal conditions; creating s. 499.0295, F.S.;
 4 providing a short title; providing definitions;
 5 providing conditions for a manufacturer to provide
 6 certain drugs, products, or devices to an eligible
 7 patient; specifying insurance coverage requirements
 8 and exceptions; providing conditions for provision of
 9 certain services by a hospital or health care
 10 facility; providing immunity from liability; providing
 11 protection from disciplinary or legal action against a
 12 physician who makes certain treatment recommendations;
 13 providing that a cause of action may not be asserted
 14 against the manufacturer of certain drugs, products,
 15 or devices or a person or entity caring for a patient
 16 using such drug, product, or device under certain
 17 circumstances; providing applicability; providing an
 18 effective date.

19
 20 Be It Enacted by the Legislature of the State of Florida:

21
 22 Section 1. Section 499.0295, Florida Statutes, is created
 23 to read:

- 24 499.0295 Experimental treatments for terminal conditions.-
 25 (1) This section may be cited as the "Right to Try Act."
 26 (2) As used in this section, the term:

27 (a) "Eligible patient" means a person who:
 28 1. Has a terminal condition that is attested to by the
 29 patient's physician and confirmed by a second independent
 30 evaluation by a board-certified physician in an appropriate
 31 specialty for that condition;
 32 2. Has considered all other treatment options for the
 33 terminal condition currently approved by the United States Food
 34 and Drug Administration;
 35 3. Has given written informed consent for the use of an
 36 investigational drug, biological product, or device; and
 37 4. Has documentation from his or her treating physician
 38 that the patient meets the requirements of this paragraph.
 39 (b) "Investigational drug, biological product, or device"
 40 means a drug, biological product, or device that has
 41 successfully completed phase 1 of a clinical trial but has not
 42 been approved for general use by the United States Food and Drug
 43 Administration and remains under investigation in a clinical
 44 trial approved by the United States Food and Drug
 45 Administration.
 46 (c) "Terminal condition" means a progressive disease or
 47 medical or surgical condition that causes significant functional
 48 impairment, is not considered by a treating physician to be
 49 reversible even with the administration of available treatment
 50 options currently approved by the United States Food and Drug
 51 Administration, and, without the administration of life-

52 sustaining procedures, will result in death within 1 year after
 53 diagnosis if the condition runs its normal course.

54 (d) "Written informed consent" means a document that is
 55 signed by a patient, a parent of a minor patient, a court-
 56 appointed guardian for a patient, or a health care surrogate
 57 designated by a patient and includes:

58 1. An explanation of the currently approved products and
 59 treatments for the patient's terminal condition.

60 2. An attestation that the patient concurs with his or her
 61 physician in believing that all currently approved products and
 62 treatments are unlikely to prolong the patient's life.

63 3. Identification of the specific investigational drug,
 64 biological product, or device that the patient is seeking to
 65 use.

66 4. A realistic description of the most likely outcomes of
 67 using the investigational drug, biological product, or device.
 68 The description shall include the possibility that new,
 69 unanticipated, different, or worse symptoms might result and
 70 death could be hastened by the proposed treatment. The
 71 description shall be based on the physician's knowledge of the
 72 proposed treatment for the patient's terminal condition.

73 5. A statement that the patient's health plan or third-
 74 party administrator and physician are not obligated to pay for
 75 care or treatment consequent to the use of the investigational
 76 drug, biological product, or device unless required to do so by
 77 law or contract.

78 6. A statement that the patient's eligibility for hospice
 79 care may be withdrawn if the patient begins treatment with the
 80 investigational drug, biological product, or device and that
 81 hospice care may be reinstated if the treatment ends and the
 82 patient meets hospice eligibility requirements.

83 7. A statement that the patient understands he or she is
 84 liable for all expenses consequent to the use of the
 85 investigational drug, biological product, or device and that
 86 liability extends to the patient's estate, unless a contract
 87 between the patient and the manufacturer of the investigational
 88 drug, biological product, or device states otherwise.

89 (3) Upon the request of an eligible patient, a
 90 manufacturer may:

91 (a) Make its investigational drug, biological product, or
 92 device available under this section.

93 (b) Provide an investigational drug, biological product,
 94 or device to an eligible patient without receiving compensation.

95 (c) Require an eligible patient to pay the costs of, or
 96 the costs associated with, the manufacture of the
 97 investigational drug, biological product, or device.

98 (4) A health plan, third-party administrator, or
 99 governmental agency may provide coverage for the cost of, or the
 100 cost of services related to the use of, an investigational drug,
 101 biological product, or device.

102 (5) A hospital or health care facility licensed under
 103 chapter 395 is not required to provide new or additional

104 services unless those services are approved by the hospital or
 105 health care facility.

106 (6) If an eligible patient dies while using an
 107 investigational drug, biological product, or device pursuant to
 108 this section, the patient's heirs are not liable for any
 109 outstanding debt related to the patient's use of the
 110 investigational drug, biological product, or device.

111 (7) A licensing board may not revoke, fail to renew,
 112 suspend, or take any action against a physician's license issued
 113 under chapter 458 or chapter 459 based solely on the physician's
 114 recommendations to an eligible patient regarding access to or
 115 treatment with an investigational drug, biological product, or
 116 device. A state entity responsible for Medicare certification
 117 may not take action against a physician's Medicare certification
 118 based solely on the physician's recommendation that an eligible
 119 patient have access to an investigational drug, biological
 120 product, or device.

121 (8) This section does not create a private cause of action
 122 against the manufacturer of an investigational drug, biological
 123 product, or device; against a person or entity involved in the
 124 care of an eligible patient who is using the investigational
 125 drug, biological product, or device; or for any harm to the
 126 eligible patient that is a result of the use of the
 127 investigational drug, biological product, or device if the
 128 manufacturer or other person or entity complies in good faith
 129 with the terms of this section and exercises reasonable care.

130 (9) This section does not expand the coverage an insurer
131 must provide under the Florida Insurance Code and does not
132 affect mandatory health coverage for participation in clinical
133 trials.

134 Section 2. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 281 Prescription Medication
SPONSOR(S): Health Innovation Subcommittee; Pigman
TIED BILLS: IDEN./SIM. **BILLS:** SB 532

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N, As CS	Castagna	Poche
2) Health & Human Services Committee		Castagna <i>PC</i>	Calamas <i>CC</i>

SUMMARY ANALYSIS

Currently, physician assistants (PAs) are authorized to order medicinal drugs for a hospitalized patient of their supervising physician. Florida law does not authorize advanced registered nurse practitioners (ARNPs) to do the same.

HB 281 authorizes ARNPs, acting under the supervision of a physician, to order medications, including controlled substances, for a patient in a facility licensed under ch. 395, F.S., including hospitals, ambulatory surgical centers, and mobile surgical facilities. The bill amends the Pharmacy Act in chapter 465, F.S., and the Controlled Substances Act in chapter 893, F.S., to exempt from the definition of prescription an order for medication that is dispensed in a facility licensed under chapter 395, F.S., to a patient.

The bill appears to have no fiscal impact on state or local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Physician Assistants

Regulation and Licensure

A physician assistant (PA) is a person licensed to perform health care services, in the specialty areas in which he or she has been trained, delegated by a supervising physician.¹ PAs are governed under the respective physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs).² PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. Currently, there are 6,511 in-state, and 724 out-of-state, active licensed PAs.³

An applicant for a PA license must apply to the Department of Health (Department). The Department must issue a license to a person certified by the Council as having met all of the following requirements:

- At least 18 years of age;
- Satisfactorily passed a proficiency examination with an acceptable score established by the National Commission on Certification of Physician Assistants;⁴
- Completed an application form and paid the registration fee;
- Holds a certificate of completion from a PA training program, including certain course descriptions relating to pharmacotherapy if the PA applicant seeks prescribing authority;
- Provides a sworn statement of any felony convictions;
- Provides a sworn statement of any revocation or denial of licensure or certification in any state; and
- Provides two letters of recommendation.

A PA license is renewed every two years by:

- Submitting an application;
- Paying a \$275 renewal fee,⁵ and
- Submitting proof of completion of at least 100 hours of continuing medical education (CME) during the two years prior to application for renewal.⁶

¹ SS. 458.347(1), F.S., and 459.022(1)(e), F.S.

² SS. 458.347, F.S., and 459.022, F.S.

³ Email correspondence with the Department of Health on March 14, 2015 (on file with subcommittee staff).

⁴ National Commission on Certification of Physician Assistants, *Physician Assistant National Certifying Exam (PANCE)*, available at <https://www.nccpa.net/pance> (last visited March 14, 2015).

⁵ Rule 64B8-30.019, F.A.C.

⁶ In addition to the above requirements, prescribing PAs must complete 10 hours of CME in each specialty of their supervising physician. These hours are included in general CME requirements. Florida Board of Medicine, *Physician Assistants*, available at <http://flboardofmedicine.gov/renewals/physician-assistants/> (last visited March 14, 2015).

Supervising Physician

A PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be qualified in the medical area in which the PA is practicing and is responsible and liable for the performance, acts, and omissions of the PA.⁷

The Boards have established that responsible supervision of a PA is the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. The following factors are used to determine if PA supervision is adequate:

- The complexity of the task;
- The risk to the patient;
- The background, training and skill of the PA;
- The adequacy of the direction in terms of its form;
- The setting in which the tasks are performed;
- The availability of the supervising physician;
- The necessity for immediate attention; and
- The number of other persons that the supervising physician must supervise.⁸

The supervising physician is required to periodically review the PA's performance.

A supervising physician may only delegate tasks and procedures to the physician assistant which are within the supervising physician's scope of practice.⁹ The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.¹⁰ Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.¹¹

Delegable Tasks

The following tasks are not permitted to be delegated to a PA, except when specifically authorized by statute:

- Prescribing, dispensing, or compounding medicinal drugs; and
- Final diagnosis.

A supervising physician may delegate authority to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice;¹²
- Order medicinal drugs for a hospitalized patient of the supervising physician;¹³ and

⁷ SS. 458.347(3), F.S., and 459.022(3), F.S.; Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.

⁸ Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

⁹Supra at FN 7.

¹⁰ Id.

¹¹ Specific procedures are not permitted to be performed under indirect supervision, including routine insertion of chest tubes, removal of pacemaker wires or atrial monitoring lines from cardiac stress testing, routine insertion of central venous catheters, injection of intrathecal medication without prior approval of the supervising physician, interpretation of laboratory tests, X-ray studies and EKG's without the supervising physician's interpretation and final review, and administration of general, spinal, and epidural anesthetics (this may be performed under direct supervision only by physician assistants who graduated from Board-approved programs for the education of anesthesiology assistants). See Rules in Supra at FN 7.

¹² SS. 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal or epidural anesthetics, and radiographic contrast materials.

¹³ In 2013, ss.458.347 and 459.022, F.S., were amended to clarify that a PA is authorized to order controlled substances for hospitalized patients.

- Administer a medicinal drug under the direction and supervision of the physician.

Currently, PAs are prohibited from prescribing controlled substances, general, spinal, or epidural anesthetics, and radiographic contrast materials.¹⁴ However, physicians may delegate to PAs the authority to order controlled substances in facilities licensed under ch. 395, F.S.¹⁵

Advanced Registered Nurse Practitioners

Regulation and Licensure

In Florida, an advanced practice nurse is an advanced registered nurse practitioner (ARNP),¹⁶ and is categorized as a certified nurse practitioner, certified nurse midwife, or certified registered nurse anesthetist.¹⁷ As of March 2015, there are 17,719 ARNPs practicing in Florida.

Section 464.003(2), F.S., defines “advanced or specialized nursing practice” to include, in addition to practice of professional nursing that registered nurses are authorized to perform, advanced-level nursing acts approved by the Board of Nursing (Board) as appropriate for ARNPs to perform based on their specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician’s protocol.¹⁸

ARNPs are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board, established under s. 464.004, F.S., provides the eligibility criteria for applicants to be certified as ARNPs and the applicable regulatory standards for ARNP nursing practices. For an applicant to be eligible to be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master’s degree; and
- Submit to the Board proof of a current national advanced practice certification from a board-approved nursing specialty board.¹⁹

Pursuant to s. 456.048, F.S., all ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility. An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and before each biennial renewal. An ARNP must have professional liability coverage of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000.²⁰

Supervising Physician

Under s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in a written physician protocol filed with the Board.²¹ Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician’s primary practice location. If the physician provides specialty

¹⁴ Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.

¹⁵ SS. 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

¹⁶ S. 464.003(3), F.S.

¹⁷ S. 464.012(4), F.S.

¹⁸ S. 464.012, F.S.

¹⁹ S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

²⁰ Rule 64B9-4.002(5), F.A.C.

²¹ Allopathic and osteopathic physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. SS. 458.348 and 459.025, F.S.

health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.²²

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.²³

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule.²⁴

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.²⁵

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.²⁶

²² SS. 458.348(4)(e), and 459.025(3)(e), F.S.

²³ Rule 64B9-4.010, F.A.C.

²⁴ S. 464.012(3), F.S. Section 464.012(4), F.S., authorizes additional acts that certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform within their specialty and a supervisory physician protocol.

²⁵ SS. 893.02(21), F.S., and 893.05(1), F.S.

²⁶ Drug Enforcement Administration, Office of Diversion Control, *Controlled Substance Schedules*, available at www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited March 14, 2015).

The Act defines "prescription" as an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so.²⁷ The Act includes provisions on required protocols for prescribing and administration of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.²⁸

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the federal Drug Enforcement Administration (DEA).²⁹ Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.³⁰ The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law. Registration numbers must be renewed every three years.³¹

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, serves to enforce the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.³²

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.³³ The DEA provides that a controlled substance prescription may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice;
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners); or
- An agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.³⁴

Effect of Proposed Changes

HB 281 permits an ARNP to order medications and controlled substances for hospitalized patients, if acting within the framework of an established protocol with a licensed physician. Such permission is limited to ordering medications and controlled substances in a licensed facility under chapter 395, F.S. The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities. The bill also clarifies the authority of a PA, delegated by a supervising physician, to

²⁷ The definition also includes protocol for out-of-state, licensed practitioners who are prescribing in Florida, pharmacist prescription verification, and prescription blank requirements for controlled substances. S. 893.02(22), F.S.

²⁸ SS. 893.04, F.S., and 893.05, F.S.

²⁹ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Questions & Answers-Registration*, available at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm#> (last visited on March 14, 2015).

³⁰ Drug Enforcement Administration, *Practitioner's Manual- Section II*, available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm> (last visited March 16, 2015).

³¹ *Id.*
³² Drug Enforcement Administration, *About Us*, available at <http://www.deadiversion.usdoj.gov/Inside.html> (last visited March 16, 2015).

³³ Drug Enforcement Administration, *Practitioner's Manual-Section V*, available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm> (last visited March 14, 2015).

³⁴ *Id.*

order medications for administration to the physician's patient in a facility licensed under chapter 395 F.S.

The bill amends s. 465.003, F.S., to clarify that the term "prescription" does not include an "order" that is dispensed for administration to a patient in a facility licensed under ch. 395, F.S. The bill clarifies that the sale of medicinal drugs dispensed as a prescription is eligible for the sales tax exemption under s. 212.08, F.S.

The bill amends several sections of the Controlled Substances Act to clarify the difference between a prescription and an order in a facility licensed under chapter 395, F.S. In s. 893.02, F.S., the definition of prescription is amended to clarify that a prescription does not include an order that is dispensed for administration to a patient in a facility licensed under ch. 395, F.S. The bill authorizes a PA or ARNP, acting under the supervision of a physician, to order a controlled substance for administration to a patient in a facility licensed under chapter 395, F.S.

The bill makes other technical changes to conform statutory language to changes made by the bill.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.

Section 2: Amends s. 459.022, F.S., relating to physician assistants.

Section 3: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners, fees.

Section 4: Amends s. 465.003, F.S., relating to definitions.

Section 5: Amends s. 465.187, F.S., relating to the sale of medicinal drugs.

Section 6: Amends s. 893.02, F.S., relating to definitions.

Section 7: Amends s. 893.04, F.S., relating to pharmacists and practitioner.

Section 8: Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence.

Section 9: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2015, the Health Innovation Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment clarifies that PAs and ARNPs, acting under the supervision of a physician rather than under the direction of a physician, may order a controlled substance for a patient in a facility licensed under ch. 395, F.S. The analysis is drafted to the committee substitute.

1 A bill to be entitled

2 An act relating to prescription medication; amending
 3 ss. 458.347 and 459.022, F.S.; authorizing a licensed
 4 physician assistant acting under the direction of a
 5 supervisory physician to order medication for
 6 administration to a specified patient; conforming
 7 provisions; amending s. 464.012, F.S.; authorizing an
 8 advanced registered nurse practitioner to order
 9 medication for administration to a specified patient;
 10 amending ss. 465.003 and 893.02, F.S.; revising the
 11 definition of the term "prescription" to exclude an
 12 order that is dispensed for administration to a
 13 specified patient; amending ss. 465.187 and 893.04,
 14 F.S.; conforming provisions; amending s. 893.05, F.S.;
 15 authorizing a licensed physician assistant or advanced
 16 registered nurse practitioner acting under the
 17 supervision of a physician to order a controlled
 18 substance for administration to a specified patient;
 19 providing an effective date.
 20

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

22
 23 Section 1. Paragraph (g) of subsection (4) of section
 24 458.347, Florida Statutes, is amended to read:

25 458.347 Physician assistants.—

26 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

27 (g) A supervisory physician may delegate to a licensed
 28 physician assistant the authority to, and the licensed physician
 29 assistant acting under the direction of the supervisory
 30 physician may, order medication medications for administration
 31 to the supervisory physician's patient ~~during his or her care in~~
 32 a facility licensed under chapter 395, ~~notwithstanding any~~
 33 ~~provisions in chapter 465 or chapter 893 which may prohibit this~~
 34 ~~delegation. For the purpose of this paragraph, an order is not~~
 35 ~~considered a prescription. A licensed physician assistant~~
 36 ~~working in a facility that is licensed under chapter 395 may~~
 37 ~~order any medication under the direction of the supervisory~~
 38 ~~physician.~~

39 Section 2. Paragraph (f) of subsection (4) of section
 40 459.022, Florida Statutes, is amended to read:

41 459.022 Physician assistants.—

42 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

43 (f) A supervisory physician may delegate to a licensed
 44 physician assistant the authority to, and the licensed physician
 45 assistant acting under the direction of the supervisory
 46 physician may, order medication medications for administration
 47 to the supervisory physician's patient ~~during his or her care in~~
 48 a facility licensed under chapter 395, ~~notwithstanding any~~
 49 ~~provisions in chapter 465 or chapter 893 which may prohibit this~~
 50 ~~delegation. For the purpose of this paragraph, an order is not~~
 51 ~~considered a prescription. A licensed physician assistant~~
 52 ~~working in a facility that is licensed under chapter 395 may~~

53 ~~order any medication under the direction of the supervisory~~
 54 ~~physician.~~

55 Section 3. Paragraph (e) is added to subsection (3) of
 56 section 464.012, Florida Statutes, to read:

57 464.012 Certification of advanced registered nurse
 58 practitioners; fees.—

59 (3) An advanced registered nurse practitioner shall
 60 perform those functions authorized in this section within the
 61 framework of an established protocol that is filed with the
 62 board upon biennial license renewal and within 30 days after
 63 entering into a supervisory relationship with a physician or
 64 changes to the protocol. The board shall review the protocol to
 65 ensure compliance with applicable regulatory standards for
 66 protocols. The board shall refer to the department licensees
 67 submitting protocols that are not compliant with the regulatory
 68 standards for protocols. A practitioner currently licensed under
 69 chapter 458, chapter 459, or chapter 466 shall maintain
 70 supervision for directing the specific course of medical
 71 treatment. Within the established framework, an advanced
 72 registered nurse practitioner may:

73 (e) Order medication for administration to a patient in a
 74 facility licensed under chapter 395.

75 Section 4. Subsection (14) of section 465.003, Florida
 76 Statutes, is amended to read:

77 465.003 Definitions.—As used in this chapter, the term:

78 (14) "Prescription" includes any order for drugs or

79 medicinal supplies written or transmitted by any means of
 80 communication by a duly licensed practitioner authorized by the
 81 laws of the state to prescribe such drugs or medicinal supplies
 82 and intended to be dispensed by a pharmacist. The term also
 83 includes an orally transmitted order by the lawfully designated
 84 agent of such practitioner. The term also includes an order
 85 written or transmitted by a practitioner licensed to practice in
 86 a jurisdiction other than this state, but only if the pharmacist
 87 called upon to dispense such order determines, in the exercise
 88 of her or his professional judgment, that the order is valid and
 89 necessary for the treatment of a chronic or recurrent illness.
 90 The term "prescription" also includes a pharmacist's order for a
 91 product selected from the formulary created pursuant to s.
 92 465.186. The term "prescription" does not include an order that
 93 is dispensed for administration to a patient in a facility
 94 licensed under chapter 395. Prescriptions may be retained in
 95 written form or the pharmacist may cause them to be recorded in
 96 a data processing system, provided that such order can be
 97 produced in printed form upon lawful request.

98 Section 5. Section 465.187, Florida Statutes, is amended
 99 to read:

100 465.187 Sale of medicinal drugs.—The sale of medicinal
 101 drugs dispensed upon the prescription ~~order~~ of a practitioner
 102 pursuant to this chapter shall be entitled to the exemption from
 103 sales tax provided for in s. 212.08.

104 Section 6. Subsection (22) of section 893.02, Florida

105 Statutes, is amended to read:

106 893.02 Definitions.—The following words and phrases as
 107 used in this chapter shall have the following meanings, unless
 108 the context otherwise requires:

109 (22) "Prescription" means and includes an order for drugs
 110 or medicinal supplies written, signed, or transmitted by any
 111 ~~word of mouth, telephone, telegram, or other~~ means of
 112 communication by a duly licensed practitioner authorized
 113 ~~licensed~~ by the laws of the state to prescribe such drugs or
 114 medicinal supplies, issued in good faith and in the course of
 115 professional practice, intended to be ~~filled, compounded, or~~
 116 dispensed by a another person authorized ~~licensed~~ by the laws of
 117 the state to do so, and meeting the requirements of s. 893.04.
 118 The term also includes an order for drugs or medicinal supplies
 119 so transmitted or written by a physician, dentist, veterinarian,
 120 or other practitioner licensed to practice in a state other than
 121 Florida, but only if the pharmacist called upon to fill such an
 122 order determines, in the exercise of his or her professional
 123 judgment, that the order was issued pursuant to a valid patient-
 124 physician relationship, that it is authentic, and that the drugs
 125 or medicinal supplies so ordered are considered necessary for
 126 the continuation of treatment of a chronic or recurrent illness.
 127 However, if the physician writing the prescription is not known
 128 to the pharmacist, the pharmacist shall obtain proof to a
 129 reasonable certainty of the validity of said prescription. A
 130 prescription order for a controlled substance shall not be

131 | issued on the same prescription blank with another prescription
 132 | order for a controlled substance which is named or described in
 133 | a different schedule, nor shall any prescription order for a
 134 | controlled substance be issued on the same prescription blank as
 135 | a prescription order for a medicinal drug, as defined in s.
 136 | 465.003(8), which does not fall within the definition of a
 137 | controlled substance as defined in this act. The term
 138 | "prescription" does not include an order that is dispensed for
 139 | administration to a patient in a facility licensed under chapter
 140 | 395.

141 | Section 7. Subsection (2) of section 893.04, Florida
 142 | Statutes, is amended to read:

143 | 893.04 Pharmacist and practitioner.—

144 | (2)(a) A pharmacist may not dispense a controlled
 145 | substance listed in Schedule II, Schedule III, or Schedule IV to
 146 | any patient or patient's agent without first determining, in the
 147 | exercise of her or his professional judgment, that the
 148 | prescription ~~order~~ is valid. The pharmacist may dispense the
 149 | controlled substance, in the exercise of her or his professional
 150 | judgment, when the pharmacist or pharmacist's agent has obtained
 151 | satisfactory patient information from the patient or the
 152 | patient's agent.

153 | (b) Any pharmacist who dispenses by mail a controlled
 154 | substance listed in Schedule II, Schedule III, or Schedule IV is
 155 | exempt from the requirement to obtain suitable identification
 156 | for the prescription dispensed by mail if the pharmacist has

157 | obtained the patient's identification through the patient's
 158 | prescription benefit plan.

159 | (c) Any controlled substance listed in Schedule III or
 160 | Schedule IV may be dispensed by a pharmacist upon an oral
 161 | prescription if, before filling the prescription, the pharmacist
 162 | reduces it to writing or records the prescription electronically
 163 | if permitted by federal law. Such prescriptions must contain the
 164 | date of the oral authorization.

165 | (d) Each ~~written~~ prescription written ~~prescribed~~ by a
 166 | practitioner in this state for a controlled substance listed in
 167 | Schedule II, Schedule III, or Schedule IV must include both a
 168 | written and a numerical notation of the quantity of the
 169 | controlled substance prescribed and a notation of the date in
 170 | numerical, month/day/year format, or with the abbreviated month
 171 | written out, or the month written out in whole. A pharmacist
 172 | may, upon verification by the prescriber, document any
 173 | information required by this paragraph. If the prescriber is not
 174 | available to verify a prescription, the pharmacist may dispense
 175 | the controlled substance but may insist that the person to whom
 176 | the controlled substance is dispensed provide valid photographic
 177 | identification. If a prescription includes a numerical notation
 178 | of the quantity of the controlled substance or date, but does
 179 | not include the quantity or date written out in textual format,
 180 | the pharmacist may dispense the controlled substance without
 181 | verification by the prescriber of the quantity or date if the
 182 | pharmacy previously dispensed another prescription for the

183 person to whom the prescription was written.

184 (e) A pharmacist may not dispense more than a 30-day
 185 supply of a controlled substance listed in Schedule III upon an
 186 oral prescription issued in this state.

187 (f) A pharmacist may not knowingly dispense ~~fill~~ a
 188 prescription that has been forged for a controlled substance
 189 listed in Schedule II, Schedule III, or Schedule IV.

190 Section 8. Subsection (1) of section 893.05, Florida
 191 Statutes, is amended to read:

192 893.05 Practitioners and persons administering controlled
 193 substances in their absence.—

194 (1) A practitioner, in good faith and in the course of his
 195 or her professional practice only, may prescribe, administer,
 196 dispense, mix, or otherwise prepare a controlled substance, or
 197 the practitioner may cause the controlled substance ~~same~~ to be
 198 administered by a licensed nurse or an intern practitioner under
 199 his or her direction and supervision only. A veterinarian may so
 200 prescribe, administer, dispense, mix, or prepare a controlled
 201 substance for use on animals only, and may cause it to be
 202 administered by an assistant or orderly under the veterinarian's
 203 direction and supervision only. A certified optometrist licensed
 204 under chapter 463 may not administer or prescribe a controlled
 205 substance listed in Schedule I or Schedule II of s. 893.03. A
 206 licensed physician assistant or advanced registered nurse
 207 practitioner, acting under the supervision of a physician, may
 208 order a controlled substance for administration to a patient,

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209 | consistent with the requirements of s. 458.347, s. 459.022, or
210 | s. 464.012.

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



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COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	<input checked="" type="checkbox"/> (Y/N)
ADOPTED AS AMENDED	<input type="checkbox"/> (Y/N)
ADOPTED W/O OBJECTION	<input type="checkbox"/> (Y/N)
FAILED TO ADOPT	<input type="checkbox"/> (Y/N)
WITHDRAWN	<input type="checkbox"/> (Y/N)
OTHER	<input type="checkbox"/>

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee

3 Representative Pigman offered the following:

4

5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Subsection (7) of section 110.12315, Florida
 8 Statutes, is amended to read:

9 110.12315 Prescription drug program.—The state employees'
 10 prescription drug program is established. This program shall be
 11 administered by the Department of Management Services, according
 12 to the terms and conditions of the plan as established by the
 13 relevant provisions of the annual General Appropriations Act and
 14 implementing legislation, subject to the following conditions:

15 (7) The department shall establish the reimbursement
 16 schedule for prescription pharmaceuticals dispensed under the
 17 program. Reimbursement rates for a prescription pharmaceutical



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18 must be based on the cost of the generic equivalent drug if a
19 generic equivalent exists, unless the physician, advanced
20 registered nurse practitioner, or physician assistant
21 prescribing the pharmaceutical clearly states on the
22 prescription that the brand name drug is medically necessary or
23 that the drug product is included on the formulary of drug
24 products that may not be interchanged as provided in chapter
25 465, in which case reimbursement must be based on the cost of
26 the brand name drug as specified in the reimbursement schedule
27 adopted by the department.

28 Section 2. Paragraph (c) of subsection (1) of section
29 310.071, Florida Statutes, is amended to read:

30 310.071 Deputy pilot certification.—

31 (1) In addition to meeting other requirements specified in
32 this chapter, each applicant for certification as a deputy pilot
33 must:

34 (c) Be in good physical and mental health, as evidenced by
35 documentary proof of having satisfactorily passed a complete
36 physical examination administered by a licensed physician within
37 the preceding 6 months. The board shall adopt rules to establish
38 requirements for passing the physical examination, which rules
39 shall establish minimum standards for the physical or mental
40 capabilities necessary to carry out the professional duties of a
41 certificated deputy pilot. Such standards shall include zero
42 tolerance for any controlled substance regulated under chapter
43 893 unless that individual is under the care of a physician,



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44 advanced registered nurse practitioner, or physician assistant
45 and that controlled substance was prescribed by that physician,
46 advanced registered nurse practitioner, or physician assistant.

47 To maintain eligibility as a certificated deputy pilot, each
48 certificated deputy pilot must annually provide documentary
49 proof of having satisfactorily passed a complete physical
50 examination administered by a licensed physician. The physician
51 must know the minimum standards and certify that the
52 certificateholder satisfactorily meets the standards. The
53 standards for certificateholders shall include a drug test.

54 Section 3. Subsection (3) of section 310.073, Florida
55 Statutes, is amended to read:

56 310.073 State pilot licensing.—In addition to meeting
57 other requirements specified in this chapter, each applicant for
58 license as a state pilot must:

59 (3) Be in good physical and mental health, as evidenced by
60 documentary proof of having satisfactorily passed a complete
61 physical examination administered by a licensed physician within
62 the preceding 6 months. The board shall adopt rules to establish
63 requirements for passing the physical examination, which rules
64 shall establish minimum standards for the physical or mental
65 capabilities necessary to carry out the professional duties of a
66 licensed state pilot. Such standards shall include zero
67 tolerance for any controlled substance regulated under chapter
68 893 unless that individual is under the care of a physician,
69 advanced registered nurse practitioner, or physician assistant



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70 and that controlled substance was prescribed by that physician,
71 advanced registered nurse practitioner, or physician assistant.
72 To maintain eligibility as a licensed state pilot, each licensed
73 state pilot must annually provide documentary proof of having
74 satisfactorily passed a complete physical examination
75 administered by a licensed physician. The physician must know
76 the minimum standards and certify that the licensee
77 satisfactorily meets the standards. The standards for licensees
78 shall include a drug test.

79 Section 4. Paragraph (b) of subsection (3) of section
80 310.081, Florida Statutes, is amended to read:

81 310.081 Department to examine and license state pilots and
82 certificate deputy pilots; vacancies.—

83 (3) Pilots shall hold their licenses or certificates
84 pursuant to the requirements of this chapter so long as they:

85 (b) Are in good physical and mental health as evidenced by
86 documentary proof of having satisfactorily passed a physical
87 examination administered by a licensed physician or physician
88 assistant within each calendar year. The board shall adopt rules
89 to establish requirements for passing the physical examination,
90 which rules shall establish minimum standards for the physical
91 or mental capabilities necessary to carry out the professional
92 duties of a licensed state pilot or a certificated deputy pilot.
93 Such standards shall include zero tolerance for any controlled
94 substance regulated under chapter 893 unless that individual is
95 under the care of a physician, advanced registered nurse



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96 practitioner, or physician assistant and that controlled
97 substance was prescribed by that physician, advanced registered
98 nurse practitioner, or physician assistant. To maintain
99 eligibility as a certificated deputy pilot or licensed state
100 pilot, each certificated deputy pilot or licensed state pilot
101 must annually provide documentary proof of having satisfactorily
102 passed a complete physical examination administered by a
103 licensed physician. The physician must know the minimum
104 standards and certify that the certificateholder or licensee
105 satisfactorily meets the standards. The standards for
106 certificateholders and for licensees shall include a drug test.

107

108 Upon resignation or in the case of disability permanently
109 affecting a pilot's ability to serve, the state license or
110 certificate issued under this chapter shall be revoked by the
111 department.

112 Section 5. Subsection (7) of section 456.072, Florida
113 Statutes, is amended to read:

114 456.072 Grounds for discipline; penalties; enforcement.—

115 (7) Notwithstanding subsection (2), upon a finding that a
116 physician has prescribed or dispensed a controlled substance, or
117 caused a controlled substance to be prescribed or dispensed, in
118 a manner that violates the standard of practice set forth in s.
119 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o)
120 or (s), or s. 466.028(1)(p) or (x), or that an advanced
121 registered nurse practitioner has prescribed or dispensed a



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122 controlled substance, or caused a controlled substance to be
123 prescribed or dispensed, in a manner that violates the standard
124 of practice set forth in s. 464.018(1)(n) or (p)6., the
125 physician or advanced registered nurse practitioner shall be
126 suspended for a period of not less than 6 months and pay a fine
127 of not less than \$10,000 per count. Repeated violations shall
128 result in increased penalties.

129 Section 6. Subsections (2) and (3) of section 456.44,
130 Florida Statutes, are amended to read:

131 456.44 Controlled substance prescribing.—

132 (2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician
133 licensed under chapter 458, chapter 459, chapter 461, or chapter
134 466, a physician assistant licensed under chapter 458 or chapter
135 459, or an advanced registered nurse practitioner certified
136 under part I of chapter 464 who prescribes any controlled
137 substance, listed in Schedule II, Schedule III, or Schedule IV
138 as defined in s. 893.03, for the treatment of chronic
139 nonmalignant pain, must:

140 (a) Designate himself or herself as a controlled substance
141 prescribing practitioner on his or her the physician's
142 practitioner profile.

143 (b) Comply with the requirements of this section and
144 applicable board rules.

145 (3) STANDARDS OF PRACTICE.—The standards of practice in
146 this section do not supersede the level of care, skill, and



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147 treatment recognized in general law related to health care
148 licensure.

149 (a) A complete medical history and a physical examination
150 must be conducted before beginning any treatment and must be
151 documented in the medical record. The exact components of the
152 physical examination shall be left to the judgment of the
153 registrant ~~elinician~~ who is expected to perform a physical
154 examination proportionate to the diagnosis that justifies a
155 treatment. The medical record must, at a minimum, document the
156 nature and intensity of the pain, current and past treatments
157 for pain, underlying or coexisting diseases or conditions, the
158 effect of the pain on physical and psychological function, a
159 review of previous medical records, previous diagnostic studies,
160 and history of alcohol and substance abuse. The medical record
161 shall also document the presence of one or more recognized
162 medical indications for the use of a controlled substance. Each
163 registrant must develop a written plan for assessing each
164 patient's risk of aberrant drug-related behavior, which may
165 include patient drug testing. Registrants must assess each
166 patient's risk for aberrant drug-related behavior and monitor
167 that risk on an ongoing basis in accordance with the plan.

168 (b) Each registrant must develop a written individualized
169 treatment plan for each patient. The treatment plan shall state
170 objectives that will be used to determine treatment success,
171 such as pain relief and improved physical and psychosocial
172 function, and shall indicate if any further diagnostic



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173 evaluations or other treatments are planned. After treatment
174 begins, the registrant ~~physician~~ shall adjust drug therapy to
175 the individual medical needs of each patient. Other treatment
176 modalities, including a rehabilitation program, shall be
177 considered depending on the etiology of the pain and the extent
178 to which the pain is associated with physical and psychosocial
179 impairment. The interdisciplinary nature of the treatment plan
180 shall be documented.

181 (c) The registrant ~~physician~~ shall discuss the risks and
182 benefits of the use of controlled substances, including the
183 risks of abuse and addiction, as well as physical dependence and
184 its consequences, with the patient, persons designated by the
185 patient, or the patient's surrogate or guardian if the patient
186 is incompetent. The registrant ~~physician~~ shall use a written
187 controlled substance agreement between the registrant ~~physician~~
188 and the patient outlining the patient's responsibilities,
189 including, but not limited to:

190 1. Number and frequency of controlled substance
191 prescriptions and refills.

192 2. Patient compliance and reasons for which drug therapy
193 may be discontinued, such as a violation of the agreement.

194 3. An agreement that controlled substances for the
195 treatment of chronic nonmalignant pain shall be prescribed by a
196 single treating registrant ~~physician~~ unless otherwise authorized
197 by the treating registrant ~~physician~~ and documented in the
198 medical record.



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199 (d) The patient shall be seen by the registrant ~~physician~~
200 at regular intervals, not to exceed 3 months, to assess the
201 efficacy of treatment, ensure that controlled substance therapy
202 remains indicated, evaluate the patient's progress toward
203 treatment objectives, consider adverse drug effects, and review
204 the etiology of the pain. Continuation or modification of
205 therapy shall depend on the registrant's ~~physician's~~ evaluation
206 of the patient's progress. If treatment goals are not being
207 achieved, despite medication adjustments, the registrant
208 ~~physician~~ shall reevaluate the appropriateness of continued
209 treatment. The registrant ~~physician~~ shall monitor patient
210 compliance in medication usage, related treatment plans,
211 controlled substance agreements, and indications of substance
212 abuse or diversion at a minimum of 3-month intervals.

213 (e) The registrant ~~physician~~ shall refer the patient as
214 necessary for additional evaluation and treatment in order to
215 achieve treatment objectives. Special attention shall be given
216 to those patients who are at risk for misusing their medications
217 and those whose living arrangements pose a risk for medication
218 misuse or diversion. The management of pain in patients with a
219 history of substance abuse or with a comorbid psychiatric
220 disorder requires extra care, monitoring, and documentation and
221 requires consultation with or referral to an addiction medicine
222 specialist or psychiatrist.

223 (f) A registrant ~~physician~~ registered under this section
224 must maintain accurate, current, and complete records that are



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225 accessible and readily available for review and comply with the
226 requirements of this section, the applicable practice act, and
227 applicable board rules. The medical records must include, but
228 are not limited to:

- 229 1. The complete medical history and a physical
230 examination, including history of drug abuse or dependence.
 - 231 2. Diagnostic, therapeutic, and laboratory results.
 - 232 3. Evaluations and consultations.
 - 233 4. Treatment objectives.
 - 234 5. Discussion of risks and benefits.
 - 235 6. Treatments.
 - 236 7. Medications, including date, type, dosage, and quantity
237 prescribed.
 - 238 8. Instructions and agreements.
 - 239 9. Periodic reviews.
 - 240 10. Results of any drug testing.
 - 241 11. A photocopy of the patient's government-issued photo
242 identification.
 - 243 12. If a written prescription for a controlled substance
244 is given to the patient, a duplicate of the prescription.
 - 245 13. The registrant's ~~physician's~~ full name presented in a
246 legible manner.
- 247 (g) Patients with signs or symptoms of substance abuse
248 shall be immediately referred to a board-certified pain
249 management physician, an addiction medicine specialist, or a
250 mental health addiction facility as it pertains to drug abuse or



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251 addiction unless the registrant is a physician who is board-
252 certified or board-eligible in pain management. Throughout the
253 period of time before receiving the consultant's report, a
254 prescribing registrant physician shall clearly and completely
255 document medical justification for continued treatment with
256 controlled substances and those steps taken to ensure medically
257 appropriate use of controlled substances by the patient. Upon
258 receipt of the consultant's written report, the prescribing
259 registrant physician shall incorporate the consultant's
260 recommendations for continuing, modifying, or discontinuing
261 controlled substance therapy. The resulting changes in treatment
262 shall be specifically documented in the patient's medical
263 record. Evidence or behavioral indications of diversion shall be
264 followed by discontinuation of controlled substance therapy, and
265 the patient shall be discharged, and all results of testing and
266 actions taken by the registrant physician shall be documented in
267 the patient's medical record.

268
269 This subsection does not apply to a board-eligible or board-
270 certified anesthesiologist, physiatrist, rheumatologist, or
271 neurologist, or to a board-certified physician who has surgical
272 privileges at a hospital or ambulatory surgery center and
273 primarily provides surgical services. This subsection does not
274 apply to a board-eligible or board-certified medical specialist
275 who has also completed a fellowship in pain medicine approved by
276 the Accreditation Council for Graduate Medical Education or the



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277 American Osteopathic Association, or who is board eligible or
278 board certified in pain medicine by the American Board of Pain
279 Medicine, the American Board of Interventional Pain Physicians,
280 the American Association of Physician Specialists, or a board
281 approved by the American Board of Medical Specialties or the
282 American Osteopathic Association and performs interventional
283 pain procedures of the type routinely billed using surgical
284 codes. This subsection does not apply to a registrant, advanced
285 registered nurse practitioner, or physician assistant who
286 prescribes medically necessary controlled substances for a
287 patient during an inpatient stay in a hospital licensed under
288 chapter 395.

289 Section 7. Paragraph (b) of subsection (2) of section
290 458.3265, Florida Statutes, is amended to read:

291 458.3265 Pain-management clinics.—

292 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
293 apply to any physician who provides professional services in a
294 pain-management clinic that is required to be registered in
295 subsection (1).

296 (b) A person may not dispense any medication on the
297 premises of a registered pain-management clinic unless he or she
298 is a physician licensed under this chapter or chapter 459. A
299 person may not prescribe any controlled substance regulated
300 under chapter 893 on the premises of a registered pain-
301 management clinic unless he or she is a physician licensed under
302 this chapter or chapter 459.



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303 Section 8. Paragraph (f) of subsection (4) of section
304 458.347, Florida Statutes, is amended to read:

305 458.347 Physician assistants.—

306 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

307 (f)1. The council shall establish a formulary of medicinal
308 drugs that a fully licensed physician assistant having
309 prescribing authority under this section or s. 459.022 may not
310 prescribe. The formulary must include ~~controlled substances as~~
311 ~~defined in chapter 893~~, general anesthetics, and radiographic
312 contrast materials.

313 2. In establishing the formulary, the council shall
314 consult with a pharmacist licensed under chapter 465, but not
315 licensed under this chapter or chapter 459, who shall be
316 selected by the State Surgeon General.

317 3. Only the council shall add to, delete from, or modify
318 the formulary. Any person who requests an addition, deletion, or
319 modification of a medicinal drug listed on such formulary has
320 the burden of proof to show cause why such addition, deletion,
321 or modification should be made.

322 4. The boards shall adopt the formulary required by this
323 paragraph, and each addition, deletion, or modification to the
324 formulary, by rule. Notwithstanding any provision of chapter 120
325 to the contrary, the formulary rule shall be effective 60 days
326 after the date it is filed with the Secretary of State. Upon
327 adoption of the formulary, the department shall mail a copy of
328 such formulary to each fully licensed physician assistant having



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329 prescribing authority under this section or s. 459.022, and to
330 each pharmacy licensed by the state. The boards shall establish,
331 by rule, a fee not to exceed \$200 to fund the provisions of this
332 paragraph and paragraph (e).

333 Section 9. Paragraph (b) of subsection (2) of section
334 459.0137, Florida Statutes, is amended to read:

335 459.0137 Pain-management clinics.—

336 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
337 apply to any osteopathic physician who provides professional
338 services in a pain-management clinic that is required to be
339 registered in subsection (1).

340 (b) A person may not dispense any medication on the
341 premises of a registered pain-management clinic unless he or she
342 is a physician licensed under this chapter or chapter 458. A
343 person may not prescribe any controlled substance regulated
344 under chapter 893 on the premises of a registered pain-
345 management clinic unless he or she is a physician licensed under
346 this chapter or chapter 458.

347 Section 10. Section 464.012, Florida Statutes, is amended
348 to read:

349 464.012 Certification of advanced registered nurse
350 practitioners; fees; controlled substance prescribing.—

351 (1) Any nurse desiring to be certified as an advanced
352 registered nurse practitioner shall apply to the department and
353 submit proof that he or she holds a current license to practice



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354 professional nursing and that he or she meets one or more of the
355 following requirements as determined by the board:

356 (a) Satisfactory completion of a formal postbasic
357 educational program of at least one academic year, the primary
358 purpose of which is to prepare nurses for advanced or
359 specialized practice.

360 (b) Certification by an appropriate specialty board. Such
361 certification shall be required for initial state certification
362 and any recertification as a registered nurse anesthetist or
363 nurse midwife. The board may by rule provide for provisional
364 state certification of graduate nurse anesthetists and nurse
365 midwives for a period of time determined to be appropriate for
366 preparing for and passing the national certification
367 examination.

368 (c) Graduation from a program leading to a master's degree
369 in a nursing clinical specialty area with preparation in
370 specialized practitioner skills. For applicants graduating on or
371 after October 1, 1998, graduation from a master's degree program
372 shall be required for initial certification as a nurse
373 practitioner under paragraph (4)(c). For applicants graduating
374 on or after October 1, 2001, graduation from a master's degree
375 program shall be required for initial certification as a
376 registered nurse anesthetist under paragraph (4)(a).

377 (2) The board shall provide by rule the appropriate
378 requirements for advanced registered nurse practitioners in the



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379 categories of certified registered nurse anesthetist, certified
380 nurse midwife, and nurse practitioner.

381 (3) An advanced registered nurse practitioner shall
382 perform those functions authorized in this section within the
383 framework of an established protocol that is filed with the
384 board upon biennial license renewal and within 30 days after
385 entering into a supervisory relationship with a physician or
386 changes to the protocol. The board shall review the protocol to
387 ensure compliance with applicable regulatory standards for
388 protocols. The board shall refer to the department licensees
389 submitting protocols that are not compliant with the regulatory
390 standards for protocols. A practitioner currently licensed under
391 chapter 458, chapter 459, or chapter 466 shall maintain
392 supervision for directing the specific course of medical
393 treatment. Within the established framework, an advanced
394 registered nurse practitioner may:

395 (a) Prescribe, dispense, administer, or order any Monitor
396 and alter drug therapies.

397 (b) Initiate appropriate therapies for certain conditions.

398 (c) Perform additional functions as may be determined by
399 rule in accordance with s. 464.003(2).

400 (d) Order diagnostic tests and physical and occupational
401 therapy.

402 (4) In addition to the general functions specified in
403 subsection (3), an advanced registered nurse practitioner may
404 perform the following acts within his or her specialty:



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405 (a) The certified registered nurse anesthetist may, to the
406 extent authorized by established protocol approved by the
407 medical staff of the facility in which the anesthetic service is
408 performed, perform any or all of the following:

409 1. Determine the health status of the patient as it
410 relates to the risk factors and to the anesthetic management of
411 the patient through the performance of the general functions.

412 2. Based on history, physical assessment, and supplemental
413 laboratory results, determine, with the consent of the
414 responsible physician, the appropriate type of anesthesia within
415 the framework of the protocol.

416 3. Order under the protocol preanesthetic medication.

417 4. Perform under the protocol procedures commonly used to
418 render the patient insensible to pain during the performance of
419 surgical, obstetrical, therapeutic, or diagnostic clinical
420 procedures. These procedures include ordering and administering
421 regional, spinal, and general anesthesia; inhalation agents and
422 techniques; intravenous agents and techniques; and techniques of
423 hypnosis.

424 5. Order or perform monitoring procedures indicated as
425 pertinent to the anesthetic health care management of the
426 patient.

427 6. Support life functions during anesthesia health care,
428 including induction and intubation procedures, the use of
429 appropriate mechanical supportive devices, and the management of
430 fluid, electrolyte, and blood component balances.

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431 7. Recognize and take appropriate corrective action for
432 abnormal patient responses to anesthesia, adjunctive medication,
433 or other forms of therapy.

434 8. Recognize and treat a cardiac arrhythmia while the
435 patient is under anesthetic care.

436 9. Participate in management of the patient while in the
437 postanesthesia recovery area, including ordering the
438 administration of fluids and drugs.

439 10. Place special peripheral and central venous and
440 arterial lines for blood sampling and monitoring as appropriate.

441 (b) The certified nurse midwife may, to the extent
442 authorized by an established protocol which has been approved by
443 the medical staff of the health care facility in which the
444 midwifery services are performed, or approved by the nurse
445 midwife's physician backup when the delivery is performed in a
446 patient's home, perform any or all of the following:

447 1. Perform superficial minor surgical procedures.

448 2. Manage the patient during labor and delivery to include
449 amniotomy, episiotomy, and repair.

450 3. Order, initiate, and perform appropriate anesthetic
451 procedures.

452 4. Perform postpartum examination.

453 5. Order appropriate medications.

454 6. Provide family-planning services and well-woman care.

455 7. Manage the medical care of the normal obstetrical
456 patient and the initial care of a newborn patient.



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457 (c) The nurse practitioner may perform any or all of the
458 following acts within the framework of established protocol:

- 459 1. Manage selected medical problems.
460 2. Order physical and occupational therapy.
461 3. Initiate, monitor, or alter therapies for certain
462 uncomplicated acute illnesses.
463 4. Monitor and manage patients with stable chronic
464 diseases.

465 5. Establish behavioral problems and diagnosis and make
466 treatment recommendations.

467 (5) The board shall certify, and the department shall
468 issue a certificate to, any nurse meeting the qualifications in
469 this section. The board shall establish an application fee not
470 to exceed \$100 and a biennial renewal fee not to exceed \$50. The
471 board is authorized to adopt such other rules as are necessary
472 to implement the provisions of this section.

473 Section 11. Paragraph (p) is added to subsection (1) of
474 section 464.018, Florida Statutes, to read:

475 464.018 Disciplinary actions.—

476 (1) The following acts constitute grounds for denial of a
477 license or disciplinary action, as specified in s. 456.072(2):

478 (p) For an advanced registered nurse practitioner:

- 479 1. Presigning blank prescription forms.
480 2. Prescribing for office use any medicinal drug appearing
481 on Schedule II in chapter 893.



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482 3. Prescribing, ordering, dispensing, administering,
483 supplying, selling, or giving a drug that is an amphetamine or a
484 sympathomimetic amine drug, or a compound designated pursuant to
485 chapter 893 as a Schedule II controlled substance, to or for any
486 person except for:

487 a. The treatment of narcolepsy; hyperkinesis; behavioral
488 syndrome in children characterized by the developmentally
489 inappropriate symptoms of moderate to severe distractibility,
490 short attention span, hyperactivity, emotional lability, and
491 impulsivity; or drug-induced brain dysfunction.

492 b. The differential diagnostic psychiatric evaluation of
493 depression or the treatment of depression shown to be refractory
494 to other therapeutic modalities.

495 c. The clinical investigation of the effects of such drugs
496 or compounds when an investigative protocol is submitted to,
497 reviewed by, and approved by the department before such
498 investigation is begun.

499 4. Prescribing, ordering, dispensing, administering,
500 supplying, selling, or giving growth hormones, testosterone or
501 its analogs, human chorionic gonadotropin (HCG), or other
502 hormones for the purpose of muscle building or to enhance
503 athletic performance. As used in this subparagraph, the term
504 "muscle building" does not include the treatment of injured
505 muscle. A prescription written for the drug products listed in
506 this paragraph may be dispensed by a pharmacist with the
507 presumption that the prescription is for legitimate medical use.



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508 5. Promoting or advertising on any prescription form a
509 community pharmacy unless the form also states: "This
510 prescription may be filled at any pharmacy of your choice."

511 6. Prescribing, dispensing, administering, mixing, or
512 otherwise preparing a legend drug, including a controlled
513 substance, other than in the course of his or her professional
514 practice. For the purposes of this subparagraph, it is legally
515 presumed that prescribing, dispensing, administering, mixing, or
516 otherwise preparing legend drugs, including all controlled
517 substances, inappropriately or in excessive or inappropriate
518 quantities is not in the best interest of the patient and is not
519 in the course of the advanced registered nurse practitioner's
520 professional practice, without regard to his or her intent.

521 7. Prescribing, dispensing, or administering a medicinal
522 drug appearing on any schedule set forth in chapter 893 to
523 himself or herself, except a drug prescribed, dispensed, or
524 administered to the advanced registered nurse practitioner by
525 another practitioner authorized to prescribe, dispense, or
526 administer medicinal drugs.

527 8. Prescribing, ordering, dispensing, administering,
528 supplying, selling, or giving amygdalin (laetrile) to any
529 person.

530 9. Dispensing a controlled substance listed on Schedule II
531 or Schedule III in chapter 893 in violation of s. 465.0276.



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532 10. Promoting or advertising through any communication
533 medium the use, sale, or dispensing of a controlled substance
534 appearing on any schedule in chapter 893.

535 Section 12. Subsection (21) of section 893.02, Florida
536 Statutes, is amended to read:

537 893.02 Definitions.—The following words and phrases as
538 used in this chapter shall have the following meanings, unless
539 the context otherwise requires:

540 (21) "Practitioner" means a physician licensed under
541 ~~pursuant to~~ chapter 458, a dentist licensed under ~~pursuant to~~
542 chapter 466, a veterinarian licensed under ~~pursuant to~~ chapter
543 474, an osteopathic physician licensed under ~~pursuant to~~ chapter
544 459, an advanced registered nurse practitioner certified under
545 chapter 464, a naturopath licensed under ~~pursuant to~~ chapter
546 462, a certified optometrist licensed under ~~pursuant to~~ chapter
547 463, ~~or~~ a podiatric physician licensed under ~~pursuant to~~ chapter
548 461, or a physician assistant licensed under chapter 458 or
549 chapter 459, provided such practitioner holds a valid federal
550 controlled substance registry number.

551 Section 13. Paragraph (n) of subsection (1) of section
552 948.03, Florida Statutes, is amended to read:

553 948.03 Terms and conditions of probation.—

554 (1) The court shall determine the terms and conditions of
555 probation. Conditions specified in this section do not require
556 oral pronouncement at the time of sentencing and may be
557 considered standard conditions of probation. These conditions



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558 may include among them the following, that the probationer or
559 offender in community control shall:

560 (n) Be prohibited from using intoxicants to excess or
561 possessing any drugs or narcotics unless prescribed by a
562 physician, advanced registered nurse practitioner, or physician
563 assistant. The probationer or community controllee may shall not
564 knowingly visit places where intoxicants, drugs, or other
565 dangerous substances are unlawfully sold, dispensed, or used.

566 Section 14. Subsection (3) of s. 310.071, Florida
567 Statutes, is reenacted for the purpose of incorporating the
568 amendment made by this act to s. 310.071, Florida Statutes, in a
569 reference thereto.

570 Section 15. Subsection (10) of s. 458.331, paragraph (g)
571 of subsection (7) of s. 458.347, subsection (10) of s. 459.015,
572 paragraph (f) of subsection (7) of s. 459.022, and paragraph (b)
573 of subsection (5) of s. 465.0158, Florida Statutes, are
574 reenacted for the purpose of incorporating the amendment made by
575 this act to s. 456.072, Florida Statutes, in references thereto.

576 Section 16. Paragraph (mm) of subsection (1) of s. 456.072
577 and s. 466.02751, Florida Statutes, are reenacted for the
578 purpose of incorporating the amendment made by this act to s.
579 456.44, Florida Statutes, in references thereto.

580 Section 17. Section 458.303, paragraph (e) of subsection
581 (4) and paragraph (c) of subsection (9) of s. 458.347, paragraph
582 (b) of subsection (7) of s. 458.3475, paragraph (e) of
583 subsection (4) and paragraph (c) of subsection (9) of s.



Amendment No.

584 459.022, and paragraph (b) of subsection (7) of s. 459.023,
585 Florida Statutes, are reenacted for the purpose of incorporating
586 the amendment made by this act to s. 458.347, Florida Statutes,
587 in references thereto.

588 Section 18. Paragraph (a) of subsection (1) of s. 456.041,
589 subsections (1) and (2) of s. 458.348, and subsection (1) of s.
590 459.025, Florida Statutes, are reenacted for the purpose of
591 incorporating the amendment made by this act to s. 464.012,
592 Florida Statutes, in references thereto.

593 Section 19. Subsection (11) of s. 320.0848, subsection (2)
594 of s. 464.008, subsection (5) of s. 464.009, subsection (2) of
595 s. 464.018, and paragraph (b) of subsection (1), subsection (3),
596 and paragraph (b) of subsection (4) of s. 464.0205, Florida
597 Statutes, are reenacted for the purpose of incorporating the
598 amendment made by this act to s. 464.018, Florida Statutes, in
599 references thereto.

600 Section 20. Section 775.051, Florida Statutes, is
601 reenacted for the purpose of incorporating the amendment made by
602 this act to s. 893.02, Florida Statutes, in a reference thereto.

603 Section 21. Paragraph (a) of subsection (3) of s. 944.17,
604 subsection (8) of s. 948.001, and paragraph (e) of subsection
605 (1) of s. 948.101, Florida Statutes, are reenacted for the
606 purpose of incorporating the amendment made by this act to s.
607 948.03, Florida Statutes, in references thereto.

608 Section 22. This act shall take effect July 1, 2015.
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Amendment No.

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

Remove everything before the enacting clause and insert:
An act relating to drug prescription by advanced registered
nurse practitioners and physician assistants; amending s.
110.12315, F.S.; expanding the categories of persons who may
prescribe brand drugs under the prescription drug program when
medically necessary; amending ss. 310.071, 310.073, and 310.081,
F.S.; exempting controlled substances prescribed by an advanced
registered nurse practitioner or a physician assistant from the
disqualifications for certification or licensure, and for
continued certification or licensure, as a deputy or state
pilot; amending s. 456.072, F.S.; applying existing penalties
for violations relating to the prescribing or dispensing of
controlled substances to an advanced registered nurse
practitioner; amending s. 456.44, F.S.; deleting an obsolete
date; requiring advanced registered nurse practitioners and
physician assistants who prescribe controlled substances for
certain pain to make a certain designation, comply with
registration requirements, and follow specified standards of
practice; providing applicability; amending ss. 458.3265 and
459.0137, F.S.; limiting the authority to prescribe a controlled
substance in a pain-management clinic to a physician licensed
under ch. 458 or ch. 459, F.S.; amending s. 458.347, F.S.;
expanding the prescribing authority of a licensed physician
assistant; amending s. 464.012, F.S.; authorizing an advanced



Amendment No.

636 registered nurse practitioner to prescribe, dispense,
637 administer, or order drugs, rather than to monitor and alter
638 drug therapies; amending s. 464.018, F.S.; specifying acts that
639 constitute grounds for denial of a license for or disciplinary
640 action against an advanced registered nurse practitioner;
641 amending s. 893.02, F.S.; redefining the term "practitioner" to
642 include advanced registered nurse practitioners and physician
643 assistants under the Florida Comprehensive Drug Abuse Prevention
644 and Control Act; amending s. 948.03, F.S.; providing that
645 possession of drugs or narcotics prescribed by an advanced
646 registered nurse practitioner or physician assistant is an
647 exception from a prohibition relating to the possession of drugs
648 or narcotics during probation; reenacting s. 310.071(3), F.S.,
649 to incorporate the amendment made to s. 310.071, F.S., in a
650 reference thereto; reenacting ss. 458.331(10), 458.347(7)(g),
651 459.015(10), 459.022(7)(f), and 465.0158(5)(b), F.S., to
652 incorporate the amendment made to s. 456.072, F.S., in
653 references thereto; reenacting ss. 456.072(1)(mm) and 466.02751,
654 F.S., to incorporate the amendment made to s. 456.44, F.S., in
655 references thereto; reenacting ss. 458.303, 458.347(4)(e) and
656 (9)(c), 458.3475(7)(b), 459.022(4)(e) and (9)(c), and
657 459.023(7)(b), F.S., to incorporate the amendment made to s.
658 458.347, F.S., in references thereto; reenacting ss.
659 456.041(1)(a), 458.348(1) and (2), and 459.025(1), F.S., to
660 incorporate the amendment made to s. 464.012, F.S., in
661 references thereto; reenacting ss. 320.0848(11), 464.008(2),





Amendment No.

662 464.009(5), 464.018(2), and 464.0205(1)(b), (3), and (4)(b),
663 F.S., to incorporate the amendment made to s. 464.018, F.S., in
664 references thereto; reenacting s. 775.051, F.S., to incorporate
665 the amendment made to s. 893.02, F.S., in a reference thereto;
666 reenacting ss. 944.17(3)(a), 948.001(8), and 948.101(1)(e),
667 F.S., to incorporate the amendment made to s. 948.03, F.S., in
668 references thereto; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 309 Patient Admission Status Notification
SPONSOR(S): Health Care Appropriations Subcommittee; Harrison
TIED BILLS: **IDEN./SIM. BILLS:** SB 786, SB 820

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee	10 Y, 0 N, As CS	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo 	Calamas 

SUMMARY ANALYSIS

When a patient enters a hospital, a physician must decide whether or not to admit the individual for inpatient care. The term "observation status" means a hospital patient who is currently considered an outpatient, but is receiving observation services to determine if admission as an inpatient is necessary.

During an observation stay in a hospital, a treating physician may order a variety of outpatient services, including laboratory tests, medication, minor procedures, x-rays, and other imaging services. Observation stays can occur anywhere in the hospital.

A patient on "observation status" may experience higher costs than a patient on admission status for time spent in a hospital because Medicare covers inpatient and outpatient hospital services differently. Medicare Part A covers inpatient hospital services, which requires a one-time deductible covering all hospital services for the first 60 days a patient is in the hospital. A patient on "observation status" is covered under Medicare Part B, which covers outpatient hospital services and requires the patient to pay a copayment for each individual service.

In addition, observation status may affect Medicare coverage for care in a skilled nursing facility (SNF). A patient must have a qualifying inpatient hospital stay, defined as three consecutive days of inpatient care, to be covered by Medicare for SNF care. A patient who qualifies for Medicare and Medicaid will not be responsible for the copayment. A patient under "observation status" in a hospital does not meet the requirements for a qualifying inpatient hospital stay for Medicare coverage for SNF care.

In Florida, hospitals are not required to inform patients of their observation status under current law.

CS/HB 309 requires that if a hospital places a patient on "observation status" rather than inpatient status, the observation services shall be documented in the patient's discharge papers. The bill requires that notice be given to the patient or patient's proxy through the discharge papers, which may include brochures, signage, or other forms of communication.

The bill appears to have a positive, yet indeterminate, fiscal impact which is anticipated to be insignificant.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Billing Transparency

Hospitals are licensed and regulated by the Agency for Health Care Administration (AHCA) under part I of ch. 395, F.S.¹ Current law requires hospitals to notify each patient, upon admission and discharge, of the right to receive an itemized bill. Upon request, the hospital must provide the patient an itemized statement detailing the specific nature of the charges or expenses incurred by the patient.²

A hospital must also give a patient, prior to providing any non-emergent medical services, within 7 days of a written request, a good faith estimate of reasonably anticipated charges for the facility to treat the patient's condition.³ Upon request, the hospital must also provide revisions to the estimate.⁴ A facility that fails to provide the estimate may be fined \$500 for each instance of the facility's failure to provide the requested information.⁵

Patient Status

When a patient enters a hospital, a physician must decide whether or not to admit the individual for inpatient care. Factors to be considered when making a decision to admit a patient include:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of an adverse event;
- The need for diagnostic studies to access whether the patient should be admitted;
- The availability of diagnostic procedures at the time when, and at the location where, the patient presents; and
- Whether the patient is expected to need at least 24 hours of hospital care.⁶

A patient in "observation status" in a hospital is considered an outpatient and receives observation services to determine if admission is necessary.⁷ Observation services are commonly ordered for a patient who presents to the emergency department and requires a period of treatment or monitoring in order to make a decision between admission and discharge.⁸ Outpatient services can include laboratory tests, medication, minor procedures, x-rays, and other imaging services. Observation stays can occur anywhere in the hospital, including the emergency department, a separate observation unit, or an inpatient unit.

The federal Medicare program does not expressly limit the number of days a patient may be on "observation status," but assumes the decision whether to admit or discharge a patient from the

¹ S. 395.002(16), F.S., defines "licensed facility" as a hospital, ambulatory surgical center, or mobile surgical facility licensed in accordance with ch. 395, F.S. The bill applies to all three facility types because it amends part I of ch. 395, F.S., but will only affect hospitals because ambulatory surgical centers and mobile surgical facilities serve patients who are receiving elective outpatient services and know in advance that they are not going to be admitted to a hospital, barring any complications.

² S. 395.301(1), F.S.

³ S. 395.301(7), F.S.

⁴ Id.

⁵ Id.

⁶ Centers for Medicare and Medicaid Services (CMS), *Medicare Benefit Policy Manual* (MBPM), ch. 1, § 10.

⁷ Id. at ch. 6, § 20.6.

⁸ Id.

hospital can often be made in less than 48 hours; only in rare cases are outpatient observation services required beyond 48 hours.⁹

A patient on "observation status" may experience higher costs than a patient on admission status for time spent in a hospital because Medicare covers inpatient and outpatient hospital services differently. Medicare Part A covers inpatient hospital services, which requires a one-time deductible covering all hospital services for the first 60 days a patient is in the hospital. A patient on "observation status" is covered under Medicare Part B, which covers outpatient hospital services and requires the patient to pay a 20-percent copayment for each individual outpatient hospital service.¹⁰

In addition, a patient's hospital status may affect their Medicare coverage for care in a skilled nursing facility (SNF). The patient must have a qualifying inpatient hospital stay, defined as three consecutive days of inpatient care, to be covered by Medicare for SNF care.¹¹ A patient who qualifies for Medicare and Medicaid will not be responsible for the copayment.¹² A patient under "observation status" in a hospital does not meet the requirements for a qualifying inpatient hospital stay for Medicare coverage for SNF care.

Four states have recently enacted legislation to require a hospital to notify a patient within 24 hours of being placed on "observation status".¹³ Currently, a Florida hospital is not required to inform a patient of his or her "observation status".

Effect of Proposed Changes

The bill requires a hospital that places a patient on "observation status" rather than inpatient status to document the observation services in the patient's discharge papers. The bill requires that notice be given to the patient or the patient's proxy through the discharge papers, which may include brochures, signage, or other forms of communication for this purpose.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 395.301, F.S., relating to itemized patient bill; form and consent prescribed by the agency.

Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill is expected to have a positive, yet indeterminate fiscal impact on AHCA. The bill requires hospitals to provide documentation of observation services in the patient's discharge papers.

Section 395.1065(2), F.S., authorizes AHCA to impose an administrative fine, not to exceed \$1,000

⁹ Id.

¹⁰ 42 CFR § 419.40(b)

¹¹ 42 CFR § 409.30

¹² 42 CFR § 440.20 Outpatient hospital services are a mandatory Medicaid benefit. For services that both Medicare and Medicaid cover, Medicare pays first, and Medicaid pays second by covering an individual's remaining costs for Medicare coinsurances and copayments.

¹³ Connecticut (2014), Substitute House Bill No. 5535, Public Act No. 14-180; Maryland (2013), Senate Bill 195, Chapter 202; New York (2013), Bill S3926A-2013; and Pennsylvania (2013), House Bill No. 1907.

per violation, per day, for a violation of part I of ch. 395, F.S., part II of ch. 408, F.S., or applicable rules. The number of violations and the amount of fines that may be collected are unknown.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals may realize a minimal increase in administrative costs associated with providing the documentation of observation services in the discharge papers. Hospitals may also realize an increase in fines for failing to provide notification of observation services included in the discharge papers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires hospitals to document observation services in the patient's discharge papers. A patient is likely to have already incurred charges prior to discharge. A requirement that the hospital notify the patient, within a certain amount of time (i.e., 24 hours), of being placed on "observation status" rather than inpatient status may allow the patient to make alternate arrangements for care and avoid additional charges.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2015, the Health Care Appropriations Subcommittee adopted one amendment to HB 309. The amendment made the following changes to the bill:

- Required that if a licensed facility places a patient on “observation status” rather than inpatient status, the observation services shall be documented in the discharge papers.
- Required that the patient or patient’s proxy be notified of observation services through discharge papers which may also include brochures, signage, or other forms of communication.

The bill was reported favorably as a Committee Substitute. This analysis is drafted to the CS/HB 309.

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A bill to be entitled
An act relating to patient admission status
notification; amending s. 395.301, F.S.; providing
requirements for licensed medical facilities for
patient notification regarding admission status;
providing an effective date.

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

Section 1. Subsections (9) through (11) of section
395.301, Florida Statutes, are renumbered as subsections (10)
through (12), respectively, and a new subsection (9) is added to
that section to read:

395.301 Itemized patient bill; form and content prescribed
by the agency; patient admission status notification.—

(9) If a licensed facility places a patient on observation
status rather than inpatient status, observation services shall
be documented in the patient's discharge papers. The patient or
the patient's proxy shall be notified of observation services
through discharge papers, which may also include brochures,
signage, or other forms of communication for this purpose.

Section 2. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 515 Physical Therapy
SPONSOR(S): Health Quality Subcommittee; Cummings
TIED BILLS: IDEN./SIM. **BILLS:**

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

SUMMARY ANALYSIS

Physical therapists are regulated under ch. 486, F.S., the Physical Therapy Practice Act (Act), and by the Board of Physical Therapy (Board) under the Department of Health's Division of Medical Quality Assurance. Physical therapy is the assessment, treatment, prevention, and rehabilitation of any disability, injury, disease, or other health condition of a human being with the use of various modalities.

CS/HB 515 amends the definition of "physical therapist" to state that a physical therapist is responsible for managing all aspects of the physical therapy care of a patient and to list services that the physical therapist must provide. The bill also amends the definition of "practice of physical therapy" to include new therapeutic techniques that a physical therapist is authorized to perform.

The bill requires a practitioner of record to review and sign a treatment plan for a patient when treatment is required beyond 42 days for a condition not previously assessed by a practitioner of record. The bill retains the current definition of practitioner of record, which includes allopathic or osteopathic physicians, chiropractors, podiatrists, or dentists.

The bill also requires a physical therapist to implement a treatment plan provided by a practitioner of record or an advanced registered nurse practitioner, or implement a treatment plan developed by the physical therapist.

The bill has an insignificant negative fiscal impact on the Department of Health and no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Physical Therapy in the United States

Physical Therapists (PTs) are licensed in all 50 states. State licensure ensures that a PT meets prescribed standards established by relevant state laws and regulatory boards.¹ Many states utilize the National Physical Therapy Exam (NPTE) which was developed by the Federation of State Boards of Physical Therapy (FSBPT), to determine if a person has met competency standards for the safe provision of nationally accepted physical therapy procedural interventions.²

The NPTE provides a common element in the evaluation of candidates so that standards will be comparable from jurisdiction to jurisdiction, and protects the public interest in having only those persons who have the requisite knowledge of physical therapy be licensed to practice physical therapy.³ To practice as a PT in the U.S., a person must earn a physical therapy degree from a state approved PT education program, pass the state approved licensure exam, and comply with other state specific licensure requirements. Currently, all entry-level PT education programs in the United States only offer the Doctor of Physical Therapy (D.P.T.) degree to all new students who enroll.⁴

Scope of Practice

Physical therapy is provided for individuals of all ages who have or may develop impairments, activity limitations, and participation restrictions related to conditions of the musculoskeletal, neuromuscular, cardiovascular, pulmonary, and/or integumentary⁵ systems. PTs are providers of rehabilitation and habilitation, performance enhancement, and prevention and risk-reduction services.⁶

There is variance among the scope of practice of PTs among the states. The NPTE categories, and the American Physical Therapy Association's (APTA) professional scope of practice guidelines,⁷ provide detailed information about the accepted techniques and procedures performed by PTs. Some examples include:

- Examining individuals with impairment, functional limitation, and disability or other health-related conditions in order to determine a diagnosis and intervention plan. Examination may include assessment of a wide variety of anatomical and psychological functions such as:
 - Muscular and cardiovascular endurance;
 - Joint mobility, range of motion, body mechanics, and posture;
 - Pain;
 - Self-care and activities of daily living;
 - Sensory ability; and
 - Arousal, attention, and cognition;

¹ American Physical Therapy Association, *Licensure*, available at <http://www.apta.org/Licensure/> (last visited March 9, 2015).

² American Physical Therapy Association, *About the National Physical Therapy Examination*, available at <http://www.apta.org/Licensure/NPTE/> (last visited March 22, 2015).

³ *Supra* fn. 1.

⁴ American Physical Therapy Association, *Physical Therapy Education Overview*, available at [http://www.apta.org/For_Prospective_Students/PT_Education/Physical_Therapist_\(PT\)_Education_Overview.aspx](http://www.apta.org/For_Prospective_Students/PT_Education/Physical_Therapist_(PT)_Education_Overview.aspx) (last visited March 8, 2015).

⁵ Integumentary system is the skin organ.

⁶ American Physical Therapy Association, *Professional Scope of Physical Therapy Practice*, available at <http://www.apta.org/ScopeOfPractice/Professional/> (last visited March 5, 2015).

⁷ *Id.*

- Alleviating impairment, functional limitation, and disabilities by designing, implementing, and modifying therapeutic interventions that include, but are not limited to:
 - Therapeutic exercise;
 - Manual therapy techniques, including mobilization or manipulation;
 - Prescription, application, and, as appropriate, fabrication of devices and equipment (assistive, adaptive, orthotic, protective, supportive, and prosthetic);⁸
 - Airway clearance techniques;⁹
 - Integumentary repair and protection techniques;¹⁰
 - Electrotherapeutic modalities;¹¹ and
 - Physical agents.^{12,13}

Referral for Treatment

The majority of states allow a PT to evaluate and treat a patient in some manner without a physician's referral.¹⁴ However, many states impose restrictions on a patient's direct access to physical therapy services, or only allow for treatment without referral under limited circumstances. Twenty states, including Florida, allow a PT to treat a patient without a physician's referral, for a limited amount of time.¹⁵ For example, in Florida, a PT may treat a patient without referral from a practitioner of record¹⁶ if the physical therapy treatment is within a 21 day timeframe, after 21 days, a practitioner of record must review and sign a patient's physical therapy treatment plan.¹⁷

PTs are trained to recognize signs and symptoms that are outside the scope of their practice. If a patient's condition is outside the scope of physical therapy practice, PTs are often mandated by state law to refer patients to other providers who can provide appropriate care for a patient's condition.¹⁸

⁸ PTs help patients apply and adjust devices and equipment such as crutches, wheelchairs, braces, slings, and supplemental oxygen. American Physical Therapy Association, *Minimum Required Skill of Physical Therapist Assistant Graduates*, available at: http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Education/MinimumRequiredSkillsPTAGrads.pdf. (last visited March 9, 2015).

⁹ Airway clearance techniques are used to remove mucus from the lungs to improve lung function. Techniques usually consist of coughing and cough stimulation techniques, breathing exercises, ventilation devices, and postural drainage which requires a patient to move into various postures to drain mucus from different lung parts to be expelled. University of Rochester Medical Center, *Airway Clearance Techniques*, available at <https://www.urmc.rochester.edu/urmcmedia/childrens-hospital/pulmonology/cystic-fibrosis/documents/airwaytechniques.pdf> (last visited March 5, 2015).

¹⁰ Integumentary or skin repair in physical therapy is most related to wound treatment. Debridement is a common method used to help wounds heal, it requires removing dead skin cells to allow healthy skin underneath to heal. Debridement may require use of sharp tools and some states require a physician's referral for this treatment. McCulloch, Joseph, *The Integumentary System-Repair and Management: An Overview*, available at: <http://web.missouri.edu/~danneckere/pt316/case/wound/integumentaryCE.pdf>. (last visited March 5, 2015).

¹¹ This type of treatment uses weak electrical currents to induce muscular stimulation. Some specific forms are biofeedback and iontophoresis. National Institutes of Health, Medline Plus, *Iontophoresis*, available at <http://www.nlm.nih.gov/medlineplus/ency/article/007293.htm>, (last visited March 5, 2015).

¹² Physical agents is a broad way of referring to hydrotherapy, light agents, heat therapy, and cryotherapy. American Physical Therapy Association, *Guidelines: Defining Physical Therapy in State Practice Acts*, available at http://www.apta.org/uploadedFiles/APTAorg/About_Us/Policies/Practice/DefiningPhysicalTherapyStatePracticeActs.pdf. (last visited March 5, 2015).

¹³ *Supra* fn. 6.

¹⁴ American Physical Therapy Association, *Summary of Direct Access Language in State Physical Therapy Practice Acts*, available at <http://www.apta.org/StateIssues/DirectAccess/FAQs/> (last visited March 8, 2015).

¹⁵ Federation of State Boards of Physical Therapy, *Jurisdiction Licensure Reference Guide*, available at <https://www.fsbpt.org/FreeResources/RegulatoryResources/LicensureReferenceGuide.aspx>. (last visited March 9, 2015).

¹⁶ A practitioner of record includes allopathic or osteopathic physicians, chiropractors, podiatrists, or dentists. Section 486.021(11)(a), F.S.

¹⁷ *Id.*

¹⁸ *Supra* fn. 14.

Physical Therapy Practice in Florida

Physical therapy practitioners are regulated by ch. 486, F.S., the Physical Therapy Practice Act (Act) and the Board of Physical Therapy (Board) under the Department of Health's Division of Medical Quality Assurance.¹⁹

A licensed PT or a licensed physical therapist assistant (PTA) must practice physical therapy in accordance with the provisions of the Act and the Board rules. Currently, there are 15,751 PTs and 8,652 PTAs who hold active licenses in Florida.²⁰

Licensure

To be licensed as a PT, an applicant must be at least 18 years old; be of good moral character; pay \$180 in fees;²¹ pass the Laws and Rules Examination offered by the FSBPT within 5 years before the date of application for licensure;²² meet the general requirements for licensure of all health care practitioners in ch. 456, F.S.; and meet one of the following requirements:

- Have graduated from an accredited PT training program and have passed the National Physical Therapy Examination (NPTE) for PTs offered by the FSBPT within 5 years before the date of application for licensure;²³
- Have graduated from a PT training program in a foreign country, have had his or her credentials deemed by the Foreign Credentialing Commission on Physical Therapy or other board-approved credentialing agency to be equivalent to those of U.S.-educated PTs and have passed the NPTE for PTs within 5 years before the date of application for licensure;²⁴ or
- Have passed a board-approved examination and holds an active license to practice physical therapy in another state or jurisdiction if the board determines that the standards for licensure in that state or jurisdiction are equivalent to those of Florida.²⁵

A PT's license is renewed every two years by submitting an application, paying an \$80 renewal fee, and submitting proof of completion of 24 hours of continuing physical therapy education. At least 1 hour of education must be on HIV/AIDS, and 2 hours must be on medical error prevention.²⁶

Section 468.081(1), F.S., authorizes a licensed PT to use the words "physical therapist" or "physiotherapist," or the letters "P.T." in connection with his or her name or place of business to denote his or her licensure. False representation of a PT license, or willful misrepresentation or false representation to obtain a PT license is unlawful. A list of titles and title abbreviations in s. 486.135, F.S., may only be used by a licensed PT.²⁷

Scope of Practice

Physical therapy is defined in s. 468.021(11), F.S., as the performance of physical therapy assessments and treatment, or prevention of any disability, injury, disease, or other health condition of human beings and rehabilitation as it relates to the use of various modalities such as: exercise,

¹⁹ MQA regulates health care practitioners to ensure the health, safety and welfare of the public. There are 22 boards and 8 councils under the MQA, and the MQA licenses 7 types of facilities and 200-plus occupations in more than 40 health care professions.

²⁰ Email correspondence with Florida Dep't of Health MQA staff on February 20, 2015 (on file with committee staff).

²¹ Section 486.041, F.S., and Rule 64B17-2.001, F.A.C.

²² Rule 64B17-3.002, F.A.C.

²³ *Id.*

²⁴ Rule 64B17-3.001, F.A.C.

²⁵ Rule 64B17-3.003, F.A.C.

²⁶ The fees vary if a PT has an inactive license and is wishing to reactivate their license. Board of Physical Therapy, *Renewal Information*, available at <http://floridasphysicaltherapy.gov/renewals/> (last visited March 8, 2015).

²⁷ Section 468.151, F.S., provides that it is a first degree misdemeanor if a person fraudulently uses the title "physical therapist," "physical therapist assistant," or any other related title without holding a valid license.

massage, ultrasound, ice, heat, water, and equipment.²⁸ A PT may use tests of neuromuscular functions as an aid to diagnose and treat various conditions.²⁹ A PT is also authorized to use electromyography, which is a diagnostic procedure used to assess the health of muscles and the nerves that control them.³⁰ A PT's professional responsibilities include:

- Interpretation of a practitioner's referral;
- Delivery of the initial physical therapy assessment of the patient;
- Identification of and documentation of precautions, special problems, contraindications;
- Development of a treatment plan for a patient including the long and short term goals;
- Implementation of or directing implementation of the treatment plan;
- Delegation of appropriate tasks;
- Direction and supervision of supportive staff in a manner appropriate for the patient's individual needs;
- Reassessment of the patient in reference to goals and, when necessary, modification of the treatment plan; and
- Collaboration with members of the health care team when appropriate.³¹

A PT must refer a patient to, or consult with, a practitioner of record if a patient's condition is found to be outside the scope of physical therapy. Section 468.021, F.S., limits treatments that PTs may provide or what procedures may be performed for diagnosing a condition. For example, a PT may not use roentgen rays and radium for diagnostic or therapeutic purposes or electricity for surgical purposes, including wound care.³² In addition, a PT may not practice chiropractic medicine, including specific spinal manipulation, and must refer a patient with the need for such to a chiropractor licensed under ch. 460, F.S.³³ Moreover, a PT is not authorized to implement a plan for a patient being treated in a hospital or an ambulatory surgical center licensed under ch. 395, F.S.³⁴

A PT is also required to keep written medical records justifying the course of treatment for a patient.³⁵

Treatment Plan and Referral for Treatment

A physical therapy treatment plan establishes the goals and specific remediation techniques that a PT will use in the course of treating a patient.³⁶ In addition to a treatment plan developed by a PT for their own use, s. 468.021(11)(a), F.S., authorizes a PT to implement a treatment plan provided by a practitioner of record or an advanced registered nurse practitioner licensed under s. 464.012, F.S. Section 486.021(11)(a), F.S., provides that a health care practitioner who is an allopathic or osteopathic physician, chiropractor, podiatrist, or dentist, that is actively engaged in practice is eligible to serve as a practitioner of record.

Currently, a PT may implement a treatment plan for a patient without a written order from a practitioner of record if the recommended treatment plan is performed within a 21 day timeframe. If the treatment plan requires treatment beyond 21 days, the condition must be assessed by a practitioner of record who is required to review and sign the treatment plan.³⁷

²⁸ PTs often help patients apply and adjust equipment such as crutches, wheelchairs, and braces.

²⁹ Section 486.021 (11), F.S.

³⁰ Specific education and practical training is required before PTs may perform electromyography. Rule 64B17-6.003. F.A.C.

³¹ Rule 64B17-6.001, F.A.C.

³² Section 486.021(11)(b), F.S.

³³ Section 486.021(11)(c), F.S.

³⁴ Section 486.021(11)(d), F.S.

³⁵ *Supra* fn. 31.

³⁶ *Id.*

³⁷ This may cause burdensome waiting periods for patients whose treatment plan requires a practitioner's approval for continuance of their physical therapy treatment. Section 486.021(11)(a), F.S.

A PT is not allowed to implement any treatment plan that, in the PT's judgment, is contraindicated. If the treatment plan was requested by a referring practitioner, the PT must immediately notify the referring practitioner that he or she is not going to follow the request and the reasons for such refusal.³⁸

Effect of Proposed Changes

Physical Therapy Practice in Florida

Practice Standards

CS/HB 515 amends the definition of "physical therapist" to require the performance of certain acts by a PT. Specifically, a PT must:

- Perform an initial evaluation of a patient;
- Create a treatment and intervention plan;
- Determine the patient's diagnosis or prognosis;
- Conduct a periodic reevaluation of each patient and related documentation;
- Document each patient visit and the patient's discharge from treatment, including the patient's response to treatment and intervention; and
- Communicate the overall plan of care with the patient or the patient's legally authorized representative.

Scope of Practice

The bill amends the definition of "practice of physical therapy" in s. 486.021(11), F.S., to authorize a PT to examine, evaluate, and test a client with:

- Mechanical, physiological, and developmental impairments;
- Functional limitations; or
- Other health and movement related conditions.

The definition of "practice of physical therapy" is also amended to authorize new therapeutic treatment procedures, including the use of:

- Functional training related to movement and mobility in self-care and activities of daily living;³⁹
- Techniques for work or community integration or reintegration;
- Manual therapy, without the use of a filiform needle,⁴⁰ including soft tissue and joint mobilization or manipulation, with the exception of specific chiropractic manipulation;
- Therapeutic massage;
- Airway clearance techniques;
- Integumentary protection and repair techniques, including debridement;
- Physical agents;⁴¹
- Patient-related instruction; and
- Apparatus and equipment.

³⁸ Rule 64B17-6.001, F.A.C.

³⁹ Physical therapists instruct patients on how to perform daily activities with supportive equipment such as wheelchairs or crutches. They also instruct patients on how to perform daily activities with physical limitations from injury or surgical procedures.

⁴⁰ Manual therapy without the use of a filiform needle means that PTs will not be able to perform acupuncture procedures. Filiform needles are solid, unlike hollow hypodermic needles. The University of Minnesota, Center for Spirituality and Healing, *Glossary*, available at <http://www.takingcharge.csh.umn.edu/glossary> (last visited March 22, 2015).

⁴¹ *Supra* fn 12.

The bill removes the authority of PTs to use specific modes of treatment in s. 468.021(11), F.S., including the use of radiant energy and ultrasound. However, the bill authorizes PTs to use “mechanical and electrotherapeutic modalities,” which would include the deleted modes of treatment.

The bill also authorizes PTs to engage in physical injury, disability, and impairment prevention through methods such as maintenance of fitness, health, and wellness in patients. PTs are also authorized to engage in administration, consultation, education, and research.

Treatment Plan and Referral for Treatment

The bill retains the requirement that a PT consult with, or refer to, a practitioner of record, if a patient’s condition is found to be outside the scope of practice of physical therapy, but moves the requirement to place it in the definition of “physical therapist.” The bill requires that a PT have a practitioner of record review and sign a patient’s treatment plan if treatment is required beyond 42 days, instead of the current 21 days, for a condition not previously assessed by a practitioner of record. The bill retains the current definition of practitioner of record, which includes allopathic (ch. 458, F.S.) or osteopathic physicians (ch. 459, F.S.), chiropractors (ch. 460, F.S.), podiatrists (ch. 461, F.S.), or dentists (ch. 466, F.S.).

The bill requires a PT to implement a treatment plan provided by a practitioner of record or an advanced registered nurse practitioner licensed under s. 464.012, F.S., or implement a treatment plan developed by the PT.

The bill removes the requirement that a PT refer a patient to a chiropractor licensed under ch. 460, F.S., for specific spinal manipulation. However, the bill prohibits a PT from practicing chiropractic medicine, including spinal manipulation, and, as previously mentioned, requires a PT to refer a patient to a practitioner of record if the patient’s condition is outside the scope of physical therapy.

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

B. SECTION DIRECTORY:

Section 1. Amends s. 486.021, F.S., relating to definitions.

Section 2. Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH may incur a recurring increase in workload associated with additional practitioner complaints, which current resources are adequate to absorb.⁴²

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 12, 2015, the Health Quality Subcommittee adopted a strike all amendment to the bill and reported the bill favorably as a committee substitute. The amendment:

- Requires physical therapists to have a practitioner of record review and sign a treatment plan for a patient when treatment is required beyond 42 days, instead of 21 days, for a condition not previously assessed by a practitioner of record.
- Clarifies that physical therapists may only perform certain techniques, including:
 - Functional training related to movement and mobility;
 - Manual therapy without the use of a filiform needle; and
 - The use of apparatus and equipment while practicing physical therapy techniques.
- Requires a physical therapist to implement a treatment plan developed by certain practitioners or a treatment plan developed by the physical therapist.
- Removes the authority of the Board of Physical Therapy to issue advisory opinions.
- Reinstates current law pertaining to the use of certain titles and title abbreviations by physical therapists or the unlawful use of such titles and abbreviations by others.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

1 A bill to be entitled
 2 An act relating to physical therapy; amending s.
 3 486.021, F.S.; revising the definitions of the terms
 4 "physical therapist" and "practice of physical
 5 therapy"; providing an effective date.

6
 7 Be It Enacted by the Legislature of the State of Florida:

8
 9 Section 1. Subsections (5) and (11) of section 486.021,
 10 Florida Statutes, are amended to read:

11 486.021 Definitions.—In this chapter, unless the context
 12 otherwise requires, the term:

13 (5) "Physical therapist" means a person who is licensed
 14 and who practices physical therapy in accordance with the
 15 provisions of this chapter. A physical therapist is responsible
 16 for managing all aspects of the physical therapy care of a
 17 patient. A physical therapist shall:

18 (a) Provide the initial evaluation, determination of
 19 diagnosis, prognosis, treatment and intervention plan, and
 20 documentation of each patient visit.

21 (b) Periodically reevaluate each patient and related
 22 documentation.

23 (c) Document a patient's discharge from treatment,
 24 including the patient's response to treatment and intervention.

25 (d) Communicate the overall plan of care to the patient or
 26 the patient's legally authorized representative.

27 (e) Consult with or refer the patient to a practitioner of
 28 record if the patient's condition is found to be outside the
 29 scope of physical therapy. For purposes of this section, a
 30 health care practitioner licensed under chapter 458, chapter
 31 459, chapter 460, chapter 461, or chapter 466 and engaged in
 32 active practice is eligible to serve as a practitioner of
 33 record.

34 (f) Obtain a practitioner of record who will review and
 35 sign a plan of treatment when physical therapy treatment for a
 36 patient is required beyond 42 days for a condition not
 37 previously assessed by a practitioner of record.

38 (11)(a) "Practice of physical therapy" means:

39 1. Examining, evaluating, and testing patients and clients
 40 with mechanical, physiological, and developmental impairments;
 41 functional limitations; disabilities; or other health and
 42 movement-related conditions in order to determine a diagnosis,
 43 prognosis, treatment and intervention plan, and to reevaluate
 44 the ongoing effect of treatment.

45 2. Alleviating impairments, functional limitations, and
 46 disabilities by designing and implementing treatments that may
 47 include, but are not limited to, therapeutic exercise;
 48 functional training related to movement and mobility in self-
 49 care and in home; community or work integration or
 50 reintegration; manual therapy without the use of a filiform
 51 needle, including soft tissue and joint mobilization or
 52 manipulation, with the exception of specific chiropractic

53 manipulation; therapeutic massage; airway clearance techniques;
 54 integumentary protection and repair techniques; debridement and
 55 wound care; physical agents or modalities; mechanical and
 56 electrotherapeutic modalities; and patient-related instruction.

57 3. Reducing the risk of injury, impairment, functional
 58 limitation, and disability through methods including, but not
 59 limited to, the promotion and maintenance of fitness, health,
 60 and wellness in patients of all ages.

61 4. Engaging in administration, consultation, education,
 62 and research.

63 5. Using apparatus and equipment in the application of
 64 this subsection the performance of physical therapy assessments
 65 and the treatment of any disability, injury, disease, or other
 66 health condition of human beings, or the prevention of such
 67 disability, injury, disease, or other condition of health, and
 68 rehabilitation as related thereto by the use of the physical,
 69 chemical, and other properties of air; electricity; exercise;
 70 massage; the performance of acupuncture only upon compliance
 71 with the criteria set forth by the Board of Medicine, when no
 72 penetration of the skin occurs; the use of radiant energy,
 73 including ultraviolet, visible, and infrared rays; ultrasound;
 74 water; the use of apparatus and equipment in the application of
 75 the foregoing or related thereto; the performance of tests of
 76 neuromuscular functions as an aid to the diagnosis or treatment
 77 of any human condition; or the performance of electromyography
 78 as an aid to the diagnosis of any human condition only upon

79 ~~compliance with the criteria set forth by the Board of Medicine.~~

80 (b)~~(a)~~ A physical therapist shall ~~may~~ implement a plan of
 81 treatment developed by the physical therapist for a patient or
 82 provided for a patient by a practitioner of record or by an
 83 advanced registered nurse practitioner licensed under s.
 84 464.012. ~~The physical therapist shall refer the patient to or~~
 85 ~~consult with a practitioner of record if the patient's condition~~
 86 ~~is found to be outside the scope of physical therapy. If~~
 87 ~~physical therapy treatment for a patient is required beyond 21~~
 88 ~~days for a condition not previously assessed by a practitioner~~
 89 ~~of record, the physical therapist shall obtain a practitioner of~~
 90 ~~record who will review and sign the plan. For purposes of this~~
 91 ~~paragraph, a health care practitioner licensed under chapter~~
 92 ~~458, chapter 459, chapter 460, chapter 461, or chapter 466 and~~
 93 ~~engaged in active practice is eligible to serve as a~~
 94 ~~practitioner of record.~~

95 (c)~~(b)~~ The use of roentgen rays and radium for diagnostic
 96 and therapeutic purposes and the use of electricity for surgical
 97 purposes, including cauterization, are not "physical therapy"
 98 for purposes of this chapter.

99 (d)~~(e)~~ The practice of physical therapy does not authorize
 100 a physical therapy practitioner to practice chiropractic
 101 medicine as defined in chapter 460, including specific spinal
 102 manipulation. ~~For the performance of specific chiropractic~~
 103 ~~spinal manipulation, a physical therapist shall refer the~~
 104 ~~patient to a health care practitioner licensed under chapter~~

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2015

105 | ~~460.~~

106 | (e)~~(d)~~ This subsection does not authorize a physical
 107 | therapist to implement a plan of treatment for a patient
 108 | currently being treated in a facility licensed pursuant to
 109 | chapter 395.

110 | Section 2. This act shall take effect July 1, 2015.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee
 3 Representative Cummings offered the following:

Amendment (with title amendment)

6 Remove everything after the enacting clause and insert:
 7 Section 1. Subsection (11) of section 486.021, Florida
 8 Statutes, is amended to read:

9 486.021 Definitions.—In this chapter, unless the context
 10 otherwise requires, the term:

11 (11) "Practice of physical therapy" means the performance
 12 of physical therapy assessments and the treatment of any
 13 disability, injury, disease, or other health condition of human
 14 beings, or the prevention of such disability, injury, disease,
 15 or other condition of health, and rehabilitation as related
 16 thereto by the use of the physical, chemical, and other
 17 properties of air; electricity; exercise; massage; the



Amendment No.

18 performance of acupuncture only upon compliance with the
19 criteria set forth by the Board of Medicine, when no penetration
20 of the skin occurs; the use of radiant energy, including
21 ultraviolet, visible, and infrared rays; ultrasound; water; the
22 use of apparatus and equipment in the application of the
23 foregoing or related thereto; the performance of tests of
24 neuromuscular functions as an aid to the diagnosis or treatment
25 of any human condition; or the performance of electromyography
26 as an aid to the diagnosis of any human condition only upon
27 compliance with the criteria set forth by the Board of Medicine.

28 (a) A physical therapist may implement a plan of treatment
29 developed by the physical therapist for a patient or provided
30 for a patient by a practitioner of record, ~~or~~ by an advanced
31 registered nurse practitioner licensed under s. 464.012, or by a
32 physician licensed in another state. The physical therapist
33 shall refer the patient to or consult with a practitioner of
34 record if the patient's condition is found to be outside the
35 scope of physical therapy. If physical therapy treatment for a
36 patient is required beyond 42 ~~21~~ days for a condition not
37 previously assessed by a practitioner of record, or by a
38 physician licensed in another state, the physical therapist
39 shall obtain a practitioner of record who will review and sign
40 the plan. For purposes of this paragraph, a health care
41 practitioner licensed under chapter 458, chapter 459, chapter
42 460, chapter 461, or chapter 466 and engaged in active practice
43 is eligible to serve as a practitioner of record.

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Amendment No.

44 (b) The use of roentgen rays and radium for diagnostic and
45 therapeutic purposes and the use of electricity for surgical
46 purposes, including cauterization, are not "physical therapy"
47 for purposes of this chapter.

48 (c) The practice of physical therapy does not authorize a
49 physical therapy practitioner to practice chiropractic medicine
50 as defined in chapter 460, including specific spinal
51 manipulation. For the performance of specific chiropractic
52 spinal manipulation, a physical therapist shall refer the
53 patient to a health care practitioner licensed under chapter
54 460.

55 (d) This subsection does not authorize a physical
56 therapist to implement a plan of treatment for a patient
57 currently being treated in a facility licensed pursuant to
58 chapter 395.

59 Section 2. Subsection (1) of section 486.081, Florida
60 Statutes, is amended to read:

61 486.081 Physical therapist; issuance of license without
62 examination to person passing examination of another authorized
63 examining board; fee.—

64 (1) The board may cause a license to be issued through the
65 department without examination to any applicant who presents
66 evidence satisfactory to the board of having passed the American
67 Registry Examination prior to 1971 or an examination in physical
68 therapy before a similar lawfully authorized examining board of
69 another state, the District of Columbia, a territory, or a



Amendment No.

70 foreign country, if the standards for licensure in physical
71 therapy in such other state, district, territory, or foreign
72 country are determined by the board to be as high as those of
73 this state, as established by rules adopted pursuant to this
74 chapter. Any person who holds a license pursuant to this section
75 may use the words "physical therapist" or "physiotherapist," or
76 the letters "P.T.," in connection with her or his name or place
77 of business to denote her or his licensure hereunder. Any person
78 who holds a license pursuant this section and has obtained a
79 doctoral degree in physical therapy may use the letters "D.P.T."
80 and the letters "P.T." A physical therapist who holds a degree
81 of Doctor of Physical Therapy may not use the title "doctor"
82 without also clearly informing the public of his or her
83 profession as a physical therapist.

84 Section 3. Subsection (1) of section 486.135, Florida
85 Statutes, is amended to read:

86 486.135 False representation of licensure, or willful
87 misrepresentation or fraudulent representation to obtain
88 license, unlawful.—

89 (1)(a) It is unlawful for any person who is not licensed
90 under this chapter as a physical therapist, or whose license has
91 been suspended or revoked, to use in connection with her or his
92 name or place of business the words "physical therapist,"
93 "physiotherapist," "physical therapy," "physiotherapy,"
94 "registered physical therapist," or "licensed physical
95 therapist"; or the letters "P.T.," or "D.P.T." ~~"Ph.T.,"~~



Amendment No.

96 ~~"R.P.T.," or "L.P.T.";~~ or any other words, letters,
 97 abbreviations, or insignia indicating or implying that she or he
 98 is a physical therapist or to represent herself or himself as a
 99 physical therapist in any other way, orally, in writing, in
 100 print, or by sign, directly or by implication, unless physical
 101 therapy services are provided or supplied by a physical
 102 therapist licensed in accordance with this chapter.

103 (b) It is unlawful for any person who is not licensed
 104 under this chapter as a physical therapist assistant, or whose
 105 license has been suspended or revoked, to use in connection with
 106 her or his name the words "physical therapist assistant,"
 107 ~~"licensed physical therapist assistant," "registered physical~~
 108 ~~therapist assistant," or "physical therapy technician";~~ or the
 109 letters "P.T.A.," ~~"L.P.T.A.," "R.P.T.A.," or "P.T.T.";~~ or any
 110 other words, letters, abbreviations, or insignia indicating or
 111 implying that she or he is a physical therapist assistant or to
 112 represent herself or himself as a physical therapist assistant
 113 in any other way, orally, in writing, in print, or by sign,
 114 directly or by implication.

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

Remove everything before the enacting clause and insert:



Amendment No.

121 An act relating to physical therapy; amending s. 486.021, F.S.;
122 revising the definition of the term "practice of physical
123 therapy"; amending s. 486.081, F.S.; revising the letters a
124 licensed physical therapist may use in connection with her or
125 his name or place of business; prohibiting a physical therapist
126 with specified doctorate degrees from using the title "doctor"
127 without informing the public of his or her profession as a
128 physical therapist; amending s. 486.135, F.S.; revising the
129 terms prohibited from use by a person who is not licensed as a
130 physical therapist or physical therapist assistant; providing an
131 effective date.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee

3 Representative Renuart offered the following:

4
5 **Amendment to Amendment (951359) by Representative Cummings**

6 Remove line 36 of the amendment and insert:

7 patient is required beyond 21 days for a condition not

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 633 Informed Patient Consent
SPONSOR(S): Sullivan
TIED BILLS: IDEN./SIM. **BILLS:** SB 724

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 4 N	McElroy	O'Callaghan
2) Judiciary Committee	12 Y, 6 N	Weber	Havlicak
3) Health & Human Services Committee		McElroy <i>CM</i>	Calamas <i>CC</i>

SUMMARY ANALYSIS

Section 390.0111, F.S., currently requires a physician performing an abortion, or a referring physician, to obtain the woman's written and informed consent before performing the procedure. To obtain informed consent, the physician, or referring physician, must orally and in person, inform the woman of the nature and risks of undergoing or not undergoing the proposed procedure and the probable gestational age of the fetus.

HB 633 requires the physician performing the abortion, or the referring physician, to be present in the same room as the woman when providing information to obtain informed consent. The bill also requires this information to be provided to the woman at least 24 hours before the procedure is performed.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Federal Case Law on Abortion

Right to Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*¹, was decided by the U.S. Supreme Court. Using strict scrutiny, the Court determined that a woman's right to an abortion is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest and must be narrowly drawn.² In 1992, the fundamental holding of *Roe* was upheld by the U.S. Supreme Court in *Planned Parenthood v. Casey*.³

The Viability Standard

In *Roe v. Wade*, the U.S. Supreme Court established a rigid trimester framework dictating when, if ever, states can regulate abortion.⁴ The Court held that states could not regulate abortions during the first trimester of pregnancy.⁵ With respect to the second trimester, the Court held that states could only enact regulations aimed at protecting the mother's health, not the fetus's life. Therefore, no ban on abortions is permitted during the second trimester. The state's interest in the life of the fetus becomes sufficiently compelling only at the beginning of the third trimester, allowing it to prohibit abortions. Even then, the Court requires states to permit an abortion in circumstances necessary to preserve the health or life of the mother.⁶

The current viability standard is set forth in *Planned Parenthood v. Casey*.⁷ Recognizing that medical advancements in neonatal care can advance viability to a point somewhat earlier than the third trimester, the U.S. Supreme Court rejected the trimester framework and, instead, limited the states' ability to regulate abortion pre-viability. Thus, while upholding the underlying holding in *Roe*, which authorizes states to "regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother[.]"⁸ the Court determined that the line for this authority should be drawn at "viability," because "there may be some medical developments that affect the precise point of viability . . . but this is an imprecision within tolerable limits given that the medical community and all those who must apply its discoveries will continue to explore the matter."⁹ Furthermore, the Court recognized that "[i]n some broad sense it might be said that a woman who fails to act before viability has consented to the State's intervention on behalf of the developing child."¹⁰

¹ *Roe v. Wade*, 410 U.S. 113 (1973).

² *Id.*

³ *Casey*, 505 U.S. 833 (1992).

⁴ *Roe*, 410 U.S. 113 (1973).

⁵ *Id.* at 163-64.

⁶ *Id.* at 164-165.

⁷ *Planned Parenthood of SE Pa. v. Casey*, 505 U.S. 833 (1992).

⁸ *See Roe*, 410 U.S. at 164-65.

⁹ *See Casey*, 505 U.S. at 870.

¹⁰ *Id.*

Undue Burden

In *Planned Parenthood v. Casey*, the U.S. Supreme Court established the undue burden standard for determining whether a law places an impermissible obstacle to a woman's right to an abortion. The Court held that health regulations which impose undue burdens on the right to abortion are invalid.¹¹ State regulation imposes an "undue burden" on a woman's decision to have an abortion if it has the purpose or effect of placing a substantial obstacle in the path of the woman who seeks the abortion of a nonviable fetus.¹² However, not every law, which makes the right to an abortion more difficult to exercise, is an infringement of that right.¹³

Informed Consent

A state may require informed consent prior to an abortion unless it creates an undue burden. The Court in *Casey* held that a state, in order to promote its profound interest in potential life throughout pregnancy, may enact measures to ensure that the woman's choice to have an abortion is informed.¹⁴ However, these measures will only be valid as long as the state's purpose is to persuade the woman to choose childbirth over abortion and does not create an undue burden on her right to an abortion.¹⁵

The informed consent requirement at issue in *Casey* required a 24-hour period¹⁶ between the provision of the information deemed necessary for informed consent and the abortion. The Court held that facially the waiting period was a reasonable measure to implement a state's interest in protecting the life of the unborn and does not amount to an undue burden.¹⁷ Whether the waiting period created an undue burden in application was a question of fact. The Court, relying on the district court's findings, acknowledged that the 24-hour requirement would:¹⁸

- Require a woman seeking an abortion to make at least two visits¹⁹ to the doctor. For a woman traveling long distances this could often result in a delay of greater than 24 hours;
- Increase the exposure of women seeking abortions to "the harassment and hostility of anti-abortion protestors demonstrating outside a clinic;"
- Be "particularly burdensome" for those women who have the fewest financial resources, those who must travel long distances, and those who have difficulty explaining their whereabouts to husbands, employers, or others; and
- Limit a physician's discretion.

¹¹ *Id.* at 878.

¹² *Id.* at 877.

¹³ *Id.* at 873.

¹⁴ *Id.* at 878.

¹⁵ *Id.*

¹⁶ Currently 25 states have waiting periods of 24 hours or greater. The states are: Alabama (Ala. C. §§ 26-23A-4); Arizona (Ariz. Rev. Stat. § 36-2153); Arkansas (Ark. C. § 20-16-903); Georgia (Ga. C. § 31-9A-3); Idaho (Id. C. §§ 18-604, 609); Kansas (Kan. Stat. § 65-6709); Kentucky (Ken. Rev. Stat. § 311.725); Louisiana (Louis. Rev. Stat. § 1299.35.6); Michigan (Mich. Compiled L. § 333.17015); Minnesota (Minn. Stat. § 145.4242); Mississippi (Miss. C. § 41-41-33); Missouri (§§ 188.027, 188.039); Nebraska (Neb. Rev. Stat. § 28-327); North Carolina (N. Car. Gen. Stat. § 90-21.82); North Dakota (N. Dak. C. §§ 14-02.1-02, 1-03); Ohio (Ohio Rev. C. § 2317.56); Oklahoma (Okla. Stat. 63 § 1-738.2); Pennsylvania (Penn. Stat. 18 § 3205); South Carolina (Cod. L. S. Car. § 44-41-330); South Dakota (S. Dak. Cod. L. § 34-23A-10.1); Texas (Tex. Health & Safety C. § 171.012); Utah (Utah Code Ann. 76-7-305); Virginia (Va. C. § 18.2-76); West Virginia (W. Va. C. § 16-2I-2); and, Wisconsin (Wis. Stat. § 253.10). However, 4 states have enjoined laws requiring a waiting period before performance or inducement of an abortion – Delaware (*Planned Parenthood of Del. v. Brady* (D. Del. 2003)); Massachusetts (*Planned Parenthood League of Mass. v. Bellotti* (1st Cir. 1981)); Montana; and Tennessee (*Planned Parenthood of Middle Tenn. v. Sundquist* (Tenn. 2000)).

¹⁷ *See Casey*, 505 U.S. at 885.

¹⁸ *Id.* at 885-86.

¹⁹ 11 states currently have waiting period requirements that necessitate two visits to the clinic. Arizona (Ariz. Rev. Stat. § 36-2153); Indiana (Ind. C. § 16-34-2-1.1); Louisiana (Louis. Rev. Stat. § 1299.35.6); Mississippi (Miss. C. § 41-41-33); Missouri (§§ 188.027, 188.039); Ohio (Ohio Rev. C. § 2317.56); South Dakota (§ 34-23A-10.1); Texas (Tex. Health & Safety C. § 171.012); Utah (Utah Code Ann. 76-7-305); Virginia (Va. C. § 18.2-76); and, Wisconsin (Wis. Stat. § 253.10).

The Court found that, although the waiting period has the effect of creating a particular burden by “increasing the cost and risk of delay of abortions,” it does not constitute an undue burden.²⁰ The Court thus held that a 24-hour waiting period was permissible as it did not create an undue burden facially or in application based upon the record before it.²¹

The Medical Emergency Exception

In *Doe v. Bolton*, the U.S. Supreme Court was faced with determining, among other things, whether a Georgia statute criminalizing abortions (pre- and post-viability), except when determined to be necessary based upon a physician’s “best clinical judgment,” was unconstitutionally void for vagueness for inadequately warning a physician under what circumstances an abortion could be performed.²² In its reasoning, the Court agreed with the district court decision that the exception was not unconstitutionally vague, by recognizing that:

[T]he medical judgment may be exercised in the light of all factors—physical, emotional, psychological, familial, and the woman’s age-relevant to the well-being of the patient. All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment.²³

This broad interpretation of what constitutes a medical emergency was later tested in *Casey*²⁴, albeit in a different context. One question before the Supreme Court in *Casey* was whether the medical emergency exception to a 24-hour waiting period for an abortion was too narrow in that there were some potentially significant health risks that would not be considered “immediate.”²⁵ The exception in question provided that a medical emergency is:

[T]hat condition which, on the basis of the physician’s good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a delay will create serious risk of substantial and irreversible impairment of a major bodily function.²⁶

In evaluating the more objective standard under which a physician is to determine the existence of a medical emergency, the Court in *Casey* determined that the exception would not significantly threaten the life and health of a woman and imposed no undue burden on the woman’s right to have an abortion.²⁷

Florida Law on Abortion

Right to Abortion

Florida affords greater privacy rights to its citizens than those provided under the U.S. Constitution. While the federal Constitution traditionally shields enumerated and implied individual liberties from state or federal intrusion, the federal Court has long held that the state

²⁰ *Casey*, 505 U.S. at 886-87.

²¹ *Id.*

²² *Doe*, 410 U.S. at 179 (1973). Other exceptions, such as in cases of rape and when, “[t]he fetus would very likely be born with a grave, permanent, and irremediable mental or physical defect.” *Id.* at 183. See also, *U.S. v. Vuitich*, 402 U.S. 62, 71-72 (1971) (determining that a medical emergency exception to a criminal statute banning abortions would include consideration of the mental health of the pregnant woman).

²³ *Doe*, 410 U.S. at 192.

²⁴ *Casey*, 505 U.S. 833 (1992).

²⁵ *Id.* at 880.

²⁶ *Id.* at 879 (quoting 18 Pa. Cons. Stat. § 3203 (1990)).

²⁷ *Id.* at 880.

constitutions may provide even greater protections.²⁸ In 1980, Florida amended its Constitution to include Article I, s. 23 which creates an express right to privacy:

Every natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.²⁹

This amendment is an independent, freestanding constitutional provision which declares the fundamental right to privacy and provides greater privacy rights than those implied by the federal Constitution.³⁰

The Florida Supreme Court has recognized Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."³¹ In *In re T.W.*, the Florida Supreme Court ruled that:

[P]rior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests . . . Under our Florida Constitution, the state's interest becomes compelling upon viability . . . Viability under Florida law occurs at that point in time when the fetus becomes capable of meaningful life outside the womb through standard medical measures.³²

The court recognized that after viability, the state can regulate abortion in the interest of the unborn child if the mother's health is not in jeopardy.³³

Abortion Regulation

In Florida, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.³⁴ An abortion must be performed by a physician³⁵ licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.³⁶

Florida law prohibits abortions after viability, as well as during the third trimester, unless a medical exception exists. Section 390.01112(1), F.S., prohibits an abortion from being performed if a physician determines that, in reasonable medical judgment, the fetus has achieved viability. Viability is defined as the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.³⁷ Section 390.0111, F.S., prohibits an abortion from being performed during the third trimester.³⁸ Exceptions to both of these prohibitions exist if:

²⁸ *In re T.W.*, 551 So.2d 1186, 1191 (Fla. 1989).

²⁹ *Id.*

³⁰ *Id.* at 1191-92.

³¹ *Id.* at 1192.

³² *Id.* at 1193-94.

³³ *Id.* at 1194.

³⁴ Section 390.011(1), F.S.

³⁵ Section 390.011(2), F.S.

³⁶ Section 390.011(8), F.S.

³⁷ Section 390.011(12), F.S.

³⁸ Section 390.011(11), F.S., defines the third trimester to mean the weeks of pregnancy after the 24th week of pregnancy.

- Two physicians certify in writing that, in reasonable medical judgment, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition; or
- One physician certifies in writing that, in reasonable medical judgment, there is a medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition, and another physician is not available for consultation.³⁹

A physician must obtain an informed and voluntary consent for an abortion from a woman before an abortion is performed, unless an emergency exists. Consent is considered voluntary and informed if the physician who is to perform the procedure, or the referring physician, orally and in person, informs the woman of the nature and risks of undergoing or not undergoing the proposed procedure and the probable gestational age of the fetus at the time the termination of pregnancy is to be performed.⁴⁰ The probable gestational age must be verified by an ultrasound.⁴¹ The woman must be offered the opportunity to view the images and hear an explanation of them.⁴² If the woman refuses this right, she must acknowledge the refusal in writing.⁴³ The woman must acknowledge, in writing and prior to the abortion, that she has been provided with all information consistent with these requirements.⁴⁴

Anyone who violates laws applicable to an abortion during viability or in the third trimester commits a third degree felony.⁴⁵ Additionally, any health care practitioner who fails to comply with such laws is subject to disciplinary action under the applicable practice act and under s. 456.072, F.S.⁴⁶

The Agency for Health Care Administration (AHCA) licenses and regulates abortion clinics in the state, pursuant to ch. 390, F.S., and part II of ch. 408, F.S.⁴⁷ All abortion clinics and physicians performing abortions are subject to the following requirements:

- An abortion may only be performed in a validly licensed hospital, abortion clinic, or in a physician's office;⁴⁸
- An abortion clinic must be operated by a person or public body with a valid and current license;⁴⁹
- An abortion performed during viability or in the third trimester may only be performed in a hospital;⁵⁰
- If a termination of pregnancy is performed in the third trimester, the physician performing the termination of pregnancy must exercise the same degree of professional skill, care, and diligence to preserve the life and health of the fetus which the physician would be required to exercise in order to preserve the life and health of a fetus intended to be born

³⁹ Sections 390.0111(1)(a) and (b) and 390.01112(1)(a) and (b), F.S.

⁴⁰ Section 390.0111(3)(a), F.S. This requirement applies except in the case of a medical emergency.

⁴¹ Section 390.0111(3)(a)1.b.II, F.S.

⁴² Section 390.0111(3)(a)1.b.III, F.S.

⁴³ Section 390.0111(3)(a)(3), F.S.

⁴⁴ *Id.*

⁴⁵ Section 390.0111(10)(a), F.S.

⁴⁶ Section 390.0111(13), F.S. The Department of Health and its professional boards regulate health care practitioners under ch. 456, F.S., and various individual practice acts. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

⁴⁷ Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.

⁴⁸ Section 797.03 (1), F.S.; this section provides an exception for an emergency care situation.

⁴⁹ Section 797.03 (2), F.S.

⁵⁰ Section 797.03(3), F.S. Per s. 797.03(4), F.S., the violation of any of these provisions results in a second degree misdemeanor.

and not aborted, unless doing so conflicts with preserving the life and health of the pregnant woman;⁵¹

- Experimentation on a live fetus is prohibited prior to or subsequent to any termination of pregnancy procedure;⁵²
- Except when there is a medical emergency, an abortion may only be performed after a patient has given voluntary and written informed consent;⁵³
- Consent includes verification of the probable gestational age via ultrasound imaging;⁵⁴
- Fetal remains are to be disposed of in a sanitary and appropriate manner;⁵⁵ and
- Actual notice⁵⁶ must be given 48 hours before performing an abortion on a minor or constructive notice⁵⁷ must be given at least 72 hours before performing an abortion on a minor, unless waived by a parent or otherwise ordered by a judge.⁵⁸

In addition, pursuant to s. 390.012, F.S., AHCA must prescribe by rule standards for clinics that perform or claim to perform abortions after the first trimester that include:

- Adequate private space for interviewing, counseling, and medical evaluations;
- Dressing rooms for staff and patients;
- Appropriate lavatory areas;
- Areas for preprocedure hand washing;
- Private procedure rooms;
- Adequate lighting and ventilation for procedures;
- Surgical or gynecological examination tables and other fixed equipment;
- Postprocedure recovery rooms that are equipped to meet the patients' needs;
- Emergency exits to accommodate a stretcher or gurney;
- Areas for cleaning and sterilizing instruments;
- Adequate areas for the secure storage of medical records and necessary equipment and supplies; and
- Conspicuous display of the clinic's current license issued by AHCA.⁵⁹

AHCA has the authority to impose a fine against clinics that are in violation of ch. 390, part II of ch. 408, or agency rules.⁶⁰

Florida Abortion Statistics

In 2014, DOH reported that there were 220,138 live births in the state of Florida.⁶¹ In the same year, AHCA reported that there were 72,073 abortion procedures⁶² performed in the state.⁶³ Of those performed:

⁵¹ Section 390.0111(4), F.S.

⁵² Section 390.0111(6), F.S.

⁵³ Section 390.0111(3), F.S. A physician violating this provision is subject to disciplinary action.

⁵⁴ Section 390.0111(3)(a)1.b., F.S.

⁵⁵ Section 390.0111(7), F.S. A person who improperly disposes of fetal remains commits a second degree misdemeanor.

⁵⁶ Section 390.01114(2)(a), F.S., defines "actual notice as" notice that is given directly, in person or by telephone, to a parent or legal guardian of a minor, by a physician, at least 48 hours before the inducement or performance of a termination of pregnancy, and documented in the minor's files.

⁵⁷ Section 390.01114(2)(c), F.S., defines "constructive notice" as notice that is given in writing, signed by the physician, and mailed at least 72 hours before the inducement or performance of the termination of pregnancy, to the last known address of the parent or legal guardian of the minor, by first-class mail and by certified mail, return receipt requested, and delivery restricted to the parent or legal guardian. After the 72 hours have passed, delivery is deemed to have occurred.

⁵⁸ Section 390.01114(3), F.S. A physician who violates this provision is subject to disciplinary action.

⁵⁹ Section 390.012(3)(a)1., F.S. Rules related to abortion are found in ch. 59A-9, F.A.C.

⁶⁰ Section 390.018, F.S.

⁶¹ Correspondence from the Department of Health to the House of Representatives Health Quality Subcommittee dated February 26, 2015, on file with Health Quality Subcommittee Staff.

- 65,902 were performed in the first trimester (12 weeks and under);
- 6,171 were performed in the second trimester (13 to 24 weeks); and
- None were performed in the third trimester (25 weeks and over).⁶⁴

The majority of the procedures (65,210) were elective.⁶⁵ The remainder of the abortions were performed due to:

- Emotional or psychological health of the mother (76);
- Physical health of the mother that was not life endangering (158);
- Life endangering physical condition (69);
- Rape (749);
- Serious fetal genetic defect, deformity, or abnormality (560); and
- Social or economic reasons (5,115).⁶⁶

Effect of Proposed Changes

HB 633 requires the physician performing the abortion, or the referring physician, to be physically present in the same room as the pregnant woman when providing information to obtain informed consent. The bill also requires this information to be provided to the woman by the physician while the physician is physically present in the same room as the woman at least 24 hours before the termination of pregnancy is performed.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 390.0111, F.S., relating to termination of pregnancies.

Section 2: Provides for an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

⁶² There are currently 65 licensed abortion clinics in Florida, of which 44 (67.7%) are licensed to provide both 1st and 2nd trimester abortions and 21 (32.3%) are licensed to provide only 1st trimester abortions. *Id.*

⁶³ Section 390.0112(1), F.S., currently requires the director of any medical facility in which any pregnancy is terminated to submit a monthly report to AHCA that contains the number of procedures performed, the reason for same, the period of gestation at the time such procedures were performed, and the number of infants born alive during or immediately after an attempted abortion.

⁶⁴ Reported Induced Terminations of Pregnancy (ITOP) by Reason, By Weeks of Gestation for Calendar Year 2014, AHCA, on file with the Health Quality Subcommittee Staff.

⁶⁵ *Id.*

⁶⁶ *Id.*

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The 24-hour waiting period could have an indeterminable negative fiscal impact on women seeking abortions associated with traveling to the clinic on separate occasions.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to informed patient consent; amending
3 s. 390.0111, F.S.; revising conditions for the
4 voluntary and informed consent to a termination of
5 pregnancy; reenacting s. 390.012(3)(d), F.S., relating
6 to Agency for Health Care Administration rules
7 regarding medical screening and evaluation of abortion
8 clinic patients, to incorporate the amendment made by
9 this act to s. 390.0111, F.S., in a reference thereto;
10 providing an effective date.

11
12 Be It Enacted by the Legislature of the State of Florida:

13
14 Section 1. Paragraph (a) of subsection (3) of section
15 390.0111, Florida Statutes, is amended to read:

16 390.0111 Termination of pregnancies.—

17 (3) CONSENTS REQUIRED.—A termination of pregnancy may not
18 be performed or induced except with the voluntary and informed
19 written consent of the pregnant woman or, in the case of a
20 mental incompetent, the voluntary and informed written consent
21 of her court-appointed guardian.

22 (a) Except in the case of a medical emergency, consent to
23 a termination of pregnancy is voluntary and informed only if:

- 24 1. The physician who is to perform the procedure, or the
- 25 referring physician, has, at a minimum, orally, while physically
- 26 present in the same room, and at least 24 hours before the

27 | procedure ~~in person~~, informed the woman of:

28 | a. The nature and risks of undergoing or not undergoing
 29 | the proposed procedure that a reasonable patient would consider
 30 | material to making a knowing and willful decision of whether to
 31 | terminate a pregnancy.

32 | b. The probable gestational age of the fetus, verified by
 33 | an ultrasound, at the time the termination of pregnancy is to be
 34 | performed.

35 | (I) The ultrasound must be performed by the physician who
 36 | is to perform the abortion or by a person having documented
 37 | evidence that he or she has completed a course in the operation
 38 | of ultrasound equipment as prescribed by rule and who is working
 39 | in conjunction with the physician.

40 | (II) The person performing the ultrasound must offer the
 41 | woman the opportunity to view the live ultrasound images and
 42 | hear an explanation of them. If the woman accepts the
 43 | opportunity to view the images and hear the explanation, a
 44 | physician or a registered nurse, licensed practical nurse,
 45 | advanced registered nurse practitioner, or physician assistant
 46 | working in conjunction with the physician must contemporaneously
 47 | review and explain the images to the woman before the woman
 48 | gives informed consent to having an abortion procedure
 49 | performed.

50 | (III) The woman has a right to decline to view and hear
 51 | the explanation of the live ultrasound images after she is
 52 | informed of her right and offered an opportunity to view the

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53 images and hear the explanation. If the woman declines, the
54 woman shall complete a form acknowledging that she was offered
55 an opportunity to view and hear the explanation of the images
56 but that she declined that opportunity. The form must also
57 indicate that the woman's decision was not based on any undue
58 influence from any person to discourage her from viewing the
59 images or hearing the explanation and that she declined of her
60 own free will.

61 (IV) Unless requested by the woman, the person performing
62 the ultrasound may not offer the opportunity to view the images
63 and hear the explanation and the explanation may not be given
64 if, at the time the woman schedules or arrives for her
65 appointment to obtain an abortion, a copy of a restraining
66 order, police report, medical record, or other court order or
67 documentation is presented which provides evidence that the
68 woman is obtaining the abortion because the woman is a victim of
69 rape, incest, domestic violence, or human trafficking or that
70 the woman has been diagnosed as having a condition that, on the
71 basis of a physician's good faith clinical judgment, would
72 create a serious risk of substantial and irreversible impairment
73 of a major bodily function if the woman delayed terminating her
74 pregnancy.

75 c. The medical risks to the woman and fetus of carrying
76 the pregnancy to term.

77 2. Printed materials prepared and provided by the
78 department have been provided to the pregnant woman, if she

79 chooses to view these materials, including:

80 a. A description of the fetus, including a description of
81 the various stages of development.

82 b. A list of entities that offer alternatives to
83 terminating the pregnancy.

84 c. Detailed information on the availability of medical
85 assistance benefits for prenatal care, childbirth, and neonatal
86 care.

87 3. The woman acknowledges in writing, before the
88 termination of pregnancy, that the information required to be
89 provided under this subsection has been provided.

90

91 Nothing in this paragraph is intended to prohibit a physician
92 from providing any additional information which the physician
93 deems material to the woman's informed decision to terminate her
94 pregnancy.

95 Section 2. For the purpose of incorporating the amendment
96 made by this act to section 390.0111, Florida Statutes, in a
97 reference thereto, paragraph (d) of subsection (3) of section
98 390.012, Florida Statutes, is reenacted to read:

99 390.012 Powers of agency; rules; disposal of fetal
100 remains.—

101 (3) For clinics that perform or claim to perform abortions
102 after the first trimester of pregnancy, the agency shall adopt
103 rules pursuant to ss. 120.536(1) and 120.54 to implement the
104 provisions of this chapter, including the following:

105 (d) Rules relating to the medical screening and evaluation
 106 of each abortion clinic patient. At a minimum, these rules shall
 107 require:

108 1. A medical history including reported allergies to
 109 medications, antiseptic solutions, or latex; past surgeries; and
 110 an obstetric and gynecological history.

111 2. A physical examination, including a bimanual
 112 examination estimating uterine size and palpation of the adnexa.

113 3. The appropriate laboratory tests, including:

114 a. Urine or blood tests for pregnancy performed before the
 115 abortion procedure.

116 b. A test for anemia.

117 c. Rh typing, unless reliable written documentation of
 118 blood type is available.

119 d. Other tests as indicated from the physical examination.

120 4. An ultrasound evaluation for all patients. The rules
 121 shall require that if a person who is not a physician performs
 122 an ultrasound examination, that person shall have documented
 123 evidence that he or she has completed a course in the operation
 124 of ultrasound equipment as prescribed in rule. The rules shall
 125 require clinics to be in compliance with s. 390.0111.

126 5. That the physician is responsible for estimating the
 127 gestational age of the fetus based on the ultrasound examination
 128 and obstetric standards in keeping with established standards of
 129 care regarding the estimation of fetal age as defined in rule
 130 and shall write the estimate in the patient's medical history.

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131 | The physician shall keep original prints of each ultrasound
132 | examination of a patient in the patient's medical history file.

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



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee
 3 Representative Berman offered the following:

Amendment (with title amendment)

Between lines 94 and 95, insert:

7 (b) A physician who is to perform a termination of
 8 pregnancy may delegate the acts in sub-subparagraph(3) (a)1.a.
 9 to a registered nurse, licensed practical nurse, advanced
 10 registered nurse practitioner, or physician assistant.

11 -----
 12
 13 **T I T L E A M E N D M E N T**

14 Remove line 5 and insert:
 15 pregnancy; allowing certain health care professionals to inform
 16 a woman of the nature and risks associated with undergoing an



COMMITTEE/SUBCOMMITTEE AMENDMENT



Bill No. HB 633 (2015)

Amendment No.

17 | abortion and with continuing with her pregnancy; reenacting s.
18 | 390.012(3)(d), F.S., relating

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 893 Blanket Health Insurance Eligibility
SPONSOR(S): Health Innovation Subcommittee; Ingoglia
TIED BILLS: IDEN./SIM. **BILLS:** SB 1134

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N, As CS	Tuszynski	Poche
2) Insurance & Banking Subcommittee	12 Y, 0 N	Haston	Cooper
3) Health & Human Services Committee		Tuszynski 	Calamas 

SUMMARY ANALYSIS

A blanket health insurance policy and contract is issued to a policyholder, such as a school, business, or an organization, to provide coverage to a group of individuals or participants for an activity or event. This is in contrast to group health insurance coverage, in which a contract exists between the insurer and a policyholder, such as an employer, for individual employees and their dependents as a benefit. Coverage under a blanket health insurance policy normally expires at the conclusion of the activity or event.

The bill adds specific groups that are eligible to purchase blanket health insurance policies and expands the categories of individuals who are eligible for coverage under such policies.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Insurance Regulation

Insurance products are regulated under chapters 624 and 627, F.S., by the Office of Insurance Regulation (OIR). OIR is responsible for regulating all insurers and other risk bearing entities doing business in the state. These responsibilities include licensure, the review of company rate and form filings across regulated lines of insurance; monitoring the financial strength, solvency and enterprise risk of insurance companies doing business in this state; and ensuring that contract provisions keep up with changing legal and market conditions.

Blanket Health Insurance

A blanket health insurance policy or contract is issued to a policyholder, such as a school, business, or organization, to provide coverage to a group of individuals or participants as a class who share a common activity or operation of the policyholder.¹ Blanket health policies are for specific policyholders, covering specific people, for a specific event. This is in contrast to group health insurance coverage, in which a contract is issued to a policyholder, such as an employer, for individual employees and their dependents as a benefit.² An individual application is not required from an individual covered under a blanket health insurance policy or contract.³ Generally, the insurer is not required to provide a written certificate of the insurance coverage to each insured person.⁴

Under current law, blanket health insurance covers certain groups of people under a policy or contract issued to the following groups:

- A common carrier – covering passengers;⁵
- An employer – covering employees defined by reference to exceptional hazards incident to employment;⁶
- A school, school district, college, university, or other institution of learning – covering students and teachers; and may cover spouses and dependent children of students;⁷
- A volunteer fire department, first aid group, or other such volunteer group – covering the members of those groups;⁸
- An organization or branch of the Boys Scouts of America, Future Farmers of America, religious or educational organizations, or similar organizations – covering attendees, instructors, counselors, and administrators at meetings and camps;⁹
- A newspaper – covering independent contractor delivery persons;¹⁰
- A health care provider – covering patients;¹¹ and

¹ s. 627.659, F.S.

² s. 627.653, F.S.

³ s. 627.660(1), F.S.

⁴ Id. An insurer is required to furnish a written certificate disclosing the essential features of the coverage to each person covered under a policy issued pursuant to s. 627.659(3), F.S., relating to policies issued to a school, district school system, college, university, or other institution of learning. s. 627.660(6), F.S. These certificates are subject to the filing requirements of ss. 627.410 and 627.640, F.S.

⁵ s. 627.659(1), F.S.

⁶ s. 627.659(2), F.S.

⁷ s. 627.659(3), F.S.

⁸ s. 627.659(4), F.S.

⁹ s. 627.659(5), F.S.

¹⁰ s. 627.659(6), F.S.

¹¹ s. 627.659(7), F.S.

- An HMO – covering subscribers.¹²

Effect of Proposed Changes

The bill expands the list of existing groups and individuals in statute that are eligible policyholders of blanket health insurance coverage or eligible to be covered under a blanket health insurance policy. Specifically, the bill changes the existing policyholder groups as follows:

- A common carrier – adds any operator, owner or lessee of a means of transportation as an eligible policyholder.
- An employer – expands coverage to dependents or guests of an employee; the bill removes the reference to coverage for “exceptional hazards incident to such employment” and replaces it with “activity or activities or operations of the policyholder,” which expands the types of activities for which blanket health coverage may be purchased by an employer.
- A School, school district, college, university, or other institution of learning – expands coverage to employees, and dependents and spouses of teachers or employees of a school, college, and university.
- A volunteer fire department, first aid group, or other such volunteer group – adds emergency management groups as eligible policyholders and expands coverage to any group of participants defined by reference to activities or operations sponsored or supervised by a volunteer fire department, first aid group, or other such volunteer group.
- An organization or branch of the Boys Scouts of America, Future Farmers of America, religious or educational organizations, or similar organizations – adds instructive, charitable, recreational, and civic groups as eligible policyholders and expands coverage to any or all persons participating in the activities or operations sponsored or supervised by the policyholder.
- A newspaper – adds other publishers as eligible policyholders and expands coverage to delivery persons employed by such publications.
- An HMO – adds other arrangers of health services as eligible policyholders and expands coverage to donors and surrogates.

The bill also adds the following new eligible policyholder groups to statute:

- A sports team, camp, or sponsor of a team or camp – covering members, campers, participants, employees, officials or supervisors.¹³
- A travel agency or other organization that provides travel related services – covering any and all persons receiving travel-related services.
- An association that has a constitution and bylaws, comprised of at least 25 members and having been organized and maintained in good faith for at least 1 year for purposes other than obtaining insurance – covering all members of the association.
- A bank, association, financial or other institution, vendor, parent holding company, or the trustees or agents designated by such entities – covering accountholders, cardholders, debtors, guarantors, or purchasers.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 627.659, F.S., relating to blanket health insurance; eligible groups.

Section 2: Provides an effective date of July 1, 2015.

¹² s. 627.659(8), F.S.

¹³ This provision emulates statutes in 26 other states (AL, AK, AZ, AR, CA, DE, GA, ID, IL, IN, KS, KY, LA, ME, MD, MA, MI, MN, MT, NV, NH, OK, OR, PA, UT, and WY).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill allows insurers to offer blanket health insurance plans covering more eligible policyholders for more risks or activities. The eligible policyholders can secure coverage for activities or events outlined in the bill, limiting the policyholder's exposure to risk of financial loss.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2015, the Health Innovation Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment removed discretionary authority of the Insurance Commissioner to determine, without further legislative action, additional groups who are eligible to purchase blanket health insurance coverage and additional individuals who may be covered under such a policy.

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

1 A bill to be entitled
 2 An act relating to blanket health insurance
 3 eligibility; amending s. 627.659, F.S.; revising the
 4 list of special groups of individuals covered by a
 5 policy or contract for blanket health insurance;
 6 providing an effective date.

7
 8 Be It Enacted by the Legislature of the State of Florida:

9
 10 Section 1. Section 627.659, Florida Statutes, is amended
 11 to read:

12 627.659 Blanket health insurance; eligible groups.—Blanket
 13 health insurance is that form of health insurance which covers
 14 special groups of individuals as enumerated in one of the
 15 following subsections:

16 (1) Under a policy or contract issued to any common
 17 carrier or to any operator, owner, or lessee of a means of
 18 transportation, which shall be deemed the policyholder, covering
 19 a group defined as all persons who may become passengers on such
 20 common carrier or such means of transportation.

21 (2) Under a policy or contract issued to an employer, who
 22 shall be deemed the policyholder, covering any group of
 23 employees or the employees' dependents or guests defined by
 24 reference to activities or operations of the policyholder
 25 ~~exceptional hazards incident to such employment~~, or under a
 26 policy or contract issued to an employer when all employees are

27 covered under any such policy or contract.

28 (3) Under a policy issued to a school, district school
 29 system, college, university, or other institution of learning,
 30 or to the official or officials of such institution insuring all
 31 or any class of its ~~the~~ students, ~~and~~ teachers, and employees.
 32 Any such policy issued may insure the spouse or dependent
 33 children of the insured student, teacher, or employee.

34 (4) Under a policy or contract issued in the name of a ~~any~~
 35 volunteer fire department, ~~or~~ first aid group, emergency
 36 management group, or other such volunteer group, which shall be
 37 deemed the policyholder, covering any group ~~all~~ of the members
 38 or employees of such department or group, or covering any group
 39 of participants defined by reference to activities or operations
 40 sponsored or supervised by such department or group.

41 (5) Under a policy or contract issued to an organization,
 42 or branch thereof, such as the Boy Scouts of America, the Future
 43 Farmers of America, any religious, instructive, or ~~or~~ educational,
 44 charitable, recreational, or civic bodies, or similar
 45 organizations, or to an individual, firm, or corporation,
 46 holding or operating meetings such as summer camps or other
 47 meetings for religious, instructive, educational, charitable, or ~~or~~
 48 recreational, or civic purposes, who shall be deemed the
 49 policyholder, covering any or all of those participating in the
 50 activities or operations sponsored or supervised by the
 51 policyholder, including attending such camps or meetings,
 52 including counselors, instructors, and persons in other

53 administrative positions.

54 (6) Under a policy or contract issued in the name of a
 55 newspaper or other publisher, which shall be deemed the
 56 policyholder, covering independent contractor newspaper or
 57 publication delivery persons.

58 (7) Under a policy or contract issued in the name of a
 59 health care provider or other arranger of health services, which
 60 shall be deemed the policyholder, covering patients, donors, or
 61 surrogates. This coverage may be offered to patients, donors, or
 62 surrogates of a health care provider or other arranger of health
 63 services but may not be made a condition of receiving care. The
 64 benefits provided under such policy or contract shall not be
 65 assignable to any health care provider.

66 (8) Under a policy or contract issued to any health
 67 maintenance organization licensed pursuant to the provisions of
 68 part I of chapter 641, which shall be deemed the policyholder,
 69 covering the subscribers of the health maintenance organization.
 70 Payment may be made directly to the health maintenance
 71 organization by the blanket health insurer for health care
 72 services rendered by providers pursuant to the health care
 73 delivery plan.

74 (9) Under a policy or contract issued to a sports team,
 75 camp, or sponsor thereof, which shall be deemed the
 76 policyholder, covering members, campers, participants,
 77 employees, officials, or supervisors.

78 (10) Under a policy or contract issued to a travel agency

79 or other organization that provides travel-related services,
 80 which shall be deemed the policyholder, to cover any or all
 81 persons for whom travel and travel-related services are
 82 provided.

83 (11) Under a policy or contract issued to an association,
 84 if the association has a constitution and bylaws, has at least
 85 25 individual members, and has been organized and maintained in
 86 good faith for at least 1 year for purposes other than obtaining
 87 insurance, covering all or any class of members of such
 88 association.

89 (12) Under a policy or contract issued to a bank,
 90 association, financial or other institution, vendor, or parent
 91 holding company, or to the trustees or agents designated by one
 92 or more banks, associations, financial or other institutions, or
 93 vendors, which shall be deemed the policyholder, covering
 94 accountholders, cardholders, debtors, guarantors, or purchasers.

95 Section 2. This act shall take effect July 1, 2015.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee

3 Representative Ingoglia offered the following:

4

5 **Amendment**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 627.659, Florida Statutes, is amended
 8 to read:

9 627.659 Blanket health insurance; eligible groups.—Blanket
 10 health insurance is that form of health insurance which covers
 11 special groups of individuals as enumerated in one of the
 12 following subsections:

13 (1) Under a policy or contract issued to any common
 14 carrier or to any operator, owner, or lessee of a means of
 15 transportation, which shall be deemed the policyholder, covering
 16 a group defined as all persons who may become passengers on such
 17 common carrier or such means of transportation.



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18 (2) Under a policy or contract issued to an employer, who
19 shall be deemed the policyholder, covering any group of
20 employees or the employees' dependents or guests defined by
21 reference to activities or operations of the policyholder
22 ~~exceptional hazards incident to such employment~~, or under a
23 policy or contract issued to an employer when all employees are
24 covered under any such policy or contract.

25 (3) Under a policy issued to a school, district school
26 system, college, university, or other institution of learning,
27 or to the official or officials of such institution insuring all
28 or any class of its the students, and teachers, and employees.
29 Any such policy issued may insure the spouse or dependent
30 children of the insured student, teacher, or employee.

31 (4) Under a policy or contract issued in the name of a any
32 volunteer fire department, or first aid group, local emergency
33 management group, as defined in s. 252.34(5), F.S., or other
34 first responder such volunteer group, as defined in s. 112.1815,
35 F.S., which is shall be deemed to be the policyholder, covering
36 all or any grouping of the members or employees of the
37 policyholder such department or group or covering all or any
38 grouping of participants which is defined by reference to an
39 activity or operation sponsored or supervised by the
40 policyholder.

41 (5) Under a policy or contract issued to an organization,
42 or branch thereof, such as the Boy Scouts of America, the Future
43 Farmers of America, any religious, instructive, or educational,



Amendment No.

44 charitable, recreational, or civic bodies, or similar
45 organizations, or to an individual, firm, or corporation,
46 holding or operating meetings such as summer camps or other
47 meetings for religious, instructive, educational, charitable, or
48 recreational, or civic purposes, who shall be deemed the
49 policyholder, covering any or all of those participating in the
50 activities or operations sponsored or supervised by the
51 policyholder, including attending such camps or meetings,
52 including counselors, instructors, and persons in other
53 administrative positions.

54 (6) Under a policy or contract issued in the name of a
55 newspaper or other publisher, which is shall be deemed to be the
56 policyholder, covering independent contractor newspaper or
57 publication delivery persons- for health insurance that may
58 contain the following benefits: coverage only for accident, or
59 disability income insurance, or any combination thereof; limited
60 scope dental or vision benefits; coverage only for a specified
61 disease or illness; or hospital indemnity or other fixed
62 indemnity insurance.

63 (7) Under a policy or contract issued in the name of a
64 health care provider, which shall be deemed the policyholder,
65 covering patients; or to an arranger of fertility medicine
66 relationships, such as a surrogacy agency, which shall be the
67 policyholder, covering donors, recipients or surrogates. This
68 coverage may be offered to patients of a health care provider or
69 to donors, recipients or surrogates of such arranged health



Amendment No.

70 services, but may not be made a condition of receiving care. The
71 benefits provided under such policy or contract shall not be
72 assignable to any health care provider.

73 (8) Under a policy or contract issued to any health
74 maintenance organization licensed pursuant to the provisions of
75 part I of chapter 641, which shall be deemed the policyholder,
76 covering the subscribers of the health maintenance organization.
77 Payment may be made directly to the health maintenance
78 organization by the blanket health insurer for health care
79 services rendered by providers pursuant to the health care
80 delivery plan.

81 (9) Under a policy or contract issued to a sports team,
82 camp, or sponsor thereof, which shall be deemed the
83 policyholder, covering members, campers, participants,
84 employees, officials, or supervisors.

85 (10) Under a policy or contract issued to a travel agency
86 or other organization that provides travel-related services,
87 which shall be deemed the policyholder, to cover any or all
88 persons for whom travel and travel-related services are
89 provided.

90 (11) Under a policy or contract issued to an association,
91 if the association has a constitution and bylaws, has at least
92 25 individual members, and has been organized and maintained in
93 good faith for at least 1 year for purposes other than obtaining
94 insurance, covering all or any class of members of such
95 association.



Amendment No.

96 (12) Under a policy or contract issued to a financial
97 institution, or parent holding company, or to the trustees or
98 agents designated by one or more banks, or financial
99 institutions, as defined in s. 655.005, F.S., which shall be
100 deemed the policyholder, covering accountholders, cardholders,
101 debtors, or guarantors for health insurance that may contain the
102 following benefits: coverage only for accident, or disability
103 income insurance, or any combination thereof; limited scope
104 dental or vision benefits; coverage only for a specified disease
105 or illness; or hospital indemnity or other fixed indemnity
106 insurance.

107 Section 2. This act shall take effect July 1, 2015.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 935 Individuals with Disabilities
SPONSOR(S): Rodrigues
TIED BILLS: HB 937, HB 939 **IDEN./SIM. BILLS:** CS/SB 642

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	12 Y, 0 N	Tuszynski	Brazzell
2) Education Appropriations Subcommittee	13 Y, 0 N	Butler	Heflin
3) Health & Human Services Committee		Tuszynski <i>TD</i>	Calamas <i>CC</i>

SUMMARY ANALYSIS

The federal Achieving a Better Life Experience Act of 2014 (ABLE Act) authorized states to establish ABLE programs or contract with other states to administer such programs if certain conditions are met. ABLE programs would provide a tax-advantaged approach for certain individuals with disabilities to build financial resources for disability related expenses without losing state or federal benefit eligibility, similar to 529 college savings plans.

HB 935 creates the Florida Achieving a Better Life Experience (ABLE program). The bill creates Florida ABLE, Inc., as a direct support organization that is organized as a not-for-profit corporation and requires it to implement the Florida ABLE Program on or before July 1, 2016. Florida ABLE, Inc., would operate under a contract with the Florida Prepaid College Board.

The bill allows an ABLE account to be established for an individual with significant disabilities which occurred before age 26. Other persons, such as family members, could contribute funds to an ABLE account. ABLE account funds under certain amounts would not affect the individual's eligibility for state and federal benefits, such as SSI and Medicaid.

The bill allows ABLE account funds to be used only for qualified disability expenses as authorized under federal law, such as education, housing, transportation, employment training and support, assistive technology, health, prevention and wellness, financial management, legal fees, and other expenses.

The bill makes the Agency for Health Care Administration a creditor of the ABLE accounts, allowing the Agency to recover funds expended to provide Medicaid services upon the death of the individual.

The bill has a fiscal impact. Estimated costs for implementation in Fiscal Year 2015-2016 would be \$3,386,000. Revenues from account fees are indeterminate.

Because the bill allows assets placed in ABLE accounts to be exempt from Medicaid eligibility determinations, the impact on increased Medicaid enrollments may be impacted, but is indeterminate. (SEE FISCAL COMMENTS).

The bill provides an effective date of October 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Disability is defined by federal law as a physical or mental impairment that substantially limits one or more major life activities, such as caring for oneself, performing manual tasks, seeing, hearing, sleeping, walking, standing, learning, reading, thinking, communicating, and working.¹ Disabilities may be lifelong, requiring significant expenditures for services and supports to address them over the lifespan of an individual. The additional costs experienced by an individual due to a disability vary based on the individual's unique circumstances. Costs may include out-of-pocket health care, behavioral therapy, speech therapy, physical therapy, occupational therapy, educational services, transportation, caregivers, and other services.

These costs may present financial challenges to individuals with disabilities. These individuals may also face significant barriers in finding and retaining employment which may affect income and assets.

In Florida, the estimated disability prevalence rate in 2012 for individuals ages 21-64 was approximately 10.3 percent.² Approximately 28.1 percent of those individuals were living below the federal poverty line, as compared to approximately 14 percent of individuals without a disability.³ The estimated employment rate of those individuals with disabilities was 29.4 percent in 2012, as compared to 73.8 percent of those without a disability⁴, highlighting the impacts of barriers to regular employment individuals with disabilities can face.

State and Federal Programs for Individuals with Disabilities

Individuals with disabilities may qualify for state or federal assistance. The Social Security Disability Insurance (SSDI)⁵ and Supplemental Security Income⁶ (SSI) programs are two such programs, administered by the federal Social Security Administration. Under these programs, disability is defined as the inability to engage in substantial gainful activity due to a medically determinable physical or mental impairment expected to result in death or last at least 12 months. An applicant must meet strict medical requirements to qualify for disability benefits.⁷

The SSDI program provides cash payments to individuals who have contributed to the Social Security system and meet certain minimum work requirements. The amount of assistance under the SSDI program varies depending on age and average earnings. SSI is a means-tested program for aged, blind, or disabled individuals who meet certain income and resource limitations. There are no contribution or minimum work requirements.⁸ The SSI program provides cash payments assuring a minimum income for aged, blind, or disabled individuals who have very limited income and assets. Effective January 1, 2015, the maximum monthly SSI benefit rate is \$733 for an eligible individual and \$1,100 for an eligible individual with an eligible spouse.⁹ The countable resource limit (maximum assets

¹ 42 U.S.C. s. 12102

² Cornell University, *2012 Disability Status Report: Florida*, available at <http://www.disabilitystatistics.org> (last viewed March 30, 2015).

³ *Id.*

⁴ *Id.*

⁵ 42 U.S.C. ss. 401-433.

⁶ 42 U.S.C. ss. 1381 note-1385 note.

⁷ See <http://www.socialsecurity.gov/disability/professionals/bluebook/general-info.htm> (last accessed February 23, 2015).

⁸ The definition of disability for disabled children receiving SSI benefits is slightly different from the definition for adults. See criteria at: <http://www.ssa.gov/ssi/text-eligibility-ussi.htm#disabled-child> (last accessed on February 23, 2015).

⁹ Generally, the maximum monthly payment changes yearly due to changes in the Consumer Price Index. The 2015 schedule is available at: <http://www.socialsecurity.gov/OACT/COLA/SSI.html> (last accessed February 23, 2015).

that may be held)¹⁰ for SSI eligibility is \$2,000 for individuals and \$3,000 for couples with exclusions.¹¹ In December 2013, there were 547,594 SSI recipients (aged, blind, or disabled) and 551,858 disabled workers that were recipients of SSDI in Florida.¹²

In contrast to the SSDI and SSI programs that provide cash assistance, Medicaid waiver programs provide individuals with disabilities support services. The Medicaid Home and Community Based Services waiver (HCBS) is a program approved and partially funded by the federal government. Waiver programs are authorized by Title XIX of the Social Security Act, Section 1915(c), and operated and partially funded by the state. It provides services in the home for persons who would otherwise require institutional care in a hospital, nursing facility, or intermediate care facility.¹³ Standard services include case management, homemaker, home health aide, personal care, adult day health services, habilitation (both day and residential), and respite care. States can also propose “other” types of services that may assist in diverting and/or transitioning individuals from institutional settings into their homes and community.¹⁴

Florida has a number of HCBS waivers serving several distinct disability groups, such as individuals with cystic fibrosis, Familial Dysautonomia, developmental disabilities, AIDS, traumatic brain injury, and spinal cord injury.¹⁵ For example, the iBudget Florida waiver specifically serves persons with developmental disabilities. As of December 2014, approximately 30,000 individuals were enrolled on the iBudget Florida waiver receiving services, and approximately 21,000 were on the enrollment waitlist.¹⁶

Federal ABLÉ Act of 2014

The federal ABLÉ Act became law on December 19, 2014¹⁷ authorizing states to implement ABLÉ programs. An ABLÉ program would provide a tax-advantaged approach for certain individuals with disabilities to build financial resources without losing state or federal benefit eligibility. The law authorizes ABLÉ accounts for individuals with disabilities who meet certain criteria, who may spend distributions on “qualified disability expenses.”¹⁸ The purposes of the federal ABLÉ Act are to encourage and assist individuals and families in saving to support individuals with disabilities in maintaining health, independence, and quality of life, and provide secure funding for disability-related expenses that will supplement, but not supplant, other sources.¹⁹

Eligible Individuals

The federal ABLÉ Act provides that an individual is eligible to establish an ABLÉ account for a taxable year if during such taxable year:

- The individual is entitled to benefits based on blindness or disability under title II or XVI of the Social Security Act, and such blindness or disability occurred before the date the individual attained age 26; or

¹⁰ The countable resource limit includes assets that can be easily converted to cash and used for food and shelter; such as bank accounts, stocks, bonds, second homes and vehicles. However, assets such as an individual’s primary home, household goods, and one vehicle are exempt from that limit.

¹¹ 20 C.F.R. s. 416.1201 and 20 C.F.R. ss. 416.1210-416.1239.

¹² Social Security Administration *Annual Statistical Supplement, 2014* available at:

<http://www.socialsecurity.gov/policy/docs/statcomps/supplement/2014/5j.pdf> and

<http://www.socialsecurity.gov/policy/docs/statcomps/supplement/2014/7b.pdf> (last accessed February 23, 2015).

¹³ See Florida Agency for Health Care Administration, http://ahca.myflorida.com/medicaid/hcbs_waivers/index.shtml (last accessed February 23, 2015)

¹⁴ See Medicaid.gov: Keeping America Healthy, <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/long-term-services-and-supports/home-and-community-based-services/home-and-community-based-services-1915-c.html> (last accessed February 24, 2015)

¹⁵ *Supra.* at Note 10

¹⁶ Agency for Persons with Disabilities. Quarterly Report on Agency Services to Floridians with Developmental Disabilities and Their Costs: Second Quarter Fiscal Year 2014-15, February 2015

¹⁷ H.R. 5771, Division B, Title I. Public Law 113-295.

¹⁸ *Id.*

¹⁹ *Id.*

- A disability certification with respect to such individual has been filed with the Secretary of the Treasury for the taxable year.

Qualified Disability Expenses

ABLE account funds may be used only for qualified disability expenses.²⁰ These include any expenses related to the eligible individual's blindness or disability that are made for the benefit of the designated beneficiary. These funds could be used for education, housing, transportation, employment training and support, assistive technology and personal support services, health, prevention and wellness, financial management and administrative services, legal fees, expenses for oversight and monitoring, funeral and burial expenses, and other expenses which are authorized pursuant to regulations to be adopted by the Secretary of the U.S. Department of Treasury.^{21,22}

Tax Advantages of ABLE Accounts

Earnings in, and distributions from, an ABLE account for qualified disability expenses do not count as taxable income of either the contributor or the designated beneficiary.²³ However, the federal ABLE Act limits aggregate contributions during a taxable year to the annual gift-tax exclusion amount (\$14,000 for 2015).²⁴ If the funds withdrawn from a qualified ABLE account are equal or less than the qualified disability expenses of the designated beneficiary, no amount is counted in the designated beneficiary's gross income. However, funds withdrawn that exceed qualified disability expenses would be included in the beneficiary's gross income and would thus be subject to federal income tax, as well as an additional 10-percent tax.²⁵

Amounts in an ABLE account may be rolled over without income tax liability to another ABLE account for the same beneficiary or another ABLE account for the designated beneficiary's brother, sister, stepbrother or stepsister who is also an eligible individual.²⁶ Taxes may apply, however, to a change of designated beneficiary during any taxable year unless, as of the beginning of the year, the new beneficiary is both an eligible individual for the taxable year and a brother, sister, stepbrother or stepsister of the former beneficiary.²⁷

ABLE Accounts and Federal Program Eligibility

Generally, any amount in an ABLE account, and any distribution for qualified disability expenses, would be disregarded for determining eligibility for and the amount of any assistance or benefit authorized by any federal means-tested program with respect to any period an individual maintains, makes contributions to, or receives distributions from such ABLE account. However, in the case of the SSI program, distributions for housing expenses and ABLE account balances in excess of \$100,000 may not be disregarded. If an individual's ABLE account balance exceeds \$100,000, the individual's SSI benefits would be suspended until the balance falls below \$100,000. However, Medicaid eligibility would not be affected.

If the designated beneficiary dies, the ABLE account is subject to Medicaid recovery for the total amount of medical assistance provided for the designated beneficiary under the Medicaid program, less

²⁰ Supra. at Note 17.

²¹ Id.

²² The Secretary of the U.S. Department of Treasury is required to issue regulations or other guidance to implement the federal ABLE Act no later than six months after the date of enactment of the act. The date of enactment was December 19, 2014, and thus regulations are to be promulgated by June 19, 2015.

²³ Supra. at Note 17.

²⁴ See Internal Revenue Service information at <http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Whats-New-Estate-and-Gift-Tax> (last visited February 23, 2015).

²⁵ Supra. at Note 17.

²⁶ Id.

²⁷ Id.

any premiums paid by or on behalf of the designated beneficiary to a Medicaid buy-in program.^{28,29} Prior to the Medicaid payback, funds in the ABLÉ account of the deceased designated beneficiary would be distributed for the payment of qualified disability expenses rendered before the designated beneficiary's death.³⁰

State ABLÉ Program

The federal ABLÉ Act authorizes the states to create and implement ABLÉ programs. A state ABLÉ program must meet many requirements to be qualified, such as:

- A designated beneficiary may only have one ABLÉ account.
- Only designated beneficiaries who are either residents of the state maintaining such ABLÉ program or residents of a contracting state³¹ may establish accounts.
- Contributions must be made in cash.
- The program must account separately for each designated beneficiary.
- Designated beneficiaries may make investment directions a maximum of two times in any calendar year.
- The program may not pledge any interest in the program as a security for a loan.
- The program must establish adequate safeguards to prevent aggregate contributions on behalf of a designated beneficiary in excess of the amount established by the state under s. 529(b)(6) of the Internal Revenue Code.
- The program must comply with federal reporting requirements.

Florida Prepaid College Board and 529 Educational Savings Plans

The Florida Prepaid College Board was created in 2002 to administer the Florida Prepaid College Program and the Florida College Savings Program.³² The Florida College Savings Program was created to promote and enhance the affordability of higher education in the state and enable persons to contribute funds that are combined and invested to pay the higher education expenses of a designated beneficiary.³³ The Florida College Savings Program is a tax-advantaged account that allows the tax-free accumulation and distribution of cash assets for qualified educational expenses under s. 529 of the Internal Revenue Code. These plans are very similar to the tax-advantaged disability savings plans envisioned by the federal ABLÉ Act under s. 529A of the Internal Revenue Code.

Direct-Support Organizations

A direct-support organization (DSO) is a not-for-profit corporate entity created by a state agency or program to provide support and conduct programs and activities for the benefit of that agency or program.

Section 20.058, F.S., requires that any law creating or authorizing the creation of a DSO must state that the creation of or authorization for the DSO be repealed on October 1 of the fifth year after enactment, unless reviewed and saved from repeal through reenactment by the Legislature. Section 215.981, F.S., imposes audit requirements on state agency DSOs.

²⁸ Id.

²⁹ Florida does not currently have a Medicaid buy-in program. Legislation was passed in 2001 authorizing a Medicaid buy-in program, subject to appropriation (Ch. 2001-104, Laws of Fla.). It was repealed, effective July 1, 2002, without appropriation.

³⁰ Supra. at Note 17

³¹ The federal ABLÉ Act allows a state that has not established an ABLÉ program to enter into a contract with a state that has established an ABLÉ program to provide ABLÉ accounts to its residents.

³² Ch. 2002-387, Laws of Fla.

³³ Id.

Effect of Proposed Changes

HB 935 creates the Florida Achieving a Better Life Experience (ABLE) Act. The Florida ABLE Act would establish the Florida ABLE program, to provide a means for individuals with disabilities to build financial resources without losing their eligibility for state and federal benefits, and encourage individuals and families in saving for the purpose of supporting individuals with disabilities to maintain health, independence, and quality of life. The bill provides a statement that the Legislature intends to establish a qualified ABLE program in Florida that is consistent with federal law and maximizes program efficiency and effectiveness. The bill also provides definitions and requirements for operation consistent with the federal ABLE Act.

The bill requires the Agency for Health Care Administration, the Agency for Persons with Disabilities, the Department of Children and Families, and the Department of Education to assist Florida ABLE in providing public information and outreach about the Florida ABLE program.

Structure and Organization of the ABLE program

The bill requires the Florida Prepaid College Board to establish the Florida ABLE program by creating Florida ABLE, Inc., (Florida ABLE), a not-for-profit direct support organization. Florida ABLE would receive, hold, invest, and administer property and make expenditures for the Florida ABLE Program.

Florida ABLE must establish and administer the Florida ABLE Program on or before July 1, 2016. Before doing so, it must obtain a legal opinion that the Florida ABLE program complies with s. 529A of the Internal Revenue Code (the federal ABLE Act), complies with federal securities law, and qualifies for tax exemptions under such law.

The bill allows Florida ABLE to contract to participate in the ABLE program of another state if Florida does not establish a qualified ABLE program. Florida may also contract with other states that do not have an authorized ABLE program to allow those states to participate in the Florida ABLE program.

The bill requires that on or before November 1, 2015, Florida ABLE provide to the Governor, President of the Senate, and Speaker of the House of Representatives a status report and recommendations on the establishment of the Florida ABLE program.

Oversight by Florida Prepaid College Board

Florida ABLE would operate under a written contract with Florida Prepaid that requires the articles of incorporation and bylaws of Florida ABLE to be approved by Florida Prepaid. Florida ABLE would be required to submit an annual budget to the Florida Prepaid College Board for its approval. Florida Prepaid would be required to certify annually that Florida ABLE is complying with contract terms and acting in accordance with statute and in the best interest of the state.

The bill allows Florida ABLE to use the resources of Florida Prepaid and would require Florida ABLE to pay reasonable consideration to Florida Prepaid for use of its products and services. Florida ABLE must authorize Florida Prepaid to solicit proposals, contract, or subcontract, or amend Florida Prepaid contractual service agreements for the benefit of Florida ABLE. Florida Prepaid would also maintain the website of Florida ABLE.

The bill provides that if Florida ABLE ceases operation, any moneys and property held in trust by Florida ABLE would revert to Florida Prepaid (or to the state if Florida Prepaid was no longer in existence).

Board of Directors of Florida ABLE

The bill designates the Florida ABLE board of directors, as follows:

- The chair of Florida Prepaid, who serves as chair of Florida ABLE board;
- An advocate for persons with disabilities appointed by the President of the Senate;
- An advocate for persons with disabilities appointed by the Speaker of the House;
- A person with expertise in accounting, risk management, or investment management appointed by the Florida Prepaid board of directors;
- A person with expertise in accounting, risk management, or investment management appointed by the Governor.

One of the two advocates for persons with disabilities must be an advocate of persons with developmental disabilities as defined in s. 393.063, F.S., which include intellectual disability, cerebral palsy, autism, spina bifida, and Prader-Willi syndrome.

Appointees to the board would serve for three years and could be reappointed. Board members would serve without compensation and could be reimbursed for travel expenses pursuant to s. 112.061, F.S. The board must meet at least quarterly and upon the call of the chair.

Operation of the ABLE program

Participation Agreements

The bill requires the Florida ABLE program to enter into participation agreements with qualified beneficiaries in order to set up an ABLE account. The bill sets forth mandatory provisions of participation agreements including provisions prohibiting beneficiaries from establishing accounts in violation of federal law (such as establishing more than one account) or in excess of federal law (currently, the maximum annual contribution is \$14,000 per year). The bill allows participation agreement to be amended to increase or decrease the level of participation, change beneficiaries, and for other authorized purposes. The participation agreement must allow the involuntary liquidation of an ABLE account if a material misrepresentation is made.

The participation agreement would not be a debt of the state but rather an obligation of the Florida ABLE program. The obligation of Florida ABLE would be limited to the amount in the Florida ABLE Trust Fund.

The Florida ABLE program would be required to inform participants of changes to the tax or securities status of their participation agreements and interests in the ABLE program.

Comprehensive Investment Plan

The bill requires Florida ABLE to establish a comprehensive investment plan for the ABLE program. The bill allows Florida ABLE to place Florida ABLE program assets in investment products, but only in proportions designated in the investment plan and in compliance with federal and state laws and regulations. Designated beneficiaries may not direct investment of their contributions unless specific fund options are offered by Florida ABLE. The federal ABLE Act prohibits direction of investments by beneficiaries more than two times in a calendar year. The comprehensive investment plan is subject to the approval of Florida Prepaid.

Auditing and Reporting

Florida ABLE is required to prepare an annual report providing a detailed accounting of the Florida ABLE program and describing the financial condition of the program. Copies of the report must be submitted to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the minority leaders of each legislative chamber. The report must be made available to designated beneficiaries.

Florida ABLE program accounts would be subject to an annual audit by the Auditor General.

State Interaction with Florida ABLE

Under the bill, the state pledges to designated beneficiaries that their vested rights will not be limited or altered until the program's obligations are met and discharged. Limiting or altering rights may be done if adequate provision is made by law to protect designated beneficiaries pursuant to the obligations of Florida ABLE.

Florida ABLE program would continue in existence until terminated by law by the Legislature. The bill specifies that the state may terminate the program if it is financially infeasible, in which case account funds must be returned in accordance with the participation agreement. Unclaimed amounts may be transferred to the Florida Prepaid Tuition Scholarship Program.

ABLE account funds of a deceased beneficiary would first be distributed for qualified disability expenses followed by distributions for a Medicaid claim. Any remaining amount would be distributed pursuant to the participation agreement.

Rulemaking Authority

The bill requires Florida Prepaid to adopt rules to administer the Florida ABLE program. The rules must include the governance and operating procedures for Florida ABLE; the conditions for Florida ABLE to use the property, facilities, or personnel of Florida Prepaid; the procedures for determining that an ABLE account has been abandoned; and the provisions necessary for the Florida ABLE program to retain status as a qualified ABLE program, tax exempt status, or other similar status for the program or participants under the Internal Revenue Code.

Direct-Support Organization Repeal

In accordance with s. 20.058, F.S., the Florida ABLE DSO would be repealed October 2, 2020, unless reviewed and saved from repeal by the Legislature.

Finally, the bill makes conforming changes in ss. 222.22 and 1009.971, F.S.

B. SECTION DIRECTORY:

- Section 1:** Creates s. 1009.985, F.S., relating to the short title.
- Section 2:** Creates s. 1009.986, F.S., relating to creation of Florida ABLE, Inc., a direct-support organization.
- Section 3:** Amends s. 222.22, F.S., relating to liability to creditors and claimants.
- Section 4:** Amends s. 1009.971, F.S., relating to powers and duties of the Florida Prepaid College Board.
- Section 5:** Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Florida ABLE, Inc., may realize revenue from fees charged to designated beneficiaries for such purposes as establishing and managing their accounts. However, since the number of accounts that will be established is unknown and a fee structure has not been determined, the amount of revenue is indeterminate.

2. Expenditures:

The Florida Prepaid College Board estimates the costs for FY 2015-2016 associated with the implementation of the Florida ABLÉ program would be \$3,386,000. This cost estimate anticipates starting the program as early as April 1, 2016, but no later than July 1, 2016.

The cost estimate includes expenditures for accounting/auditing, legal fees, marketing, records administration, trustee, consulting, investment management, salary and benefits, travel, communications, and miscellaneous overhead.³⁴

Description	FY 2015-16		
	Recurring	Non-Recurring	Total
Accounting/Auditing	\$15,000		\$15,000
Banking & Lockbox	21,000		21,000
Legal	150,000	100,000	250,000
Marketing Agent	1,250,000	520,000	1,770,000
Records Administrator	200,000	550,000	750,000
Trustee	25,000		25,000
Investment Consultant	75,000		75,000
Investment Management	0		0
Other Professional Consulting	125,000	50,000	175,000
Florida Prepaid - HR Service Charge	225,000		225,000
SBA-Admin Service Charges	20,000		20,000
Travel	20,000		20,000
Communications	31,000		31,000
Freight	1,000		1,000
Insurance & Surety Bonds	1,500		1,500
Office Materials & Supplies	2,000		2,000
Other Charges & Obligations	2,000		2,000
Printing	2,500		2,500
Total	\$2,166,000	\$1,220,000	\$3,386,000

Marketing costs are discretionary to implementation.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Florida ABLÉ program will assist individuals with disabilities in saving money in tax-advantaged accounts without losing their eligibility for state and federal benefits. The bill would allow an indeterminate number of individuals to save additional assets or resources in these accounts and use the funds to pay for qualified disability expenses.

³⁴ ABLÉ Program Budget Detail, Kevin Thompson, Executive Director, Florida Prepaid College Board; on file with Children, Families & Seniors Subcommittee staff.

D. FISCAL COMMENTS:

The Congressional Budget Office (CBO) expects that enacting the ABLA Act would increase the number of disabled adults under the age of 65 who enroll in Medicaid because they could hold cash assets in an ABLA account that would not count against Medicaid eligibility. Because a beneficiary of an ABLA account must have a disability that occurred before he reached age 26, CBO does not expect an increase in the number of elderly individuals who enroll in Medicaid. Additionally, the CBO does not expect that establishment of ABLA accounts would increase the number of children and nondisabled adults enrolled in Medicaid because those individuals are not required to meet an asset test under current law.³⁵

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill gives the Florida Prepaid College Board sufficient authority to adopt rules to administer the Florida ABLA program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

³⁵ Congressional Budget Office Cost Estimate, H.R. 647, September 23, 2014, as ordered reported by the House Committee on Ways and Means on July 31, 2014.

1 A bill to be entitled
2 An act relating to individuals with disabilities;
3 creating s. 1009.985, F.S.; providing a short title;
4 creating s. 1009.986, F.S.; providing legislative
5 intent; defining terms; requiring the Florida Prepaid
6 College Board to establish a direct-support
7 organization known as "Florida ABLE, Inc."; specifying
8 requirements for the registration, organization,
9 incorporation, and operation of the organization;
10 requiring the organization to operate under a written
11 contract with the Florida Prepaid College Board;
12 specifying provisions that must be included in the
13 contract; requiring the organization to provide for an
14 annual financial audit and supplemental data under
15 certain circumstances; establishing and providing for
16 the membership of a board of directors for the
17 organization; providing limits on a director's
18 authority; specifying meeting and quorum requirements;
19 prohibiting compensation for the service of directors
20 and other specified members; authorizing specified
21 reimbursement for the travel expenses of directors and
22 specified members of the organization; authorizing the
23 organization to use certain services, property, and
24 facilities of the Florida Prepaid College Board;
25 authorizing the organization to establish the Florida
26 ABLE program; specifying requirements that must be met

27 before implementation of the program; requiring that
 28 the organization develop a participation agreement
 29 that contains specified provisions; authorizing other
 30 provisions that may be included in the agreement;
 31 providing for the amendment of the agreement under
 32 certain circumstances; providing for the use of the
 33 balance of an abandoned ABLE account by the
 34 organization; providing that contracts and
 35 participation agreements entered into by the
 36 organization do not constitute a debt or obligation of
 37 the state; authorizing the organization to contract
 38 with other states for specified purposes; providing
 39 for termination of the program under certain
 40 circumstances and for the disposition of certain
 41 assets upon termination; prohibiting the state from
 42 limiting or altering the specified vested rights of
 43 designated beneficiaries except under specified
 44 circumstances; requiring the organization to establish
 45 a comprehensive investment plan for the program;
 46 exempting funds paid into the program's trust fund
 47 from the claims of specified creditors; providing for
 48 recovery by Medicaid of certain medical assistance
 49 provided to a deceased designated beneficiary;
 50 providing for the distribution of the balance of a
 51 deceased designated beneficiary's ABLE account;
 52 requiring the organization to provide specified data

53 and files to the Agency for Health Care
 54 Administration; providing that specified payroll
 55 deduction authority applies to the Florida Prepaid
 56 College Board and the organization for the purpose of
 57 administering the program; requiring the organization
 58 to submit an annual report to specified entities;
 59 requiring the Florida Prepaid College Board to adopt
 60 rules; providing that the section is repealed on a
 61 specified date; amending s. 222.22, F.S.; providing
 62 that specified moneys, assets, and income of a
 63 qualified ABLE program, including the Florida ABLE
 64 program, are not subject to attachment, levy,
 65 garnishment, or certain legal process in favor of
 66 certain creditors or claimants; amending s. 1009.971,
 67 F.S.; conforming provisions to changes made by the
 68 act; providing an effective date.

69
 70 Be It Enacted by the Legislature of the State of Florida:

71
 72 Section 1. Section 1009.985, Florida Statutes, is created
 73 to read:

74 1009.985 Short title.—Sections 1009.985-1009.988 may be
 75 cited as the "Florida Achieving a Better Life Experience (ABLE)
 76 Act."

77 Section 2. Section 1009.986, Florida Statutes, is created
 78 to read:

79 1009.986 Florida ABLE program.-

80 (1) LEGISLATIVE INTENT.-It is the intent of the
 81 Legislature to establish a qualified ABLE program in this state
 82 which will encourage and assist the saving of private funds in
 83 tax-exempt accounts in order to pay for the qualified disability
 84 expenses of eligible individuals with disabilities. The
 85 Legislature intends that the qualified ABLE program be
 86 implemented in a manner that is consistent with federal law
 87 authorizing the program and that maximizes program efficiency
 88 and effectiveness.

89 (2) DEFINITIONS.-As used in ss. 1009.986-1009.988, the
 90 term:

91 (a) "ABLE account" means an account established by an
 92 eligible individual which is owned by the eligible individual
 93 and maintained under the Florida ABLE program.

94 (b) "Contracting state" means a state that does not have a
 95 qualified ABLE program and that has entered into a contract with
 96 Florida ABLE, Inc., to provide residents of the contracting
 97 state with access to the Florida ABLE program.

98 (c) "Designated beneficiary" means an eligible individual
 99 who established an ABLE account and is the owner of the account.

100 (d) "Disability certification" has the same meaning as
 101 provided in s. 529A of the Internal Revenue Code.

102 (e) "Eligible individual" means a resident of this state
 103 or a contracting state:

104 1. Who is entitled to benefits or disability under Title

105 | II or Title XVI of the Social Security Act for a taxable year
 106 | and whose blindness or disability occurred before the date on
 107 | which the individual attained the age of 26 years; or

108 | 2. For whom a disability certification is filed with the
 109 | United States Department of Treasury for the taxable year.

110 | (f) "Florida ABLE program" means the qualified ABLE
 111 | program established and maintained under this section by Florida
 112 | ABLE, Inc.

113 | (g) "Internal Revenue Code" means the United States
 114 | Internal Revenue Code of 1986, as defined in s. 220.03(1), and
 115 | regulations adopted pursuant thereto.

116 | (h) "Participation agreement" means the agreement between
 117 | Florida ABLE, Inc., and a participant in the Florida ABLE
 118 | program.

119 | (i) "Qualified ABLE program" means the program authorized
 120 | under s. 529A of the Internal Revenue Code which may be
 121 | established by a state, agency, or instrumentality thereof to
 122 | allow a person to make contributions for a taxable year to an
 123 | ABLE account established for the purpose of meeting the
 124 | qualified disability expenses of the designated beneficiary of
 125 | the ABLE account.

126 | (j) "Qualified disability expense" has the meaning
 127 | provided in s. 529A of the Internal Revenue Code.

128 | (3) DIRECT-SUPPORT ORGANIZATION; FLORIDA ABLE, INC.—

129 | (a) The Florida Prepaid College Board shall establish a
 130 | direct-support organization to be known as "Florida ABLE, Inc.,"

131 which is:

132 1. A Florida not-for-profit corporation registered,
 133 incorporated, organized, and operated in compliance with chapter
 134 617.

135 2. Organized and operated to receive, hold, invest, and
 136 administer property and to make expenditures for the benefit of
 137 the Florida ABLE program.

138 (b) Florida ABLE, Inc., shall operate under a written
 139 contract with the Florida Prepaid College Board. The contract
 140 must include, but is not limited to, provisions that:

141 1. Require the articles of incorporation and bylaws of
 142 Florida ABLE, Inc., to be approved by the Florida Prepaid
 143 College Board.

144 2. Require Florida ABLE, Inc., to submit an annual budget
 145 for approval by the Florida Prepaid College Board. The budget
 146 must comply with rules adopted by the Florida Prepaid College
 147 Board.

148 3. Require Florida ABLE, Inc., to pay reasonable
 149 consideration to the Florida Prepaid College Board for products
 150 or services provided directly or indirectly by the Florida
 151 Prepaid College Board.

152 4. Authorize the Florida Prepaid College Board to solicit
 153 proposals, contract or subcontract, or amend contractual service
 154 agreements of the Florida Prepaid College Board for the benefit
 155 of Florida ABLE, Inc.

156 5. Authorize the Florida Prepaid College Board to maintain

157 the website of Florida ABLE, Inc.

158 6. Require the Florida Prepaid College Board to annually
 159 certify that Florida ABLE, Inc., is complying with the terms of
 160 the contract and acting in a manner consistent with this section
 161 and in the best interest of the state. The certification must be
 162 reported in the official minutes of a meeting of the Florida
 163 Prepaid College Board.

164 7. Require the reversion of moneys and property to the
 165 Florida Prepaid College Board, or to the state if the Florida
 166 Prepaid College Board ceases to exist, which are held in trust
 167 by Florida ABLE, Inc., for the benefit of the Florida ABLE
 168 program if Florida ABLE, Inc., is no longer approved to operate.

169 8. Require the disclosure of material provisions in the
 170 contract and of the distinction between the Florida Prepaid
 171 College Board and Florida ABLE, Inc., to donors of gifts,
 172 contributions, or bequests, and the inclusion of such disclosure
 173 on all promotional and fundraising publications.

174 9. Require the fiscal year for Florida ABLE, Inc., to
 175 begin on July 1 and end on June 30 of the following year.

176 (c) Florida ABLE, Inc., shall provide for an annual
 177 financial audit in accordance with s. 215.981. The Florida
 178 Prepaid College Board and Auditor General may require Florida
 179 ABLE, Inc., or its independent auditor, to provide any
 180 supplemental data relating to the operation of Florida ABLE,
 181 Inc.

182 (d)1. The board of directors of Florida ABLE, Inc., shall

183 consist of:

184 a. The chair and the executive director of the Florida
 185 Prepaid College Board and the director of the Agency for Persons
 186 with Disabilities. The chair of the Florida Prepaid College
 187 Board shall serve as the chair of the board of directors of
 188 Florida ABLE, Inc.

189 b. Two individuals who possess knowledge, skill, and
 190 experience in the areas of accounting, risk management, or
 191 investment management, one of whom shall be appointed by the
 192 President of the Senate and one of whom shall be appointed by
 193 the Speaker of the House of Representatives.

194 c. Two individuals who are advocates of persons with
 195 disabilities, one of whom shall be appointed by the President of
 196 the Senate and one of whom shall be appointed by the Speaker of
 197 the House of Representatives. At least one of the individuals
 198 appointed under this sub-subparagraph must be an advocate of
 199 persons with developmental disabilities, as that term is defined
 200 in s. 393.063.

201 2. The term of the appointees under sub-subparagraphs 1.b.
 202 and c. shall be 3 years. An appointee may be reappointed for up
 203 to one consecutive term.

204 3. Unless authorized by the board of directors of Florida
 205 ABLE, Inc., an individual director has no authority to control
 206 or direct the operations of Florida ABLE, Inc., or the actions
 207 of its officers and employees.

208 4. The board of directors of Florida ABLE, Inc.:

209 a. Shall meet at least quarterly and at other times upon
 210 the call of the chair.

211 b. May use any method of telecommunications to conduct, or
 212 establish a quorum at, its meetings or the meetings of a
 213 subcommittee or other subdivision if the public is given proper
 214 notice of the telecommunications meeting and provided reasonable
 215 access to observe and, if appropriate, to participate.

216 5. A majority of the total current membership of the board
 217 of directors of Florida ABLE, Inc., constitutes a quorum of the
 218 board.

219 6. Members of the board of directors of Florida ABLE,
 220 Inc., and the board's subcommittees or other subdivisions shall
 221 serve without compensation; however, the members may be
 222 reimbursed for reasonable, necessary, and actual travel expenses
 223 pursuant to s. 112.061.

224 (e) Subject to rules adopted by the Florida Prepaid
 225 College Board, Florida ABLE, Inc., may use property, other than
 226 money, facilities, and personal services of the Florida Prepaid
 227 College Board, provided that Florida ABLE, Inc., offers equal
 228 employment opportunities to all persons regardless of race,
 229 color, religion, sex, age, or national origin. As used in this
 230 paragraph, the term "personal services" means use of the Florida
 231 Prepaid College Board's full-time and part-time personnel,
 232 payroll processing services, and other services prescribed by
 233 rule of the Florida Prepaid College Board.

234 (4) FLORIDA ABLE PROGRAM.-

235 (a) Florida ABLE, Inc., is authorized to establish and
 236 administer the Florida ABLE program. Before implementing the
 237 program, Florida ABLE, Inc., must obtain a written opinion from
 238 counsel specializing in:

239 1. Federal tax matters which indicates that the Florida
 240 ABLE program is designed to comply with s. 529A of the Internal
 241 Revenue Code.

242 2. Federal securities law which indicates that the Florida
 243 ABLE program and the offering of participation in the program
 244 are designed to comply with applicable federal securities law
 245 and qualify for the available tax exemptions under such law.

246 (b) Florida ABLE, Inc., must develop a participation
 247 agreement which must state that:

248 1. The participation agreement is only a debt or
 249 obligation of the Florida ABLE program and the Florida ABLE
 250 Trust Fund and, as provided under paragraph (f), is not a debt
 251 or obligation of the state.

252 2. Participation in the Florida ABLE program does not
 253 guarantee that sufficient funds will be available to cover all
 254 qualified disability expenses for any designated beneficiary and
 255 does not guarantee the receipt or continuation of any product or
 256 service for the designated beneficiary.

257 3. The establishment of an ABLE account in violation of
 258 federal law is prohibited.

259 4. Contributions in excess of the limitations set forth in
 260 s. 529A of the Internal Revenue Code are prohibited.

261 5. The withdrawal of funds from an ABLE account must
 262 comply with the requirements and procedures established by
 263 Florida ABLE, Inc., for a withdrawal. In establishing the
 264 requirements and procedures, Florida ABLE, Inc., shall provide
 265 for distributions to be made in as efficient and expeditious
 266 manner as is prudent and possible, consistent with the
 267 requirements of s. 529A of the Internal Revenue Code.

268 6. The state is a creditor of ABLE accounts as, and to the
 269 extent, set forth in s. 529A of the Internal Revenue Code.

270 7. Material misrepresentations by a party to the
 271 participation agreement, other than Florida ABLE, Inc., in the
 272 application for the participation agreement or in any
 273 communication with Florida ABLE, Inc., regarding the Florida
 274 ABLE program may result in the involuntary liquidation of the
 275 ABLE account. If an account is involuntarily liquidated, the
 276 designated beneficiary is entitled to a refund, subject to any
 277 fees or penalties provided by the participation agreement and
 278 the Internal Revenue Code.

279 (c) The participation agreement may include provisions
 280 specifying:

281 1. The requirements and applicable restrictions for
 282 opening an ABLE account.

283 2. The eligibility requirements for a party to a
 284 participation agreement and the rights of the party.

285 3. The requirements and applicable restrictions for making
 286 contributions to an ABLE account.

287 4. The requirements and applicable restrictions for
 288 directing the investment of the contributions or balance of the
 289 ABLE account.

290 5. The administrative fee and other fees and penalties
 291 applicable to an ABLE account.

292 6. The terms and conditions under which an ABLE account or
 293 participation agreement may be modified, transferred, or
 294 terminated.

295 7. The disposition of abandoned ABLE accounts.

296 8. Other terms and conditions determined by Florida ABLE,
 297 Inc., to be necessary or proper.

298 (d) The participation agreement may be freely amended
 299 throughout its term for purposes that include, but are not
 300 limited to, allowing a participant to increase or decrease the
 301 level of participation and to change designated beneficiaries
 302 and other matters authorized by this section and s. 529A of the
 303 Internal Revenue Code.

304 (e) If an ABLE account is determined to be abandoned
 305 pursuant to rules adopted by the Florida Prepaid College Board,
 306 Florida ABLE, Inc., may use the balance of the account to
 307 operate the Florida ABLE program or may transfer the balance to
 308 the Florida Prepaid Tuition Scholarship Program to provide
 309 matching funds for prepaid tuition scholarships for economically
 310 disadvantaged youth under s. 1009.984.

311 (f) A contract or participation agreement entered into by
 312 or an obligation of Florida ABLE, Inc., on behalf of and for the

313 benefit of the Florida ABLE program does not constitute a debt
 314 or obligation of the state but is the obligation of the Florida
 315 ABLE program. The state does not have an obligation to a
 316 designated beneficiary or any other person as a result of the
 317 Florida ABLE program. The obligation of the Florida ABLE program
 318 is limited solely to amounts in the Florida ABLE Trust Fund. All
 319 amounts obligated to be paid from the Florida ABLE Trust Fund
 320 are limited to the amounts available for such obligation. The
 321 amounts held in the Florida ABLE program may be disbursed only
 322 in accordance with this section.

323 (g) Florida ABLE, Inc., may contract with other states to
 324 participate under the rules of another state's qualified ABLE
 325 program or to authorize the participation of a contracting state
 326 in the Florida ABLE program.

327 (h) The Florida ABLE program shall continue in existence
 328 until terminated by law. If the state determines that the
 329 program is financially infeasible, the state may terminate the
 330 program. Upon termination, amounts in the Florida ABLE Trust
 331 Fund held for designated beneficiaries shall be returned in
 332 accordance with the participation agreement. Any unclaimed
 333 amounts remaining in the trust fund may be transferred to the
 334 Florida Prepaid Tuition Scholarship Program to provide matching
 335 funds for prepaid tuition scholarships for economically
 336 disadvantaged youth under s. 1009.984.

337 (i) The state pledges to the designated beneficiaries that
 338 the state will not limit or alter their rights under this

339 section which are vested in the Florida ABLE program until the
 340 program's obligations are met and discharged. However, this
 341 paragraph does not preclude such limitation or alteration if
 342 adequate provision is made by law for the protection of the
 343 designated beneficiaries pursuant to the obligations of Florida
 344 ABLE, Inc., and does not preclude termination of the Florida
 345 ABLE program if the state or the Florida Prepaid College Board
 346 determines that the program is not financially feasible. Florida
 347 ABLE, Inc., on behalf of the state, may include this pledge and
 348 undertaking by the state in participation agreements.

349 (5) COMPREHENSIVE INVESTMENT PLAN.—Florida ABLE, Inc.,
 350 shall establish a comprehensive investment plan for the Florida
 351 ABLE program, subject to the approval of the Florida Prepaid
 352 College Board. The comprehensive investment plan must specify
 353 the investment policies to be used by Florida ABLE, Inc., in its
 354 administration of the program. Florida ABLE, Inc., may place
 355 assets of the program in investment products and in such
 356 proportions as may be designated or approved in the
 357 comprehensive investment plan. Such products shall be
 358 underwritten and offered in compliance with the applicable
 359 federal and state laws or regulations or exemptions therefrom. A
 360 designated beneficiary may not direct the investment of any
 361 contributions to the Florida ABLE program, unless specific fund
 362 options are offered by Florida ABLE, Inc. Directors, officers,
 363 and employees of Florida ABLE, Inc., may enter into
 364 participation agreements, notwithstanding their fiduciary

365 responsibilities or official duties related to the Florida ABLE
 366 program.

367 (6) EXEMPTION FROM CLAIMS OF CREDITORS.—Moneys paid into
 368 or out of the Florida ABLE Trust Fund by or on behalf of a
 369 designated beneficiary are exempt, as provided by s. 222.22,
 370 from all claims of creditors of the designated beneficiary if
 371 the participation agreement has not been terminated. Moneys paid
 372 into the Florida ABLE program and benefits accrued through the
 373 program may not be pledged for the purpose of securing a loan.

374 (7) MEDICAID RECOVERY; PRIORITY OF DISTRIBUTIONS.—

375 (a) Upon the death of the designated beneficiary, the
 376 Agency for Health Care Administration or the state Medicaid
 377 program for a contracting state may file a claim with the
 378 Florida ABLE program for the total amount of medical assistance
 379 provided for the designated beneficiary under the Medicaid
 380 program, less any premiums paid by or on behalf of the
 381 designated beneficiary to a Medicaid buy-in program. Funds in
 382 the ABLE account of the deceased designated beneficiary must
 383 first be distributed for qualified disability expenses followed
 384 by distributions for the Medicaid claim authorized under this
 385 paragraph. Any remaining amount shall be distributed as provided
 386 in the participation agreement.

387 (b) Florida ABLE, Inc., shall provide to the Agency for
 388 Health Care Administration or the agency's contractor data
 389 files, layouts, data dictionaries, and any other necessary
 390 materials used by Florida ABLE, Inc., to carry out this section.

391 The exchange of data must occur on a schedule mutually agreed
 392 upon by both parties.

393 (8) PAYROLL DEDUCTION AUTHORITY.—The payroll deduction
 394 authority provided under s. 1009.975 applies to the Florida
 395 Prepaid College Board and Florida ABLE, Inc., for purposes of
 396 administering this section.

397 (9) ANNUAL REPORT.—On or before March 31 of each year,
 398 Florida ABLE, Inc., shall prepare or cause to be prepared a
 399 report setting forth in appropriate detail an accounting of the
 400 Florida ABLE program which includes a description of the
 401 financial condition of the program at the close of the fiscal
 402 year. Florida ABLE, Inc., shall submit copies of the report to
 403 the Governor, the President of the Senate, the Speaker of the
 404 House of Representatives, and the minority leaders of the Senate
 405 and the House of Representatives and shall make the report
 406 available to each designated beneficiary. The accounts of the
 407 Florida ABLE program are subject to annual audit by the Auditor
 408 General.

409 (10) RULES.—The Florida Prepaid College Board shall adopt
 410 rules to administer this section. Such rules must include, but
 411 are not limited to:

412 (a) Specifying the procedures by which Florida ABLE, Inc.,
 413 shall be governed and operate, including requirements for the
 414 budget of Florida ABLE, Inc., and conditions with which Florida
 415 ABLE, Inc., must comply to use property, facilities, or personal
 416 services of the Florida Prepaid College Board.

417 (b) The procedures for determining that an ABLE account
 418 has been abandoned.

419 (c) Adoption of provisions determined necessary by the
 420 Florida Prepaid College Board for the Florida ABLE program to
 421 retain its status as a qualified ABLE program or the tax-exempt
 422 status or other similar status of the program or its
 423 participants under the Internal Revenue Code. Florida ABLE,
 424 Inc., shall inform participants in the Florida ABLE program of
 425 changes to the tax or securities status of their interests in
 426 the ABLE program and participation agreements.

427 (11) REPEAL.—In accordance with s. 20.058, this section is
 428 repealed October 1, 2020, unless reviewed and saved from repeal
 429 by the Legislature.

430 Section 3. Subsection (5) is added to section 222.22,
 431 Florida Statutes, to read:

432 222.22 Exemption of assets in qualified tuition programs,
 433 medical savings accounts, Coverdell education savings accounts,
 434 and hurricane savings accounts from legal process.—

435 (5) Except as provided in s. 1009.986(7), as it relates to
 436 any validly existing qualified ABLE program authorized by s.
 437 529A of the Internal Revenue Code of 1986, as amended,
 438 including, but not limited to, the Florida ABLE program
 439 participation agreements under s. 1009.986, moneys paid into or
 440 out of such a program, and the income and assets of such a
 441 program, are not liable to attachment, levy, garnishment, or
 442 legal process in this state in favor of any creditor of or

443 claimant against any designated beneficiary or other program
 444 participant.

445 Section 4. Subsections (1) and (4) of section 1009.971,
 446 Florida Statutes, are amended to read:

447 1009.971 Florida Prepaid College Board.—

448 (1) FLORIDA PREPAID COLLEGE BOARD; CREATION.—The Florida
 449 Prepaid College Board is hereby created as a body corporate with
 450 all the powers of a body corporate for the purposes delineated
 451 in this section. The board shall administer the prepaid program
 452 and the savings program, and shall perform essential
 453 governmental functions as provided in ss. 1009.97-1009.988 ~~ss.~~
 454 ~~1009.97-1009.984~~. For the purposes of s. 6, Art. IV of the State
 455 Constitution, the board shall be assigned to and
 456 administratively housed within the State Board of
 457 Administration, but it shall independently exercise the powers
 458 and duties specified in ss. 1009.97-1009.988 ~~ss. 1009.97-~~
 459 ~~1009.984~~.

460 (4) FLORIDA PREPAID COLLEGE BOARD; POWERS AND DUTIES.—The
 461 board shall have the powers and duties necessary or proper to
 462 carry out the provisions of ss. 1009.97-1009.988 ~~ss. 1009.97-~~
 463 ~~1009.984~~, including, but not limited to, the power and duty to:

464 (a) Appoint an executive director to serve as the chief
 465 administrative and operational officer of the board and to
 466 perform other duties assigned to him or her by the board.

467 (b) Adopt an official seal and rules.

468 (c) Sue and be sued.

469 (d) Make and execute contracts and other necessary
 470 instruments.

471 (e) Establish agreements or other transactions with
 472 federal, state, and local agencies, including state universities
 473 and Florida College System institutions.

474 (f) Administer the trust fund in a manner that is
 475 sufficiently actuarially sound to defray the obligations of the
 476 prepaid program and the savings program, considering the
 477 separate purposes and objectives of each program. The board
 478 shall annually evaluate or cause to be evaluated the actuarial
 479 soundness of the prepaid fund. If the board perceives a need for
 480 additional assets in order to preserve actuarial soundness of
 481 the prepaid program, the board may adjust the terms of
 482 subsequent advance payment contracts to ensure such soundness.

483 (g) Invest funds not required for immediate disbursement.

484 (h) Appear in its own behalf before boards, commissions,
 485 or other governmental agencies.

486 (i) Hold, buy, and sell any instruments, obligations,
 487 securities, and property determined appropriate by the board.

488 (j) Require a reasonable length of state residence for
 489 qualified beneficiaries.

490 (k) Segregate contributions and payments to the trust fund
 491 into the appropriate fund.

492 (l) Procure and contract for goods and services, employ
 493 personnel, and engage the services of private consultants,
 494 actuaries, managers, legal counsel, and auditors in a manner

495 determined to be necessary and appropriate by the board.

496 (m) Solicit and accept gifts, grants, loans, and other
 497 aids from any source or participate in any other way in any
 498 government program to carry out the purposes of ss. 1009.97-
 499 1009.988 ~~ss. 1009.97-1009.984~~.

500 (n) Require and collect administrative fees and charges in
 501 connection with any transaction and impose reasonable penalties,
 502 including default, for delinquent payments or for entering into
 503 an advance payment contract or a participation agreement on a
 504 fraudulent basis.

505 (o) Procure insurance against any loss in connection with
 506 the property, assets, and activities of the trust fund or the
 507 board.

508 (p) Impose reasonable time limits on use of the benefits
 509 provided by the prepaid program or savings program. However, any
 510 such limitations shall be specified within the advance payment
 511 contract or the participation agreement, respectively.

512 (q) Delineate the terms and conditions under which
 513 payments may be withdrawn from the trust fund and impose
 514 reasonable fees and charges for such withdrawal. Such terms and
 515 conditions shall be specified within the advance payment
 516 contract or the participation agreement.

517 (r) Provide for the receipt of contributions in lump sums
 518 or installment payments.

519 (s) Require that purchasers of advance payment contracts
 520 or benefactors of participation agreements verify, under oath,

521 any requests for contract conversions, substitutions, transfers,
 522 cancellations, refund requests, or contract changes of any
 523 nature. Verification shall be accomplished as authorized and
 524 provided for in s. 92.525(1)(a).

525 (t) Delegate responsibility for administration of one or
 526 both of the comprehensive investment plans required in s.
 527 1009.973 to persons the board determines to be qualified. Such
 528 persons shall be compensated by the board.

529 (u) Endorse insurance coverage written exclusively for the
 530 purpose of protecting advance payment contracts, and
 531 participation agreements, and the purchasers, benefactors, and
 532 beneficiaries thereof, including group life policies and group
 533 disability policies, which are exempt from the provisions of
 534 part V of chapter 627.

535 (v) Form strategic alliances with public and private
 536 entities to provide benefits to the prepaid program, savings
 537 program, and participants of either or both programs.

538 (w) Solicit proposals and contract, pursuant to s.
 539 287.057, for the marketing of the prepaid program or the savings
 540 program, or both together. Any materials produced for the
 541 purpose of marketing the prepaid program or the savings program
 542 shall be submitted to the board for review. No such materials
 543 shall be made available to the public before the materials are
 544 approved by the board. Any educational institution may
 545 distribute marketing materials produced for the prepaid program
 546 or the savings program; however, all such materials shall be

547 approved by the board prior to distribution. Neither the state
 548 nor the board shall be liable for misrepresentation of the
 549 prepaid program or the savings program by a marketing agent.

550 (x) Establish other policies, procedures, and criteria to
 551 implement and administer the provisions of ss. 1009.97-1009.988
 552 ~~ss. 1009.97-1009.984~~.

553 (y) Adopt procedures to govern contract dispute
 554 proceedings between the board and its vendors.

555 Section 5. This act shall take effect October 1, 2015.



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COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee

3 Representative Rodrigues, R. offered the following:

4
 5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 1009.985, Florida Statutes, is created
 8 to read:

9 1009.985 Short title.—Sections 1009.985-1009.988 may be
 10 cited as the "Florida Achieving a Better Life Experience (ABLE)
 11 Act."

12 Section 2. Section 1009.986, Florida Statutes, is created
 13 to read:

14 1009.986 Florida ABLE program.—

15 (1) LEGISLATIVE INTENT.—It is the intent of the
 16 Legislature to establish a qualified ABLE program in this state
 17 which will encourage and assist the saving of private funds in



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18 tax-exempt accounts in order to pay for the qualified disability
19 expenses of eligible individuals with disabilities. The
20 Legislature intends that the qualified ABLE program be
21 implemented in a manner that is consistent with federal law
22 authorizing the program and that maximizes program efficiency
23 and effectiveness.

24 (2) DEFINITIONS.—As used in ss. 1009.986-1009.988, the
25 term:

26 (a) "ABLE account" means an account established and
27 maintained under the Florida ABLE program.

28 (b) "Contracting state" means a state that has entered
29 into a contract with Florida ABLE, Inc., to provide residents of
30 Florida or that state with access to a qualified ABLE program.

31 (c) "Designated beneficiary" means the eligible individual
32 who established an ABLE account or the eligible individual to
33 whom an ABLE account was transferred.

34 (d) "Eligible individual" has the same meaning as provided
35 in s. 529A of the Internal Revenue Code.

36 (e) "Florida ABLE program" means the qualified ABLE
37 program established and maintained under this section by Florida
38 ABLE, Inc.

39 (f) "Internal Revenue Code" means the United States
40 Internal Revenue Code of 1986, as defined in s. 220.03(1), and
41 regulations adopted pursuant thereto.



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42 (g) "Participation agreement" means the agreement between
43 Florida ABLE, Inc., and a participant in the Florida ABLE
44 program.

45 (h) "Qualified ABLE program" means the program authorized
46 under s. 529A of the Internal Revenue Code which may be
47 established by a state or agency, or instrumentality thereof, to
48 allow a person to make contributions for a taxable year to an
49 ABLE account established for the purpose of meeting the
50 qualified disability expenses of the designated beneficiary of
51 the ABLE account.

52 (i) "Qualified disability expense" has the same meaning as
53 provided in s. 529A of the Internal Revenue Code.

54 (3) DIRECT-SUPPORT ORGANIZATION; FLORIDA ABLE, INC.—

55 (a) The Florida Prepaid College Board shall establish a
56 direct-support organization to be known as "Florida ABLE, Inc.,"
57 which is:

58 1. A Florida not-for-profit corporation registered,
59 incorporated, organized, and operated in compliance with chapter
60 617.

61 2. Organized and operated to receive, hold, invest, and
62 administer property and to make expenditures for the benefit of
63 the Florida ABLE program.

64 (b) Florida ABLE, Inc., shall operate under a written
65 contract with the Florida Prepaid College Board. The contract
66 must include, but is not limited to, provisions that require:



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- 67 1. The articles of incorporation and bylaws of Florida
68 ABLE, Inc., to be approved by the Florida Prepaid College Board.
- 69 2. Florida ABLE, Inc., to submit an annual budget for
70 approval by the Florida Prepaid College Board. The budget must
71 comply with rules adopted by the Florida Prepaid College Board.
- 72 3. Florida ABLE, Inc., to pay reasonable consideration to
73 the Florida Prepaid College Board for products or services
74 provided directly or indirectly by the Florida Prepaid College
75 Board.
- 76 4. The Florida Prepaid College Board to solicit proposals,
77 to contract or subcontract, or to amend contractual service
78 agreements of the Florida Prepaid College Board for the benefit
79 of Florida ABLE, Inc.
- 80 5. The Florida Prepaid College Board to maintain the
81 website of Florida ABLE, Inc.
- 82 6. The Florida Prepaid College Board to annually certify
83 that Florida ABLE, Inc., is complying with the terms of the
84 contract and acting in a manner consistent with this section and
85 in the best interest of the state. The certification must be
86 reported in the official minutes of a meeting of the Florida
87 Prepaid College Board.
- 88 7. The disclosure of material provisions in the contract
89 and of the distinction between the Florida Prepaid College Board
90 and Florida ABLE, Inc., to donors of gifts, contributions, or
91 bequests, and the inclusion of such disclosure on all
92 promotional and fundraising publications.

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93 8. The fiscal year for Florida ABLE, Inc., to begin on
94 July 1 and end on June 30 of the following year.

95 (c) Florida ABLE, Inc., shall provide for an annual
96 financial audit in accordance with s. 215.981. The Florida
97 Prepaid College Board and the Auditor General may require
98 Florida ABLE, Inc., or its independent auditor, to provide any
99 supplemental data relating to the operation of Florida ABLE,
100 Inc.

101 (d)1. The board of directors of Florida ABLE, Inc., shall
102 consist of:

103 a. The chair of the Florida Prepaid College Board, who
104 shall serve as the chair of the board of directors of Florida
105 ABLE, Inc.

106 b. One individual who possesses knowledge, skill, and
107 experience in the areas of accounting, risk management, or
108 investment management, who shall be appointed by the Florida
109 Prepaid College Board. A current member of the Florida Prepaid
110 College Board, other than the chair, may be appointed.

111 c. One individual who possesses knowledge, skill, and
112 experience in the areas of accounting, risk management, or
113 investment management, who shall be appointed by the Governor.

114 d. Two individuals who are advocates of persons with
115 disabilities, one of whom shall be appointed by the President of
116 the Senate and one of whom shall be appointed by the Speaker of
117 the House of Representatives. At least one of the individuals
118 appointed under this sub-subparagraph must be an advocate of



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119 persons with developmental disabilities, as that term is defined
120 in s. 393.063.

121 2.a. The term of the appointee under sub-subparagraph 1.b.
122 shall be up to 3 years as determined by the Florida Prepaid
123 College Board. Such appointee may be reappointed.

124 b. The term of the appointees under sub-subparagraphs 1.c.
125 and d. shall be 3 years. Such appointees may be reappointed for
126 up to one consecutive term.

127 3. Unless authorized by the board of directors of Florida
128 ABLE, Inc., an individual director has no authority to control
129 or direct the operations of Florida ABLE, Inc., or the actions
130 of its officers and employees.

131 4. The board of directors of Florida ABLE, Inc.:

132 a. Shall meet at least quarterly and at other times upon
133 the call of the chair.

134 b. May use any method of telecommunications to conduct, or
135 establish a quorum at, its meetings or the meetings of a
136 subcommittee or other subdivision if the public is given proper
137 notice of the telecommunications meeting and provided reasonable
138 access to observe and, if appropriate, to participate.

139 5. A majority of the total current membership of the board
140 of directors of Florida ABLE, Inc., constitutes a quorum of the
141 board.

142 6. Members of the board of directors of Florida ABLE,
143 Inc., and the board's subcommittees or other subdivisions shall
144 serve without compensation; however, the members may be



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145 reimbursed for reasonable, necessary, and actual travel expenses
146 pursuant to s. 112.061.

147 (e) Subject to rule adopted by the Florida Prepaid College
148 Board, Florida ABLE, Inc., may use property, other than money,
149 facilities, and personal services of the Florida Prepaid College
150 Board, provided that Florida ABLE, Inc., offers equal employment
151 opportunities to all persons regardless of race, color,
152 religion, sex, age, or national origin. As used in this
153 paragraph, the term "personal services" means use of the Florida
154 Prepaid College Board's full-time and part-time personnel,
155 payroll processing services, and other services prescribed by
156 rule of the Florida Prepaid College Board.

157 (4) FLORIDA ABLE PROGRAM.—

158 (a) On or before July 1, 2016, Florida ABLE, Inc., shall
159 establish and administer the Florida ABLE program. Before
160 implementing the program, Florida ABLE, Inc., must obtain a
161 written opinion from counsel specializing in:

162 1. Federal tax matters which indicates that the Florida
163 ABLE program is designed to comply with s. 529A of the Internal
164 Revenue Code.

165 2. Federal securities law which indicates that the Florida
166 ABLE program and the offering of participation in the program
167 are designed to comply with applicable federal securities law
168 and qualify for the available tax exemptions under such law.

169 (b) The participation agreement must include provisions
170 specifying that:



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171 1. The participation agreement is only a debt or
172 obligation of the Florida ABLE program and the Florida ABLE
173 Program Trust Fund and, as provided under paragraph (f), is not
174 a debt or obligation of the Florida Prepaid College Board or the
175 state.

176 2. Participation in the Florida ABLE program does not
177 guarantee that sufficient funds will be available to cover all
178 qualified disability expenses for any designated beneficiary and
179 does not guarantee the receipt or continuation of any product or
180 service for the designated beneficiary.

181 3. The designated beneficiary must be a resident of this
182 state or a resident of a contracting state at the time the ABLE
183 account is established.

184 4. The establishment of an ABLE account in violation of
185 federal law is prohibited.

186 5. Contributions in excess of the limitations set forth in
187 s. 529A of the Internal Revenue Code are prohibited.

188 6. The state is a creditor of ABLE accounts as, and to the
189 extent, set forth in s. 529A of the Internal Revenue Code.

190 7. Material misrepresentations by a party to the
191 participation agreement, other than Florida ABLE, Inc., in the
192 application for the participation agreement or in any
193 communication with Florida ABLE, Inc., regarding the Florida
194 ABLE program may result in the involuntary liquidation of the
195 ABLE account. If an account is involuntarily liquidated, the
196 designated beneficiary is entitled to a refund, subject to any



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197 fees or penalties provided by the participation agreement and
198 the Internal Revenue Code.

199 (c) The participation agreement may include provisions
200 specifying:

201 1. The requirements and applicable restrictions for
202 opening an ABLE account.

203 2. The eligibility requirements for a party to a
204 participation agreement and the rights of the party.

205 3. The requirements and applicable restrictions for making
206 contributions to an ABLE account.

207 4. The requirements and applicable restrictions for
208 directing the investment of the contributions or balance of the
209 ABLE account.

210 5. The administrative fee and other fees and penalties
211 applicable to an ABLE account.

212 6. The terms and conditions under which an ABLE account or
213 participation agreement may be modified, transferred, or
214 terminated.

215 7. The disposition of abandoned ABLE accounts.

216 8. Other terms and conditions determined to be necessary
217 or proper.

218 (d) The participation agreement may be amended throughout
219 its term for purposes that include, but are not limited to,
220 allowing a participant to increase or decrease the level of
221 participation and to change designated beneficiaries and other



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222 matters authorized by this section and s. 529A of the Internal
223 Revenue Code.

224 (e) If an ABLE account is determined to be abandoned
225 pursuant to rules adopted by the Florida Prepaid College Board,
226 Florida ABLE, Inc., may use the balance of the account to
227 operate the Florida ABLE program.

228 (f) A contract or participation agreement entered into by
229 or an obligation of Florida ABLE, Inc., on behalf of and for the
230 benefit of the Florida ABLE program does not constitute a debt
231 or obligation of the Florida Prepaid College Board or the state,
232 but is only a debt or obligation of the Florida ABLE program and
233 the Florida ABLE Program Trust Fund. The state does not have an
234 obligation to a designated beneficiary or any other person as a
235 result of the Florida ABLE program. The obligation of the
236 Florida ABLE program is limited solely to amounts in the Florida
237 ABLE Program Trust Fund. All amounts obligated to be paid from
238 the Florida ABLE Program Trust Fund are limited to the amounts
239 available for such obligation. The amounts held in the Florida
240 ABLE program may be disbursed only in accordance with this
241 section.

242 (g) Notwithstanding any other provision of law, Florida
243 ABLE, Inc., may enter into an agreement with a contracting state
244 which allows Florida ABLE, Inc., to participate under the
245 design, operation, and rules of the contracting state's
246 qualified ABLE program or which allows the contracting state to
247 participate under the Florida ABLE program.



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248 (h) The Florida ABLE program shall continue in existence
249 until terminated by law. If the state determines that the
250 program is financially infeasible, the state may terminate the
251 program. Upon termination, amounts in the Florida ABLE Program
252 Trust Fund held for designated beneficiaries shall be returned
253 in accordance with the participation agreement.

254 (i) The state pledges to the designated beneficiaries that
255 the state will not limit or alter their rights under this
256 section which are vested in the Florida ABLE program until the
257 program's obligations are met and discharged. However, this
258 paragraph does not preclude such limitation or alteration if
259 adequate provision is made by law for the protection of the
260 designated beneficiaries pursuant to the obligations of Florida
261 ABLE, Inc., and does not preclude termination of the Florida
262 ABLE program if the state determines that the program is not
263 financially feasible. This pledge and undertaking by the state
264 may be included in participation agreements.

265 (5) COMPREHENSIVE INVESTMENT PLAN.—Florida ABLE, Inc.,
266 shall establish a comprehensive investment plan for the Florida
267 ABLE program, subject to the approval of the Florida Prepaid
268 College Board. The comprehensive investment plan must specify
269 the investment policies to be used by Florida ABLE, Inc., in its
270 administration of the program. Florida ABLE, Inc., may place
271 assets of the program in investment products and in such
272 proportions as may be designated or approved in the
273 comprehensive investment plan. Such products shall be



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274 underwritten and offered in compliance with the applicable
275 federal and state laws or regulations or exemptions therefrom. A
276 designated beneficiary may not direct the investment of any
277 contributions to the Florida ABLE program, unless specific fund
278 options are offered by Florida ABLE, Inc. Directors, officers,
279 and employees of Florida ABLE, Inc., may enter into
280 participation agreements, notwithstanding their fiduciary
281 responsibilities or official duties related to the Florida ABLE
282 program.

283 (6) EXEMPTION FROM CLAIMS OF CREDITORS.—Moneys paid into
284 or out of the Florida ABLE Program Trust Fund by or on behalf of
285 a designated beneficiary are exempt, as provided by s. 222.22,
286 from all claims of creditors of the designated beneficiary if
287 the participation agreement has not been terminated. Moneys paid
288 into the Florida ABLE program and benefits accrued through the
289 program may not be pledged for the purpose of securing a loan.

290 (7) MEDICAID RECOVERY; PRIORITY OF DISTRIBUTIONS.—

291 (a) Upon the death of the designated beneficiary, the
292 Agency for Health Care Administration and the Medicaid program
293 for another state may file a claim with the Florida ABLE program
294 for the total amount of medical assistance provided for the
295 designated beneficiary under the Medicaid program, less any
296 premiums paid by or on behalf of the designated beneficiary to a
297 Medicaid buy-in program. Funds in the ABLE account of the
298 deceased designated beneficiary must first be distributed for
299 qualified disability expenses followed by distributions for the



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300 Medicaid claim authorized under this paragraph. Any remaining
301 amount shall be distributed as provided in the participation
302 agreement.

303 (b) Florida ABLE, Inc., shall assist and cooperate with
304 the Agency for Health Care Administration and Medicaid programs
305 in other states by providing the agency and programs with the
306 information needed to accomplish the purpose and objective of
307 this subsection.

308 (8) PAYROLL DEDUCTION AUTHORITY.—The payroll deduction
309 authority provided under s. 1009.975 applies to the Florida
310 Prepaid College Board and Florida ABLE, Inc., for purposes of
311 administering this section.

312 (9) REPORTS.—

313 (a) On or before November 1, 2015, Florida ABLE, Inc.,
314 shall prepare a report on the status of the establishment of the
315 Florida ABLE program by Florida ABLE, Inc. The report must also
316 include, if warranted, recommendations for statutory changes to
317 enhance the effectiveness and efficiency of the program. Florida
318 ABLE, Inc., shall submit copies of the report to the Governor,
319 the President of the Senate, and the Speaker of the House of
320 Representatives.

321 (b) On or before March 31 of each year, Florida ABLE,
322 Inc., shall prepare or cause to be prepared a report setting
323 forth in appropriate detail an accounting of the Florida ABLE
324 program which includes a description of the financial condition
325 of the program at the close of the fiscal year. Florida ABLE,



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326 Inc., shall submit copies of the report to the Governor, the
327 President of the Senate, the Speaker of the House of
328 Representatives, and the minority leaders of the Senate and the
329 House of Representatives and shall make the report available to
330 each designated beneficiary. The accounts of the Florida ABLE
331 program are subject to annual audit by the Auditor General.

332 (10) RULES.—The Florida Prepaid College Board shall adopt
333 rules to administer this section. Such rules must include, but
334 are not limited to:

335 (a) Specifying the procedures by which Florida ABLE, Inc.,
336 shall be governed and operate, including requirements for the
337 budget of Florida ABLE, Inc., and conditions with which Florida
338 ABLE, Inc., must comply to use property, facilities, or personal
339 services of the Florida Prepaid College Board.

340 (b) The procedures for determining that an ABLE account
341 has been abandoned.

342 (c) Adoption of provisions determined necessary by the
343 Florida Prepaid College Board for the Florida ABLE program to
344 retain its status as a qualified ABLE program or the tax-exempt
345 status or other similar status of the program or its
346 participants under the Internal Revenue Code. Florida ABLE,
347 Inc., shall inform participants in the Florida ABLE program of
348 changes to the tax or securities status of their interests in
349 the ABLE program and participation agreements.

350 (11) STATE OUTREACH PARTNERS.—The Agency for Health Care
351 Administration, the Agency for Persons with Disabilities, the



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352 Department of Children and Families, and the Department of
353 Education shall assist, cooperate, and coordinate with Florida
354 ABLE, Inc., in the provision of public information and outreach
355 for the Florida ABLE program.

356 (12) REPEAL.—In accordance with s. 20.058, this section is
357 repealed October 1, 2020, unless reviewed and saved from repeal
358 by the Legislature.

359 Section 3. Subsection (5) is added to section 222.22,
360 Florida Statutes, to read:

361 222.22 Exemption of assets in qualified tuition programs,
362 medical savings accounts, Coverdell education savings accounts,
363 and hurricane savings accounts from legal process.—

364 (5) Except as provided in s. 1009.986(7), as it relates to
365 any validly existing qualified ABLE program authorized by s.
366 529A of the Internal Revenue Code, including, but not limited
367 to, the Florida ABLE program participation agreements under s.
368 1009.986, moneys paid into or out of such a program, and the
369 income and assets of such a program, are not liable to
370 attachment, levy, garnishment, or legal process in this state in
371 favor of any creditor of or claimant against any designated
372 beneficiary or other program participant.

373 Section 4. Subsections (1) and (4) of section 1009.971,
374 Florida Statutes, are amended to read:

375 1009.971 Florida Prepaid College Board.—

376 (1) FLORIDA PREPAID COLLEGE BOARD; CREATION.—The Florida
377 Prepaid College Board is hereby created as a body corporate with



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378 all the powers of a body corporate for the purposes delineated
379 in this section. The board shall administer the prepaid program
380 and the savings program, and shall perform essential
381 governmental functions as provided in ss. 1009.97-1009.988 ~~ss.~~
382 ~~1009.97-1009.984~~. For the purposes of s. 6, Art. IV of the State
383 Constitution, the board shall be assigned to and
384 administratively housed within the State Board of
385 Administration, but it shall independently exercise the powers
386 and duties specified in ss. 1009.97-1009.988 ~~ss. 1009.97-~~
387 ~~1009.984~~.

388 (4) FLORIDA PREPAID COLLEGE BOARD; POWERS AND DUTIES.—The
389 board shall have the powers and duties necessary or proper to
390 carry out the provisions of ss. 1009.97-1009.988 ~~ss. 1009.97-~~
391 ~~1009.984~~, including, but not limited to, the power and duty to:

392 (a) Appoint an executive director to serve as the chief
393 administrative and operational officer of the board and to
394 perform other duties assigned to him or her by the board.

395 (b) Adopt an official seal and rules.

396 (c) Sue and be sued.

397 (d) Make and execute contracts and other necessary
398 instruments.

399 (e) Establish agreements or other transactions with
400 federal, state, and local agencies, including state universities
401 and Florida College System institutions.

402 (f) Administer the trust fund in a manner that is
403 sufficiently actuarially sound to defray the obligations of the



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404 prepaid program and the savings program, considering the
405 separate purposes and objectives of each program. The board
406 shall annually evaluate or cause to be evaluated the actuarial
407 soundness of the prepaid fund. If the board perceives a need for
408 additional assets in order to preserve actuarial soundness of
409 the prepaid program, the board may adjust the terms of
410 subsequent advance payment contracts to ensure such soundness.

411 (g) Invest funds not required for immediate disbursement.

412 (h) Appear in its own behalf before boards, commissions,
413 or other governmental agencies.

414 (i) Hold, buy, and sell any instruments, obligations,
415 securities, and property determined appropriate by the board.

416 (j) Require a reasonable length of state residence for
417 qualified beneficiaries.

418 (k) Segregate contributions and payments to the trust fund
419 into the appropriate fund.

420 (l) Procure and contract for goods and services, employ
421 personnel, and engage the services of private consultants,
422 actuaries, managers, legal counsel, and auditors in a manner
423 determined to be necessary and appropriate by the board.

424 (m) Solicit and accept gifts, grants, loans, and other
425 aids from any source or participate in any other way in any
426 government program to carry out the purposes of ss. 1009.97-
427 1009.988 ~~ss. 1009.97-1009.984~~.

428 (n) Require and collect administrative fees and charges in
429 connection with any transaction and impose reasonable penalties,



Amendment No.

430 including default, for delinquent payments or for entering into
431 an advance payment contract or a participation agreement on a
432 fraudulent basis.

433 (o) Procure insurance against any loss in connection with
434 the property, assets, and activities of the trust fund or the
435 board.

436 (p) Impose reasonable time limits on use of the benefits
437 provided by the prepaid program or savings program. However, any
438 such limitations shall be specified within the advance payment
439 contract or the participation agreement, respectively.

440 (q) Delineate the terms and conditions under which
441 payments may be withdrawn from the trust fund and impose
442 reasonable fees and charges for such withdrawal. Such terms and
443 conditions shall be specified within the advance payment
444 contract or the participation agreement.

445 (r) Provide for the receipt of contributions in lump sums
446 or installment payments.

447 (s) Require that purchasers of advance payment contracts
448 or benefactors of participation agreements verify, under oath,
449 any requests for contract conversions, substitutions, transfers,
450 cancellations, refund requests, or contract changes of any
451 nature. Verification shall be accomplished as authorized and
452 provided for in s. 92.525(1)(a).

453 (t) Delegate responsibility for administration of one or
454 both of the comprehensive investment plans required in s.



Amendment No.

455 1009.973 to persons the board determines to be qualified. Such
456 persons shall be compensated by the board.

457 (u) Endorse insurance coverage written exclusively for the
458 purpose of protecting advance payment contracts, and
459 participation agreements, and the purchasers, benefactors, and
460 beneficiaries thereof, including group life policies and group
461 disability policies, which are exempt from the provisions of
462 part V of chapter 627.

463 (v) Form strategic alliances with public and private
464 entities to provide benefits to the prepaid program, savings
465 program, and participants of either or both programs.

466 (w) Solicit proposals and contract, pursuant to s.
467 287.057, for the marketing of the prepaid program or the savings
468 program, or both together. Any materials produced for the
469 purpose of marketing the prepaid program or the savings program
470 shall be submitted to the board for review. No such materials
471 shall be made available to the public before the materials are
472 approved by the board. Any educational institution may
473 distribute marketing materials produced for the prepaid program
474 or the savings program; however, all such materials shall be
475 approved by the board prior to distribution. Neither the state
476 nor the board shall be liable for misrepresentation of the
477 prepaid program or the savings program by a marketing agent.

478 (x) Establish other policies, procedures, and criteria to
479 implement and administer the provisions of ss. 1009.97-1009.988
480 ~~ss. 1009.97-1009.984.~~

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Amendment No.

481 (y) Adopt procedures to govern contract dispute
482 proceedings between the board and its vendors.

483 (z) Amend board contracts to provide Florida ABLE, Inc.,
484 or the Florida ABLE program with contractual services.

485 Section 5. This act shall take effect upon becoming a law.
486

487 -----

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

489 Remove everything before the enacting clause and insert:
490 An act relating to individuals with disabilities; creating s.
491 1009.985, F.S.; providing a short title; creating s. 1009.986,
492 F.S.; providing legislative intent; defining terms; requiring
493 the Florida Prepaid College Board to establish a direct-support
494 organization known as "Florida ABLE, Inc."; specifying
495 requirements for the registration, organization, incorporation,
496 and operation of the organization; requiring the organization to
497 operate under a written contract with the Florida Prepaid
498 College Board; specifying provisions that must be included in
499 the contract; requiring the organization to provide for an
500 annual financial audit and supplemental data under certain
501 circumstances; establishing and providing for the membership of
502 a board of directors for the organization; providing limits on a
503 director's authority; specifying meeting and quorum
504 requirements; prohibiting compensation for the service of
505 directors and other specified members; authorizing specified
506 reimbursement for the travel expenses of directors and specified



Amendment No.

507 members of the organization; authorizing the organization to use
508 certain services, property, and facilities of the Florida
509 Prepaid College Board; requiring the organization to establish
510 and administer the Florida ABLE program by a specified date;
511 specifying requirements that must be met before implementation
512 of the program; requiring a participation agreement for the
513 program which contains specified provisions; authorizing other
514 provisions that may be included in the agreement; providing for
515 the amendment of the agreement under certain circumstances;
516 providing for the use of the balance of an abandoned ABLE
517 account by the organization; providing that a contract or
518 participation agreement entered into by the organization or an
519 obligation of the organization does not constitute a debt or
520 obligation of the Florida Prepaid College Board or the state;
521 authorizing the organization to contract with other states for
522 specified purposes under certain circumstances; providing for
523 termination of the program under certain circumstances and for
524 the disposition of certain assets upon termination; prohibiting
525 the state from limiting or altering the specified vested rights
526 of designated beneficiaries except under specified
527 circumstances; requiring the organization to establish a
528 comprehensive investment plan for the program; exempting funds
529 paid into the program's trust fund from the claims of specified
530 creditors; providing for recovery by Medicaid of certain medical
531 assistance provided to a deceased designated beneficiary;
532 providing for the distribution of the balance of a deceased

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


Amendment No.

533 designated beneficiary's ABLE account; requiring the
534 organization to assist and cooperate with the Agency for Health
535 Care Administration and Medicaid program in other states by
536 providing specified information; providing that specified
537 payroll deduction authority applies to the Florida Prepaid
538 College Board and the organization for the purpose of
539 administering the program; requiring the organization to submit
540 certain reports to specified entities; requiring the Florida
541 Prepaid College Board to adopt rules; requiring the Agency for
542 Health Care Administration, the Agency for Persons with
543 Disabilities, the Department of Children and Families, and the
544 Department of Education to assist, cooperate, and coordinate
545 with the organization in the provision of public information and
546 outreach for the program; providing that the section is repealed
547 on a specified date; amending s. 222.22, F.S.; providing that
548 specified moneys, assets, and income of a qualified ABLE
549 program, including the Florida ABLE program, are not subject to
550 attachment, levy, garnishment, or certain legal process in favor
551 of certain creditors or claimants; amending s. 1009.971, F.S.;
552 conforming provisions to changes made by the act; authorizing
553 the Florida Prepaid College Board to amend its contracts to
554 provide the organization or program with contractual services;
555 providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 937 Trust Funds/Florida ABLE Trust Fund/State Board of Administration
SPONSOR(S): Rodrigues
TIED BILLS: HB 935 **IDEN./SIM. BILLS:** CS/SB 644

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	12 Y, 0 N	Tuszynski	Brazzell
2) Education Appropriations Subcommittee	13 Y, 0 N	Butler	Heflin
3) Health & Human Services Committee		Tuszynski 	Calamas 

SUMMARY ANALYSIS

The federal Achieving a Better Life Experience of 2014 (ABLE Act) authorized states to establish ABLE programs or contract with other states to administer such programs if certain conditions are met. ABLE programs would provide a tax-advantaged approach for certain individuals with disabilities to build financial resources for disability related expenses without losing state or federal benefit eligibility, similar to 529 college savings plans.

HB 935 establishes the Florida ABLE Program. This bill, tied to HB 935, creates the Florida ABLE Program Trust Fund (trust fund) within the State Board of Administration. The trust fund will hold appropriations and moneys acquired from private or governmental sources for the Florida ABLE program. The trust fund will also hold ABLE account moneys.

Article III, section 19(f) of the Florida Constitution requires that every trust fund be created by a three-fifths vote of the membership of each house of the Legislature in a separate bill for the sole purpose of creating a trust fund.

The bill has no fiscal impact.

This bill is effective on the same date that HB 935 or similar legislation takes effect.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Trust Funds

Section 19(f), Art. III of the Florida Constitution requires that every trust fund be created by a three-fifths vote of the membership in each house of the Legislature in a separate bill for the sole purpose of creating that trust fund. The Constitution also provides that all newly created trust funds terminate not more than 4 years after the initial creation unless recreated.

Federal ABLE Act

The federal Achieving a Better Life Experience Act of 2014 (ABLE Act) became law on December 19, 2014. The purposes of the federal ABLE Act are to encourage and assist individuals and families in saving to support individuals with disabilities in maintaining health, independence, and quality of life, and provide secure funding for disability-related expenses that will supplement, but not supplant, other sources.¹ The ABLE Act permits a state to implement a qualified ABLE program and establish ABLE accounts for individuals with disabilities that meet certain criteria and are deemed "eligible individuals."

Florida ABLE Program

HB 937 is tied to and implement HB 935, which requires the Florida Prepaid College Board to create Florida ABLE, Inc., as a direct support organization that is organized as a not-for-profit corporation to receive, hold, invest, and administer property and to make expenditures for the benefit of the Florida ABLE program. HB 935 requires Florida ABLE, Inc., to operate under a contract with the Florida Prepaid College Board, which administers the Florida College Savings program. The Florida College Savings Program is a tax-advantaged account that allows the tax-free accumulation and distribution of cash assets for qualified educational expenses under s. 529 of the Internal Revenue Code. These plans are very similar to the tax advantaged disability savings plans envisioned by the federal ABLE Act under s. 529A of the Internal Revenue Code.

Under the Florida ABLE Program, eligible individuals² with disabilities, family members and others can contribute funds to an ABLE account without affecting the individual's eligibility for state and federal benefits, such as Supplemental Security Income and Medicaid. A beneficiary may use the funds for qualified disability expenses relating to the individual's blindness or disability. These expenses include education, housing, transportation, employment support, health, prevention, wellness, financial, and legal expenses, and other expenses authorized by federal regulations. Funds placed in the ABLE program would supplement rather than supplant benefits provided through state and federal programs, earnings, and other sources.

Effect of Proposed Changes

The bill creates the Florida ABLE Program Trust Fund within the State Board of Administration. The trust fund will hold appropriations and moneys acquired from private sources or other governmental

¹ H.R. 5771, Division B, Title I. Public Law 113-295.

² An individual is eligible to establish an ABLE account for a taxable year if during such taxable year:

- The individual is entitled to benefits based on blindness or disability under title II or XVI of the Social Security Act, and such blindness or disability occurred before the date on which the individual attained age 26; or
- A disability certification with respect to such individual is filed with the Secretary of the Department of Treasury for such taxable year.

sources for the Florida ABLE program. The trust fund will also hold moneys held in ABLE accounts. The priority of expending trust fund assets is first to make payment to, or on behalf of, designated beneficiaries of the Florida ABLE program and then to pay administrative and operational costs of the Florida ABLE program.

Trust fund assets shall be maintained, expended, and invested only for the purposes of the Florida ABLE program. Florida ABLE, Inc., may, however, make investments in bonds, notes, or other obligations of the state, a state agency, or instrumentality of the state. Any year-end balance remains in the trust fund. Trust fund assets are exempt from the investment requirements of s. 17.57, F.S., and may be invested pursuant to s. 215.47, F.S.

The trust fund terminates on October 1, 2019, as required by s. 19(f)(2), Art. III of the Florida Constitution. Prior to termination, the trust fund will be reviewed by the State Board of Administration and the Governor, who will recommend to the President of the Senate and the Speaker of the House of Representatives whether the trust fund should be allowed to terminate or be re-created.

The bill will take effect on the same date as HB 935 or similar legislation if such legislation is adopted in the same legislative session, or an extension of the same session, and becomes law. The effective date of HB 935 is October 1, 2015.

B. SECTION DIRECTORY:

Section 1: Creates the Florida ABLE Program Trust Fund.

Section 2: Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

Article II, subsection 19(f) of the Florida Constitution prohibits the Legislature from creating or re-creating a trust fund unless the trust fund is created or re-created by law and approved by a three-fifths vote of the membership of each house of the Legislature in a separate bill for that purpose only.

State trust funds must terminate within 4 years after the effective date of the act authorizing the initial creation of the trust fund. Once re-created, a trust fund remains in existence indefinitely.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to trust funds; creating s. 1009.988,
 3 F.S.; creating the Florida ABLE Trust Fund within the
 4 State Board of Administration; authorizing sources of
 5 funds; specifying the purpose of the trust fund and
 6 authorized uses of the assets; providing for future
 7 review and termination or re-creation of the trust
 8 fund; providing a contingent effective date.

9
 10 Be It Enacted by the Legislature of the State of Florida:

11
 12 Section 1. Section 1009.988, Florida Statutes, is created
 13 to read:

14 1009.988 Florida ABLE Trust Fund.-

15 (1) The Florida ABLE Trust Fund is created within the
 16 State Board of Administration.

17 (2) The Florida ABLE trust fund shall consist of
 18 appropriations, moneys acquired from other governmental or
 19 private sources for the Florida ABLE program, and moneys
 20 remitted in accordance with participation agreements. Assets
 21 held in the trust fund may be expended only to carry out the
 22 purposes of the Florida ABLE program.

23 (a) Any balance in the trust fund at the end of a fiscal
 24 year shall remain in the trust fund and shall be available for
 25 carrying out the purpose of the Florida ABLE program. Assets
 26 held in the trust fund are exempt from the investment

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

27 requirements of s. 17.57 and may be invested pursuant to s.
 28 215.47.

29 (b) Assets held in the trust fund shall be maintained,
 30 invested, and expended solely for the purposes of the Florida
 31 ABLE program and may not be loaned, transferred, or otherwise
 32 used by the state for any purpose other than the Florida ABLE
 33 program. This paragraph does not prohibit Florida ABLE, Inc.,
 34 from investing in, by purchase or otherwise, bonds, notes, or
 35 other obligations of the state or an agency or instrumentality
 36 of the state. Unless otherwise specified by Florida ABLE, Inc.,
 37 assets held in the trust fund shall be expended in the priority
 38 of making payments to, or on behalf of, designated beneficiaries
 39 and then paying for the costs of administration and operations
 40 for the Florida ABLE program.

41 (3) In accordance with s. 19(f)(2), Art. III of the State
 42 Constitution, unless terminated sooner, the Florida ABLE Trust
 43 Fund shall be terminated on October 1, 2019. Before its
 44 scheduled termination, the trust fund shall be reviewed as
 45 provided under s. 215.3206(1) and (2).

46 Section 2. This act shall take effect on the same date
 47 that HB 935 or similar legislation takes effect, if such
 48 legislation is enacted in the same legislative session or an
 49 extension thereof and becomes law, and only if this act is
 50 enacted by a three-fifths vote of the membership of each house
 51 of the Legislature.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 939 Pub. Rec./Florida Prepaid College Board/Florida ABLE, Inc./Florida ABLE Program

SPONSOR(S): Government Operations Subcommittee; Rodrigues and others

TIED BILLS: HB 935 **IDEN./SIM. BILLS:** CS/SB 646

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	12 Y, 0 N	Tuszynski	Brazzell
2) Government Operations Subcommittee	12 Y, 0 N, As CS	Williamson	Williamson
3) Health & Human Services Committee		Tuszynski	Calamas

SUMMARY ANALYSIS

The federal ABLE Act of 2014 (ABLE Act) authorized states to establish ABLE programs or contract with other states to administer such programs if certain conditions are met. ABLE programs would provide a tax-advantaged approach for certain individuals with disabilities to build financial resources for disability-related expenses without losing state or federal benefit eligibility, similar to 529 college savings plans.

CS/HB 935 establishes the Florida ABLE Program. HB 939, which is tied to the passage of HB 935, creates a public records exemption for personal financial and health information of a consumer, or any information that would identify a consumer, which is held by the Florida Prepaid College Board, Florida ABLE, Inc., or Florida ABLE.

The bill authorizes the release of such information in certain instances. It also provides that the exemption is subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2020, unless reviewed and saved from repeal through reenactment by the Legislature. The bill provides a public necessity statement as required by the State Constitution.

The bill appears to have no fiscal impact on the state or local government.

The bill provides that CS/HB 939 becomes effective on the same date that HB 935 or similar legislation takes effect.

Article I, s. 24(c) of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates a public record exemption; thus, it requires a two-thirds vote for final passage.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Public Records

Article I, s. 24(a) of the State Constitution sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a) of the State Constitution.

Public policy regarding access to government records is addressed further in the Florida Statutes. Section 119.07(1), F.S., guarantees every person the right to inspect and copy any state, county, or municipal record.

Open Government Sunset Review Act¹

The Open Government Sunset Review Act (act) prescribes a legislative review process for newly created or substantially amended public records exemptions.² The act provides that an exemption automatically repeals on October 2nd of the fifth year after creation or substantial amendment; in order to save an exemption from repeal, the Legislature must reenact the exemption.³

The act provides that a public records exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary.⁴ An exemption serves an identifiable purpose if it meets one of the following criteria:

- It allows the state or its political subdivision to effectively and efficiently administer a program, and administration would be significantly impaired without the exemption;⁵
- Releasing sensitive personal information would be defamatory or would jeopardize an individual's safety. If this public purpose is cited as the basis of an exemption, however, only personal identifying information is exempt;⁶ or
- It protects trade or business secrets.⁷

In addition, the Legislature must find that the identifiable public purpose is compelling enough to override Florida's open government public policy and that the purpose of the exemption cannot be accomplished without the exemption.⁸

Federal ABLÉ Act

The federal Achieving a Better Life Experience Act of 2014 (ABLE Act) became law on December 19, 2014.⁹ The purposes of the federal ABLÉ Act are to encourage and assist individuals and families in

¹ See s. 119.15, F.S.

² Section 119.15, F.S. Section 119.15(4)(b), F.S. provides that an exemption is considered substantially amended if it is expanded to include more information or to include meetings. The act does not apply to an exemption that is required by federal law or that applies solely to the Legislature or the State Court System pursuant to section 119.15(2), F.S.

³ Section 119.15(3), F.S.

⁴ Section 119.15(6)(b), F.S.

⁵ Section 119.15(6)(b)1., F.S.

⁶ Section 119.15(6)(b)2., F.S.

⁷ Section 119.15(6)(b)3., F.S.

⁸ Section 119.15(6)(b), F.S.

saving to support individuals with disabilities in maintaining health, independence, and quality of life, and provide secure funding for disability-related expenses that will supplement, but not supplant, other sources.¹⁰ The ABLE Act permits a state to implement a qualified ABLE program and establish ABLE accounts for individuals with disabilities that meet certain criteria.

Florida ABLE Program

CS/HB 939 is tied to and helps implement HB 935, which requires the Florida Prepaid College Board to create the Florida ABLE, Inc., as a direct support organization that is organized as a not-for-profit corporation. Florida ABLE, Inc., would establish and administer the Florida ABLE Program. HB 935 provides that the Florida ABLE, Inc., would operate under a contract with the Florida Prepaid College Board. The Florida College Savings Program is a tax-advantaged account that allows the tax-free accumulation and distribution of cash assets for qualified educational expenses under s. 529 of the Internal Revenue Code. These plans are very similar to the tax advantaged disability savings plans envisioned by the federal ABLE Act under s. 529A of the Internal Revenue Code.

Under the Florida ABLE Program, eligible individuals¹¹ with disabilities, family members and others would be able to contribute funds to an ABLE account without affecting the individual's eligibility for state and federal benefits, such as Supplemental Security Income and Medicaid. The bill provides that those funds could be used for qualified disability expenses relating to the individual's blindness or disability. These expenses would include education, housing, transportation, employment support, health, prevention, wellness, financial, and legal expenses, and other expenses authorized through federal regulations. Funds placed in the ABLE program would supplement rather than supplant benefits provided through state and federal programs, earnings, and other sources.

Effect of Proposed Changes

The bill creates a public records exemption for personal financial and health information of a consumer held by the Florida Prepaid College Board, Florida ABLE, Inc., Florida ABLE program, or an agent or service provider of one of these entities relating to an ABLE account or a participation agreement, or any information that could identify a consumer. The information is made confidential and exempt¹² from s. 119.07(1), F.S., and s. 24(a), Art. I, of the State Constitution.

For purposes of the bill, the term "consumer" means a party to a participation agreement of the Florida ABLE program. The bill defines the term "personal financial and health information" to mean:

- A consumer's personal health condition, disease, injury, or medical diagnosis or treatment;
- The existence, nature, source, or amount of a consumer's personal income or expenses;
- Records of or relating to a consumer's personal financial transactions of any kind; or
- The existence, identification, nature, or value of a consumer's assets, liabilities, or net worth.

The bill authorizes Florida Prepaid College Board or Florida ABLE, Inc., to disclose information made confidential and exempt to another state or federal government entity if disclosure is necessary for the

⁹ H.R. 5771, Division B, Title I. Public Law 113-295.

¹⁰ *Id.*

¹¹ An individual is an eligible individual for establishing an ABLE account for a taxable year if during such taxable year:

- The individual is entitled to benefits based on blindness or disability under title II or XVI of the Social Security Act, and such blindness or disability occurred before the date on which the individual attained age 26; or
- A disability certification with respect to such individual is filed with the Secretary of the Department of Treasury for such taxable year. *See* H.R. 5771, Division B, Title I. Public Law 113-295.

¹² There is a difference between records the Legislature designates as exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *See WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48, 53 (Fla. 5th DCA 2004), *review denied* 892 So.2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So.2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So.2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released by the custodian of public records to anyone other than the persons or entities specifically designated in statute. *See* Attorney General Opinion 85-62 (August 1, 1985).

receiving entity to perform its duties or responsibilities or to verify the eligibility of an eligible individual or authorize the use of an ABLE account.

The bill provides that the public records exemption is subject to the Open Government Sunset Review Act in accordance with s. 119.15, F.S., and will stand repealed on October 2, 2020, unless reviewed and saved from repeal through reenactment by the Legislature.

The bill provides a statement of public necessity for the public records exemption. The Legislature finds that it is a public necessity to protect a consumer's:

- Personal identifying information in order to encourage participation in the program, thus ensuring the effective and efficient administration of the program;
- Personal financial information due to the possibility of jeopardizing the individual's financial security through identity theft, fraud, or other illegal activity; and
- Health information due to the possibility of detrimental effects on the consumer's personal and business relationships and finances.

The bill will take effect on the same date as HB 935 or similar legislation if such legislation is adopted in the same legislative session, or an extension of the same session, and becomes law. The effective date of HB 935 is October 1, 2015.

B. SECTION DIRECTORY:

Section 1: Creates s.1009.987, F.S., relating to public record exemption for health information.

Section 2: Provides a public necessity statement.

Section 3: Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

This bill creates a public-records exemption. It complies with the requirements of s. 24(c), Art. I of the Florida Constitution that the Legislature address public-records exemptions in legislation separate from substantive law changes.

Because the bill creates an exemption, it contains a statement of public necessity and is subject to a two-thirds vote of each house of the Legislature for passage as required by s. 24(c), Art. I of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2015, the Government Operations Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment conforms the public necessity statement to the public record exemption.

This analysis is drafted to the committee substitute as approved by the Government Operations Subcommittee.

1 A bill to be entitled
 2 An act relating to public records; creating s.
 3 1009.987, F.S.; providing an exemption from public
 4 records requirements for certain personal financial
 5 and health information held by the Florida Prepaid
 6 College Board, Florida ABLE, Inc., the Florida ABLE
 7 program, or an agent or service provider thereof;
 8 authorizing the release of such information under
 9 specified circumstances; providing for future
 10 legislative review and repeal of the exemption;
 11 providing a statement of public necessity; providing a
 12 contingent effective date.

13
 14 Be It Enacted by the Legislature of the State of Florida:

15
 16 Section 1. Section 1009.987, Florida Statutes, is created
 17 to read:

- 18 1009.987 Public records exemption.-
 19 (1) As used in this section, the term:
 20 (a) "Consumer" means a party to a participation agreement.
 21 (b) "Personal financial and health information" means:
 22 1. A consumer's personal health condition, disease,
 23 injury, or medical diagnosis or treatment;
 24 2. The existence, nature, source, or amount of a
 25 consumer's personal income or expenses;
 26 3. Records of or relating to a consumer's personal

27 financial transactions of any kind; or

28 4. The existence, identification, nature, or value of a
 29 consumer's assets, liabilities, or net worth.

30 (2) The personal financial and health information of a
 31 consumer held by the board, Florida ABLE, Inc., the Florida ABLE
 32 program, or an agent or service provider thereof relating to an
 33 ABLE account or a participation agreement, or any information
 34 that would identify a consumer, is confidential and exempt from
 35 s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

36 (3) The board or Florida ABLE, Inc., may authorize the
 37 disclosure of information made confidential and exempt under
 38 subsection (2) to another state or federal government entity if
 39 disclosure is necessary for the receiving entity to perform its
 40 duties or responsibilities or to verify the eligibility of an
 41 eligible individual or authorize the use of an ABLE account.

42 (4) This section is subject to the Open Government Sunset
 43 Review Act in accordance with s. 119.15 and shall stand repealed
 44 on October 2, 2020, unless reviewed and saved from repeal
 45 through reenactment by the Legislature.

46 Section 2. The Legislature finds that it is a public
 47 necessity that the personal financial and health information of
 48 a consumer held by the Florida Prepaid College Board, Florida
 49 ABLE, Inc., the Florida ABLE program, or an agent or service
 50 provider thereof relating to an ABLE account or a participation
 51 agreement, or any information that would identify a consumer, be
 52 made confidential and exempt from s. 119.07(1), Florida

53 Statutes, and s. 24(a), Article I of the State Constitution. The
54 Florida ABLE program allows eligible individuals with
55 disabilities, family members, and others to contribute funds to
56 an ABLE account without affecting the individual's eligibility
57 for state and federal benefits. It allows the individual to use
58 those funds for qualified disability expenses, such as
59 education, housing, transportation, or other expenses authorized
60 through federal regulations. The public records exemption for
61 information that would identify a consumer ensures that
62 information of a sensitive, personal nature concerning a party
63 to a participation agreement is protected. Without such
64 protection, an individual may be less likely to take advantage
65 of the program, thus hindering the effective and efficient
66 administration of the Florida ABLE program. It may also make the
67 individual vulnerable to abuse and exploitation. Disclosure of
68 sensitive financial information regarding a consumer under the
69 Florida ABLE program could create the opportunity for theft,
70 identity theft, fraud, and other illegal activity, thereby
71 jeopardizing the financial security of the consumer and placing
72 him or her at risk for substantial financial harm. Further, each
73 individual has a reasonable expectation of and a right to
74 privacy in all matters concerning personal financial interests.
75 The Legislature further finds that it is a public necessity to
76 protect a consumer's personal health information because such
77 information is traditionally a private and confidential matter
78 between the patient and health care provider. The private and

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2015

79 | confidential nature of personal health matters pervades both the
80 | public and private health care sectors, and public disclosure of
81 | such personal health information relating to a consumer under
82 | the Florida ABLE program could negatively affect an individual's
83 | business and personal relationships and cause detrimental
84 | financial consequences.

85 | Section 3. This act shall take effect on the same date
86 | that HB 935 or similar legislation takes effect, if such
87 | legislation is adopted in the same legislative session or an
88 | extension thereof and becomes a law.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee
3 Representative Rodrigues, R. offered the following:

4
5 **Amendment**

6 Remove line 20 and insert:

7 (a) "Consumer" means a party to a participation agreement
8 with the Florida ABLE program.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1001 Assisted Living Facilities
SPONSOR(S): Health Care Appropriations Subcommittee; Ahern
TIED BILLS: IDEN./SIM. BILLS: CS/SB 382

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee	9 Y, 0 N, As CS	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo <i>JG</i>	Calamas <i>CC</i>

SUMMARY ANALYSIS

Assisted Living Facilities (ALFs) are regulated by the Agency for Health Care Administration (AHCA) under part I of ch. 429, F.S., and part II of ch. 408, F.S. CS/HB 1001 strengthens the regulation of ALFs and makes other regulatory changes to improve the quality of ALFs. Specifically, the bill:

- Clarifies who is responsible for assuring that mental health residents in an ALF receive necessary services;
- Requires ALFs to inform new residents upon admission that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right;
- Allows licensed registered nurses to practice to the full scope of their professional license in ALFs that have a Limited Nursing Services specialty license;
- Creates a provisional Extended Congregate Care (ECC) license for new ALFs and specifies when the Agency for Health Care Administration (AHCA) may deny or revoke a facility's ECC license;
- Requires facilities with one or more, rather than three or more, state-supported mental health residents to obtain a Limited Mental Health license;
- Specifies circumstances under which AHCA must impose an immediate moratorium on admissions to a facility;
- Requires AHCA to impose a \$500 fine against a facility that does not comply with the background screening requirements of s. 408.809, F.S.;
- Allows AHCA to impose a \$2,500 fine against a facility that does not show good cause for terminating the residency of an individual;
- Authorizes ALF staff to perform certain additional duties to assist with self-administration of medication and increases the applicable staff training requirements from 4 hours to 6 hours;
- Adds certain responsible parties and agency personnel to the list of people who must report abuse or neglect to the Department of Children and Families' central abuse hotline;
- Requires AHCA to conduct an additional inspection of a facility cited for certain serious violations.
- Requires new facility staff that have not previously completed core training to attend a 2-hour pre-service orientation before interacting with residents; and
- Requires AHCA to add certain content to its website by November 1, 2015, to assist consumers in selecting an ALF.

The bill appears to have no fiscal impact on state or local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Assisted Living Facility Reform

In April of 2011, the Miami Herald completed a three part investigative series relating to assisted living facilities (ALFs). This series highlighted concerns with the management and administration of ALFs and garnered the attention of not only the public, but many state lawmakers, stakeholders, and facility residents and their families.

Assisted Living Facility Workgroups

In July 2011, Governor Rick Scott directed the Agency for Health Care Administration (AHCA) to examine the regulation and oversight of ALFs. In response, AHCA created the ALF workgroup. The workgroup's objective was to make recommendations to the Governor and Legislature that would improve the monitoring of safety in ALFs to help ensure the well-being of residents. After a series of meetings, the workgroup produced a final report and recommendations that they felt could strengthen oversight and reassure the public that ALFs are safe. Such recommendations included increasing administrator qualifications, expanding training for administrators and other staff, increasing survey inspection activity, and improving the integration of information among all agencies involved in the regulation of ALFs. The workgroup also noted several other issues that would require more time to evaluate and recommended they be examined by a Phase II workgroup.

Phase II of the workgroup began meeting in June 2012 to resume examining those issues not addressed by Phase I of the workgroup. Phase II of the workgroup will concluded in October, 2012 and produced a final report and recommendations to the Governor and the Legislature on November 26, 2012.

The issue of improving inter-agency communication was included in the workgroup's recommendations. Specifically, the workgroup recommended improving coordination between various federal, state and local agencies with any role in long-term care facilities oversight, especially ALFs. This includes AHCA, the Long Term Care Ombudsman Program, local fire authorities, local health departments, the Department of Children and Families (DCF), the Department of Elder Affairs (DOEA), local law enforcement and the Attorney General's Office.¹

Assisted Living Facility Negotiated Rulemaking Committee

In June, 2012, DOEA, in consultation with AHCA, DCF, and DOH, began conducting negotiated rulemaking meetings to address ALF regulation. The purpose of the meetings was to draft and amend mutually acceptable proposed rules addressing the safety and quality of services and care provided to residents within ALFs. Most of the issues addressed by the Committee were identified by Phase I of the workgroup as areas of concern that could be reformed via the rulemaking process. The Committee produced a Final Summary Report containing all the proposed rule changes agreed upon by the Committee. These proposed rule changes are currently in the final stages of the standard proposed rule making process required by law.

¹ Florida Assisted Living Workgroup, Phase II Recommendations, November 26, 2012, available at <http://www.ahca.myflorida.com/SCHSCommitteesCouncils/ALWG/index.shtm>.

Assisted Living Facility - Licensure

An 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.^{2,3} A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.⁴ Activities of daily living include: ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.⁵

ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S. ALFs are also regulated by DOEA under Rule 58A-5, F.A.C. The DOEA is responsible for developing and enforcing training requirements for ALF administrators and staff under Rule 58A-5, F.A.C.

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.⁶ The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on certain criteria.⁷ If a resident no longer meets the criteria for continued residency, or the facility is unable to meet the resident's needs, as determined by the facility administrator or health care provider, the resident must be discharged in accordance with the Resident Bill of Rights.⁸

As of March 7, 2015, there are 3,042 licensed ALFs in Florida with 88,879 beds.⁹ An ALF must have a standard license issued by AHCA, pursuant to part I of ch. 429, F.S., and part II of ch. 408, F.S.

Specialty Licensed Facilities

In addition to a standard license, an ALF may have one or more specialty licenses that allow the ALF to provide additional care. These specialty licenses include: limited nursing services,¹⁰ limited mental health services,¹¹ and extended congregate care services.¹²

Limited Mental Health License

A mental health resident is "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."¹³ A limited mental health (LMH) license is required for any facility serving 3 or more mental health residents.¹⁴ To obtain this license, the facility may not have any current uncorrected deficiencies or violations and facility administrator, as well as staff providing direct care to residents must complete 6 hours of training related to LMH duties, which is either provided by or approved by DCF.¹⁵ A LMH license can be obtained during initial licensure, during relicensure, or upon

² S. 429.02(5), F.S.

³ An ALF does not include an adult family-care home or a non-transient public lodging establishment.

⁴ S. 429.02(16), F.S.

⁵ S. 429.02(1), F.S.

⁶ For specific minimum standards see Rule 58A-5.0182, F.A.C.

⁷ S. 429.26, F.S., and Rule 58A-5.0181, F.A.C.

⁸ S. 429.28, F.S.

⁹ Agency for Health Care Administration, *Facility/Provider Search Results-Assisted Living Facilities*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (report generated on March 7, 2015).

¹⁰ S. 429.07(3)(c), F.S.

¹¹ S. 429.075, F.S.

¹² S. 429.07(3)(b), F.S.

¹³ S. 429.02, F.S.

¹⁴ S. 429.075, F.S.

¹⁵ S. 429.075, F.S.

request of the licensee.¹⁶ There are 913 facilities in Florida with LMH licenses, providing 14,172 beds.¹⁷

Extended Congregate Care License

The ECC specialty license allows an ALF to provide, directly or through contract, services performed by licensed nurses and supportive services to individuals who would otherwise be disqualified from continued residency in an ALF.¹⁸

In order for ECC services to be provided, AHCA must first determine that all requirements in law and rule are met. ECC licensure is regulated pursuant to s. 429.07, F.S., and Rule 58A-5, F.A.C.

The primary purpose of ECC services is to allow residents, as their acuity level rises, to remain in a familiar setting. An ALF licensed to provide ECC 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 ECC facility. 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 supervision.

Licensed ECC facilities may provide the following additional services:

- 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, including providing special diets, monitoring nutrition, and observing the resident's food and fluid intake and output;
- Assisting with self-administered medications;
- Supervising residents with dementia and cognitive impairments;
- Health education, counseling, and implementing health-promoting programs;
- Rehabilitative services; and
- Escort services to health-related appointments.¹⁹

Before being admitted to an ECC licensed facility to receive ECC services, the prospective resident must undergo a medical examination.²⁰ The ALF must develop a service plan that sets forth how the facility will meet the resident's needs and must maintain a written progress report on each resident who receives ECC services.

ALFs with an ECC license must meet the following staffing requirements:

- Specify a staff member to serve as the ECC supervisor if the administrator does not perform this function;
- The administrator of an ECC licensed facility must have a minimum of 2 years of managerial, nursing, social work, therapeutic recreation, or counseling experience in a residential, long-term care, or acute care setting; and
- A baccalaureate degree may be substituted for one year of the required experience and a nursing home administrator licensed under chapter 468, F.S., shall be considered qualified.²¹

¹⁶ S. 429.075, F.S.

¹⁷ Agency for Health Care Administration, *Assisted Living Facilities with Limited Mental Health*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_LMH.pdf (last viewed on March 7, 2015).

¹⁸ S. 429.07(3)(b), F.S.

¹⁹ Rule 58A-5.030(8)(b), F.A.C.

²⁰ Rule 58A-5.030(6), F.A.C.

²¹ Rule 58A-5.030(4), F.A.C.

An ECC administrator or supervisor, if different from the administrator, must complete the core training required of a standard licensed ALF administrator (26 hours plus a competency test), and 4 hours of initial training in ECC care within 3 months of beginning employment. The administrator must complete a minimum of 4 hours of continued education every 2 years.²²

All staff providing direct ECC care to residents must complete at least 2 hours of initial service training, provided by the administrator, within 6 months of beginning employment.²³

ALFs with a standard license must pay a biennial license fee of \$300 per license, with an additional fee of \$50 per resident. The total fee may not exceed \$10,000. In addition to the total fee assessed for standard licensed ALFs, facilities providing ECC services must pay an additional fee of \$400 per license, with an additional fee of \$10 per resident.²⁴ There are 261 facilities in Florida with ECC licenses, providing 16,161 beds.²⁵

Limited Nursing Services License

Limited nursing services are services beyond those provided by standard licensed ALFs. A licensed registered nurse in a facility with a LNS specialty license may only perform certain acts, as specified by rule.²⁶ Pursuant to Rule 58A-5.031, F.A.C., a licensed registered nurse may provide the following services in an ALF with an LNS license:

- Passive range of motion exercises;
- Ice caps or heat relief;
- Cutting toenails of diabetic residents;
- Ear and Eye irrigations;
- Urine dipstick tests;
- Replacement of urinary catheters;
- Digital stool removal therapies;
- Applying and changing routine dressings that do not require packing or irrigation;
- Care for stage 2 pressure sores;
- Caring for casts, braces and splints;
- Conducting nursing assessments;
- Caring for and monitoring the application of anti-embolism stockings or hosiery;
- Administration and regulation of portable oxygen;
- Applying, caring for and monitoring a transcutaneous electric nerve stimulator; and
- Catheter, colostomy, ileostomy care and maintenance.

A facility holding only a standard or LNS license must meet the admission and continued residency criteria contained in Rule 59A-5.0181, F.A.C.²⁷ The following admission and continued residency criteria for potential residents must be met:

- Be at least 18 years of age;
- Be free from signs and symptoms of any communicable disease;
- Be able to perform the activities of daily living;
- Be able to transfer, with assistance if necessary;
- Be capable of taking their own medications with assistance from staff if necessary;

²² Rule 58A-5.0191(7), F.A.C.

²³ Id.

²⁴ S.429.07(4), F.S.

²⁵ Agency for Health Care Administration, *Assisted Living Facilities with Extended Congregate Care*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_ECC.pdf (last viewed on March 7, 2015).

²⁶ S. 429.02(13), F.S.

²⁷ Rule 58A-5.031(2), F.A.C.

- Not be a danger to themselves or others;
- Not require licensed professional mental health treatment on a 24-hour a day basis;
- Not be bedridden;
- Not have any stage 3 or 4 pressure sores;
- Not require nursing services for oral or other suctioning, assistance with tube feeding, monitoring of blood gases, intermittent positive pressure breathing therapy, or treatment of surgical incisions or wounds;
- Not require 24-hour nursing supervision;
- Not require skilled rehabilitative services; and
- Have been determined by the administrator to be appropriate for admission to the facility.²⁸

Facilities licensed to provide limited nursing services must employ or contract with a nurse to provide necessary services to facility residents.²⁹ Licensed LNS facilities must maintain written progress reports on each resident receiving LNS. A registered nurse representing AHCA must visit these facilities at least twice a year to monitor residents and determine compliance.³⁰ A nursing assessment must be conducted at least monthly on each resident receiving limited nursing services.³¹

Facilities licensed to provide LNS must pay the standard licensure fee of \$300 per license, with an additional fee of \$50 per resident and the total fee may not exceed \$10,000. In addition to the standard fee, in order to obtain the LNS specialty license facilities must pay an additional biennial fee of \$250 per license, with an additional fee of \$10 per bed.³² There are 775 facilities with LNS licenses, offering 31,062 slots.³³

Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established by the DOEA by rule.^{34,35} This training and education is intended to assist facilities to appropriately respond to the needs of residents, maintain resident care and facility standards, and meet licensure requirements.³⁶

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 3 months after becoming a facility administrator or manager. The minimum passing score for the competency test is 75 percent.³⁷

Administrators and managers must participate in 12 hours of continuing education in topics related to assisted living every 2 years. 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

²⁸ Rule 58A-5.0181(1), F.A.C.

²⁹ Rule 58A-5.031(2), F.A.C.

³⁰ S. 429.07(2)(c), F.S.

³¹ Id.

³² S. 429.07(4)(c), F.S.

³³ Agency for Health Care Administration, *Assisted Living Facilities with Limited Nursing Services*, as of March 2, 2015, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/Directory_ALF_LNS.pdf (last viewed on March 7, 2015).

³⁴ Rule 58A-5.0191, F.A.C.

³⁵ Many of the training requirements in rule may be subject to change due to the recent DOEA negotiated rulemaking process.

³⁶ S. 429.52(1), F.S.

³⁷ 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.

the continuing education requirements, must retake the ALF core training and retake the competency test.³⁸

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for 6 hours of in-service training for facility staff who provide direct care to residents. The training covers a variety of topics as provided by rule.³⁹ Staff training requirements must generally be met within 30 days after staff begin employment at the facility, however, staff must have at least 1 hour of infection control training before providing direct care to residents. Also, 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 6 hours of in-service training, staff must also complete 1 hour of elopement training and 1 hour of training on do not resuscitate orders, and may have to complete training on special topics such as self-administration of medication and persons with Alzheimer's disease, if applicable.

ECC Specific Training

The administrator and ECC supervisor, if different from the administrator, must complete 4 hours of initial training in extended congregate care prior to the facility receiving its ECC license or within 3 months after beginning employment in the facility as an administrator or ECC supervisor. They must also complete a minimum of 4 hours of continuing education every 2 years in topics relating to the physical, psychological, or social needs of frail elderly and disabled persons, or persons with Alzheimer's disease or related disorders.⁴⁰

All direct care staff providing care to residents in an ECC program must complete at least 2 hours of in-service training, provided by the facility administrator or ECC supervisor, within 6 months after beginning employment in the facility. The training must address ECC concepts and requirements, including the delivery of personal care and supportive services in an ECC facility.⁴¹

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 6 hours of specialized training in working with individuals with mental health diagnoses and a minimum of 3 hours of continuing education dealing with mental health diagnoses or mental health treatment every 2 years.⁴²

Assistance with Self-Administration of Medication Training

Staff involved with the management of medications and assisting with the self-administration of medications under s. 429.256, F.S., must complete a minimum of 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.⁴³ Unlicensed persons who will be providing assistance with self-administered medications must meet the training requirements pursuant to s. 429.52(5), F.S., prior to assuming this responsibility.

Courses provided in fulfillment of this requirement must meet the following criteria: Training must cover state law and rule requirements with respect to the supervision, assistance, administration, and management of medications in assisted living facilities; procedures and techniques for assisting the resident with self-administration of medication including how to read a prescription label; providing the

³⁸ Rule 58A-5.0191, F.A.C.

³⁹ Id.

⁴⁰ Rule 58A-5.0191(7)(b), F.A.C.

⁴¹ Rule 58A-5.0191(7)(c), F.A.C.

⁴² S. 429.075, F.S. and Rule 58A-5.0191(8), F.A.C.

⁴³ S. 429.52(5), F.S.

right medications to the right resident; common medications; the importance of taking medications as prescribed; recognition of side effects and adverse reactions and procedures to follow when residents appear to be experiencing side effects and adverse reactions; documentation and record keeping; and medication storage and disposal.⁴⁴

Training shall include demonstrations of proper techniques and provide opportunities for hands-on learning through practice exercises.⁴⁵

The training must be provided by a registered nurse or licensed pharmacist who shall issue a training certificate to a trainee who demonstrates an ability to read and understand a prescription label and provide assistance with self-administration in accordance with Section 429.256, F.S., and Rule 58A-5.0185, F.A.C., including:

- Assisting with oral dosage forms, topical dosage forms, and topical ophthalmic, otic and nasal dosage forms;
- Measuring liquid medications, breaking scored tablets, and crushing tablets in accordance with prescription directions;
- Recognizing the need to obtain clarification of an “as needed” prescription order;
- Recognizing a medication order which requires judgment or discretion, and advising the resident, resident’s health care provider or facility employer of inability to assist in the administration of such orders;
- Completing a medication observation record;
- Retrieving and storing medication; and
- Recognizing the general signs of adverse reactions to medications and reporting such reactions.⁴⁶

Unlicensed persons, as defined in Section 429.256(1)(b), F.S., who provide assistance with self-administered medications and have successfully completed the initial 4 hour training, must obtain, annually, a minimum of 2 hours of continuing education training on providing assistance with self-administered medications and safe medication practices in an ALF. The 2 hours of continuing education training shall only be provided by a licensed registered nurse, or a licensed pharmacist.⁴⁷

Inspections and Surveys

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 facilities licensed to provide LNS or ECC services, or facilities cited in the previous year for a class I or class II, or four or more uncorrected class III, violations.⁴⁸
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents.
- If AHCA has reason to believe a facility 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.
- To determine if a facility is operating without a license.⁴⁹

⁴⁴ Rule 58A-5.0191(5)(a), F.A.C.

⁴⁵ Id.

⁴⁶ Rule 58A-5.0191(5)(b), F.A.C.

⁴⁷ Rule 58A-5.0191(5)(c), F.A.C.

⁴⁸ See *below* information under subheading “Violations and Penalties” for a description of each class of violation.

⁴⁹ S. 429.34, F.S., and Rule 58A-5.033, F.A.C.

Abbreviated Surveys

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

- Class I or class II violations or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to AHCA by the council.
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.⁵⁰

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items that AHCA must inspect.⁵¹ AHCA is required to expand an abbreviated survey or conduct a full survey if violations which threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.⁵²

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by AHCA in which the agency inspects the facility for compliance with the requirements of the specialty license type. 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 LNS and to determine if the facility is complying with applicable regulatory requirements.⁵³ An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. 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.⁵⁴

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all facilities regulated by AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by 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 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. AHCA must issue a fine between \$5,000 and \$10,000 for each violation.
- Class II violations are those conditions that AHCA determines directly threaten the physical or emotional health, safety, or security of the clients. Examples include having no qualified staff in the facility, the failure to call 911 in a timely manner for resident in a semi-comatose state, and rodents in food storage area. AHCA must issue a fine between \$1,000 and \$5,000 for each violation.
- Class III violations are those conditions that 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. AHCA

⁵⁰ Rule 58A-5.033(2), F.A.C.

⁵¹ Rule 58A-5.033(2)(b)

⁵² Id.

⁵³ S. 429.07(3)(c), F.S.

⁵⁴ S. 429.07(3)(b), F.S.

must issue a fine between \$500 and \$1,000 for each violation, but no fine may be imposed if the facility corrects the violation.

- 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. AHCA can only fine a facility (between \$100 and \$200 for each violation) if the problem is not corrected.^{55,56}

Violations for Fiscal Years 2013-14

	Class I Violations	Class II Violations	Class III Violations	Class IV Violations
Total Violations	39	335	260	3
Average Fine Amount: ALFs With Less than 100 beds	\$7,033	\$1,862	\$602	\$300
Average Fine Amount: ALFs With More Than 100 Beds	\$6,056	\$1,909	\$639	\$0

In addition to financial penalties, AHCA can take other actions against a facility. AHCA may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. 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 previous 2 years.⁵⁷ AHCA may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition presents a threat to the health, safety, or welfare of a client.⁵⁸ AHCA is required to publicly post notification of a license suspension or revocation, or denial of a license renewal, at the facility.⁵⁹ Finally, Florida's Criminal Code, under ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons⁶⁰ and disabled adults.⁶¹

ALF License Suspensions, Revocations, Denials, Failed to Renew and Closed

	FY 2009-10	FY 2010-11	FY 2011-12	FY 2012-13	FY 2013-14	Total
Suspensions	1	2	5	6	3	17
Revocations	12	7	17	15	14	65
Denials	7	5	9	12	14	47
Closed/Failed to Renew During Legal Case	40	46	30	28	29	173
Total	60	60	61	61	60	302

⁵⁵ 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. S. 429.19(3), F.S.

⁵⁶ S. 429.19(2), F.S.

⁵⁷ S. 429.14(4), F.S.

⁵⁸ S. 408.814, F.S.

⁵⁹ S. 429.14(7), F.S.

⁶⁰ "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. S. 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. S. 825.104, F.S.

⁶¹ "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. S. 825.101(4), F.S.

Central Abuse Hotline

The Department of Children and Families 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 adult⁶² at any hour of the day or night, any day of the week.⁶³ 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.⁶⁴

Personal Property of Residents

Facilities are required under s. 429.27(3), F.S., upon mutual consent with the resident, to provide for the safekeeping of a resident's personal effects not in excess of \$500 in value and funds not in excess of \$200 cash. The facility must keep complete and accurate records of all such funds and personal effects received. If a resident is absent from a facility for 24 hours or more, the facility may provide for the safekeeping of the resident's personal effects in excess of \$500.

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.⁶⁵ 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.⁶⁶

The ombudsman program administers 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.⁶⁷ The names or 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.⁶⁸ In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in facilities, referred to as administrative assessments.

⁶² "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. S. 415.102(27), F.S.

⁶³ 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; immediately identify and locate prior reports of abuse, neglect, or exploitation through the central abuse hotline; Section 415.103(1), F.S.

⁶⁴ S. 415.1034, F.S.

⁶⁵ 42 U.S.C. 3058, et. seq.. See also s. 400.0061(1), F.S.

⁶⁶ S. 400.0063, F.S.

⁶⁷ S. 400.0078(2), F.S.

⁶⁸ S. 400.0077(1)(b), F.S.

Effect of Proposed Changes

Limited Mental Health License

The bill amends s. 394.4574, F.S., to clarify that Medicaid managed care plans are responsible for enrolled state-supported mental health residents and that managing entities under contract with the DCF are responsible for such residents who are not enrolled with a Medicaid health plan. This section requires a mental health resident and his or her mental health case manager to complete the mental health resident's community living support plan and provide it to the administrator of the ALF within 30 days of admitting a mental health resident. The plan must be updated when there is a significant change to the resident's behavioral health status. The resident's case manager must keep a 2-year record of any face-to-face interaction with the resident and make the records available for inspection. Finally, this section charges the case manager responsible for a mental health resident to ensure 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.

The bill amends s. 429.075, F.S., to require facilities with one or more, instead of three or more, mental health residents to obtain a LMH license. It also permits a facility with a LMH license, if it does not have a copy of the resident's community living support plan and cooperative agreement, to provide written evidence that it requested the plan and agreement from the Medicaid managed care plan or the managing entity within 72 hours of the resident's admission.

Long-Term Care Ombudsman Program

Administrative Assessment

The bill amends s. 400.0074, F.S., to require any administrative assessment of an ALF performed by the Long-Term Care Ombudsman to be comprehensive. Further, the bill requires the local Ombudsman to conduct an exit consultation with the long-term care facility administrator to discuss issues and concerns affecting residents and make recommendations for improvement, if necessary.

Resident Grievances

The bill amends s. 400.0078, F.S., to require that ALFs inform new residents upon admission to the facility that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right. An ALF can also provide this information to the resident's representative.

Extended Congregate Care License

The bill amends s. 429.07, F.S., to make changes to improve the regulation of facilities with ECC and LNS specialty licenses. These changes include:

- Requiring that an ALF be licensed for 2 or more years before being issued an ECC license that is not provisional.
- Clarifying under what circumstances AHCA may deny or revoke a facility's ECC license.
- Creating a provisional ECC license for ALFs that have been licensed for less than 2 years.
- The provisional license lasts for a period of 6 months.
- The facility must inform AHCA when it has admitted one or more residents requiring ECC services.
- After the facility admits one or more ECC residents, 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, AHCA must grant the facility an ECC license.

- If the licensee fails to demonstrate compliance with the requirements of an ECC license or fails to admit an ECC resident within 3 months, the licensee must immediately suspend ECC services and the provisional ECC license expires.
- Authorizing AHCA to extend a provisional ECC license for 1 month in order to complete a follow-up visit.
- Reducing monitoring visits for facilities with ECC licenses from quarterly to twice a year, and for facilities with LNS licenses from twice a year to once a year.
- Clarifying under what circumstances AHCA may waive one of the required monitoring visits for facilities with ECC licenses and also allowing AHCA to waive the required monitoring visit for facilities with an LNS license under the same conditions.

Violations and Penalties

The bill amends s. 429.14, F.S., to:

- Add additional criteria under which AHCA must deny or revoke a facility's license. The criteria include:
 - There are 2 moratoria issued and imposed by final order within a 2-year period.
 - The facility is cited for 2 or more class I violations arising from unrelated circumstances during the same survey or investigation.
 - The facility is cited for 2 or more class I violations within 2 years.
- Require AHCA to impose an immediate moratorium on a facility that fails to provide AHCA with access to the facility or prohibits a regulatory inspection;
- Prohibit a licensee from restricting AHCA staff access to records or prohibiting the confidential interview of facility staff or residents.
- Exempt a facility from the 45-day notice requirement in s. 429.28(k), F.S., if that facility is required to relocate all or some of its residents due to action by AHCA.

The bill amends s. 429.19, F.S., to require AHCA to impose an administrative fine of \$500 if a facility is found to be not in compliance with the background screening requirements of s. 408.809, F.S.

Assistance with Self-Administration of Medication

The bill amends s. 429.256, F.S., to allow all facility staff who received the required training to provide several additional services in assisting with self-administration of medication.⁶⁹ Specifically, the additional duties are:

- Taking a prefilled insulin syringe from its place of storage and bringing it to a resident;
- Removing the cap of a nebulizer, opening the unit dose of nebulizer solution, and pouring the pre-measured dose of medication into the dispensing cup of the nebulizer;
- Assisting a resident in using a nebulizer;
- Using a glucometer to perform blood glucose checks;
- Assisting with anti-embolism stockings;
- Assisting with applying and removing an oxygen cannula;
- Assisting with the use of a continuous positive airway pressure device;
- Assisting with the measuring of vital signs; and
- Assisting with the use of colostomy bags.

Personal Property of Residents

The bill amends s. 429.27(3), F.S., to increase the amount of cash that a facility may provide safe-keeping of for a resident from \$200 to \$500.

Resident Bill of Rights

The bill amends s. 429.28, F.S., to require that the telephone number of Disability Rights Florida⁷⁰ (DRF) be included in the posted notice of a resident's rights, obligations, and prohibitions, and that the facility ensure each resident have access to a telephone to call DRF. The notice must also specify that complaints made to the ombudsman program, as well as the names and identities of the complainant and any residents involved in the complaint, are confidential and that retaliatory action cannot be taken against a resident for presenting a grievance or exercising a right. This section also creates a fine of \$2,500, which is imposed if a facility cannot show good cause in state court for terminating the residency of an individual who has exercised an enumerated right.

The bill requires AHCA to adopt rules for uniform standards and criteria that will be used to determine a facility's compliance with facility standards and residents' rights.

Right of Entry and Inspection

The bill amends s. 429.34, F.S., to require certain state officials, such as Medicaid Fraud investigators and state or local fire marshals, to report any knowledge or reasonable suspicion that a vulnerable adult has been or is being abused, neglected, or exploited to the DCF central abuse hotline.

The bill requires AHCA to inspect each licensed ALF at least once every 24 months to determine compliance with statute and rules. The bill provides that a facility 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 be subject to an additional inspection within 6 months.

Staffing and Training Requirements

The bill amends s. 429.41, F.S., to clarify that ALF staffing requirements for a continuing care facility or retirement community apply only to residents who receive personal limited nursing services or extended congregate care services. The facility must keep a log of the names and unit numbers of residents receiving such services and make the log available to surveyors upon request.

The bill amends s. 429.52, F.S., to require facilities to provide a 2-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 the employee provide responsible care and respond to the needs of the residents. The 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 a trainer registered with DOEA.

Consumer Information Resources

The bill creates s. 429.55, F.S., which provides Legislative findings that consumers need additional information in order to select an ALF. To facilitate this, the bill requires AHCA to create a consumer guide website which contains information on each licensed ALF. By November 1, 2015, the website must include:

- The name and address of the facility;
- The name of the owner or operator of the facility;
- The number and type of licensed beds in the facility;

⁷⁰ Disability Rights Florida is the designated protection and advocacy agency required as a condition of certain federal funding under 42 U.S.C. 15041-15045 and 45 C.F.R. 1386.20. The protection and advocacy designation is made by gubernatorial executive order.

- The types of licenses held by the facility;
- The facility's license expiration date and status;
- The total number of clients that the facility is licensed to serve and the most recent occupancy levels;
- The number of private and semi-private rooms offered;
- The bed-hold policy;
- The religious affiliation, if any, of the ALF;
- The languages spoken by the staff;
- Availability of nurses;
- Forms of payment accepted;
- Identification if the licensee is operating under bankruptcy protection;
- Recreational and other programs available;
- Special care units or programs offered;
- Whether the facility is part of a retirement community that offers other services;
- Links to the State Long-Term Care Ombudsman Program website and the program's statewide toll-free telephone number;
- Links to the internet websites of the providers;
- Other relevant information currently collected by AHCA; and
- Survey and violation information including a list of the facility's violations committed during the previous 60 months, which must be updated monthly and include for each violation:
 - A summary of the violation, with all licensure, revisit, and complaint survey information;
 - Any sanctions imposed by final order; and
 - The date the corrective action was confirmed by AHCA; and
- Links to inspection reports on file with AHCA.

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

B. SECTION DIRECTORY:

- Section 1:** Amends s. 394.4574, F.S., relating to department responsibilities for a mental health resident who resides in an assisted living facility that holds a limited mental health license.
- Section 2:** Amends s. 400.0074, F.S., relating to local ombudsman council onsite administrative assessments.
- Section 3:** Amends s. 400.0078, F.S., relating to citizen access to State Long-Term Care Ombudsman Program services.
- Section 4:** Amends s. 409.212, F.S., relating to optional supplementation.
- Section 5:** Amends s. 429.02, F.S., relating to definitions.
- Section 6:** Amends s. 429.07, F.S., relating to license required; fee.
- Section 7:** Amends s. 429.075, F.S., relating to limited mental health license.
- Section 8:** Amends s. 429.14, F.S., relating to administrative penalties.
- Section 9:** Amends s. 429.178, F.S., relating to special care for persons with Alzheimer's disease or other related disorders.
- Section 10:** Amends s. 429.19, F.S., relating to violations; imposition of administrative fines; grounds.
- Section 11:** Amends s. 429.256, F.S., relating to assistance with self-administration of medication.
- Section 12:** Amends s. 429.27, F.S., relating to property and personal affairs of residents.
- Section 13:** Amends s. 429.28, F.S., relating to resident bill of rights.
- Section 14:** Amends s. 429.34, F.S., relating to right of entry and inspection.
- Section 15:** Amends s. 429.41, F.S., relating to rules establishing standards.
- Section 16:** Amends s. 429.52, F.S., relating to staff training and educational programs; core educational requirements.
- Section 17:** Creates s. 429.55, F.S., relating to consumer information website.
- Section 18:** Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Facilities would be required to provide new employees that have not already gone through the ALF core training program with a 2 hour pre-service training session before they work with residents. The cost of this training is not expected to be significant and in many cases is already provided.

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

Facilities with any state supported mentally ill residents would have to meet limited mental health licensure requirements with one or more mental health residents. Facilities with one or two state supported mentally ill residents that do not meet these requirements may see increased costs to comply. Some facilities with one or two such residents however, may already meet the requirements for a limited mental health license.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides AHCA with sufficient rulemaking authority, as necessary, to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2015, the Health Care Appropriations Subcommittee adopted one amendment to HB 1001. The amendment made the following changes to the bill:

- Removed language related to having the Office of Program Policy Analysis and Government Accountability conduct a study related to intersurveyor reliability for assisted living facilities.
- Removed an appropriation and two full-time equivalent (FTE) positions with associated salary and rate that were included in the bill.

The bill was reported favorably as a Committee Substitute. This analysis is drafted to the Committee Substitute.

1 A bill to be entitled
2 An act relating to assisted living facilities;
3 amending s. 394.4574, F.S.; providing that Medicaid
4 managed care plans are responsible for enrolled mental
5 health residents; providing that managing entities
6 under contract with the Department of Children and
7 Families are responsible for mental health residents
8 who are not enrolled with a Medicaid managed care
9 plan; requiring that a community living support plan
10 be completed and provided to the administrator of a
11 facility within a specified period after the
12 resident's admission; requiring that the community
13 living support plan be updated when there is a
14 significant change to the mental health resident's
15 behavioral health; requiring a mental health resident
16 case manager to keep certain records of interactions
17 with the resident and to make the records available
18 for inspection; requiring retention of the records for
19 a specified period; requiring the responsible entity
20 to ensure monitoring and implementation of community
21 living support plans and cooperative agreements;
22 amending s. 400.0074, F.S.; requiring a local
23 ombudsman council to conduct comprehensive onsite
24 administrative assessments; requiring a local council
25 to conduct an exit consultation with the facility
26 administrator or administrator designee; amending s.

27 400.0078, F.S.; requiring that a long-term care
 28 resident or resident representative be informed of
 29 resident immunity from retaliatory action for
 30 presenting grievances or exercising resident rights;
 31 amending s. 409.212, F.S.; increasing the cap on
 32 additional supplementation that a person may receive
 33 under certain conditions; amending s. 429.02, F.S.;
 34 revising the definition of the term "limited nursing
 35 services"; amending s. 429.07, F.S.; requiring that an
 36 extended congregate care license be issued to certain
 37 facilities licensed as assisted living facilities
 38 under certain circumstances and authorizing the
 39 issuance of such license if a specified condition is
 40 met; providing that the initial extended congregate
 41 care license is provisional under certain
 42 circumstances; requiring a licensee to notify the
 43 agency of acceptance of a resident who qualifies for
 44 extended congregate care services; requiring the
 45 agency to inspect the facility for compliance with
 46 license requirements; requiring the licensee to
 47 suspend extended congregate care services under
 48 certain circumstances; revising the frequency of
 49 monitoring visits to a facility by a registered nurse
 50 representing the agency; authorizing the agency to
 51 waive a required yearly monitoring visit under certain
 52 circumstances; authorizing the agency to deny or

53 | revoke a facility's extended congregate care license;
 54 | authorizing the agency to waive the required yearly
 55 | monitoring visit for a facility that is licensed to
 56 | provide limited nursing services under certain
 57 | circumstances; amending s. 429.075, F.S.; requiring an
 58 | assisted living facility that serves mental health
 59 | residents to obtain a limited mental health license;
 60 | requiring a limited mental health facility to provide
 61 | written evidence that certain documentation was sent
 62 | to the department within a specified period; amending
 63 | s. 429.14, F.S.; requiring the agency to deny or
 64 | revoke the license of an assisted living facility
 65 | under certain circumstances; requiring the agency to
 66 | impose an immediate moratorium on the license of an
 67 | assisted living facility under certain circumstances;
 68 | deleting a requirement that the agency provide a list
 69 | of facilities with denied, suspended, or revoked
 70 | licenses to the Department of Business and
 71 | Professional Regulation; exempting a facility from the
 72 | 45-day notice requirement if it is required to
 73 | relocate residents; amending s. 429.178, F.S.;
 74 | conforming cross-references; amending s. 429.19, F.S.;
 75 | requiring the agency to levy a fine for violations
 76 | that are corrected before an inspection if
 77 | noncompliance occurred within a specified period of
 78 | time; amending s. 429.256, F.S.; revising the term

79 "assistance with self-administration of medication" as
 80 it relates to the Assisted Living Facilities Act;
 81 amending s. 429.27, F.S.; revising the amount of cash
 82 for which a facility may provide safekeeping for a
 83 resident; amending s. 429.28, F.S.; providing notice
 84 requirements regarding confidentiality of resident
 85 identity in a complaint made to the State Long-Term
 86 Care Ombudsman Program or a local long-term care
 87 ombudsman council and immunity from retaliatory action
 88 for presenting grievances or exercising resident
 89 rights; providing a fine if a facility terminates an
 90 individual's residency after the filing of a complaint
 91 if good cause is not shown for the termination;
 92 requiring the agency to adopt rules; amending s.
 93 429.34, F.S.; requiring certain persons to report
 94 elder abuse in assisted living facilities; requiring
 95 the agency to regularly inspect a licensed assisted
 96 living facility; requiring the agency to conduct
 97 periodic inspections; amending s. 429.41, F.S.;
 98 providing that certain staffing requirements apply
 99 only to residents in continuing care facilities who
 100 are receiving certain services; amending s. 429.52,
 101 F.S.; requiring each newly hired employee of an
 102 assisted living facility to attend a preservice
 103 orientation; requiring the employee and administrator
 104 to sign a statement of completion and keep the

105 statement in the employee's personnel record;
 106 requiring additional hours of training for assistance
 107 with medication; creating s. 429.55, F.S.; directing
 108 the agency to create an assisted living facility
 109 consumer information website; providing criteria for
 110 webpage content; providing content requirements;
 111 authorizing the agency to adopt rules; providing an
 112 effective date.

113

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

115

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

118 394.4574 ~~Department~~ Responsibilities for coordination of
 119 services for a mental health resident who resides in an assisted
 120 living facility that holds a limited mental health license.—

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

128 (2) Medicaid managed care plans are responsible for
 129 Medicaid enrolled mental health residents, and managing entities
 130 under contract with the department are responsible for mental

131 health residents who are not enrolled in a Medicaid health plan.

132 A Medicaid managed care plan or a managing entity shall ~~The~~
 133 ~~department must~~ ensure that:

134 (a) A mental health resident has been assessed by a
 135 psychiatrist, clinical psychologist, clinical social worker, or
 136 psychiatric nurse, or an individual who is supervised by one of
 137 these professionals, and determined to be appropriate to reside
 138 in an assisted living facility. The documentation must be
 139 provided to the administrator of the facility within 30 days
 140 after the mental health resident has been admitted to the
 141 facility. An evaluation completed upon discharge from a state
 142 mental hospital meets the requirements of this subsection
 143 related to appropriateness for placement as a mental health
 144 resident if it was completed within 90 days before ~~prior to~~
 145 admission to the facility.

146 (b) A cooperative agreement, as required in s. 429.075, is
 147 developed by ~~between~~ the mental health care services provider
 148 that serves a mental health resident and the administrator of
 149 the assisted living facility with a limited mental health
 150 license in which the mental health resident is living. ~~Any~~
 151 ~~entity that provides Medicaid prepaid health plan services shall~~
 152 ~~ensure the appropriate coordination of health care services with~~
 153 ~~an assisted living facility in cases where a Medicaid recipient~~
 154 ~~is both a member of the entity's prepaid health plan and a~~
 155 ~~resident of the assisted living facility. If the entity is at~~
 156 ~~risk for Medicaid targeted case management and behavioral health~~

157 ~~services, the entity shall inform the assisted living facility~~
 158 ~~of the procedures to follow should an emergent condition arise.~~

159 (c) The community living support plan, as defined in s.
 160 429.02, has been prepared by a mental health resident and his or
 161 her ~~a mental health case manager of that resident~~ in
 162 consultation with the administrator of the facility or the
 163 administrator's designee. The plan must be completed and
 164 provided to the administrator of the assisted living facility
 165 with a limited mental health license in which the mental health
 166 resident lives within 30 days after the resident's admission.
 167 The support plan and the agreement may be in one document.

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

171 (e) The mental health services provider assigns a case
 172 manager to each mental health resident for whom the entity is
 173 responsible who lives in an assisted living facility with a
 174 limited mental health license. The case manager shall coordinate
 175 is responsible for coordinating the development ~~of~~ and
 176 implementation of the community living support plan defined in
 177 s. 429.02. The plan must be updated at least annually, or when
 178 there is a significant change in the resident's behavioral
 179 health status. Each case manager shall keep a record of the date
 180 and time of any face-to-face interaction with the resident and
 181 make the record available to the responsible entity for
 182 inspection. The record must be retained for at least 2 years

183 after the date of the most recent interaction.

184 (f) Consistent monitoring and implementation of community
 185 living support plans and cooperative agreements are conducted by
 186 the resident's case manager.

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

191 (3) The Secretary of Children and Families, in
 192 consultation with the Agency for Health Care Administration,
 193 shall ~~annually~~ require each district administrator to develop,
 194 with community input, a detailed annual plan that demonstrates
 195 ~~detailed plans that demonstrate~~ how the district will ensure the
 196 provision of state-funded mental health and substance abuse
 197 treatment services to residents of assisted living facilities
 198 that hold a limited mental health license. This plan ~~These plans~~
 199 must be consistent with the substance abuse and mental health
 200 district plan developed pursuant to s. 394.75 and must address
 201 case management services; access to consumer-operated drop-in
 202 centers; access to services during evenings, weekends, and
 203 holidays; supervision of the clinical needs of the residents;
 204 and access to emergency psychiatric care.

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

208 400.0074 Local ombudsman council onsite administrative

209 assessments.-

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

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

222 (h) Upon completion of an administrative assessment, the
 223 local council shall conduct an exit consultation with the
 224 facility administrator or a designee representing the facility
 225 to discuss issues and concerns in areas affecting residents'
 226 rights, health, safety, and welfare and, if needed, make
 227 recommendations for improvement.

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

230 400.0078 Citizen access to State Long-Term Care Ombudsman
 231 Program services.-

232 (2) ~~Every resident or representative of a resident shall~~
 233 ~~receive~~, Upon admission to a long-term care facility, each
 234 resident or representative of a resident must receive

235 information regarding the purpose of the State Long-Term Care
 236 Ombudsman Program, the statewide toll-free telephone number for
 237 receiving complaints, information that retaliatory action cannot
 238 be taken against a resident for presenting grievances or for
 239 exercising any other resident right, and other relevant
 240 information regarding how to contact the program. Each resident
 241 or his or her representative ~~Residents or their representatives~~
 242 must be furnished additional copies of this information upon
 243 request.

244 Section 4. Paragraph (c) of subsection (4) of section
 245 409.212, Florida Statutes, is amended to read:

246 409.212 Optional supplementation.—

247 (4) In addition to the amount of optional supplementation
 248 provided by the state, a person may receive additional
 249 supplementation from third parties to contribute to his or her
 250 cost of care. Additional supplementation may be provided under
 251 the following conditions:

252 (c) The additional supplementation shall not exceed four
 253 ~~two~~ times the provider rate recognized under the optional state
 254 supplementation program.

255 Section 5. Subsection (13) of section 429.02, Florida
 256 Statutes, is amended to read:

257 429.02 Definitions.—When used in this part, the term:

258 (13) "Limited nursing services" means acts that may be
 259 performed by a person licensed under ~~pursuant to~~ part I of
 260 chapter 464 ~~by persons licensed thereunder while carrying out~~

261 ~~their professional duties but limited to those acts which the~~
 262 ~~department specifies by rule. Acts which may be specified by~~
 263 ~~rule as allowable~~ Limited nursing services shall be for persons
 264 who meet the admission criteria established by the department
 265 for assisted living facilities and shall not be complex enough
 266 to require 24-hour nursing supervision and may include such
 267 services as the application and care of routine dressings, and
 268 care of casts, braces, and splints.

269 Section 6. Paragraphs (b) and (c) of subsection (3) of
 270 section 429.07, Florida Statutes, are amended to read:

271 429.07 License required; fee.—

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

278 (b) An extended congregate care license shall be issued to
 279 each facility that has been licensed as an assisted living
 280 facility for 2 or more years and that provides services
 281 ~~facilities providing~~, directly or through contract, ~~services~~
 282 beyond those authorized in paragraph (a), including services
 283 performed by persons licensed under part I of chapter 464 and
 284 supportive services, as defined by rule, to persons who would
 285 otherwise be disqualified from continued residence in a facility
 286 licensed under this part. An extended congregate care license

287 may be issued to a facility that has a provisional extended
 288 congregate care license and meets the requirements for licensure
 289 under subparagraph 2. The primary purpose of extended congregate
 290 care services is to allow residents the option of remaining in a
 291 familiar setting from which they would otherwise be disqualified
 292 for continued residency as they become more impaired. A facility
 293 licensed to provide extended congregate care services may also
 294 admit an individual who exceeds the admission criteria for a
 295 facility with a standard license, if he or she is determined
 296 appropriate for admission to the extended congregate care
 297 facility.

298 1. In order for extended congregate care services to be
 299 provided, the agency must first determine that all requirements
 300 established in law and rule are met and must specifically
 301 designate, on the facility's license, that such services may be
 302 provided and whether the designation applies to all or part of
 303 the facility. This ~~Such~~ designation may be made at the time of
 304 initial licensure or relicensure, or upon request in writing by
 305 a licensee under this part and part II of chapter 408. The
 306 notification of approval or the denial of the request shall be
 307 made in accordance with part II of chapter 408. Each existing
 308 facility that qualifies ~~facilities qualifying~~ to provide
 309 extended congregate care services must have maintained a
 310 standard license and may not have been subject to administrative
 311 sanctions during the previous 2 years, or since initial
 312 licensure if the facility has been licensed for less than 2

313 years, for any of the following reasons:

314 a. A class I or class II violation;

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

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

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

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

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

330

331 The agency may deny or revoke a facility's extended congregate
 332 care license for not meeting the criteria for an extended
 333 congregate care license as provided in this subparagraph.

334 2. If an assisted living facility has been licensed for
 335 less than 2 years, the initial extended congregate care license
 336 must be provisional and may not exceed 6 months. The licensee
 337 shall notify the agency, in writing, when it has admitted at
 338 least one extended congregate care resident, after which an

339 unannounced inspection shall be made to determine compliance
 340 with the requirements of an extended congregate care license. A
 341 licensee with a provisional extended congregate care license
 342 that demonstrates compliance with all the requirements of an
 343 extended congregate care license during the inspection shall be
 344 issued an extended congregate care license. In addition to
 345 sanctions authorized under this part, if violations are found
 346 during the inspection and the licensee fails to demonstrate
 347 compliance with all assisted living facility requirements during
 348 a followup inspection, the licensee shall immediately suspend
 349 extended congregate care services, and the provisional extended
 350 congregate care license expires. The agency may extend the
 351 provisional license for not more than 1 month in order to
 352 complete a followup visit.

353 3.2. A facility that is licensed to provide extended
 354 congregate care services shall maintain a written progress
 355 report on each person who receives services which describes the
 356 type, amount, duration, scope, and outcome of services that are
 357 rendered and the general status of the resident's health. A
 358 registered nurse, or appropriate designee, representing the
 359 agency shall visit the facility at least twice a year ~~quarterly~~
 360 to monitor residents who are receiving extended congregate care
 361 services and to determine if the facility is in compliance with
 362 this part, part II of chapter 408, and relevant rules. One of
 363 the visits may be in conjunction with the regular survey. The
 364 monitoring visits may be provided through contractual

365 arrangements with appropriate community agencies. A registered
 366 nurse shall serve as part of the team that inspects the
 367 facility. The agency may waive one of the required yearly
 368 monitoring visits for a facility that has:

369 a. Held an extended congregate care license for at least
 370 24 months; ~~been licensed for at least 24 months to provide~~
 371 ~~extended congregate care services, if, during the inspection,~~
 372 ~~the registered nurse determines that extended congregate care~~
 373 ~~services are being provided appropriately, and if the facility~~
 374 ~~has~~

375 b. No class I or class II violations and no uncorrected
 376 class III violations; and-

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

384 4.3. A facility that is licensed to provide extended
 385 congregate care services must:

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

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

391 by rule.

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

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

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

404 f. Implement the concept of managed risk.

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

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

410 5.4. A facility that is licensed to provide extended
 411 congregate care services is exempt from the criteria for
 412 continued residency set forth in rules adopted under s. 429.41.
 413 A licensed facility must adopt its own requirements within
 414 guidelines for continued residency set forth by rule. However,
 415 the facility may not serve residents who require 24-hour nursing
 416 supervision. A licensed facility that provides extended

417 | congregate care services must also provide each resident with a
 418 | written copy of facility policies governing admission and
 419 | retention.

420 | ~~5. The primary purpose of extended congregate care~~
 421 | ~~services is to allow residents, as they become more impaired,~~
 422 | ~~the option of remaining in a familiar setting from which they~~
 423 | ~~would otherwise be disqualified for continued residency. A~~
 424 | ~~facility licensed to provide extended congregate care services~~
 425 | ~~may also admit an individual who exceeds the admission criteria~~
 426 | ~~for a facility with a standard license, if the individual is~~
 427 | ~~determined appropriate for admission to the extended congregate~~
 428 | ~~care facility.~~

429 | 6. Before the admission of an individual to a facility
 430 | licensed to provide extended congregate care services, the
 431 | individual must undergo a medical examination as provided in s.
 432 | 429.26(4) and the facility must develop a preliminary service
 433 | plan for the individual.

434 | 7. If ~~When~~ a facility can no longer provide or arrange for
 435 | services in accordance with the resident's service plan and
 436 | needs and the facility's policy, the facility must ~~shall~~ make
 437 | arrangements for relocating the person in accordance with s.
 438 | 429.28(1)(k).

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

442 | (c) A limited nursing services license shall be issued to

443 a facility that provides services beyond those authorized in
 444 paragraph (a) and as specified in this paragraph.

445 1. In order for limited nursing services to be provided in
 446 a facility licensed under this part, the agency must first
 447 determine that all requirements established in law and rule are
 448 met and must specifically designate, on the facility's license,
 449 that such services may be provided. This ~~Such~~ designation may be
 450 made at the time of initial licensure or licensure renewal
 451 ~~relicensure~~, or upon request in writing by a licensee under this
 452 part and part II of chapter 408. Notification of approval or
 453 denial of such request shall be made in accordance with part II
 454 of chapter 408. An existing facility that qualifies ~~facilities~~
 455 ~~qualifying~~ to provide limited nursing services must ~~shall~~ have
 456 maintained a standard license and may not have been subject to
 457 administrative sanctions that affect the health, safety, and
 458 welfare of residents for the previous 2 years or since initial
 459 licensure if the facility has been licensed for less than 2
 460 years.

461 2. A facility ~~Facilities~~ that is ~~are~~ licensed to provide
 462 limited nursing services shall maintain a written progress
 463 report on each person who receives such nursing services. The
 464 ~~which~~ report must describe ~~describes~~ the type, amount, duration,
 465 scope, and outcome of services that are rendered and the general
 466 status of the resident's health. A registered nurse representing
 467 the agency shall visit the facility ~~such facilities~~ at least
 468 annually ~~twice a year~~ to monitor residents who are receiving

469 limited nursing services and to determine if the facility is in
 470 compliance with applicable provisions of this part, part II of
 471 chapter 408, and related rules. The monitoring visits may be
 472 provided through contractual arrangements with appropriate
 473 community agencies. A registered nurse shall also serve as part
 474 of the team that inspects such facility. Visits may be in
 475 conjunction with other agency inspections. The agency may waive
 476 the required yearly monitoring visit for a facility that has:

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

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

481 c. No ombudsman council complaints that resulted in a
 482 citation for licensure.

483 3. A person who receives limited nursing services under
 484 this part must meet the admission criteria established by the
 485 agency for assisted living facilities. When a resident no longer
 486 meets the admission criteria for a facility licensed under this
 487 part, arrangements for relocating the person shall be made in
 488 accordance with s. 429.28(1)(k), unless the facility is licensed
 489 to provide extended congregate care services.

490 Section 7. Section 429.075, Florida Statutes, is amended
 491 to read:

492 429.075 Limited mental health license.—An assisted living
 493 facility that serves one ~~three~~ or more mental health residents
 494 must obtain a limited mental health license.

495 (1) To obtain a limited mental health license, a facility
 496 must hold a standard license as an assisted living facility,
 497 must not have any current uncorrected ~~deficiencies or~~
 498 violations, and must ensure that, within 6 months after
 499 receiving a limited mental health license, the facility
 500 administrator and the staff of the facility who are in direct
 501 contact with mental health residents must complete training of
 502 no less than 6 hours related to their duties. This ~~Such~~
 503 designation may be made at the time of initial licensure or
 504 relicensure or upon request in writing by a licensee under this
 505 part and part II of chapter 408. Notification of approval or
 506 denial of such request shall be made in accordance with this
 507 part, part II of chapter 408, and applicable rules. This
 508 training must ~~will~~ be provided by or approved by the Department
 509 of Children and Families.

510 (2) A facility that is ~~Facilities~~ licensed to provide
 511 services to mental health residents must ~~shall~~ provide
 512 appropriate supervision and staffing to provide for the health,
 513 safety, and welfare of such residents.

514 (3) A facility that has a limited mental health license
 515 must:

516 (a) Have a copy of each mental health resident's community
 517 living support plan and the cooperative agreement with the
 518 mental health care services provider or provide written evidence
 519 that a request for the community living support plan and the
 520 cooperative agreement was sent to the Medicaid managed care plan

521 | or managing entity under contract with the Department of
 522 | Children and Families within 72 hours after admission. The
 523 | support plan and the agreement may be combined.

524 | (b) Have documentation ~~that is~~ provided by the department
 525 | ~~of Children and Families~~ that each mental health resident has
 526 | been assessed and determined to be able to live in the community
 527 | in an assisted living facility that has ~~with~~ a limited mental
 528 | health license or provide written evidence that a request for
 529 | documentation was sent to the department within 72 hours after
 530 | admission.

531 | (c) Make the community living support plan available for
 532 | inspection by the resident, the resident's legal guardian or
 533 | ~~the resident's~~ health care surrogate, and other individuals who
 534 | have a lawful basis for reviewing this document.

535 | (d) Assist the mental health resident in carrying out the
 536 | activities identified in the resident's ~~individual's~~ community
 537 | living support plan.

538 | (4) A facility that has ~~with~~ a limited mental health
 539 | license may enter into a cooperative agreement with a private
 540 | mental health provider. For purposes of the limited mental
 541 | health license, the private mental health provider may act as
 542 | the case manager.

543 | Section 8. Section 429.14, Florida Statutes, is amended to
 544 | read:

545 | 429.14 Administrative penalties.—

546 | (1) In addition to the requirements of part II of chapter

547 408, the agency may deny, revoke, and suspend any license issued
 548 under this part and impose an administrative fine in the manner
 549 provided in chapter 120 against a licensee for a violation of
 550 any provision of this part, part II of chapter 408, or
 551 applicable rules, or for any of the following actions by a
 552 licensee, ~~for the actions of~~ any person subject to level 2
 553 background screening under s. 408.809, or ~~for the actions of~~ any
 554 facility staff ~~employee~~:

555 (a) An intentional or negligent act seriously affecting
 556 the health, safety, or welfare of a resident of the facility.

557 (b) A ~~The~~ determination by the agency that the owner lacks
 558 the financial ability to provide continuing adequate care to
 559 residents.

560 (c) Misappropriation or conversion of the property of a
 561 resident of the facility.

562 (d) Failure to follow the criteria and procedures provided
 563 under part I of chapter 394 relating to the transportation,
 564 voluntary admission, and involuntary examination of a facility
 565 resident.

566 (e) A citation for ~~of~~ any of the following violations
 567 ~~deficiencies~~ as specified in s. 429.19:

- 568 1. One or more cited class I violations ~~deficiencies~~.
- 569 2. Three or more cited class II violations ~~deficiencies~~.
- 570 3. Five or more cited class III violations ~~deficiencies~~
 571 that have been cited on a single survey and have not been
 572 corrected within the times specified.

573 (f) Failure to comply with the background screening
 574 standards of this part, s. 408.809(1), or chapter 435.
 575 (g) Violation of a moratorium.
 576 (h) Failure of the license applicant, the licensee during
 577 relicensure, or a licensee that holds a provisional license to
 578 meet the minimum license requirements of this part, or related
 579 rules, at the time of license application or renewal.
 580 (i) An intentional or negligent life-threatening act in
 581 violation of the uniform firesafety standards for assisted
 582 living facilities or other firesafety standards which ~~that~~
 583 threatens the health, safety, or welfare of a resident of a
 584 facility, as communicated to the agency by the local authority
 585 having jurisdiction or the State Fire Marshal.
 586 (j) Knowingly operating any unlicensed facility or
 587 providing without a license any service that must be licensed
 588 under this chapter or chapter 400.
 589 (k) Any act constituting a ground upon which application
 590 for a license may be denied.
 591 (2) Upon notification by the local authority having
 592 jurisdiction or by the State Fire Marshal, the agency may deny
 593 or revoke the license of an assisted living facility that fails
 594 to correct cited fire code violations that affect or threaten
 595 the health, safety, or welfare of a resident of a facility.
 596 (3) The agency may deny a license of an ~~to any~~ applicant
 597 or a controlling interest as defined in part II of chapter 408
 598 which has or had a 25 percent ~~25-percent~~ or greater financial or

599 ownership interest in any other facility that is licensed under
 600 this part, or in any entity licensed by this state or another
 601 state to provide health or residential care, if that ~~which~~
 602 facility or entity during the 5 years prior to the application
 603 for a license closed due to financial inability to operate; had
 604 a receiver appointed or a license denied, suspended, or revoked;
 605 was subject to a moratorium; or had an injunctive proceeding
 606 initiated against it.

607 (4) The agency shall deny or revoke the license of an
 608 assisted living facility if:

609 (a) There are two moratoria, issued pursuant to this part
 610 or part II of chapter 408, within a 2-year period which are
 611 imposed by final order;

612 (b) The facility is cited for two or more class I
 613 violations arising from unrelated circumstances during the same
 614 survey or investigation; or

615 (c) The facility is cited for two or more class I
 616 violations arising from separate surveys or investigations
 617 within a 2-year period ~~that has two or more class I violations~~
 618 ~~that are similar or identical to violations identified by the~~
 619 ~~agency during a survey, inspection, monitoring visit, or~~
 620 ~~complaint investigation occurring within the previous 2 years.~~

621 (5) An action taken by the agency to suspend, deny, or
 622 revoke a facility's license under this part or part II of
 623 chapter 408, in which the agency claims that the facility owner
 624 or an employee of the facility has threatened the health,

625 safety, or welfare of a resident of the facility, shall be heard
 626 by the Division of Administrative Hearings of the Department of
 627 Management Services within 120 days after receipt of the
 628 facility's request for a hearing, unless that time limitation is
 629 waived by both parties. The administrative law judge shall ~~must~~
 630 render a decision within 30 days after receipt of a proposed
 631 recommended order.

632 (6) As provided under s. 408.814, the agency shall impose
 633 an immediate moratorium on an assisted living facility that
 634 fails to provide the agency with access to the facility or
 635 prohibits the agency from conducting a regulatory inspection.
 636 The licensee may not restrict agency staff from accessing and
 637 copying records at the agency's expense or from conducting
 638 confidential interviews with facility staff or any individual
 639 who receives services from the facility ~~provide to the Division~~
 640 ~~of Hotels and Restaurants of the Department of Business and~~
 641 ~~Professional Regulation, on a monthly basis, a list of those~~
 642 ~~assisted living facilities that have had their licenses denied,~~
 643 ~~suspended, or revoked or that are involved in an appellate~~
 644 ~~proceeding pursuant to s. 120.60 related to the denial,~~
 645 ~~suspension, or revocation of a license.~~

646 (7) Agency notification of a license suspension or
 647 revocation, or denial of a license renewal, shall be posted and
 648 visible to the public at the facility.

649 (8) If a facility is required to relocate some or all of
 650 its residents due to agency action, that facility is exempt from

651 the 45-day notice requirement imposed under s. 429.28(1)(k).
 652 This subsection does not exempt the facility from any deadlines
 653 for corrective action set by the agency.

654 Section 9. Paragraphs (a) and (b) of subsection (2) of
 655 section 429.178, Florida Statutes, are amended to read:

656 429.178 Special care for persons with Alzheimer's disease
 657 or other related disorders.—

658 (2)(a) An individual who is employed by a facility that
 659 provides special care for residents who have ~~with~~ Alzheimer's
 660 disease or other related disorders, and who has regular contact
 661 with such residents, must complete up to 4 hours of initial
 662 dementia-specific training developed or approved by the
 663 department. The training must ~~shall~~ be completed within 3 months
 664 after beginning employment and satisfy ~~shall satisfy~~ the core
 665 training requirements of s. 429.52(3)(g) ~~429.52(2)(g)~~.

666 (b) A direct caregiver who is employed by a facility that
 667 provides special care for residents who have ~~with~~ Alzheimer's
 668 disease or other related disorders, ~~and who~~ provides direct care
 669 to such residents, ~~must~~ complete the required initial training
 670 and 4 additional hours of training developed or approved by the
 671 department. The training must ~~shall~~ be completed within 9 months
 672 after beginning employment and satisfy ~~shall satisfy~~ the core
 673 training requirements of s. 429.52(3)(g) ~~429.52(2)(g)~~.

674 Section 10. Paragraph (e) is added to subsection (2) of
 675 section 429.19, Florida Statutes, to read:

676 429.19 Violations; imposition of administrative fines;

677 grounds.—

678 (2) Each violation of this part and adopted rules shall be
 679 classified according to the nature of the violation and the
 680 gravity of its probable effect on facility residents. The agency
 681 shall indicate the classification on the written notice of the
 682 violation as follows:

683 (e) Regardless of the class of violation cited, instead of
 684 the fine amounts listed in paragraphs (a)-(d), the agency shall
 685 impose an administrative fine of \$500 if a facility is found not
 686 to be in compliance with the background screening requirements
 687 as provided in s. 408.809.

688 Section 11. Subsection (3) and paragraph (c) of subsection
 689 (4) of section 429.256, Florida Statutes, are amended to read:

690 429.256 Assistance with self-administration of
 691 medication.—

692 (3) Assistance with self-administration of medication
 693 includes:

694 (a) Taking the medication, in its previously dispensed,
 695 properly labeled container, including an insulin syringe that is
 696 prefilled with the proper dosage by a pharmacist and an insulin
 697 pen that is prefilled by the manufacturer, from where it is
 698 stored, and bringing it to the resident.

699 (b) In the presence of the resident, reading the label,
 700 opening the container, removing a prescribed amount of
 701 medication from the container, and closing the container.

702 (c) Placing an oral dosage in the resident's hand or

703 placing the dosage in another container and helping the resident
 704 by lifting the container to his or her mouth.

705 (d) Applying topical medications.

706 (e) Returning the medication container to proper storage.

707 (f) Keeping a record of when a resident receives
 708 assistance with self-administration under this section.

709 (g) Assisting with the use of a nebulizer, including
 710 removing the cap of a nebulizer, opening the unit dose of
 711 nebulizer solution, and pouring the prescribed premeasured dose
 712 of medication into the dispensing cup of the nebulizer.

713 (h) Using a glucometer to perform blood-glucose level
 714 checks.

715 (i) Assisting with putting on and taking off antiembolism
 716 stockings.

717 (j) Assisting with applying and removing an oxygen cannula
 718 but not with titrating the prescribed oxygen settings.

719 (k) Assisting with the use of a continuous positive airway
 720 pressure device but not with titrating the prescribed setting of
 721 the device.

722 (l) Assisting with measuring vital signs.

723 (m) Assisting with colostomy bags.

724 (4) Assistance with self-administration does not include:

725 ~~(c) Administration of medications through intermittent~~
 726 ~~positive pressure breathing machines or a nebulizer.~~

727 Section 12. Subsection (3) of section 429.27, Florida
 728 Statutes, is amended to read:

729 429.27 Property and personal affairs of residents.-

730 (3) A facility, upon mutual consent with the resident,
 731 shall provide for the safekeeping in the facility of personal
 732 effects not in excess of \$500 and funds of the resident not in
 733 excess of \$500 ~~\$200~~ cash, and shall keep complete and accurate
 734 records of all such funds and personal effects received. If a
 735 resident is absent from a facility for 24 hours or more, the
 736 facility may provide for the safekeeping of the resident's
 737 personal effects in excess of \$500.

738 Section 13. Paragraph (a) of subsection (3) and
 739 subsections (2), (5), and (6) of section 429.28, Florida
 740 Statutes, are amended to read:

741 429.28 Resident bill of rights.-

742 (2) The administrator of a facility shall ensure that a
 743 written notice of the rights, obligations, and prohibitions set
 744 forth in this part is posted in a prominent place in each
 745 facility and read or explained to residents who cannot read. The
 746 ~~This~~ notice must ~~shall~~ include the name, address, and telephone
 747 numbers of the local ombudsman council, the ~~and~~ central abuse
 748 hotline, and, if ~~when~~ applicable, Disability Rights Florida the
 749 ~~Advocacy Center for Persons with Disabilities, Inc., and the~~
 750 ~~Florida local advocacy council~~, where complaints may be lodged.
 751 The notice must state that a complaint made to the Office of
 752 State Long-Term Care Ombudsman or a local long-term care
 753 ombudsman council, the names and identities of the residents
 754 involved in the complaint, and the identity of complainants are

755 kept confidential pursuant to s. 400.0077 and that retaliatory
 756 action cannot be taken against a resident for presenting
 757 grievances or for exercising any other resident right. The
 758 facility must ensure a resident's access to a telephone to call
 759 the local ombudsman council, central abuse hotline, and
 760 Disability Rights Florida Advocacy Center for Persons with
 761 Disabilities, Inc., and the Florida local advocacy council.

762 (3)(a) The agency shall conduct a survey to determine
 763 general compliance with facility standards and compliance with
 764 residents' rights as a prerequisite to initial licensure or
 765 licensure renewal. The agency shall adopt rules for uniform
 766 standards and criteria that will be used to determine compliance
 767 with facility standards and compliance with residents' rights.

768 (5) A ~~No~~ facility or employee of a facility may not serve
 769 notice upon a resident to leave the premises or take any other
 770 retaliatory action against any person who:

771 (a) Exercises any right set forth in this section.
 772 (b) Appears as a witness in any hearing, inside or outside
 773 the facility.

774 (c) Files a civil action alleging a violation of the
 775 provisions of this part or notifies a state attorney or the
 776 Attorney General of a possible violation of such provisions.

777 (6) A ~~Any~~ facility that ~~which~~ terminates the residency of
 778 an individual who participated in activities specified in
 779 subsection (5) must ~~shall~~ show good cause in a court of
 780 competent jurisdiction. If good cause is not shown, the agency

781 shall impose a fine of \$2,500 in addition to any other penalty
 782 assessed against the facility.

783 Section 14. Section 429.34, Florida Statutes, is amended
 784 to read:

785 429.34 Right of entry and inspection.—

786 (1) In addition to the requirements of s. 408.811, any
 787 duly designated officer or employee of the department, the
 788 Department of Children and Families, the Medicaid Fraud Control
 789 Unit of the Office of the Attorney General, the state or local
 790 fire marshal, or a member of the state or local long-term care
 791 ombudsman council has ~~shall have~~ the right to enter unannounced
 792 upon and into the premises of any facility licensed pursuant to
 793 this part in order to determine the state of compliance with ~~the~~
 794 ~~provisions of~~ this part, part II of chapter 408, and applicable
 795 rules. Data collected by the state or local long-term care
 796 ombudsman councils or the state or local advocacy councils may
 797 be used by the agency in investigations involving violations of
 798 regulatory standards. A person specified in this section who
 799 knows or has reasonable cause to suspect that a vulnerable adult
 800 has been or is being abused, neglected, or exploited shall
 801 immediately report such knowledge or suspicion to the central
 802 abuse hotline pursuant to chapter 415.

803 (2) The agency shall inspect each licensed assisted living
 804 facility at least once every 24 months to determine compliance
 805 with this chapter and related rules. If an assisted living
 806 facility is cited for a class I violation or two or more class

807 | II violations arising from separate surveys within a 60-day
808 | period or due to unrelated circumstances during the same survey,
809 | the agency must conduct an additional licensure inspection
810 | within 6 months.

811 | Section 15. Subsection (2) of section 429.41, Florida
812 | Statutes, is amended to read:

813 | 429.41 Rules establishing standards.—

814 | (2) In adopting any rules pursuant to this part, the
815 | department, in conjunction with the agency, shall make distinct
816 | standards for facilities based upon facility size; the types of
817 | care provided; the physical and mental capabilities and needs of
818 | residents; the type, frequency, and amount of services and care
819 | offered; and the staffing characteristics of the facility. Rules
820 | developed pursuant to this section may ~~shall~~ not restrict the
821 | use of shared staffing and shared programming in facilities that
822 | are part of retirement communities that provide multiple levels
823 | of care and otherwise meet the requirements of law and rule. If
824 | a continuing care facility licensed under chapter 651 or a
825 | retirement community offering multiple levels of care licenses a
826 | building or part of a building designated for independent living
827 | for assisted living, staffing requirements established in rule
828 | apply only to residents who receive personal, limited nursing,
829 | or extended congregate care services under this part. Such
830 | facilities shall retain a log listing the names and unit number
831 | for residents receiving these services. The log must be
832 | available to surveyors upon request. Except for uniform

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

833 firesafety standards, the department shall adopt by rule
 834 separate and distinct standards for facilities with 16 or fewer
 835 beds and for facilities with 17 or more beds. The standards for
 836 facilities with 16 or fewer beds must ~~shall~~ be appropriate for a
 837 noninstitutional residential environment; however, ~~provided that~~
 838 the structure may not be ~~is no~~ more than two stories in height
 839 and all persons who cannot exit the facility unassisted in an
 840 emergency must reside on the first floor. The department, in
 841 conjunction with the agency, may make other distinctions among
 842 types of facilities as necessary to enforce ~~the provisions of~~
 843 this part. Where appropriate, the agency shall offer alternate
 844 solutions for complying with established standards, based on
 845 distinctions made by the department and the agency relative to
 846 the physical characteristics of facilities and the types of care
 847 offered ~~therein~~.

848 Section 16. Subsections (1) through (11) of section
 849 429.52, Florida Statutes, are renumbered as subsections (2)
 850 through (12), respectively, present subsections (5) and (9) are
 851 amended, and a new subsection (1) is added to that section, to
 852 read:

853 429.52 Staff training and educational programs; core
 854 educational requirement.—

855 (1) Effective October 1, 2015, each new assisted living
 856 facility employee who has not previously completed core training
 857 must attend a preservice orientation provided by the facility
 858 before interacting with residents. The preservice orientation

859 must be at least 2 hours in duration and cover topics that help
 860 the employee provide responsible care and respond to the needs
 861 of facility residents. Upon completion, the employee and the
 862 administrator of the facility must sign a statement that the
 863 employee completed the required preservice orientation. The
 864 facility must keep the signed statement in the employee's
 865 personnel record.

866 (6)(5) Staff involved with the management of medications
 867 and assisting with the self-administration of medications under
 868 s. 429.256 must complete a minimum of 6 4 additional hours of
 869 training provided by a registered nurse, licensed pharmacist, or
 870 department staff. The department shall establish by rule the
 871 minimum requirements of this additional training.

872 (10)(9) The training required by this section other than
 873 the preservice orientation must ~~shall~~ be conducted by persons
 874 registered with the department as having the requisite
 875 experience and credentials to conduct the training. A person
 876 seeking to register as a trainer must provide the department
 877 with proof of completion of the minimum core training education
 878 requirements, successful passage of the competency test
 879 established under this section, and proof of compliance with the
 880 continuing education requirement in subsection (5) ~~(4)~~.

881 Section 17. Section 429.55, Florida Statutes, is created
 882 to read:

883 429.55 Consumer information website.—The Legislature finds
 884 that consumers need additional information on the quality of

885 care and service in assisted living facilities in order to
 886 select the best facility for themselves or their loved ones.
 887 Therefore, the Agency for Health Care Administration shall
 888 create content that is easily accessible through the home page
 889 of the agency's website either directly or indirectly through
 890 links to one or more other established websites of the agency's
 891 choosing. The website must be searchable by facility name,
 892 license type, city, or zip code. By November 1, 2015, the agency
 893 shall include all content in its possession on the website and
 894 add content when received from facilities. At a minimum, the
 895 content must include:

896 (1) Information on each licensed assisted living facility,
 897 including, but not limited to:

- 898 (a) The name and address of the facility.
- 899 (b) The name of the owner or operator of the facility.
- 900 (c) The number and type of licensed beds in the facility.
- 901 (d) The types of licenses held by the facility.
- 902 (e) The facility's license expiration date and status.
- 903 (f) The total number of clients that the facility is
 904 licensed to serve and the most recently available occupancy
 905 levels.
- 906 (g) The number of private and semiprivate rooms offered.
- 907 (h) The bed-hold policy.
- 908 (i) The religious affiliation, if any, of the assisted
 909 living facility.
- 910 (j) The languages spoken by the staff.

- 911 (k) Availability of nurses.
- 912 (l) Forms of payment accepted, including, but not limited
- 913 to, Medicaid, Medicaid long-term managed care, private
- 914 insurance, health maintenance organization, United States
- 915 Department of Veterans Affairs, CHAMPUS program, or workers'
- 916 compensation coverage.
- 917 (m) Indication if the licensee is operating under
- 918 bankruptcy protection.
- 919 (n) Recreational and other programs available.
- 920 (o) Special care units or programs offered.
- 921 (p) Whether the facility is a part of a retirement
- 922 community that offers other services pursuant to this part or
- 923 part III of this chapter, part II or part III of chapter 400, or
- 924 chapter 651.
- 925 (q) Links to the State Long-Term Care Ombudsman Program
- 926 website and the program's statewide toll-free telephone number.
- 927 (r) Links to the websites of the providers.
- 928 (s) Other relevant information that the agency currently
- 929 collects.
- 930 (2) Survey and violation information for the facility,
- 931 including a list of the facility's violations committed during
- 932 the previous 60 months, which on July 1, 2015, may include
- 933 violations committed on or after July 1, 2010. The list shall be
- 934 updated monthly and include for each violation:
- 935 (a) A summary of the violation, including all licensure,
- 936 revisit, and complaint survey information, presented in a manner

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937 understandable by the general public.

938 (b) Any sanctions imposed by final order.

939 (c) The date the corrective action was confirmed by the
940 agency.

941 (3) Links to inspection reports that the agency has on
942 file.

943 (4) The agency may adopt rules to administer this section.

944 Section 18. This act shall take effect July 1, 2015.



COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 1001 (2015)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee
 3 Representative Ahern offered the following:

Amendment

Remove line 806 and insert:

facility is cited for a class I violation or three or more class

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1049 Practice of Pharmacy
SPONSOR(S): Health Quality Subcommittee; Peters and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Langston	O'Callaghan
2) Business & Professions Subcommittee	12 Y, 0 N	Anstead	Luczynski
3) Health & Human Services Committee		Langston <i>W</i>	Calamas <i>pc</i>

SUMMARY ANALYSIS

Compounding is the practice in which a licensed pharmacist, or other legally permitted individual, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient when the health needs of that patient cannot be met by a medication approved by the U.S. Food and Drug Administration.

The practice of veterinary medicine, defined in the Veterinary Medical Practice Act, ch. 474, F.S., includes prescribing, dispensing, and administering drugs to treat animals.

The bill specifies that the Florida Pharmacy Act, ch. 465, F.S., and the rules adopted under it, do not prevent a veterinarian from administering a compounded drug to an animal that is a patient or dispensing a compounded drug to that animal's owner or caretaker.

There is no fiscal impact on state or local governments.

The bill provides for an effective date of July 1, 2015.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Compounding

Compounding is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools.¹ It is a practice in which a licensed pharmacist or other legally permitted individual combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient when the health needs of that patient cannot be met by a medication approved by the U.S. Food and Drug Administration (FDA).² For example, compounding could be necessary when a patient with an allergy needs a medication to be made without a certain dye or an elderly patient or a child is unable to swallow a pill and needs a medicine in a liquid form that is not otherwise available.³

Compounded drugs can pose both direct and indirect health risks.⁴ Compounded drugs may be unsafe and pose direct health risks because of the use of poor quality compounding practices; they may be sub- or super-potent, contaminated, or otherwise adulterated.⁵ Some pharmacists are well trained and well equipped to compound certain medications safely, but not all pharmacists have the same level of skills and equipment, and some drugs may be inappropriate for compounding.⁶ However, in other cases, compounders may lack sufficient controls (e.g., equipment, training, testing, or facilities) to ensure product quality or to compound complex drugs like sterile or extended-release drugs.⁷

Regulation of Compounded Medications

Florida

Compounding is defined in s. 465.003(18), F.S., as the combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.

The Florida Administrative Code defines compounding as the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient, or for administration by a practitioner or the practitioner's agent.⁸ This definition also specifically includes the professional act of preparing a unique finished product containing any ingredient or device and the preparation of:

- Drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

¹ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002).

² U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> (last visited March 30, 2015).

³ *Id.*

⁴ U.S. Food and Drug Administration, *Compounded Menopausal Hormone Therapy Questions and Answers*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm183088.htm#MenopausalHormoneTherapy> (last visited March 30, 2015).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ Rule 64B16-27.700, F.A.C.

- Drugs or devices which are not commercially available, pursuant to a prescription.
- Commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient is aware that the pharmacist will prepare the compounded product. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.⁹

Section 465.0276, F.S., provides that only a licensed pharmacist, or other person authorized under ch. 465, F.S., or a practitioner authorized by law, may dispense medicinal drugs. Dispensing is defined as the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent.¹⁰ Dispensing is broader than administration. Administration is defined as obtaining and giving a single dose of medicinal drug by a legally authorized person to a patient for his or her consumption.¹¹

Federal

Compounded drugs are not FDA-approved; this means that the FDA does not verify the safety, or effectiveness of compounded drugs and these drugs lack an FDA finding of manufacturing quality before such drugs are marketed.¹² However, federal rules currently require that compounded medications only be modified versions of FDA-approved medications.¹³ In other words, compounded medications should only be prepared using FDA-approved drugs that have been crushed, had a flavor added, or otherwise changed from the original form.¹⁴

The FDA has traditionally regulated the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients.¹⁵ The FDA states that, generally, state boards of pharmacy continue to have primary responsibility for oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding.¹⁶ However, the FDA retains some authority over the entities compounding the drugs through the "Compounding Quality Act," in Title I of the Drug Quality and Security Act (DQSA)¹⁷ and the Food, Drug, and Cosmetic Act (FDCA).¹⁸ The FDA has indicated its intention to continue to cooperate with state authorities to address pharmacy compounding activities that may violate the FDCA.¹⁹

Compounding in Veterinary Medicine

The American Veterinary Medical Association (AVMA) states that the use of compounded medications offers myriad benefits to veterinarians, particularly when dealing with animals that require very small or very large doses of a particular medication or for which the traditional route of administration might not

⁹ Rule 64B16-27.700(1), F.A.C.

¹⁰ S. 465.033(6), F.S.

¹¹ S. 465.003(1), F.S.

¹² *Id.*

¹³ See 21 U.S.C. § 353a(b)(3) (2014) for drugs compounded for human use and 21 C.F.R. § 530.13(a) (2014) for drugs compounded for animal use.

¹⁴ American Veterinary Medical Association, *Compounding: FAQ for Pet Owners*, <https://www.avma.org/KB/Resources/FAQs/Pages/Compounding-FAQ-for-Pet-Owners.aspx> (last visited March 13, 2015).

¹⁵ *Supra*, note 2.

¹⁶ *Id.*, see also U.S. Food and Drug Administration, "Compliance Policy Guide s. 608.400: Compounding of Drugs for Use in Animals," 61 FR 34846 (June 26, 1996) (updated July 8, 2003 at 68 FR 41591)

¹⁷ The DQSA describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA. See FDCA, s. 503(A), 21 U.S.C. § 353a (2014).

¹⁸ U.S. Food and Drug Administration, *Compounding – Compounding Quality Act*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm> (last visited March 13, 2015).

¹⁹ U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Guidance – Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (July 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf>.

be optimal or even feasible.²⁰ Compounding is usually necessary when an animal is suffering from a medical condition and there is no FDA-approved human or veterinary product available and medically appropriate to treat the patient.²¹ In some situations, veterinarians may find it necessary to compound from a source that has not been approved by the FDA to relieve the animal's suffering, in these cases, veterinarians and pharmacists must carefully assess whether the use is consistent with state and federal law and FDA policy.²²

The AVMA notes that while the benefits of compounded medications for animals are not readily apparent because compounding may affect the absorption and depletion of a drug resulting in drug concentrations that are above or below the therapeutic range, it is an essential tool that provides therapeutic flexibility for difficult or irregular cases.²³ However, the AVMA cautions that compounded medications should be used judiciously.²⁴

The FDA has issued a Compliance Policy Guide s. 608.400 entitled "Compounding of Drugs for Use in Animals,"²⁵ to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. The FDCA does not distinguish compounding from manufacturing or other processing of drugs for use in animals; however, the DQSA does not apply to animals.

The most widely covered incidents relating to compounding in veterinary medicine in Florida involved horses. In 2009, 21 polo horses died at the United States Open Polo Championship in Florida as the result of a mathematical error by the compounding pharmacy that altered the strength of an ingredient in a medication given to the horses.²⁶ Another incident occurred in 2014, when eight Florida horses and two from Kentucky were sickened from a compounded drug.²⁷ Both of the horses from Kentucky and two of the eight horses from Florida died or had to be euthanized; the six remaining horses in Florida suffered neurological problems.²⁸

Florida Regulation of Veterinarians

Veterinarians are licensed and regulated under the Board of Veterinary Medicine²⁹ under the Department of Business and Professional Regulation (DBPR).³⁰

As part of the practice of veterinary medicine, veterinarians are authorized to prescribe, dispense, and administer drugs or medicine to their animal patients.³¹ Veterinarians who dispense medications from an office are subject to regulation and inspection by DBPR.³²

Compounded drugs for animals are not addressed in the Veterinary Medical Practice Act, ch. 474, F.S., nor are they addressed in DBPR's rules regulating veterinarians. However, in addition to authorization to prescribe, dispense, and administers drugs and medicine, veterinarians may engage in "treatment of

²⁰ Michael J. White, *Unraveling the confounding world of Compounding*, JAVMANews (Feb. 13, 2013), <https://www.avma.org/News/JAVMANews/Pages/130301o.aspx> (last visited March 30, 2015).

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ 61 FR 34846 (June 26, 1996) (updated July 8, 2003 at 68 FR 41591)

²⁶ Katie Thomas, *Polo Ponies Were Given Incorrect Medication*, New York Times (April 23, 2009), available at <http://www.nytimes.com/2009/04/24/sports/othersports/24polo.html> (last visited March 30, 2015).

²⁷ Carlos E. Medina, *Report: 2 thoroughbreds in Ocala, 2 in Kentucky die after being given compounded drug*, The Gainesville Sun (May 18, 2014), available at <http://www.gainesville.com/article/20140518/ARTICLES/140519684> (last visited March 30, 2015).

²⁸ *Id.*

²⁹ S. 474.204, F.S.

³⁰ Ch. 61G18, F.A.C.

³¹ S. 474.202(9), F.S.

³² Florida Department of Health, *2015 Agency Analysis Senate Bill 1180* (Feb. 27, 2015) (SB 1180 is identical to HB 1049, as filed.) (on file with Health and Human Services Committee staff).

whatever nature” to prevent, treat, or cure any wound, injury, or disease of one of their patients. This authority allows them to compound drugs.³³

Effect of Proposed Changes

The bill amends s. 465.0276, F.S., to clarify the impact of the Florida Pharmacy Act and the Board of Pharmacy’s rules on a veterinarian’s authority to administer or dispense compounded drugs. Specifically, the bill states that nothing in ch. 465, F.S., or the rules adopted under it prevent a veterinarian from administering a compounded drug to an animal patient or dispensing compounded drugs to the animal’s owner or caretaker.

The act will take effect July 1, 2015.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.0276, F.S., relating to dispensing practitioners.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The Department of Health notes that pharmacists may be unwilling to continue dispensing compounded drugs to veterinarians if those compounded drugs are going to be dispensed or sold by the veterinarians.³⁴

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

³³ *Id.* (emphasis added).

³⁴ *Id.*

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 16, 2015, the Health Quality Subcommittee adopted a strike-all amendment to HB 1049 and reported the bill favorably as a committee substitute. The amendment:

- Removes the definition of “office use compounding” from the bill; and
- Provides the Florida Pharmacy Act or rules adopted by the Board of Pharmacy do not prevent veterinarians licensed under ch. 474, F.S., from administering a compounded drug to his or her animal patient, or dispensing a compounded drug to the animal patient’s owner or caretaker.

The analysis is drafted to the committee substitute.

1 A bill to be entitled
 2 An act relating to the practice of pharmacy; amending
 3 s. 465.0276, F.S.; specifying that the Florida
 4 Pharmacy Act and rules adopted thereunder do not
 5 prohibit a veterinarian from administering a
 6 compounded drug to a patient or dispensing a
 7 compounded drug to the patient's owner or caretaker;
 8 providing an effective date.

9

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

11

12 Section 1. Subsection (6) is added to section 465.0276,
 13 Florida Statutes, to read:

14 465.0276 Dispensing practitioner.—

15 (6) This chapter and the rules adopted thereunder do not
 16 prohibit a veterinarian licensed under chapter 474 from
 17 administering a compounded drug to a patient, as defined in s.
 18 474.202, or dispensing a compounded drug to the patient's owner
 19 or caretaker.

20 Section 2. This act shall take effect July 1, 2015.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee
 3 Representative Peters offered the following:

Amendment (with title amendment)



6 Remove line 19 and insert:
 7 or caretaker. This subsection does not affect the regulation of
 8 the practice of pharmacy as set forth in this chapter.

10 -----
 11 **T I T L E A M E N D M E N T**

12 Remove line 8 and insert:
 13 Clarifying that such provision does not affect the Florida
 14 Pharmacy Act; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1305 Home Medical Equipment Providers
SPONSOR(S): Eagle
TIED BILLS: **IDEN./SIM. BILLS:** SB 996

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee	9 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo 	Calamas 

SUMMARY ANALYSIS

Home medical equipment providers are licensed and regulated by the Agency for Health Care Administration (AHCA) under part VII of ch. 400, F.S. The licensure requirements for home medical equipment providers apply to any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services. Certain individuals and entities are exempt from the licensure requirements, including:

- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Hospices;
- Intermediate care facilities;
- Hospitals;
- Manufacturers and wholesale distributors;
- Pharmacies; and
- 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.

Electrostimulation medical equipment can be used to treat a number of medical symptoms and conditions. Electrical stimulators can provide direct, alternating, and pulsed waveforms of energy to the human body through electrodes that may be implanted in the skin or used on the surface of the skin. 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.

The bill amends s. 400.93, F.S., to exempt physicians licensed under chapters 458 and 459, F.S., and chiropractors licensed under ch. 460, F.S., who sell or rent electrostimulation medical equipment to their patients in the course of their practice from licensure as a home medical equipment provider.

The bill will have an insignificant negative fiscal impact on AHCA resulting from a reduction in licensure fees collected.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Home Medical Equipment Providers

Home medical equipment providers are licensed and regulated by the Agency for Health Care Administration (AHCA), under part VII of ch. 400, F.S., and Chapter 59A-25, F.A.C. A home medical equipment license is required for any person or entity that:

- Holds itself out to the public as providing home medical equipment¹ and services;²
- Accepts physician orders for home medical equipment and services; or
- Provides home medical equipment that typically requires home medical services.³

Section 400.931, F.S., requires any person or entity applying for a home medical equipment provider license to submit certain information to AHCA with the application, including:

- A report of the medical equipment and services that will be provided, and whether the equipment will be provided directly or by contract;
- A list of the persons and entities with whom the applicant contracts;
- Documentation of accreditation, or an application for accreditation, from an accrediting organization recognized by AHCA;
- Proof of liability insurance; and
- An application fee of \$300 and an inspection fee of \$400⁴.

Section 400.934, F.S., requires home medical equipment providers to comply with minimum standards of operation relating to topics such as services, training and personnel, and emergency standards.

A home medical equipment provider must offer and provide home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services, and must provide at least one category of equipment directly from their own inventory.⁵ A home medical equipment provider is required to respond to orders for other equipment from either their own inventory or from the inventory of other contracted companies and must maintain and repair, either directly or through contract, items rented to consumers.⁶

Home medical equipment providers are required to maintain trained personnel to coordinate orders and scheduling of equipment and service deliveries and must ensure that their delivery personnel are

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 product 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; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need. Home medical equipment does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner.

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 customer's regular or temporary place of residence.

³ S. 400.93(1) and (2), F.S.

⁴ S. 400.933, F.S.; Provides that the home medical equipment provider is exempt from the inspection fee if a survey or inspection has been conducted by an accrediting organization.

⁵ S. 400.934(1) and (2), F.S.

⁶ S. 400.934(3) and (11), F.S.

appropriately trained.⁷ Home medical equipment providers are required to ensure that all personnel have the necessary training and background screening.⁸

A home medical equipment provider must comply with certain emergency standards, including:

- Ensuring that patients are aware of service hours and emergency service procedures;
- 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;

Home medical equipment providers are also required to maintain a record for each patient that includes the equipment and services provided, 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 and Medicaid Services, and licensure complaint investigations.¹⁰ Currently there are 779 licensed home medical equipment providers in Florida.¹¹

Certain individuals and entities are considered exempt from licensure, including:

- 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 patient; and
- Pharmacies.¹²

⁷ S. 400.934(4) and (5), F.S.

⁸ S. 400.934(16), F.S.

⁹ S. 400.94, F.S.

¹⁰ S. 400.932, F.S.

¹¹ AHCA, Florida Health Finder, *Facility/Provider Search, Home Medical Equipment Providers*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (search conducted March 15, 2015).

¹² S. 400.93(5), F.S.

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, and pulsed waveforms of energy to the human body through electrodes that may be implanted or used on the surface of the skin.¹³ 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.¹⁴

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.¹⁵

A second type of electrical stimulation is Transcutaneous Electrical Nerve Stimulation (TENS). A TENS device consists of an electrical signal generator that transmits pulses of electrical current to electrodes on the skin.¹⁶ The TENS unit is programmable and the generators are capable of delivering stimulation in different rates and intensities. Conventional TENS devices have a high stimulation frequency and low intensity. Pulsed burst TENS devices use low-intensity stimulation in high-frequency bursts.

Other types of electrical stimulation include interferential therapy (IFT) and neuromuscular electrical stimulation (NMES). IFT uses two alternating currents applied to the affected area through electrodes to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. NMES applies electrical currents through the skin to cause muscle contractions and 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

Effect of Proposed Changes

The bill amends s. 400.93, F.S., to exempt physicians licensed under Chapters 458 and 459, F.S., and chiropractors licensed under ch. 460, F.S., who sell or rent electrostimulation medical equipment to their patients in the course of their practice from home medical equipment provider licensure requirements. The bill permits physicians and chiropractors to sell or rent this type of home medical equipment directly to their patients without incurring a fee for licensure or licensure renewal.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 400.93, F.S., relating to licensure required; exemptions; unlawful acts; penalties.

Section 2: Provides an effective date of July 1, 2015.

¹³ 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](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Electrical%20Stim%20Tx%20Pain%20Muscle%20Rehab.pdf) (last viewed March 15, 2015).

¹⁴ Id.

¹⁵ Id.

¹⁶ United Healthcare Medical Policy, *Transcutaneous Electrical Nerve Stimulation (TENS) for the Treatment of Nausea and Vomiting*, p. 2, (November 1, 2014) [https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/TENS Tx Nausea Vomiting.pdf](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/TENS%20Tx%20Nausea%20Vomiting.pdf) (last viewed March 15, 2015).

¹⁷ Supra at FN 8, pg. 5.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA may experience a decrease in revenues resulting from a reduction in the number of physicians and chiropractors paying licensure fees to sell or rent electrostimulation medical equipment directly to their patients. The exact amount is uncertain but not significant.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed physicians and chiropractors who sell or rent electrostimulation medical equipment to their patients will not have to pay licensure and licensure renewal fees.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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A bill to be entitled
An act relating to home medical equipment providers;
amending s. 400.93, F.S.; exempting allopathic,
osteopathic, and chiropractic physicians who sell or
rent electrostimulation medical equipment from
licensure requirements under certain circumstances;
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 under 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.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7045 PCB HIS 15-01 State Veterans' Nursing Homes
SPONSOR(S): Health Innovation Subcommittee, Sprowls
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Innovation Subcommittee	13 Y, 0 N	Guzzo	Poche
1) Health Care Appropriations Subcommittee	10 Y, 0 N	Garner	Pridgeon
2) Health & Human Services Committee		Guzzo 	Calamas 

SUMMARY ANALYSIS

The bill creates a site selection process for new state veterans' nursing homes to be administered by the Florida Department of Veterans' Affairs (FDVA).

The State Veterans' Homes Program, administered by FDVA, provides care to eligible veterans in need of either long-term skilled nursing care or assisted living services. Currently, there are six state veterans' nursing homes in Florida. Because of the size and age of the veteran population, Florida is near the top of the list of states with a "Great Need" for veterans' nursing home beds as determined by the U.S. Department of Veterans' Affairs (VA). As a result, Florida will receive priority over other states applying to the VA for grants for the construction of new state veterans' nursing homes.

Currently, no Florida law governs the FDVA's site selection process. FDVA's current process is two-tiered. First, FDVA contracts for a Site Selection Study (Study) to rank each county based on greatest need using certain measureable criteria. Second, FDVA sends applications to the top ten counties identified in the Study. Each county that wishes to be considered in the selection process must submit an application, which includes other measureable criteria, to FDVA by a specified date. The application is scored by a Site Selection Committee appointed by the Executive Director of FDVA. The county with the highest score is awarded the site, subject to approval by the Governor and the Cabinet.

The bill creates a single-step site selection process, in new s. 296.42, F.S. The bill requires FDVA to contract for a study to determine the most appropriate county for construction of a nursing home based on the greatest level of need. The study must be delivered to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2015. The bill requires that the study rank each county using the following criteria:

- The distance from the geographic center of the county to the nearest existing state veterans' nursing home;
- The number of veterans aged 65 years and older living in the county;
- The availability of emergency health care in the county;
- The presence of an existing Veterans' Health Administration Medical Center or Outpatient Clinic in the county;
- The number of existing nursing home beds per 1,000 elderly male residents of the county;
- The presence of accredited education institutions with health care programs in the county; and
- The county poverty rate.

FDVA must select the county with the highest ranking as the site for the new home, subject to approval by the Governor and the Cabinet. The bill requires the next highest ranked county to be selected if a higher ranked county cannot participate. The study must be used to determine the site of any new veterans' nursing home authorized before July 1, 2020. The bill requires the Site Selection Study dated February 7, 2014, to be used to select a county for a new veterans' nursing home before November 1, 2015, if authorized.

The bill provides for expiration of s. 296.42, F.S., on July 1, 2020, unless reviewed and rescued from repeal by the Legislature prior to that date.

The House Proposed General Appropriations Act provides a \$50,000 nonrecurring appropriation from the Operations and Maintenance Trust Fund for the study.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h7045b.HHSC.DOCX

DATE: 3/30/2015

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

State Veterans' Homes Program

The Florida Department of Veterans' Affairs (FDVA) operates the State Veterans' Homes Program (Program) as authorized by Chapters 292 and 296, F.S.¹ The Program provides care to eligible veterans in need of either long-term skilled nursing care or assisted living services. Care is provided to veterans with qualifying war or peacetime service, who are residents of Florida and who require skilled care as certified by a U.S. Department of Veterans' Affairs (USDVA) physician.² There are approximately 729,000 veterans aged 65 years and older in the state.³

Currently, there are six state veterans' nursing homes in Florida. Five of the six homes have dementia-specific care.⁴ The six nursing homes are located in Daytona Beach, Land O' Lakes, Pembroke Pines, Panama City, Port Charlotte, and St. Augustine. The Program has a total of 720 skilled-nursing beds and an average occupancy rate of 97.8% for FY 2013-14.⁵ In 2014, St. Lucie County was selected as the site for the seventh nursing home.

Funding

The construction of a new nursing home is subject to approval by the Governor and Cabinet. Funding is based on a 65% / 35% federal/state split of the cost.⁶ Florida is near the top of the list of states with a "Great Need" for veterans' nursing home beds as determined by the USDVA.⁷ As a result, Florida will receive priority over other states applying to USDVA for grants for the construction of new state veterans' nursing homes. The estimated cost to build a new nursing home can range from \$37 million to \$50 million, depending on style, land condition, materials used, weather resistance and energy efficiency.⁸

The state pro-rata share for the seventh nursing home in St. Lucie County is approximately \$12.5 million based on a VA "cost to build" estimate of \$37 million.⁹ According to FDVA, the cost figures are estimates as architectural plans are still being completed and are yet to be approved by the USDVA.¹⁰ The state's cost will be paid from the FDVA Operations and Maintenance Trust Fund. Funding for future nursing homes will need to be supported by General Revenue funding.¹¹

¹ S. 292.05(7), F.S. "The Department shall administer this chapter and shall have the authority and responsibility to apply for and administer any federal programs and develop and coordinate such state programs as may be beneficial to the particular interests of the veterans of this state."; part II of ch. 296, F.S., titled "The Veterans' Nursing Home of Florida Act" provides for the establishment of basic standards by FDVA for the operation of veteran's nursing homes for eligible veterans in need of such services."

² S. 296.36, F.S.

³ Florida Department of Veterans' Affairs, *Annual Report: Fiscal Year 2013-14*, page 15, available at <http://floridavets.org/about-us/annual-report/> (last visited February 20, 2015).

⁴ Id. at page 7.

⁵ Id.

⁶ 38 CFR §59.80

⁷ 38 CFR §59.50(1)(iii); see also 38 CFR §§59.40 and .50.

⁸ E-mail correspondence, FDVA, February 12, 2015, (on file with Health Innovation Subcommittee staff).

⁹ Id.

¹⁰ Id.

¹¹ Id.

Site Selection Process for Recently Authorized State Veterans' Nursing Homes

State Veterans' Nursing Home Seven (St. Lucie County)

In 2013, the Legislature appropriated funds for FDVA to contract with a private entity to conduct a Site Selection Study (Study).¹² The purpose of the Study was to identify five communities, defined as single-county or multi-county areas, to be given priority for development of a new state veterans' nursing home.

Counties that did not meet certain minimum threshold criteria, including access to emergency care and the availability of health care professionals, were eliminated from consideration before the Study began. Counties with an existing state veterans' nursing home and those located within 25 miles of an existing home were also eliminated from consideration.

The Study used the following criteria to score the counties, rank ordered from greatest to least value assigned:

- Number of elderly veterans in the county;
- Ratio of existing nursing home beds per/1,000 elderly male residents in the county;
- County poverty rate;
- Distance to an existing state veterans' nursing home;
- Presence of an existing veterans' health care facility in the county; and
- Presence of nursing education programs in the county.

The Study identified the following top ten counties with the greatest need for a new state veterans' nursing home, ranked in order of greatest need based on the scoring criteria:

Study Ranking	County
1	Collier
2	Lee
3	Polk
4	Manatee
5	Marion
6	Putnam
7	St. Lucie
8	Hillsborough
9	Palm Beach
10	Sumter

FDVA sent applications to all ten counties listed in the Study. Six of the counties submitted applications: Collier County, Polk County, Manatee County, Marion County, Putnam County, and St. Lucie County. A Site Selection Committee (Committee) was created by the Executive Director of FDVA to evaluate each application.

The Committee established factors for consideration, and assigned a score of 0 to 50 points for each of the following criteria:

- Number of veterans aged 65 or older living within a 75 mile radius of the proposed site;
- Number of nursing home beds and assisted living facility beds located within 10 miles of the proposed site;

¹² Hoy & Stark Architects, *Site Selection Study; Phase I State Veterans' Nursing Homes Statewide*, February 7, 2014, (on file with the Health Innovation Subcommittee staff).

- Suitability of the donated site in terms of its general surroundings and support capabilities;
- Availability of emergency health care, as determined by:
 - Number of hospitals and/or emergency care centers within 25 miles of the proposed site;
 - Number of emergency room holding beds per facility;
 - Presence of in-house physicians on staff in the emergency room 24 hours/day, 7 days/week; and
 - The nursing workforce.
- Availability of health care professionals, as determined by the number of accredited educational institutions located within 50 miles of the proposed site; and
- Availability of infrastructure at the site, including roads, water, sewer, telephone lines, and electricity/natural gas services, all of which must link to the property line of the proposed site at no cost to the state.

The Committee's final rankings were:

Committee Ranking	County	Study Ranking
1	St. Lucie	7
2	Marion	5
3	Collier Site B	1
4	Collier Site A	1
5	Polk Site A	3
6	Polk Site B	3

St. Lucie County was selected as the site for the seventh nursing home, and approved by the Governor and Cabinet on September 23, 2014.

State Veterans' Nursing Home Six (St. Johns County)

The same site selection process was used to determine the site of the sixth nursing home. A Study¹³ was conducted in 2004 and the home was built in 2010. The extended length of time between site selection and construction of the nursing home was due to a lack of funds caused by the economic recession in the mid-2000s.

The Study identified the following top twelve areas, which included counties and multi-county groups, with the greatest need for a veterans' nursing home:

Study Ranking	County or Area
1	Lake/Marion/Sumter
2	Duval
3	Brevard
4	Escambia/Santa Rosa/Okaloosa
5	Indian River/Martin/St. Lucie
6	Orange/Seminole
7	Collier/Lee
8	Palm Beach
9	Sarasota/Manatee
10	Polk
11	Citrus/Hernando
12	Pinellas

The Committee selected St. Johns County as the site for sixth veterans' nursing home. St. Johns County was not identified in the Study as an area of need.

¹³ Health Strategies, Inc., *Nursing Home Site Selection Study*, February 2004, (on file with the Health Innovation Subcommittee staff).

Effect of Proposed Changes

The bill creates a single-step site selection process, in new s. 296.42, F.S. The bill requires FDVA to contract for a study to determine the most appropriate county for construction of a new nursing home based on the greatest level of need. The study must be delivered to the Governor, President of the Senate, and the Speaker of the House of Representatives by November 1, 2015.

The bill requires the study to use the following criteria to rank each county:

- The distance from the geographic center of the county to the nearest existing state veterans' nursing home;
- The number of veterans aged 65 years and older living in the county;
- The availability of emergency health care in the county, as determined by:
 - The number of general hospitals;
 - The number of emergency room holding beds per hospital; and
 - The number of in-house physicians per hospital on staff in the emergency room 24 hours per day.
- The presence of an existing Veterans' Health Administration Medical Center or Outpatient Clinic in the county;
- The number of existing nursing home beds per 1,000 elderly male residents of the county;
- The presence of accredited education institutions with health care programs in the county; and
- The county poverty rate.

The county with the highest ranking must be selected as the site for the new home, subject to approval by the Governor and the Cabinet. The bill requires the next highest ranked county to be selected if a higher ranked county cannot participate. The study must be used to determine the site for any veterans' nursing home authorized before July 1, 2020. For any veterans' nursing home authorized before November 1, 2015, the bill requires the FDVA to use the 2014 Site Selection Study.

Lastly, the bill provides for the expiration of s. 296.42, F.S., on July 1, 2020, unless reviewed and saved from repeal by the Legislature prior to that date.

B. SECTION DIRECTORY:

Section 1: Creates s. 296.42, F.S., relating to the site selection process for state veterans' nursing homes.

Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill requires the FDVA to contract for a study to rank each county according to greatest need to determine the most appropriate site for a new veterans' nursing home. The Site Selection Study for the determination of the seventh state nursing home location was competitively procured and a

contract was awarded to Hoy + Stark Architects, P.A. for a total cost of \$38,692.¹⁴ The House Proposed General Appropriations Act provides a \$50,000 nonrecurring appropriation from the Operations and Maintenance Trust Fund for this purpose.

FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

B. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

C. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

¹⁴ E-mail correspondence, FDVA, March 19, 2015, (on file with Health Care Appropriations Subcommittee staff).
STORAGE NAME: h7045b.HHSC.DOCX
DATE: 3/30/2015

HB 7045

2015

1 A bill to be entitled
2 An act relating to state veterans' nursing homes;
3 creating s. 296.42, F.S.; directing the Department of
4 Veterans' Affairs to contract for a study to determine
5 the need for additional state veterans' nursing homes
6 and the most appropriate counties in which to locate
7 the homes; directing the department to submit the
8 study to the Governor and Legislature; providing study
9 criteria for ranking each county according to need;
10 requiring the department to use specified studies to
11 select new nursing home sites; providing for
12 expiration; providing an effective date.

13
14 Be It Enacted by the Legislature of the State of Florida:

15
16 Section 1. Section 296.42, Florida Statutes, is created to
17 read:

18 296.42 Site selection process for state veterans' nursing
19 homes.-

20 (1) The department shall contract for a study to determine
21 the need for new state veterans' nursing homes and the most
22 appropriate counties in which to locate the homes based on the
23 greatest level of need. The department shall submit the study to
24 the Governor, the President of the Senate, and the Speaker of
25 the House of Representatives by November 1, 2015.

26 (2) The study shall use the following criteria to rank

27 each county according to need:

28 (a) The distance from the geographic center of the county
 29 to the nearest existing state veterans' nursing home.

30 (b) The number of veterans age 65 years or older residing
 31 in the county.

32 (c) The presence of an existing federal Veterans' Health
 33 Administration medical center or outpatient clinic in the
 34 county.

35 (d) Elements of emergency health care in the county, as
 36 determined by:

37 1. The number of general hospitals.

38 2. The number of emergency room holding beds per hospital.

39 3. The number of in-house physicians per hospital on staff
 40 in the emergency room 24 hours per day.

41 (e) The number of existing community nursing home beds per
 42 1,000 males age 65 years or older residing in the county.

43 (f) The presence of an accredited educational institution
 44 offering health care programs in the county.

45 (g) The county poverty rate.

46 (3) The department shall use the study ranking to select
 47 each new state veterans' nursing home site authorized before
 48 July 1, 2020, subject to approval by the Governor and Cabinet.

49 For each new nursing home, the department shall select the
 50 highest-ranked county in the study which does not have a
 51 veterans' nursing home. If the highest-ranked county cannot
 52 serve as the site, the department shall select the next-highest

HB 7045

2015

53 | ranked county. The department shall use the 2014 Site Selection
54 | Study to select a county for any new state veterans' nursing
55 | home authorized before November 1, 2015, subject to approval by
56 | the Governor and Cabinet.

57 | (4) This section expires July 1, 2020.

58 | Section 2. This act shall take effect July 1, 2015.



Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

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

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee

3 Representative Sprowls offered the following:

4
5 **Amendment (with title amendment)**

6 Remove line 57 and insert:

7 (4) A new study shall be conducted and submitted in
 8 accordance with this section by November 1, 2019, and every 4
 9 years thereafter.

10
11 -----
 12 **T I T L E A M E N D M E N T**

13 Remove lines 11-12 and insert:

14 select new nursing home sites; requiring the department to
 15 ensure that subsequent studies are conducted and submitted to
 16 the Governor and the Legislature every four years; providing an
 17 effective date.