The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Bean, Chair
Senator Sobel, Vice Chair

MEETING DATE: Tuesday, April 1, 2014
TIME: 3:00 —6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Sobel, Vice Chair; Senators Brandes, Braynon, Flores, Galvano, Garcia, Grimsley, and Joyner

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**CS/SB 1106** Community Affairs / Simpson (Similar CS/CS/H 593)	Building Construction; Providing an additional method for local governments to provide notices to alleged code enforcement violators; requiring application for an operating permit before filing an application for a building permit for a public swimming pool; specifying inspection criteria for construction or modification of manufactured buildings or modules; authorizing use of smoke alarms powered by 10-year nonremovable, nonreplaceable batteries in certain circumstances, etc. CA 03/19/2014 Fav/CS HP 04/01/2014 Favorable RI AP	Favorable Yeas 7 Nays 2
2	**SB 1388** Montford (Similar CS/H 1041)	Registered Interns in Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling; Requiring an individual who has not satisfied specified requirements to register as an intern in clinical social work, marriage and family therapy, or mental health counseling; requiring an individual to remain under supervision while practicing under registered intern status; requiring a licensed health professional to be on the premises when clinical services are provided by a registered intern of clinical social work, marriage and family therapy, or mental health counseling in a private practice setting, etc. CF 03/18/2014 Not Considered CF 03/25/2014 Favorable HP 04/01/2014 Favorable AP	Favorable Yeas 9 Nays 0
3	**SB 1230** Hays (Identical CS/H 1275, Compare H 501, S 502, S 1420)	Physician Assistants; Increasing the number of licensed physician assistants that a physician may supervise at any one time; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; revising application requirements for licensure as a physician assistant and license renewal, etc. HP 04/01/2014 Fav/1 Amendment AP RC	Fav/1 Amendment (630784) Yeas 8 Nays 1

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	Consideration of proposed committee bill:		
4	**SPB 7124**	Program of All-Inclusive Care for the Elderly; Authorizing the Department of Elderly Affairs, in consultation with the Agency for Health Care Administration, to contract with specified entities to provide benefits pursuant to the Program of All-Inclusive Care for the Elderly (PACE); establishing a selection process for PACE providers; establishing PACE plan payments and financial responsibility requirements, etc.	Amendment Adopted - Temporarily Postponed
5	**SB 1700** Bean (Compare H 859, S 962, Link CS/S 1030)	Public Records/Personal Identifying Information/Compassionate Use Registry; Exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry; exempting information related to ordering and dispensing low-THC marijuana; providing for future legislative review and repeal; providing a statement of public necessity, etc. HP 04/01/2014 Favorable GO RC	Favorable Yeas 9 Nays 0
6	**CS/SB 836** Regulated Industries / Bean (Similar CS/H 687, Compare H 689)	Medical Gas; Requiring a person or establishment located inside or outside the state which intends to distribute medical gas within or into this state to obtain an applicable permit before operating; requiring the Department of Business and Professional Regulation to establish the form and content of an application; setting the minimum requirements for the storage and handling of medical gas; authorizing the department to require a facility that engages in wholesale distribution to undergo an inspection, etc. RI 03/06/2014 Fav/CS HP 03/25/2014 Temporarily Postponed HP 04/01/2014 Fav/CS	Fav/CS Yeas 9 Nays 0
7	**SB 918** Flores (Similar CS/H 1047)	Termination of Pregnancies; Revising the circumstances under which a pregnancy in the third trimester may be terminated; authorizing administrative discipline for a violation of certain provisions by certain licensed professionals; requiring a physician to perform certain examinations to determine the viability of a fetus; prohibiting an abortion of a viable fetus outside of a hospital, etc. HP 03/05/2014 Temporarily Postponed HP 04/01/2014 Fav/CS JU RC	Fav/CS Yeas 6 Nays 3

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**CS/SB 1160** Environmental Preservation and Conservation / Evers (Similar CS/H 1113)	Onsite Sewage Treatment and Disposal Systems; Delaying the effective date of the prohibition against the land application of septage from onsite sewage treatment and disposal systems; requiring the Department of Environmental Protection to examine and report on potential options for safely and appropriately disposing or reusing septage; requiring the department to submit a report of its findings and recommendations, etc. EP 03/26/2014 Fav/CS HP 04/01/2014 Favorable AG	Favorable Yeas 9 Nays 0
9	**SB 992** Bean (Compare CS/H 647)	Infectious Disease Control; Providing duties of the Department of Health relating to the dissemination of information regarding treatment-resistant bacterial infections; providing for the establishment of a research panel and an interagency task force; requiring the department to adopt and enforce minimum standards for infection control practices in certain licensed facilities, etc. HP 04/01/2014 Fav/CS AHS AP	Fav/CS Yeas 9 Nays 0
10	**SB 1470** Thompson (Similar CS/H 1225)	HIV Testing; Differentiating between the notification and consent procedures for performing an HIV test in a health care setting and a nonhealth care setting; deleting the exemption from the requirement to obtain informed consent before testing a pregnant woman, etc. HP 04/01/2014 Fav/CS JU CA	Fav/CS Yeas 9 Nays 0
11	**SB 1212** Bean (Similar CS/H 1085)	Behavior Analysts; Creating the Board of Applied Behavior Analysis; specifying the authority and duties of the board; establishing maximum fees for applications, initial licenses, and license renewals; requiring a licensee or his or her employer to report to the board certain felony convictions on the part of a licensee or suspicions that a licensee has committed fraud or deceit; providing penalties for practicing applied behavior analysis without a license or wrongfully identifying oneself as a licensed behavior analyst, etc. HP 04/01/2014 Fav/CS RI AP	Fav/CS Yeas 6 Nays 3

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
12	**CS/SB 316** Children, Families, and Elder Affairs / Bean (Compare H 579)	Certification of Assisted Living Facility Administrators; Requiring assisted living facility administrators to meet the training and education requirements established by a third-party credentialing entity or by the Department of Elderly Affairs; requiring the department to establish a competency test; authorizing the department to approve third-party credentialing entities for the purpose of developing and administering a professional credentialing program for assisted living facility administrators; requiring an approved third-party credentialing entity to establish the core competencies for administrators according to the standards set forth by the National Commission for Certifying Agencies, etc. CF 03/25/2014 Fav/CS HP 04/01/2014 Fav/CS AP	Fav/CS Yeas 8 Nays 1
13	**SB 1428** Joyner (Similar H 1203)	Reducing Racial and Ethnic Health Disparities; Requiring the Office of Program Policy Analysis and Government Accountability to conduct a study and provide recommendations relating to Medicaid provider networks; requiring a report to the Governor and Legislature; providing for expiration, etc. HP 04/01/2014 Favorable AHS AP	Favorable Yeas 9 Nays 0
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1106
INTRODUCER:	Community Affairs Committee and Senator Simpson
SUBJECT:	Building Construction
DATE:	March 26, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	White	Yeatman	CA	**Fav/CS**
2.	Looke	Stovall	HP	**Favorable**
3.			RI	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1106 amends several statutes related to building construction, codes, and permitting. The bill:

- Requires an application to the Department of Health (DOH) for an operating permit for a public swimming pool before an application may be filed for a building permit, and provides additional requirements for obtaining an operating permit;
- Specifies inspection criteria for construction or modification of manufactured buildings or building modules;
- Revises the allocation of funds from building permit surcharges to include $250,000 allocated to the Future Builders of America Program;
- Authorizes building officials, local enforcement agencies, and the Florida Building Commission to interpret the Florida Accessibility Code for Building Construction and provides specific procedures for those interpretations;
- Revises education and training requirements for the Florida Building Code Compliance and Mitigation Program;
- Provides a criteria-based definition for "building energy-efficiency rating system";
- Provides homeowners doing renovations with an additional fire safety alarm option; and,
- Exempts certain tents from the Florida Fire Prevention Code.

II. Present Situation:

Florida Building Commission

The Florida Building Commission (commission), which is housed within the Department of Business and Professional Regulation (DBPR), is a 26-member technical body responsible for the development, maintenance and interpretation of the Florida Building Code. The commission also approves products for statewide acceptance and administers the Building Code Training Program. Members are appointed by the Governor and confirmed by the Senate and include design professionals, contractors, and government experts in the various disciplines covered by the code.[1]

Code Enforcement Notices

Notices to alleged violators of local government codes and ordinances are governed by s. 162.12, F.S. There are four options cited in s. 162.12(1), F.S., by which notices may be provided:

- Certified mail to the address listed in the tax collector's office for tax notices, or to any other address provided by the property owner in writing to the local government for the purpose of receiving notices. For property owned by a corporation, notices may be provided by certified mail to the registered agent of the corporation. If any notice sent by certified mail is not signed as received within 30 days after the date of mailing, notice may be provided by posting as described in subparagraphs s. 162.12(2)(b)1. and 2., F.S.[2]
- Hand delivery by the sheriff, code inspector, or other designated person;
- Leaving the notice at the violator's residence with any person residing there above the age of 15; or,
- For commercial premises, leaving the notice with the manager or other person in charge.[3]

In addition to the noticing provisions outlined in s. 162.12(1), F.S., the code enforcement board may serve notice through publication or posting methods.[4]

Pool Construction and Operation in Florida

The DOH estimates that there are approximately 37,000 public pools in Florida.[5] A "public swimming pool" or "public pool" is defined as:

> A watertight structure of concrete, masonry, or other approved materials which is located either indoors or outdoors, used for bathing or swimming by humans, and filled with a filtered and disinfected water supply, together with buildings, appurtenances, and equipment used in connection therewith. This term includes a conventional pool, spa-type pool, wading pool, special purpose pool, or water recreation attraction, to which

[1] Sections 553.74, 553.76 and 553.77, F.S.
[2] Relating to publication of notices and the physical posting of notices, respectively.
[3] *See* ss. 162.12(1)(b)-(d), F.S.
[4] *See* s.162.12(2), F.S.
[5] E-mail from DOH staff on Mar. 27, 2014.

> admission may be gained with or without payment of a fee and includes, but is not limited to, pools operated by or serving camps, churches, cities, counties, day care centers, group home facilities for eight or more clients, health spas, institutions, parks, state agencies, schools, subdivisions, or the cooperative living-type projects of five or more living units, such as apartments, boardinghouses, hotels, mobile home parks, motels, recreational vehicle parks, and townhouses.[6]

A "public bathing place" is defined as:

> A body of water, natural or modified by humans, for swimming, diving, and recreational bathing used by consent of the owner or owners and held out to the public by any person or public body, irrespective of whether a fee is charged for the use thereof. The bathing water areas of public bathing places include, but are not limited to, lakes, ponds, rivers, streams, artificial impoundments, and waters along the coastal and intracoastal beaches and shores of the state.[7]

In 2012, the Legislature determined that local building departments would have jurisdiction over permitting, plan reviews, and inspections of public swimming pools and public bathing places and that the DOH would continue to have jurisdiction over the operating permits for public swimming pools and public bathing places.[8] In order to operate or continue to operate a public swimming pool, a valid operating permit from DOH must be obtained. Application for an operating permit must include the following:

- Description of the source or sources of water supply, and the amount and quality of water available and intended to be used;
- Method and manner of water purification, treatment, disinfection, and heating;
- Safety equipment and standards to be used; and
- Any other pertinent information deemed necessary by the DOH.[9]

If the DOH determines that the public swimming pool is, or may reasonably be expected to be, operated in compliance with state laws and departmental rules, the DOH will issue a permit. However, if the DOH determines that the pool is not in compliance with state laws and departmental rules, the DOH will deny the application for a permit. The denial must be in writing and must list the circumstances for the denial. Upon correction of those circumstances, the applicant may reapply for a permit.[10] The operating permit must be renewed annually and posted in a conspicuous place.[11]

[6] Section 514.011(2), F.S.
[7] Section 514.011(4), F.S.
[8] Chapter 2012-184, Laws of Fla.
[9] Section 514.031(1), F.S.
[10] *Id.*
[11] Section 514.031(4), F.S.

Manufactured Buildings and Building Modules per the Florida Building Code

Section 553.72, F.S., provides that the Florida Building Code (code) is "a single set of documents that apply to the design, construction, erection, alteration, modification, repair, or demolition of public or private buildings, structures, or facilities in this state," and its enforcement "will allow effective and reasonable protection for public safety, health, and general welfare for all the people of Florida at the most reasonable cost to the consumer." The Florida Building Commission adopts requirements, within the Florida Building Code, for construction or modification of manufactured buildings and building modules, to address:[12]

- Submission to and approval by the DBPR of manufacturers' drawings and specifications, including any amendments.
- Submission to and approval by the DBPR of manufacturers' internal quality control procedures and manuals, including any amendments.
- Minimum inspection criteria.

"Manufactured building" or "modular building" means a closed structure, building assembly, or system of subassemblies, which may include structural, electrical, plumbing, heating, ventilating, or other service systems manufactured for installation or erection as a finished building or as part of a finished building, including, but not limited to, residential, commercial, institutional, storage, and industrial structures. The term includes buildings not intended for human habitation such as lawn storage buildings and storage sheds manufactured and assembled offsite by a manufacturer certified in conformance with this part, but does not include a mobile home.[13]

"Module" means a separately transported three-dimensional component of a manufactured building which contains all or a portion of structural systems, electrical systems, plumbing systems, mechanical systems, fire systems, and thermal systems.[14]

Florida Building Code Surcharge

The Florida Building Commission is authorized to adopt, modify, update, interpret, and maintain the Florida Building Code and provide that code enforcement will be performed by authorized state and local government enforcement agencies.[15] In order for DBPR to administer and carry out the code provisions, there is a surcharge that is assessed at 1.5 percent of the permit fees associated with enforcement of the code.[16]

The amount of revenue generated by the surcharge has ranged from approximately $1,000,000 to $5,000,000 per year over the past 10 years.[17] The funds that are collected from the surcharge and remitted to DBPR are deposited in the Professional Regulation Trust Fund and then allocated to fund the Florida Building Commission and the Florida Building Code Compliance and Mitigation Program.[18]

[12] Section 553.37(1), F.S.
[13] Section 553.36(13), F.S.
[14] Section 553.36(15), F.S.
[15] Section 553.72(3), F.S.
[16] The minimum amount collected on any permit issued is $2. Section 553.721, F.S.
[17] DBPR, *Legislative Analysis of HB 593* (Feb. 20, 2014).
[18] The Florida Building Code Compliance and Mitigation Program is established in Section 553.841, F.S.

Future Builders of America

The Future Builders of America Program is a nonprofit workforce development and student leadership program of the Florida Home Builders Foundation. The program links students in school with local building communities and industries.[19] As of November 2013, there were 11 chapters in Florida, located in Charlotte, DeSoto, Manatee, Okaloosa, Polk, Sarasota, Volusia, and Walton Counties, and the Treasure Coast.[20]

Florida Building Code Interpretation

Section 553.775, F.S., authorizes the Florida Building Code to be interpreted by building officials, local enforcement agencies, and the commission, and provides specific procedures to be used when interpreting the code.

The Florida Accessibility Code for Building Construction (accessibility code), an element of the code, is adopted by the commission and prescribes requirements related to ensuring access for the disabled for new construction activity, including things such as ramps, door widths, and particular plumbing fixtures. The accessibility code combines requirements imposed by the federal regulations that implement the Americans with Disabilities Act and Florida-specific requirements described in part I of ch. 553, F.S.

In accordance with s. 120.565, F.S., the commission may render declaratory statements relating to the provisions of the accessibility code not attributable to the Americans with Disabilities Act Accessibility Guidelines. However, the accessibility code may not be interpreted by building officials, local enforcement agencies, and the commission.

Florida Building Code Compliance and Mitigation Program

The DBPR administers the Florida Building Code Compliance and Mitigation Program, which was created to develop, coordinate, and maintain education and outreach to people who are required to comply with the Florida Building Code and ensure consistent education, training, and communication of the code's requirements, including, but not limited to, methods for mitigation of storm-related damage.[21] The program is geared toward persons *licensed* in the design and construction industries, but does not address those *employed* in the design and construction industries. The services and materials under the program must be provided by a private, nonprofit corporation under contract with DBPR.[22]

Building Energy-Efficiency Rating System

In 1993, the Legislature enacted the Florida Building Energy-Efficiency Rating Act,[23] in order to identify systems for rating the energy efficiency of buildings, and encourage the consideration of

[19] Future Builders of America, http://www.futurebuildersofamerica.org (Last visited Mar. 26, 2014).
[20] *Id.*
[21] Section 553.841(2), F.S.
[22] Section 553.841(3), F.S.
[23] Chapter 93-249, s.12, Laws of Fla.

energy-efficiency rating systems in the market.[24] The current statutory definition of such a rating system specifically relies upon identification by "the Residential Energy Services Network, the Commercial Energy Services Network, the Building Performance Institute, or the Florida Solar Center."[25] Information about a building's energy-efficiency must be provided to a prospective purchaser of real property, if available. Prior to contracting for construction, renovation, or acquisition of a public building, the building must be rated pursuant to the system provided for in s. 553.995, F.S. Public bodies proposing to contract must consider energy-efficiency ratings when comparing contract alternatives.[26]

III. Effect of Proposed Changes:

Code Violation Notices (Section 1)

The bill amends s. 162.12, F.S., relating to notifying alleged violators of local codes and ordinances, to give local government notices by certified mail the option of requiring a return receipt request when sending notices by certified mail.

Public Swimming Pools and Public Bathing Places (Sections 2, 3, and 7)

The bill amends s. 514.03, F.S., to require those desiring to construct, develop, or modify a public swimming pool to apply to the DOH for an operating permit before applying for a building permit. The bill amends s. 553.79, F.S., to prohibit the local enforcing agency from issuing a building permit to construct, develop, or modify a public swimming pool without proof of application for an operating permit. The bill also amends s 514.031, F.S., to provide that a certificate of occupancy may not be issued until the operating permit is issued. Additional documentation is required in the operating permit application: proof of final inspection, and a description of the structure, its appurtenances, and its operation.

Construction or Modification of Manufactured Buildings and Building Modules (Section 4)

The bill amends s. 553.37, F.S., to detail inspection criteria that must be adopted by the Florida Building Commission within the Florida Building Code. The criteria require the approved inspection agency to do the following:

- Inspect the first building built, or the first unit assembled with components, and all its subsystems, after certification from the manufacturer.
- Continue observation of the manufacturing process until the agency determines that the manufacturer's quality control program and the plans approved by the agency will result in a building and components that meet or exceed the applicable Florida Building Code requirements.
- With respect to manufactured buildings, inspect each module produced at least once during the manufacturing process and to inspect at least 75 percent of the subsystems of each module.

[24] Section 553.991, F.S.
[25] Section 553.993(3), F.S.
[26] Section 553.997(1), F.S.

- With respect to components, inspect at least 75 percent of the manufactured building components or 20 percent of storage sheds that are not designed for human habitation and that have a floor area of 720 square feet or less.

Florida Building Code Surcharge (Section 5)

The bill amends s. 553.721, F.S. to allocate $250,000 per year, beginning in Fiscal Year 2014-2015, from the building permit fees remitted to DBPR to the Future Builders of America Program.

Florida Building Code Interpretation (Section 6)

The bill amends s. 553.775, F.S., to authorize building officials, local enforcement agencies, and the commission to interpret the accessibility code and to remove language restricting declaratory statements to Florida-specific requirements of the accessibility code.

Florida Building Code Compliance and Mitigation Program (Section 8)

The bill amends s. 553.841, F.S., to revise education and training requirements of the Florida Building Code Compliance and Mitigation program. In addition to maintaining a thorough knowledge of the code, participants in the design and construction industry should have a thorough knowledge of:

- Code compliance and enforcement;
- Duties related to consumers;
- Project completion; and
- Compliance of design and construction to protect from consumer harm, and storm damage.

The bill expands the scope of the program to provide education and outreach concerning compliance with the Florida Fire Prevention Code, construction plan and permitting requirements, and construction liens. The bill further expands the applicability of the program to include people employed in the design and construction industries.

Smoke Alarms (Section 9)

The bill amends s. 553.883, F.S., to allow homeowners in the process of a renovation to install a smoke alarm with a non-removable, non-replaceable, 10-year battery, instead of hardwiring a smoke alarm into the electrical system. Currently, s. 553.88, F.S., provides for the adoption of electrical and alarm standards, which includes the adoption of the National Fire Alarm Code.[27]

Building Energy-Efficiency Rating System (Section 10)

The bill amends s. 553.993, F.S., to define the "Building energy-efficiency rating system" with specific criteria, including:

- The ability to provide reliable and scientifically-based analysis of a building's energy consumption or energy features;

[27] NFPA No. 72.

- The ability to compare similar building types in similar climate zones;
- Use of standard calculations, formulas, and scoring methods;
- National applicability;
- Clearly defined and researched baselines or benchmarks;
- Ratings that are performed by qualified professionals;
- A labeling and recognition program with specific criteria or levels;
- Residential program benchmarks that must be consistent with national building standards and home energy rating standards; and
- At least one level of oversight performed by a group of professionals with subject matter expertise in energy efficiency, energy rating, and evaluation methods.

Tents (Section 11)

The bill amends s. 633.202, F.S., to exempt tents smaller than 30 feet by 30 feet from the Florida Fire Prevention Code.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1106 provides a clarification regarding the order in which permits must be obtained for public swimming pools and public bathing places. This may result in cost savings due to issues and problems being identified prior to construction.

C. Government Sector Impact:

The bill allocates $250,000 to the Future Builders of America Program from funds that are remitted to the Professional Regulation Trust Fund. These funds are generated from an existing 1.5 percent surcharge on each building permit application fee.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Section 2 of the bill requires application to the DOH for an operating permit for a public swimming pool before applying for a building permit. Section 3 provides criteria for the application of the operating permit including proof of final inspection. It is unclear how an applicant is to provide proof of final inspection before applying for a building permit.

If an applicant is unable to provide a final inspection in their initial application, these provisions would cause that permit application to be submitted incomplete. Under s. 120.60, F.S., the DOH would be required to notify the applicant within 30 days of receipt of the application that the application is incomplete. After receiving this notification, the applicant may request additional time to complete the application which the DOH must grant.

This back and forth process could create a logistical obstacle course for some people who are applying for swimming pool operating permits. This process could be streamlined by exempting the DOH from the timeframes under s. 120.60, F.S., for such permit applications and granting the DOH rulemaking authority to create a specific application process for these permits.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 162.12, 514.03, 514.031, 553.37, 553.721, 553.775, 553.79, and 553.841.

IX. Additional Information:

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

CS by Community Affairs Committee on March 19, 2014:
The CS for SB 1106:

- Adds proof of inspection to the list of items required as part of an application for a public swimming pool operating permit;
- Clarifies that final inspection of a pool can occur prior to obtaining an operating permit, but issuance of a certificate of completion may not;
- Clarifies that inspection is required of each subsystem of the first manufactured building assembled;
- Increases the percent of manufactured building components that must be inspected from 50 percent to 75 percent;
- Allows homeowners doing a renovation to install a smoke alarm with a 10-year battery, instead of hardwiring a smoke alarm into the electrical system;
- Defines “building energy-efficiency rating system”; and,
- Recognizes that a tent need not adhere to the Florida Fire Prevention Code.

B. Amendments:

None.

By the Committee on Community Affairs; and Senator Simpson

578-02837-14 20141106c1

A bill to be entitled

An act relating to building construction; amending s. 162.12, F.S.; providing an additional method for local governments to provide notices to alleged code enforcement violators; amending s. 514.03, F.S.; requiring application for an operating permit before filing an application for a building permit for a public swimming pool; amending s. 514.031, F.S.; providing additional requirements for obtaining a public swimming pool operating permit; amending s. 553.37, F.S.; specifying inspection criteria for construction or modification of manufactured buildings or modules; amending s. 553.721, F.S.; revising the allocation of funds from the building permit surcharge; amending s. 553.775, F.S.; authorizing building officials, local enforcement agencies, and the Florida Building Commission to interpret the Florida Accessibility Code for Building Construction; specifying procedures for such interpretations; deleting provisions relating to declaratory statements and interpretations of the Florida Accessibility Code for Building Construction, to conform; amending s. 553.79, F.S.; prohibiting a local enforcing agency from issuing a building permit for a public swimming pool without proof of application for an operating permit; requiring issuance of an operating permit before a certificate of completion or occupancy is issued; amending s. 553.841, F.S.; revising education and training requirements of the Florida Building Code

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Compliance and Mitigation Program; creating s. 553.883, F.S.; authorizing use of smoke alarms powered by 10-year nonremovable, nonreplaceable batteries in certain circumstances; requiring use of such alarms by a certain date; amending s. 553.993, F.S.; revising the definition of the term "building energy-efficiency rating system" to require consistency with certain national standards for new construction and existing construction; providing for oversight; amending s. 633.202, F.S.; exempting certain tents from the Florida Fire Prevention Code; providing an effective date.

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

Section 1. Section 162.12, Florida Statutes, is amended to read:

162.12 Notices.—

(1) All notices required by this part must be provided to the alleged violator by:

(a) Certified mail, and at the option of the local government return receipt requested, to the address listed in the tax collector's office for tax notices or to the address listed in the county property appraiser's database. The local government may also provide an additional notice to any other address it may find for the property owner. For property owned by a corporation, notices may be provided by certified mail to the registered agent of the corporation. If any notice sent by certified mail is not signed as received within 30 days after

the postmarked date of mailing, notice may be provided by posting as described in subparagraphs (2)(b)1. and 2.;

(b) Hand delivery by the sheriff or other law enforcement officer, code inspector, or other person designated by the local governing body;

(c) Leaving the notice at the violator's usual place of residence with any person residing therein who is above 15 years of age and informing such person of the contents of the notice; or

(d) In the case of commercial premises, leaving the notice with the manager or other person in charge.

(2) In addition to providing notice as set forth in subsection (1), at the option of the code enforcement board or the local government, notice may be served by publication or posting, as follows:

(a)1. Such notice shall be published once during each week for 4 consecutive weeks (four publications being sufficient) in a newspaper of general circulation in the county where the code enforcement board is located. The newspaper shall meet such requirements as are prescribed under chapter 50 for legal and official advertisements.

2. Proof of publication shall be made as provided in ss. 50.041 and 50.051.

(b)1. In lieu of publication as described in paragraph (a), such notice may be posted at least 10 days prior to the hearing, or prior to the expiration of any deadline contained in the notice, in at least two locations, one of which shall be the property upon which the violation is alleged to exist and the other of which shall be, in the case of municipalities, at the

primary municipal government office, and in the case of counties, at the front door of the courthouse or the main county governmental center in said county.

2. Proof of posting shall be by affidavit of the person posting the notice, which affidavit shall include a copy of the notice posted and the date and places of its posting.

(c) Notice by publication or posting may run concurrently with, or may follow, an attempt or attempts to provide notice by hand delivery or by mail as required under subsection (1).

(3) Evidence that an attempt has been made to hand deliver or mail notice as provided in subsection (1), together with proof of publication or posting as provided in subsection (2), shall be sufficient to show that the notice requirements of this part have been met, without regard to whether or not the alleged violator actually received such notice.

Section 2. Section 514.03, Florida Statutes, is amended to read:

514.03 Approval necessary to construct, develop, or modify public swimming pools or public bathing places.—

(1) A person or public body desiring to construct, develop, or modify a public swimming pool must apply to the department for an operating permit before filing an application for a building permit under s. 553.79.

(2) Local governments or local enforcement districts may determine compliance with the general construction standards of the Florida Building Code, pursuant to s. 553.80. Local governments or local enforcement districts may conduct plan reviews and inspections of public swimming pools and public bathing places for this purpose.

Section 3. Paragraph (a) of subsection (1) of section 514.031, Florida Statutes, is amended to read:

514.031 Permit necessary to operate public swimming pool.—

(1) It is unlawful for any person or public body to operate or continue to operate any public swimming pool without a valid permit from the department, such permit to be obtained in the following manner:

(a) Any person or public body desiring to operate any public swimming pool shall file an application for an operating ~~a~~ permit with the department, on application forms provided by the department, and shall accompany such application with:

1. A description of the structure, its appurtenances, and its operation.

2.~~1.~~ A description of the source or sources of water supply, and the amount and quality of water available and intended to be used.

3.~~2.~~ The method and manner of water purification, treatment, disinfection, and heating.

4.~~3.~~ The safety equipment and standards to be used.

5. A copy of the final inspection from the local enforcement agency as defined in chapter 553.

6.~~4.~~ Any other pertinent information deemed necessary by the department.

Section 4. Paragraph (c) of subsection (1) of section 553.37, Florida Statutes, is amended to read:

553.37 Rules; inspections; and insignia.—

(1) The Florida Building Commission shall adopt within the Florida Building Code requirements for construction or modification of manufactured buildings and building modules, to

address:

(c) ~~Minimum~~ Inspection criteria, which shall require the approved inspection agency to:

1. Observe the first building built, or with regard to components, observe the first unit assembled, after certification from the manufacturer, from start to finish, inspecting all subsystems: electrical, plumbing, structural, mechanical, or thermal.

2. Continue observation of the manufacturing process until the approved inspection agency determines that the manufacturer's quality control program, in conjunction with the application of the plans approved by the approved inspection agency, will result in a building and components that meet or exceed the applicable Florida Building Code requirements.

3. Inspect each module produced during at least one point of the manufacturing process and inspect at least 75 percent of the subsystems of each module: electrical, plumbing, structural, mechanical, or thermal.

4. With respect to components, inspect at least 75 percent of the manufactured building components and at least 20 percent of the storage sheds that are not designed for human habitation and that have a floor area of 720 square feet or less.

Section 5. Section 553.721, Florida Statutes, is amended to read:

553.721 Surcharge.—In order for the Department of Business and Professional Regulation to administer and carry out the purposes of this part and related activities, there is created a surcharge, to be assessed at the rate of 1.5 percent of the permit fees associated with enforcement of the Florida Building

Code as defined by the uniform account criteria and specifically the uniform account code for building permits adopted for local government financial reporting pursuant to s. 218.32. The minimum amount collected on any permit issued shall be $2. The unit of government responsible for collecting a permit fee pursuant to s. 125.56(4) or s. 166.201 shall collect the surcharge and electronically remit the funds collected to the department on a quarterly calendar basis for the preceding quarter and continuing each third month thereafter. The unit of government shall retain 10 percent of the surcharge collected to fund the participation of building departments in the national and state building code adoption processes and to provide education related to enforcement of the Florida Building Code. All funds remitted to the department pursuant to this section shall be deposited in the Professional Regulation Trust Fund. Funds collected from the surcharge shall be allocated to fund the Florida Building Commission, ~~and~~ the Florida Building Code Compliance and Mitigation Program under s. 553.841, and the Future Builders of America program. ~~Beginning in the 2013-2014 fiscal year,~~ Funds allocated to the Florida Building Code Compliance and Mitigation Program shall be $925,000 each fiscal year. Beginning in the 2014-2015 fiscal year, funds allocated to the Future Builders of America program shall be $250,000 each fiscal year. The funds collected from the surcharge may not be used to fund research on techniques for mitigation of radon in existing buildings. Funds used by the department as well as funds to be transferred to the Department of Health shall be as prescribed in the annual General Appropriations Act. The department shall adopt rules governing the collection and

remittance of surcharges pursuant to chapter 120.

Section 6. Section 553.775, Florida Statutes, is amended to read:

553.775 Interpretations.—

(1) It is the intent of the Legislature that the Florida Building Code and the Florida Accessibility Code for Building Construction be interpreted by building officials, local enforcement agencies, and the commission in a manner that protects the public safety, health, and welfare at the most reasonable cost to the consumer by ensuring uniform interpretations throughout the state and by providing processes for resolving disputes regarding interpretations of the Florida Building Code and the Florida Accessibility Code for Building Construction which are just and expeditious.

(2) Local enforcement agencies, local building officials, state agencies, and the commission shall interpret provisions of the Florida Building Code and the Florida Accessibility Code for Building Construction in a manner that is consistent with declaratory statements and interpretations entered by the commission, except that conflicts between the Florida Fire Prevention Code and the Florida Building Code shall be resolved in accordance with s. 553.73(11)(c) and (d).

(3) The following procedures may be invoked regarding interpretations of the Florida Building Code or the Florida Accessibility Code for Building Construction:

(a) Upon written application by any substantially affected person or state agency or by a local enforcement agency, the commission shall issue declaratory statements pursuant to s. 120.565 relating to the enforcement or administration by local

governments of the Florida Building Code or the Florida Accessibility Code for Building Construction.

(b) When requested in writing by any substantially affected person or state agency or by a local enforcement agency, the commission shall issue a declaratory statement pursuant to s. 120.565 relating to this part and ss. 515.25, 515.27, 515.29, and 515.37. Actions of the commission are subject to judicial review under s. 120.68.

(c) The commission shall review decisions of local building officials and local enforcement agencies regarding interpretations of the Florida Building Code or the Florida Accessibility Code for Building Construction after the local board of appeals has considered the decision, if such board exists, and if such appeals process is concluded within 25 business days.

1. The commission shall coordinate with the Building Officials Association of Florida, Inc., to designate panels composed of five members to hear requests to review decisions of local building officials. The members must be licensed as building code administrators under part XII of chapter 468 and must have experience interpreting and enforcing provisions of the Florida Building Code and the Florida Accessibility Code for Building Construction.

2. Requests to review a decision of a local building official interpreting provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction may be initiated by any substantially affected person, including an owner or builder subject to a decision of a local building official or an association of owners or builders having members

who are subject to a decision of a local building official. In order to initiate review, the substantially affected person must file a petition with the commission. The commission shall adopt a form for the petition, which shall be published on the Building Code Information System. The form shall, at a minimum, require the following:

a. The name and address of the county or municipality in which provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction are being interpreted.

b. The name and address of the local building official who has made the interpretation being appealed.

c. The name, address, and telephone number of the petitioner; the name, address, and telephone number of the petitioner's representative, if any; and an explanation of how the petitioner's substantial interests are being affected by the local interpretation of the Florida Building Code or the Florida Accessibility Code for Building Construction.

d. A statement of the provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction which are being interpreted by the local building official.

e. A statement of the interpretation given to provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction by the local building official and the manner in which the interpretation was rendered.

f. A statement of the interpretation that the petitioner contends should be given to the provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction and a statement supporting the petitioner's

interpretation.

g. Space for the local building official to respond in writing. The space shall, at a minimum, require the local building official to respond by providing a statement admitting or denying the statements contained in the petition and a statement of the interpretation of the provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction which the local jurisdiction or the local building official contends is correct, including the basis for the interpretation.

3. The petitioner shall submit the petition to the local building official, who shall place the date of receipt on the petition. The local building official shall respond to the petition in accordance with the form and shall return the petition along with his or her response to the petitioner within 5 days after receipt, exclusive of Saturdays, Sundays, and legal holidays. The petitioner may file the petition with the commission at any time after the local building official provides a response. If no response is provided by the local building official, the petitioner may file the petition with the commission 10 days after submission of the petition to the local building official and shall note that the local building official did not respond.

4. Upon receipt of a petition that meets the requirements of subparagraph 2., the commission shall immediately provide copies of the petition to a panel, and the commission shall publish the petition, including any response submitted by the local building official, on the Building Code Information System in a manner that allows interested persons to address the issues

by posting comments.

5. The panel shall conduct proceedings as necessary to resolve the issues; shall give due regard to the petitions, the response, and to comments posed on the Building Code Information System; and shall issue an interpretation regarding the provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction within 21 days after the filing of the petition. The panel shall render a determination based upon the Florida Building Code or the Florida Accessibility Code for Building Construction or, if the code is ambiguous, the intent of the code. The panel's interpretation shall be provided to the commission, which shall publish the interpretation on the Building Code Information System and in the Florida Administrative Register. The interpretation shall be considered an interpretation entered by the commission, and shall be binding upon the parties and upon all jurisdictions subject to the Florida Building Code or the Florida Accessibility Code for Building Construction, unless it is superseded by a declaratory statement issued by the Florida Building Commission or by a final order entered after an appeal proceeding conducted in accordance with subparagraph 7.

6. It is the intent of the Legislature that review proceedings be completed within 21 days after the date that a petition seeking review is filed with the commission, and the time periods set forth in this paragraph may be waived only upon consent of all parties.

7. Any substantially affected person may appeal an interpretation rendered by a hearing officer panel by filing a petition with the commission. Such appeals shall be initiated in

accordance with chapter 120 and the uniform rules of procedure and must be filed within 30 days after publication of the interpretation on the Building Code Information System or in the Florida Administrative Register. Hearings shall be conducted pursuant to chapter 120 and the uniform rules of procedure. Decisions of the commission are subject to judicial review pursuant to s. 120.68. The final order of the commission is binding upon the parties and upon all jurisdictions subject to the Florida Building Code or the Florida Accessibility Code for Building Construction.

8. The burden of proof in any proceeding initiated in accordance with subparagraph 7. is on the party who initiated the appeal.

9. In any review proceeding initiated in accordance with this paragraph, including any proceeding initiated in accordance with subparagraph 7., the fact that an owner or builder has proceeded with construction may not be grounds for determining an issue to be moot if the issue is one that is likely to arise in the future.

This paragraph provides the exclusive remedy for addressing requests to review local interpretations of the Florida Building Code or the Florida Accessibility Code for Building Construction and appeals from review proceedings.

(d) Upon written application by any substantially affected person, contractor, or designer, or a group representing a substantially affected person, contractor, or designer, the commission shall issue or cause to be issued a formal interpretation of the Florida Building Code or the Florida

Accessibility Code for Building Construction as prescribed by paragraph (c).

(e) Local decisions declaring structures to be unsafe and subject to repair or demolition are not subject to review under this subsection and may not be appealed to the commission if the local governing body finds that there is an immediate danger to the health and safety of the public.

(f) Upon written application by any substantially affected person, the commission shall issue a declaratory statement pursuant to s. 120.565 relating to an agency's interpretation and enforcement of the specific provisions of the Florida Building Code or the Florida Accessibility Code for Building Construction which the agency is authorized to enforce. This subsection does not provide any powers, other than advisory, to the commission with respect to any decision of the State Fire Marshal made pursuant to chapter 633.

(g) The commission may designate a commission member who has demonstrated expertise in interpreting building plans to attend each meeting of the advisory council created in s. 553.512. The commission member may vary from meeting to meeting, shall serve on the council in a nonvoting capacity, and shall receive per diem and expenses as provided in s. 553.74(3).

(h) The commission shall by rule establish an informal process of rendering nonbinding interpretations of the Florida Building Code and the Florida Accessibility Code for Building Construction. The commission is specifically authorized to refer interpretive issues to organizations that represent those engaged in the construction industry. The commission shall immediately implement the process before completing formal

rulemaking. It is the intent of the Legislature that the commission create a process to refer questions to a small, rotating group of individuals licensed under part XII of chapter 468, to which a party may pose questions regarding the interpretation of code provisions. It is the intent of the Legislature that the process provide for the expeditious resolution of the issues presented and publication of the resulting interpretation on the Building Code Information System. Such interpretations shall be advisory only and nonbinding on the parties and the commission.

(4) In order to administer this section, the commission may adopt by rule and impose a fee for filing requests for declaratory statements and binding and nonbinding interpretations to recoup the cost of the proceedings which may not exceed $125 for each request for a nonbinding interpretation and $250 for each request for a binding review or interpretation. For proceedings conducted by or in coordination with a third party, the rule may provide that payment be made directly to the third party, who shall remit to the department that portion of the fee necessary to cover the costs of the department.

~~(5) The commission may render declaratory statements in accordance with s. 120.565 relating to the provisions of the Florida Accessibility Code for Building Construction not attributable to the Americans with Disabilities Act Accessibility Guidelines. Notwithstanding the other provisions of this section, the Florida Accessibility Code for Building Construction and chapter 11 of the Florida Building Code may not be interpreted by, and are not subject to review under, any of~~

~~the procedures specified in this section. This subsection has no effect upon the commission's authority to waive the Florida Accessibility Code for Building Construction as provided by s. 553.512.~~

Section 7. Present subsections (11) through (18) of section 553.79, Florida Statutes, are redesignated as subsections (12) through (19), respectively, and a new subsection (11) is added to that section, to read:

553.79 Permits; applications; issuance; inspections.—

(11) The local enforcing agency may not issue a building permit to construct, develop, or modify a public swimming pool without proof of application for an operating permit under s. 514.031. A certificate of completion or occupancy may not be issued until such operating permit is issued.

Section 8. Subsections (1) and (2) of section 553.841, Florida Statutes, are amended to read:

553.841 Building code compliance and mitigation program.—

(1) The Legislature finds that knowledge and understanding by persons licensed or employed in the design and construction industries of the importance and need for complying with the Florida Building Code and related laws is vital to the public health, safety, and welfare of this state, especially for protecting consumers and mitigating damage caused by hurricanes to residents and visitors to the state. The Legislature further finds that the Florida Building Code can be effective only if all participants in the design and construction industries maintain a thorough knowledge of the code, code compliance and enforcement, duties related to consumers, and changes that ~~additions thereto which~~ improve construction standards, project

completion, and compliance of design and construction to protect against consumer harm, storm damage, and other damage. Consequently, the Legislature finds that there is a need for a program to provide ongoing education and outreach activities concerning compliance with the Florida Building Code, the Florida Fire Prevention Code, construction plan and permitting requirements, construction liens, and hurricane mitigation.

(2) The Department of Business and Professional Regulation shall administer a program, designated as the Florida Building Code Compliance and Mitigation Program, to develop, coordinate, and maintain education and outreach to persons required to comply with the Florida Building Code and related provisions as specified in subsection (1) and ensure consistent education, training, and communication of the code's requirements, including, but not limited to, methods for design and construction compliance and mitigation of storm-related damage. The program shall also operate a clearinghouse through which design, construction, and building code enforcement licensees, suppliers, and consumers in this state may find others in order to exchange information relating to mitigation and facilitate repairs in the aftermath of a natural disaster.

Section 9. Section 553.883, Florida Statutes, is created to read:

553.883 Smoke alarms in one-family and two-family dwellings and townhomes.—One-family and two-family dwellings and townhomes undergoing a repair, or a level 1 alteration as defined in the Florida Building Code, Existing Building, may use smoke alarms powered by 10-year nonremovable, nonreplaceable batteries in lieu of retrofitting such dwelling with smoke alarms powered by

the dwelling's electrical system. Effective January 1, 2015, a battery-powered smoke alarm that is newly installed or replaces an existing battery-powered smoke alarm must be powered by a nonremovable, nonreplaceable battery that powers the alarm for at least 10 years.

Section 10. Subsection (3) of section 553.993, Florida Statutes, is amended to read:

553.993 Definitions.—For purposes of this part:

(3) "Building energy-efficiency rating system" means a whole building energy evaluation system that provides a reliable and scientifically-based analysis of a building's energy consumption or energy features and allows a comparison to similar building types in similar climate zones where applicable. Specifically, the rating system shall use standard calculations, formulas, and scoring methods; be applicable nationally; compare a building to a clearly defined and researched baseline or benchmark; require qualified professionals to conduct the rating or assessment; and provide a labeling and recognition program with specific criteria or levels. Residential program benchmarks for new construction must be consistent with national building standards. Residential building program benchmarks for existing construction must be consistent with national home energy rating standards. The building energy-efficiency rating system shall require at least one level of oversight performed by an organized and balanced group of professionals with subject matter expertise in energy efficiency, energy rating, and evaluation methods ~~established by the Residential Energy Services Network, the Commercial Energy Services Network, the Building Performance Institute, or the~~

~~Florida Solar Energy Center~~.

Section 11. Subsection (15) of section 633.202, Florida Statutes, is amended to read:

633.202 Florida Fire Prevention Code.—

(15)~~(a)~~ For one-story or two-story structures that are less than 10,000 square feet, whose occupancy is defined in the Florida Building Code and the Florida Fire Prevention Code as business or mercantile, a fire official shall enforce the wall fire-rating provisions for occupancy separation as defined in the Florida Building Code.

(16)(a)~~(b)~~ A structure, located on property that is classified for ad valorem purposes as agricultural, which is part of a farming or ranching operation, in which the occupancy is limited by the property owner to no more than 35 persons, and which is not used by the public for direct sales or as an educational outreach facility, is exempt from the Florida Fire Prevention Code, including the national codes and Life Safety Code incorporated by reference. This paragraph does not include structures used for residential or assembly occupancies, as defined in the Florida Fire Prevention Code.

(b) A tent up to 30 feet by 30 feet is exempt from the Florida Fire Prevention Code, including the national codes incorporated by reference.

Section 12. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Community Affairs, *Chair*
Appropriations Subcommittee on General Government
Appropriations Subcommittee on Transportation, Tourism, and Economic Development
Commerce and Tourism
Communications, Energy, and Public Utilities
Environmental Preservation and Conservation

JOINT COMMITTEE:
Joint Legislative Auditing Committee

SENATOR WILTON SIMPSON
18th District

March 26, 2014

Senator Aaron Bean, Chair
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399

Senator Bean,

Please place Senate Bill 1106 relating to building construction, on the next Committee on Health Policy agenda.

Please contact my office with any questions.

Wilton Simpson
Senator, 18th District

REPLY TO:
☐ 322 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5018
☐ Post Office Box 938, Brooksville, Florida 34605
☐ Post Office Box 787, New Port Richey, Florida 34656-0787 (727) 816-1120 FAX: (888) 263-4821

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

DON GAETZ
President of the Senate

GARRETT RICHTER
President Pro Tempore

ENTERED

THE FLORIDA SENATE

APPEARANCE RECORD

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

9/1/14
Meeting Date

Topic 1106 Bill Number 1106 *(if applicable)*

Name Casey Cook Amendment Barcode *(if applicable)*

Job Title Legislative Advocate

Address PO Box 1757 Phone 701 3701
Street

Tallahassee FL 32302 E-mail ccook@flcities.com
City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing Florida League of Cities

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Building Const. Bill Number SB 1106 *(if applicable)*

Name Bruce Kershner Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 231 West Bay Avenue Phone 407-830-1882
Street

Longwood FL 32750 E-mail RBKershner@att.net
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing United Pool & Spa Association

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

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic BUILDING CONSTRUCTION

Bill Number CS #8 SR SB 1106 *(if applicable)*

Name RANDALL KING

Amendment Barcode _____ *(if applicable)*

Job Title BUSINESS MANAGER I.B.E.W. LU. 915

Address 5621 HARNEY RD

Phone 813-621-6451

Street

TAMPA FL. 33610

E-mail RANDALKING@IBEW915.ORG

City *State* *Zip*

Speaking: ☐ For ☑ Against ☐ Information

Representing _____

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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4-1-14
Meeting Date

Topic Building Construction

Bill Number For CS SB 1106
(if applicable)

Name Larry Kidd

Amendment Barcode
(if applicable)

Job Title Construction Worker

Address 820 Virginia Pr
Street
Orlando Fl 32803
City *State* *Zip*

Phone 407-896-7271

E-mail LKidd01@Aol.com

Speaking: ☐ For ☒ Against ☐ Information

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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4 / 1 / 2014
Meeting Date

Topic _____ Bill Number 1106 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☑ Against ☑ Information

Representing JUSTICE-2-JESUS

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

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic ~~CS-SB 1106~~ BUILDING Construction

Bill Number CS-SB 1106 *(if applicable)*

Name John Parker

Amendment Barcode _____ *(if applicable)*

Job Title President

Address 200 E. COLLEGE AVE
Street

TALLAHASSEE, FL 32301
City *State* *Zip*

Phone 850-224-4446

E-mail FLORIDABUILDINTRADES@HOTMAIL.COM

Speaking: ☐ For ☒ Against ☐ Information

Representing FLORIDA BUILDING TRADES

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic BUILDING CODES/CONSTRUCTION

Bill Number SB 1106 *(if applicable)*

Name KARI HEBRANK

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 113 EAST COLLEGE, #200
Street
TALLAHASSEE FL 32301
City *State* *Zip*

Phone 850-566-7824

E-mail Khebrank@wilsonmgmt.com

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

Representing FLORIDA HOME BUILDERS ASSOCIATION

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

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

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic BUILDING CONSTRUCTION

Bill Number CS-SB-1106 *(if applicable)*

Name J. B. CLARK

Amendment Barcode *(if applicable)*

Job Title LOBBYIST

Address 2041 CYNTHIA DRIVE
Street

Phone 850-556-8143

TALLAHASSEE, FL 32303
City *State* *Zip*

E-mail

Speaking: ☐ For ☑ Against ☑ Information

Representing FL. ASSOCIATION OF APPRENTICESHIP ADMINISTRATORS

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date

Topic _____ Bill Number SB 1106 *(if applicable)*

Name Gerard Somers Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 8164 English Elm Cir Phone 585-613-5571

Street

Spring Hill FL 34606 E-mail gerardfsomers@aol.com

City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing Self

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

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1388
INTRODUCER:	Senator Montford
SUBJECT:	Registered Interns in Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling
DATE:	March 28, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Sanford	Hendon	CF	**Favorable**
2.	Looke	Stovall	HP	**Favorable**
3.			AP	

I. Summary:

SB 1388 updates and revises provisions in ch. 491, F.S., which regulates interns in the fields of clinical social work, marriage and family therapy, and mental health. Internship status is designed in these professions to allow candidates for licensure to meet the clinical experience requirements of the license. The bill:

- Requires that a licensed mental health professional be on the premises when clinical services are provided by a registered intern in a private practice setting;
- Prohibits a registered intern from engaging in his or her own independent private practice.
- Limits intern registration to 5 years; and,
- Prohibits an individual who has held a provisional license from applying for an intern registration in the same profession.

II. Present Situation:

Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling

The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (the board) is located within the Department of Health (DOH) and is responsible for licensing and regulating the practice of clinical social work, marriage and family therapy, and mental health counseling pursuant to ch. 491, F.S.

The practice of clinical social work uses scientific and applied knowledge, theories, and methods for the purpose of describing, preventing, evaluating, and treating individual, couple, marital, family, or group behavior. The purpose of such services is the prevention and treatment of undesired behavior and enhancement of mental health. The practice of clinical social work includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent

emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. Such practice also includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[1]

The practice of marriage and family therapy is the use of scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family systems, including the context of marital formation and dissolution. The practice is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic and marriage and family therapy theories and techniques. The practice of marriage and family therapy includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. Such practice includes, but is not limited to, marriage and family therapy, psychotherapy, including behavioral family therapy, hypnotherapy, and sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[2]

The practice of mental health counseling is the use of scientific and applied behavioral science theories, methods, and techniques for the purpose of describing, preventing, and treating undesired behavior and enhancing mental health and human development and is based on the person-in-situation perspectives derived from research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation. Such practice includes methods of a psychological nature used to evaluate, assess, diagnose, and treat emotional and mental dysfunctions or disorders (whether cognitive, affective, or behavioral), behavioral disorders, interpersonal relationships, sexual dysfunction, alcoholism, and substance abuse. It also includes, but is not limited to, psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[3]

Board Rule 64B4-2.006, F.A.C, defines a "mental health professional," as used in s. 491.005(1)(c), (3)(c), and (4)(c), F.S., to mean a psychotherapist licensed under ch. 491, F.S., a psychologist licensed under ch. 490, F.S., a psychiatrist licensed under ch. 458 or 459, F.S., who is certified by the American Board of Psychiatry and Neurology; or an advanced registered nurse practitioner certified under s. 464.012, F.S., and who is certified by a board approved national certification organization pursuant to Rule 64B9-4.002, F.A.C.

[1] Section 491.003(7), F.S.
[2] Section 491.003(8), F.S.
[3] Section 491.003(9), F.S.

In order to practice any of these professions, an individual must be licensed by the board after having met a series of requirements. The two major requirements, other than payment of a fee, and completion of educational requirements, for licensure in any of the fields is completion of a supervised internship and the successful completion of a theory and practice examination.[4]

Internships

In order to be licensed as a clinical social worker, a marriage and family counselor, or a mental health counselor, an individual must have completed designated educational requirements and at least 2 years of practice supervised by a licensed practitioner.[5] During the time that the person is completing the experience requirement, he or she must register as an intern.[6]

To become an intern the applicant must complete the application form and submit a nonrefundable application fee not exceeding $200 as set by the board. The applicant must also have completed the necessary education requirements, submitted an acceptable supervision plan, and identified a qualified supervisor.[7]

An intern may renew his or her registration every 2 years, indefinitely, by payment of a renewal fee of $80 for each 2-year period. No continuing education is required for interns. Currently, there are 3,239 clinical social work interns, 859 marriage and family therapy interns, and 4,237 mental health counseling interns. Of this total, more than 700 interns have been renewing their registered intern license for over 10 years, and 150 of them have been renewing since the inception of this law in 1998.[8]

Disciplinary cases have shown that those who have held intern registration for many years are no longer remaining under supervision as is required by law, and many are in private practice without meeting minimum competency standards. The DOH has received increasing numbers of complaints against registered interns for various infractions including filing false reports, failing to meet minimum standards, boundary violations, sexual misconduct, Medicaid fraud, and false advertising. To date, the DOH has received 134 formal complaints against clinical social work interns, 51 complaints against marriage and family interns, and 238 complaints against mental health counselor interns. 67 complaints have resulted in disciplinary actions, including two recent emergency restriction orders signed by the State Surgeon General.[9]

Provisional License

A provisional license permits an individual who is applying by endorsement or examination and who has satisfied the clinical experience requirements to practice under supervision while completing licensure requirements. Provisional licenses expire 24 months after the date issued

[4] Section 491.005(1)(d), (3)(d), and (4)(d), F.S.
[5] Section 491.005, F.S.
[6] Section 491.0045, F.S.
[7] *Id.*
[8] Department of Health, *Senate Bill 1388 Fiscal Analysis* (Mar. 4, 2014) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[9] *Id.*

and may not be renewed or reissued.[10] Currently there are 66 provisionally licensed clinical social workers, 11 provisionally licensed marriage and family therapists, and 107 provisionally licensed mental health counselors. In the past, the board has accepted applications for registered internships from practitioners whose provisional licenses have expired without their having met the requirements for licensure, as there is no prohibition against a provisional licensee applying for an intern registration.[11]

III. Effect of Proposed Changes:

Section 1 amends s. 491.0045, F.S., to provide that registration as a social worker, marriage and family counselor, or mental health counselor intern is, in general, valid for 5 years from the date of issue. Registrations issued on or before March 31, 2015, expire March 31, 2020, and may not re-renewed or reissued. Registrations issued after March 31, 2015, expire 60 months after the date of issue and may be renewed only if the candidate has passed the theory and practice examination required for full licensure.

The bill requires that persons registered as interns must remain under the supervision of a licensed practitioner while practicing under registered intern status. Individuals who fail to comply with statutory internship requirements may not be granted a license, and the experience accrued by such individuals while not in compliance may not count toward satisfying the experience requirements for licensure. This section also prohibits persons who have held a provisional license from applying for an intern license in the same profession.

Section 2 amends s. 491.005, F.S., to require that a "licensed mental health professional" be on the premises when clinical services are provided by a registered intern in any of the three disciplines, in a private practice setting. The bill prohibits registered interns from engaging in their own independent private practice.

Section 3 provides for an effective date of July 1, 2014.

In addition to substantive changes, revisions are made throughout the bill to remove obsolete language and to make grammatical and conforming changes.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[10] Section 491.0046, F.S.
[11] Department of Health, *ibid.*

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Interns will no longer be required to pay a biennial renewal fee but will be required to pay initial fees and renewal for full licensure after 5 years in order to continue to practice in these professions. Some interns may not be able to meet the requirements for full licensure and may not be able to continue to practice in these fields.

C. Government Sector Impact:

The DOH expects to experience an insignificant fiscal impact related to updating its Customer Oriented Medical Practitioner Administration System (COMPAS) licensure system to accommodate the changes in SB 1388.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 491.0045 and 491.005.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Montford

3-01221A-14 20141388__

A bill to be entitled

An act relating to registered interns in clinical social work, marriage and family therapy, and mental health counseling; amending s. 491.0045, F.S.; requiring an individual who has not satisfied specified requirements to register as an intern in clinical social work, marriage and family therapy, or mental health counseling; requiring an individual to remain under supervision while practicing under registered intern status; providing that an intern registration is valid for 5 years; providing expiration dates of registrations issued on, before, or after specified dates; prohibiting an individual who has held a provisional license from applying for an intern registration in the same profession; conforming provisions to changes made by the act; amending s. 491.005, F.S.; requiring a licensed health professional to be on the premises when clinical services are provided by a registered intern of clinical social work, marriage and family therapy, or mental health counseling in a private practice setting; prohibiting such registered interns from engaging in their own independent private practice; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 491.0045, Florida Statutes, is amended

3-01221A-14 20141388__

to read:

491.0045 Intern registration; requirements.—

(1) ~~Effective January 1, 1998,~~ An individual who has not satisfied ~~intends to practice in Florida to satisfy~~ the postgraduate or post-master's level experience requirements~~,~~ as specified in s. 491.005(1)(c), (3)(c), or (4)(c)~~,~~ must register as an intern in the profession for which he or she is seeking licensure before ~~prior to~~ commencing the post-master's experience requirement. ~~or~~ An individual who intends to satisfy part of the required graduate-level practicum, internship, or field experience~~,~~ outside the academic arena for any profession~~,~~ must register as an intern in the profession for which he or she is seeking licensure before ~~prior to~~ commencing the practicum, internship, or field experience.

(2) The department shall register as a clinical social worker intern, marriage and family therapist intern, or mental health counselor intern each applicant who the board certifies has:

(a) Completed the application form and remitted a nonrefundable application fee of up to ~~not to exceed~~ $200, as set by board rule;

(b)1. Completed the education requirements as specified in s. 491.005(1)(c), (3)(c), or (4)(c) for the profession for which he or she is applying for licensure, if needed; and

2. Submitted an acceptable supervision plan, as determined by the board, for meeting the practicum, internship, or field work required for licensure which ~~that~~ was not satisfied in his or her graduate program.

(c) Identified a qualified supervisor.

(3) An individual registered under this section must remain under supervision while practicing under registered intern status ~~until he or she is in receipt of a license or a letter from the department stating that he or she is licensed to practice the profession for which he or she applied~~.

(4) An individual who fails ~~has applied for intern registration on or before December 31, 2001, and has satisfied the education requirements of s. 491.005 that are in effect through December 31, 2000, will have met the educational requirements for licensure for the profession for which he or she has applied.~~

~~(5) Individuals who have commenced the experience requirement as specified in s. 491.005(1)(c), (3)(c), or (4)(c) but failed to register as required by subsection (1) shall register with the department before January 1, 2000. Individuals who fail~~ to comply with this section may ~~subsection shall~~ not be granted a license under this chapter, and any time spent by the individual completing the experience requirement as specified in s. 491.005(1)(c), (3)(c), or (4)(c) before ~~prior to~~ registering as an intern does ~~shall~~ not count toward completion of the ~~such~~ requirement.

(5) Except as provided in subsection (6), an intern registration is valid for 5 years from the date of issue.

(6) An intern registration issued on or before March 31, 2015, expires March 31, 2020, and may not be renewed or reissued. An intern registration issued after March 31, 2015, expires 60 months after the date it is issued. A subsequent intern registration may not be issued unless the candidate has passed the theory and practice examination described in s.

491.005(1)(d), (3)(d), and (4)(d).

(7) An individual who has held a provisional license issued by the board may not apply for an intern registration in the same profession.

Section 2. Subsection (1), subsection (3), paragraphs (a) and (c) of subsection (4), and subsections (5) and (6) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(1) CLINICAL SOCIAL WORK.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost to the department for purchase of the examination from the American Association of State Social Work ~~Worker's~~ Boards or a similar national organization, the department shall issue a license as a clinical social worker to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(b)1. Has received a doctoral degree in social work from a graduate school of social work which at the time the applicant graduated was accredited by an accrediting agency recognized by the United States Department of Education or has received a master's degree in social work from a graduate school of social work which at the time the applicant graduated:

a. Was accredited by the Council on Social Work Education;

b. Was accredited by the Canadian Association of Schools of Social Work; or

c. Has been determined to have been a program equivalent to programs approved by the Council on Social Work Education by the Foreign Equivalency Determination Service of the Council on

Social Work Education. An applicant who graduated from a program at a university or college outside of the United States or Canada must present documentation of the equivalency determination from the council in order to qualify.

2. The applicant's graduate program must have emphasized direct clinical patient or client health care services, including, but not limited to, coursework in clinical social work, psychiatric social work, medical social work, social casework, psychotherapy, or group therapy. The applicant's graduate program must have included all of the following coursework:

a. A supervised field placement which was part of the applicant's advanced concentration in direct practice, during which the applicant provided clinical services directly to clients.

b. Completion of 24 semester hours or 32 quarter hours in theory of human behavior and practice methods as courses in clinically oriented services, including a minimum of one course in psychopathology, and no more than one course in research, taken in a school of social work accredited or approved pursuant to subparagraph 1.

3. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

(c) Has had at least ~~not less than~~ 2 years of clinical social work experience, which took place subsequent to completion of a graduate degree in social work at an institution

meeting the accreditation requirements of this section, under the supervision of a licensed clinical social worker or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If the applicant's graduate program was not a program that ~~which~~ emphasized direct clinical patient or client health care services as described in subparagraph (b)2., the supervised experience requirement must take place after the applicant has completed a minimum of 15 semester hours or 22 quarter hours of the coursework required. A doctoral internship may be applied toward the clinical social work experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. A registered intern may not engage in his or her own independent private practice ~~The experience requirement may be met by work performed on or off the premises of the supervising clinical social worker or the equivalent, provided the off-premises work is not the independent private practice rendering of clinical social work that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services~~.

(d) Has passed a theory and practice examination provided by the department for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental

health counseling.

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual cost to the department for the purchase of the examination from the Association of Marital and Family Therapy Regulatory Boards ~~Board~~, or similar national organization, the department shall issue a license as a marriage and family therapist to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(b)1. Has a minimum of a master's degree with major emphasis in marriage and family therapy, or a closely related field, and has completed all of the following requirements:

a. Thirty-six semester hours or 48 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level course credits in each of the following nine areas: dynamics of marriage and family systems; marriage therapy and counseling theory and techniques; family therapy and counseling theory and techniques; individual human development theories throughout the life cycle; personality theory or general counseling theory and techniques; psychopathology; human sexuality theory and counseling techniques; psychosocial theory; and substance abuse theory and counseling techniques. Courses in research, evaluation, appraisal, assessment, or testing theories and procedures; thesis or dissertation work; or practicums, internships, or fieldwork may not be applied toward this requirement.

b. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in legal, ethical, and professional

standards issues in the practice of marriage and family therapy or a course determined by the board to be equivalent.

c. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in diagnosis, appraisal, assessment, and testing for individual or interpersonal disorder or dysfunction; and a minimum of one 3-semester-hour or 4-quarter-hour graduate-level course in behavioral research which focuses on the interpretation and application of research data as it applies to clinical practice. Credit for thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

d. A minimum of one supervised clinical practicum, internship, or field experience in a marriage and family counseling setting, during which the student provided 180 direct client contact hours of marriage and family therapy services under the supervision of an individual who met the requirements for supervision under paragraph (c). This requirement may be met by a supervised practice experience which took place outside the academic arena, but which is certified as equivalent to a graduate-level practicum or internship program which required a minimum of 180 direct client contact hours of marriage and family therapy services currently offered within an academic program of a college or university accredited by an accrediting agency approved by the United States Department of Education, or an institution which is publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada or a training institution accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education.

Certification shall be required from an official of such college, university, or training institution.

2. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

The required master's degree must have been received in an institution of higher education which at the time the applicant graduated was: fully accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation; publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada; or an institution of higher education located outside the United States and Canada, which at the time the applicant was enrolled and at the time the applicant graduated maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists. The burden of establishing that the requirements of this provision have been met shall be upon the applicant, and the board shall require documentation, such as, but not limited to,

an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. An applicant with a master's degree from a program which did not emphasize marriage and family therapy may complete the coursework requirement in a training institution fully accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education.

(c) Has had at least ~~not less than~~ 2 years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must be at the post-master's level under the supervision of a licensed marriage and family therapist who has ~~with~~ at least 5 years of experience, or the equivalent, and who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field which ~~that~~ did not include all the coursework required under sub-subparagraphs (b)1.a.-c., credit for the post-master's level clinical experience may ~~shall~~ not commence until the applicant has completed a minimum of 10 of the courses required under sub-subparagraphs (b)1.a.-c., as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 3 years of required experience, the applicant shall provide

direct individual, group, or family therapy and counseling, to include the following categories of cases: unmarried dyads, married couples, separating and divorcing couples, and family groups including children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. A registered intern may not engage in his or her own independent private practice ~~The clinical experience requirement may be met by work performed on or off the premises of the supervising marriage and family therapist or the equivalent, provided the off-premises work is not the independent private practice rendering of marriage and family therapy services that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services~~.

(d) Has passed a theory and practice examination provided by the department for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

(f) For the purposes of dual licensure, the department shall license as a marriage and family therapist any person who meets the requirements of s. 491.0057. Fees for dual licensure shall not exceed those stated in this subsection.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost to the department

for purchase of the examination from the Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors or a similar national organization, the department shall issue a license as a mental health counselor to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(c) Has had at least ~~not less than~~ 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling which ~~that~~ did not include all the coursework required under sub-subparagraphs (b)1.a.-b., credit for the post-master's level clinical experience may ~~shall~~ not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a.-b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. A registered intern may not engage in his or her own independent private practice ~~The clinical experience requirement may be met by work performed on or off the premises of the supervising~~

~~mental health counselor or the equivalent, provided the off-premises work is not the independent private practice rendering of services that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services~~.

~~(5) INTERNSHIP.—An individual who is registered as an intern and has satisfied all of the educational requirements for the profession for which the applicant seeks licensure shall be certified as having met the educational requirements for licensure under this section.~~

(5) ~~(6)~~ RULES.—The board may adopt rules necessary to implement any education or experience requirement in ~~of~~ this section for licensure as a clinical social worker, marriage and family therapist, or mental health counselor.

Section 3. This act shall take effect July 1, 2014.

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic ~~Program Assistants~~ Mental Health Counselors

Bill Number ~~1259~~ 1388 *(if applicable)*

Name Corinne Mixon

Amendment Barcode _____ *(if applicable)*

Job Title Lobbyist

Address 119 E. Park Avenue
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-222-2591

E-mail corinne@mixonandassociates.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Mental Health Counselors Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date

Topic _____ Bill Number SB 1388 *(if applicable)*

Name JIM ATKIN Amendment Barcode _____ *(if applicable)*

Job Title EXECUTIVE DIRECTOR

Address 1931 DENWOOD DRIVE Phone 850-224-2400
Street

TALLAHASSEE, FL 32306 E-mail JIM@NASWFL.ORG
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing NATIONAL ASSN. OF SOCIAL WORKERS - FLORIDA

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-01-14
Meeting Date

Topic Mental Health Registered Interns Bill Number SB 1388 *(if applicable)*

Name Larry Barlow Amendment Barcode _____ *(if applicable)*

Job Title Executive Director, FL Assoc. for Marriage & Family Therapy

Address 2888-1 Mahan Dr Phone (850)681-3639
Street

Tallahassee FL 32308 E-mail lbarlow110@msn.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☑ Information

Representing FL Assoc for Marriage & Family Therapy

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

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1230
INTRODUCER:	Senator Hays
SUBJECT:	Physician Assistants
DATE:	April 1, 2014
REVISED:	04/02/14

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Fav/1 amendment**
2.			AP	
3.			RC	

Please see Section IX. for Additional Information:

AMENDMENTS - Significant amendments were recommended

I. Summary:

SB 1230 increases the number of physician assistants a medical or osteopathic physician may supervise by raising the cap from four to eight. The bill makes minor modifications to the documentation a physician assistant must submit for licensure.

II. Present Situation:

Chapter 458, F.S., sets forth the provisions for the regulation of the practice of medicine by the Board of Medicine. Chapter 459, F.S., similarly sets forth the provisions for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine. Physician assistants are regulated by both boards. Licensure of physician assistants is overseen jointly by the boards through the Council on Physician Assistants.[1]

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.[2] Supervision is responsible supervision and requires the easy availability, which includes telecommunication, or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant.[3] In

[1] The council consists of three physicians who are members of the Board of Medicine; one physician who is a member of the Board of Osteopathic Medicine; and a physician assistant appointed by the State Surgeon General. (ss. 458.348(9) and 459.022(9), F.S.).
[2] Sections 458.347(4) and 459.022(4), F.S.
[3] *See* ss. 458.347(2)(f) and 459.022(2)(f), F.S.

determining whether supervision is responsible, board rules direct that the following be considered:[4]

- The complexity of the task;
- The risk to the patient;
- The background, training and skill of the physician assistant;
- 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 people who the supervising physician must supervise.

Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and must be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant.[5]

The Board of Medicine and the Board of Osteopathic Medicine have adopted rules that set out the general principles a supervising physicians must use in developing the scope of practice of the physician assistant under both direct[6] and indirect[7] supervision. A supervising physician's decision to permit a physician assistant to perform a task or procedure under direct or indirect supervision must be based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. The supervising physician must be certain that the physician assistant is knowledgeable and skilled in performing the tasks and procedures assigned.[8]

Rules of both boards prohibit the delegation of prescribing, dispensing, or compounding of medicinal drugs, or final diagnosis, except as authorized by statute.[9] Current law allows a supervisory physician to delegate authority to prescribe or dispense any medication used in the physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials.[10] Rules of both boards also prohibit the performance of specified duties under indirect supervision, including certain invasive procedures, performance of stress testing, interpretation of laboratory tests, X-rays, and EKGs, and administration of certain anesthetics.[11]

Currently, a physician practicing in Florida may not supervise more than four licensed physician assistants at any one time.[12] Supervision of physician assistants varies nationwide. Some states

[4] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[5] Sections 458.347(3) and 459.022(3), F.S.
[6] "Direct supervision" requires the physician to be on the premises and immediately available. (*See* Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.)
[7] "Indirect supervision" requires the physician to be within reasonable physical proximity. (Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.
[8] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[9] *Id.*
[10] Sections 458.347(4)(e) and (f)1 and 459.022(4)(e)., F.S. *But see* ss. 458.347(4)(g) and 459.022(4)(f), F.S., which allow the ordering of controlled substances.
[11] *See supra* note 8.
[12] Sections 458.347(3) and 459.022(3), F.S.

apply straight ratios. Some have no restriction. Some establish a higher or no ratio in designated practice settings, e.g. hospital or correctional facility. Some establish lower ratios for supervision offsite (remote locations) and some allow physicians to petition for a higher ratio. In general, ten states have no restriction;[13] nine states allow supervision of up to two physician assistants;[14] six states allow supervision of up to three physician assistants;[15] and 16 states (plus the District of Columbia) allow supervision of up to four physician assistants.[16] The six remaining states have ratios up to 1 to 7.[17]

There are 61,033 medical physicians, 6,045 osteopathic physicians, and 6,628 physician assistants who are licensed and currently authorized to practice in the state.[18] The 2013 Physician Workforce Annual Report[19] found that 69.7 percent of the state's licensed physicians are actively practicing in Florida. Nearly two-thirds (61.7 percent) of the actively practicing physicians are age 50 or older and 13.2 percent plan to retire in the next 5 years.[20] A study released in 2011 projects that nationwide the number of physician assistants with an active clinical practice will increase by 72 percent during the 15-year period: 2010 – 2025.[21]

III. Effect of Proposed Changes:

The bill increases from four to eight the number of physician assistants a medical or osteopathic physician may supervise.

The bill changes the format for the DOH to obtain certain information required for licensure. Instead of submitting a signed affidavit related to certain continuing medical education, the bill requires the physician assistant to certify compliance with the continuing medical education requirement. The requirement that statements related to prior felony convictions or license revocation or denial be sworn is also removed. The DOH indicates that most practice acts do not require sworn or notarized statements. By signing the application, the applicant certifies to the

[13] Alabama, Arkansas, Maine, Montana, New Mexico, North Carolina, North Dakota, Rhode Island, Tennessee, and Vermont.
[14] Hawaii, Indiana, Kansas, Kentucky, Louisiana, Ohio, Mississippi, Oklahoma, and Wisconsin.
[15] Idaho, Missouri, Nevada, South Carolina, West Virginia, and Wyoming.
[16] Arizona, California, Colorado, Delaware, Florida, Georgia, Maryland, Michigan, Nebraska, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, South Dakota, and Utah.
[17] American Academy of Physician Assistants, *State Laws and Regulations Governing the Number of Physician Assistants that One Physician may [sic] Supervise* (August 2013) (on file with the Senate Committee on Health Policy).
[18] *See* Fla. Dept. of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan FY 2012-2013*, 8 - 9, *available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-12-13.pdf (last visited Mar. 5, 2014). These numbers reflect practitioners with in-state active, out-of-state active, and military active licenses.
[19] Sections 458.3191 and 459.0081, F.S., require DOH to administer a survey in conjunction with physician licensure renewal. Physician participation is mandatory. Results of the survey are provided to the Governor, President of the Senate, and Speaker of the House and shared with the Physician Workforce Advisory Council.
[20] Fla. Dept. of Health, *2013 Physician Workforce Annual Report*, 3 (Nov. 2013), *available at* http://www.floridahealth.gov/provider-and-partner-resources/community-health-workers/physician-workforce-development-and-recruitment/physicianworkforce13final.pdf (last visited Mar. 5, 2014).
[21] Roderick S. Hooker, PhD, PA et al., *Predictive Modeling the Physician Assistant Supply: 2010 – 2025*, PUBLIC HEALTH REPORTS, (Sept. – Oct. 2011), *available at* http://www.publichealthreports.org/issueopen.cfm?articleID=2714 (last visited Mar. 5, 2014). The study used the cohort of physician assistants who graduated in 2010 as the basis for projecting supply. Growth was projected based on physician assistant program growth and the number of graduates adjusted for attrition.

truth of its content, thus the additional requirement of sworn or notarized statements add burden to the applicant without adding benefit to the licensure process.[22] An applicant who lies on an application is subject to disciplinary action, thus the DOH has recourse.[23] The bill also eliminates the requirement for a physician assistant to submit two letters of recommendation. This requirement exists currently only for physician assistants and anesthesiology assistants and not for any other regulated health care practitioner. Likewise, it does not add value to the licensure application review.[24]

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians may experience greater efficiency in operations, resulting in cost savings, by utilizing more physician assistants in their operations. For SB 1230 to have a substantial impact on the market; however, Florida would need to see a significant increase in the number of licensed physician assistants.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

[22] Conversation with Allison M. Dudley, J.D., Executive Director, Fla. Board of Medicine, Fla. Dept. of Health (Mar. 26, 2014).
[23] Sections 458.331(1)(a) and 459.015(1)(a), F.S.
[24] *Supra* note 22.

VII. Related Issues:

Current law requires applicants for licensure as physician assistants to indicate on the application whether the applicant has a prior felony conviction. The law does not, however, require the applicant to provide a set of fingerprints. As a result, the DOH does not have a means to verify the information or receive immediate notification of any subsequent criminal violations, except when notified by the physician assistant or third party. The Legislature may wish to address this issue.

Sections 458.347 and 459.022, F.S., establish limitations on the prescribing authority that may be delegated to a physician assistant and conditions under which the physician assistant may exercise that authority. Both sections require that prescriptions be written in a form that complies with ch. 499, F.S. Part I of ch. 499 is the "Florida Drug and Cosmetic Act." The act is administered and enforced by the Department of Business and Professional Regulation "to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics."[25] The act does not contain standards for prescriptions. Those requirements are in ss. 456.42(1), and 456.0392(1), F.S. In addition, the prescribing language in current law also contemplates written prescriptions, only. Many prescriptions are now submitted electronically.

Both issues may be addressed by an amendment that strikes lines 58–59 and 152-153 and inserts:

5. The prescription may ~~must~~ be written or electronic, but must be in a form that complies with ss. 456.0392(1) and 456.42(1) ~~chapter 499~~ and must contain, in addition to the . . .

The bill raises the cap on the number of physician assistants a physician may supervise, but does not address the number of offices a physician may supervise. Depending on the intent of the bill, the office supervision caps may create a barrier to its full implementation in some settings.[26]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.347 and 459.022.

IX. Additional Information:

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

None.

[25] Section 499.002(2), F.S.
[26] A primary care physician may supervise up to five offices, a specialty physician may supervise up to three offices, and a physician providing certain dermatological services may supervise two offices. The law provides exceptions. *See* ss. 458.348(4) and 459.024(3), F.S.

B. Amendments:

Barcode 630784 by Health Policy on April 1, 2014:
The amendment revises the bill to reduce the number of physician assistants that a physician may supervise to five and to except physicians who supervise offices that provide certain dermatological services from the higher limit. The amendment requires physician assistants applying for initial licensure on or after January 1, 2015, to submit to background screening and requires physician assistants to provide the DOH with contact information of a designated supervising physician, if supervised by more than one. The amendment also corrects a reference to the required elements for a prescription and allows prescriptions by a physician assistant to be filed in electronic form. Finally, the amendment authorizes a physician who is not board eligible or board certified in dermatology to supervise two offices, in addition to the physician's primary office, where nonablative aesthetic services are provided if the services are performed by a physician assistant who has completed a specified number of hours of education and clinical training in the physiology of the skin, laser technology, and injectables. (WITH TITLE AMENDMENT)

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730402

LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
04/02/2014	.	
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The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a), (c), and (e) of subsection (7) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant

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must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than five ~~four~~ currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant. Notwithstanding this subsection, a physician may only supervise up to four physician assistants in an office regulated under s. 458.348(4)(c) or s. 459.025(3)(c).

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a

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supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic, but must be in a form that complies with ss. 456.0392(1) and 456.42(1), ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall

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issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

e. As of January 1, 2015, for physician assistants seeking

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initial licensure, fingerprints pursuant to the procedures established in s. 456.0135.

(c) The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

(e) Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. Any subsequent change in the designated supervising physician shall be reported by the physician assistant to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

Section 2. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a), (b), and (d) of subsection (7) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than five ~~four~~ currently licensed physician

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assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant. Notwithstanding this subsection, a physician may only supervise up to four physician assistants in an office regulated under s. 458.348(4)(c) or s. 459.025(3)(c).

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that she or he has completed a minimum of 10 continuing medical education hours in the

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specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic, but must be in a form that complies with ss. 456.0392(1) and 456.42(1) ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on

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Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

e. As of January 1, 2015, for physician assistants seeking initial licensure, fingerprints pursuant to the procedures established in s. 456.0135.

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

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2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

(d) Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. Any subsequent change in the designated supervising physician shall be reported by the physician assistant to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

Section 3. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; providing an exception; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; specifying that a prescription may be in written or electronic form and must meet certain requirements; revising application requirements for

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licensure as a physician assistant and license renewal; revising the notification requirements for a physician assistant to the Department of Health upon employment as a physician assistant; providing an effective date.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RE	.	
04/02/2014	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment to Amendment (730402) (with title amendment)

Between lines 115 and 116
insert:

Section 2. Paragraph (c) of subsection (4) of section 458.348, Florida Statutes, is amended to read:

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

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A

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physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(c) A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The physician shall submit to the board the addresses of all offices where he or she is supervising an advanced registered nurse practitioner or a physician's assistant which are not the physician's primary practice location.

2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.

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3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

4. The physician may supervise only one office other than the physician's primary place of practice except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board.

5.a. Subparagraphs 2. and 4. do not apply to an office where nonablative aesthetic skin care services are being performed by a physician assistant under the supervision of a physician if the physician assistant has successfully completed at least:

(I) Eighty hours of education and clinical training on physiology of the skin, skin conditions, skin disorders, skin diseases, pre- and post-skin procedure care, and infection control;

(II) Ten hours of education and clinical training on laser and light technologies and skin applications; and

(III) Thirty-two hours of education and clinical training on injectables and fillers.

b. As used in this paragraph, the term "nonablative

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aesthetic services" includes, but is not limited to, services provided using intense pulsed light, lasers, radio frequency, ultrasound, injectables, and fillers. The supervising physician shall submit to the board documentation evidencing successful completion of the education and training required by this paragraph for the physician assistants that he or she is supervising. A physician may not supervise more than two offices in addition to the physician's primary practice location.

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

And the title is amended as follows:

Delete lines 234 - 235

and insert:

An act relating to physician assistants; amending s. 458.347, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; providing an exception; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; specifying that a prescription may be in written or electronic form and must meet certain requirements; revising application requirements for licensure as a physician assistant and license renewal; revising the notification requirements for a physician assistant to the Department of Health upon employment as a physician assistant; amending s. 458.348, F.S.; providing exceptions to the requirements for supervising physician assistants at offices providing certain skin care services under certain

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circumstances; defining the term "nonablative aesthetic services"; requiring a supervising physician to submit to the Board of Medicine certain documentation regarding the physician assistant; limiting the number of offices that such physician may supervise in addition to his or her primary practice location; amending s. 459.022, F.S.; increasing the number of

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LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
04/02/2014	.	
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The Committee on Health Policy (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a), (c), and (e) of subsection (7) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant

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must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than five ~~four~~ currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant. Notwithstanding this subsection, a physician may only supervise up to four physician assistants in an office regulated under s. 458.348(4)(c) or s. 459.025(3)(c).

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a

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supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic, but must be in a form that complies with ss. 456.0392(1) and 456.42(1), ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall

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issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

e. As of January 1, 2015, for physician assistants seeking

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initial licensure, fingerprints pursuant to the procedures established in s. 456.0135.

(c) The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

(e) Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. Any subsequent change in the designated supervising physician shall be reported by the physician assistant to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

Section 2. Paragraph (c) of subsection (4) of section 458.348, Florida Statutes, is amended to read:

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

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For

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the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(c) A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The physician shall submit to the board the addresses of all offices where he or she is supervising an advanced registered nurse practitioner or a physician's assistant which are not the physician's primary practice location.

2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.

3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

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4. The physician may supervise only one office other than the physician's primary place of practice except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board.

5.a. Subparagraphs 2. and 4. do not apply to an office where nonablative aesthetic skin care services are being performed by a physician assistant under the supervision of a physician if the physician assistant has successfully completed at least:

(I) Eighty hours of education and clinical training on physiology of the skin, skin conditions, skin disorders, skin diseases, pre- and post-skin procedure care, and infection control;

(II) Ten hours of education and clinical training on laser and light technologies and skin applications; and

(III) Thirty-two hours of education and clinical training on injectables and fillers.

b. As used in this paragraph, the term "nonablative aesthetic services" includes, but is not limited to, services provided using intense pulsed light, lasers, radio frequency, ultrasound, injectables, and fillers. The supervising physician shall submit to the board documentation evidencing successful completion of the education and training required by this paragraph for the physician assistants that he or she is

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supervising. A physician may not supervise more than two offices in addition to the physician's primary practice location.

Section 3. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a), (b), and (d) of subsection (7) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than five ~~four~~ currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant. Notwithstanding this subsection, a physician may only supervise up to four physician assistants in an office regulated under s. 458.348(4)(c) or s. 459.025(3)(c).

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore,

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the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic, but must be in a form that complies with ss. 456.0392(1) and 456.42(1) ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the

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prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial

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of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

e. As of January 1, 2015, for physician assistants seeking initial licensure, fingerprints pursuant to the procedures established in s. 456.0135.

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

(d) Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. Any subsequent change in the designated supervising physician shall be reported by the physician assistant to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

Section 4. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to physician assistants; amending s. 458.347, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; providing an exception; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; specifying that a prescription may be in written or electronic form and must meet certain requirements; revising application requirements for licensure as a physician assistant and license renewal; revising the notification requirements for a physician assistant to the Department of Health upon employment as a physician assistant; amending s. 458.348, F.S.; providing exceptions to the requirements for supervising physician assistants at offices providing certain skin care services under certain circumstances; defining the term "nonablative aesthetic services"; requiring a supervising physician to submit to the Board of Medicine certain documentation regarding the physician assistant; limiting the number of offices that such physician may supervise in addition to his or her primary practice location; amending s. 459.022, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; providing an


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exception; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; specifying that a prescription may be in written or electronic form and must meet certain requirements; revising application requirements for licensure as a physician assistant and license renewal; revising the notification requirements for a physician assistant to the Department of Health upon employment as a physician assistant; providing an effective date.

582424

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/01/2014	.	
	.	
	.	
	.	

The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Between lines 106 and 107
insert:

Section 2. Paragraph (c) of subsection (4) of section 458.348, Florida Statutes, is amended to read:

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

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A physician who supervises an advanced registered nurse

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practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

(c) A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.

1. The physician shall submit to the board the addresses of all offices where he or she is supervising an advanced registered nurse practitioner or a physician's assistant which are not the physician's primary practice location.

2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.

3. All such offices that are not the physician's primary

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place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to the county of the physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.

4. The physician may supervise only one office other than the physician's primary place of practice except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board.

5.a. Subparagraphs 2. and 4. do not apply to an office where nonablative aesthetic skin care services are being performed by a physician assistant under the supervision of a physician if the physician assistant has successfully completed at least:

(I) Eighty hours of education and clinical training on physiology of the skin, skin conditions, skin disorders, skin diseases, pre- and post- skin procedure care, and infection control;

(II) Ten hours of education and clinical training on laser and light technologies and skin applications; and

(III) Thirty-two hours of education and clinical training on injectables and fillers.

b. As used in this paragraph, the term "nonablative aesthetic services" includes, but is not limited to, services

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provided using intense pulsed light, lasers, radio frequency, ultrasound, injectables, and fillers. The supervising physician shall submit to the board documentation evidencing successful completion of the education and training required by this paragraph for the physician assistants that he or she is supervising. A physician may not supervise more than two offices in addition to the physician's primary practice location.

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

And the title is amended as follows:

Delete lines 2 - 3

and insert:

An act relating to physician assistants; amending s. 458.347, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; revising application requirements for licensure as a physician assistant and license renewal; amending s. 458.348, F.S.; providing exceptions to the requirements for supervising physician assistants at offices providing certain skin care services under certain circumstances; defining the term "nonablative aesthetic services"; requiring a supervising physician to submit to the Board of Medicine certain documentation regarding the physician assistant; limiting the number of offices that such physician may supervise in addition to his or her primary practice location; amending s. 459.022, F.S.;

582424

increasing the number of

By Senator Hays

11-01202A-14 20141230__

A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; revising application requirements for licensure as a physician assistant and license renewal; providing an effective date.

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

Section 1. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a) and (c) of subsection (7) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than eight ~~four~~ currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully

11-01202A-14 20141230__

licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies

with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an

application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

(c) The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

Section 2. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a) and (b) of subsection (7) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may

not supervise more than eight ~~four~~ currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must certify to ~~file with~~ the department ~~a signed affidavit~~ that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has

prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on

Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. A ~~sworn~~ statement of any prior felony convictions.

c. A ~~sworn~~ statement of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. A ~~sworn~~ statement of no felony convictions in the previous 2 years.

Section 3. This act shall take effect July 1, 2014.

THE FLORIDA SENATE
Tallahassee, Florida 32399-1100

SENATOR ALAN HAYS
11th District

COMMITTEES:
Appropriations Subcommittee on General Government, *Chair*
Children, Families, and Elder Affairs, *Vice Chair*
Governmental Oversight and Accountability, *Vice Chair*
Appropriations
Appropriations Subcommittee on Criminal and Civil Justice
Banking and Insurance
Commerce and Tourism

JOINT COMMITTEES:
Joint Select Committee on Collective Bargaining, *Co-Chair*
Joint Legislative Auditing Committee
Joint Legislative Budget Commission

MEMORANDUM

To: Senator Aaron Bean, Chair
Health Policy Committee
CC: Sandra Stovall, Staff Director
Celia Georgiades, Committee Administrative Assistant

From: Senator D. Alan Hays

Subject: **Request to agenda SB 1230 – Physician Assistants**

Date: February 28, 2014

I respectfully request that you agenda the above referenced bill at your earliest convenience. If you have any questions regarding this legislation, I welcome the opportunity to meet with you one-on-one to discuss it in further detail. Thank you so much for your consideration of this request.

Sincerely,

D. Alan Hays, DMD
State Senator, District 11

REPLY TO:
☐ 871 South Central Avenue, Umatilla, Florida 32784-9290 (352) 742-6441
☐ 320 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5011
☐ 1104 Main Street, The Villages, Florida 32159 (352) 360-6739 FAX: (352) 360-6748
☐ 685 West Montrose Street, Suite 110, Clermont, Florida 34711 (352) 241-9344 FAX: (888) 263-3677

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

DON GAETZ
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Physician Assistants

Bill Number 1230 *(if applicable)*

Name Nicole Strothman

Amendment Barcode 568886 *(if applicable)*

Job Title General Counsel

Address 4830 W. Kennedy Blvd. Ste 440
Street

Tamqa FL 33609
City *State* *Zip*

Phone 813-286-8100

E-mail nicole.strothman@idealimage.com

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

Representing Ideal Image

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

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic _____ Bill Number 1230

Name Chris Nland Amendment Barcode 588240A WD
(if applicable) *(if applicable)*

Job Title _____

Address 1000 Riverside Ave #115 Phone 904-233-3051
Street

Jacksonville, FL 32204 E-mail nlandlaw@aol.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Representing Florida Society of Plastic Surgeons

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4.1.14
Meeting Date

Topic Physician Assistants Bill Number 1230 *(if applicable)*

Name Monika Alesnyk Amendment Barcode *(if applicable)*

Job Title Director USF development

Address 4202 E Fowler Phone 8139744837
Street

Tampa FL 33620 E-mail mmarti309@health.usf.edu
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing USF Health

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Physician Assistants

Bill Number SB 1230 *(if applicable)*

Name Corinne Mixon

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 119 E. Park Avenue
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-222-2591

E-mail corinne@mixonandassociates.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Academy of Physician Assistants

Appearing at request of Chair: ☑ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SPB 7124
INTRODUCER:	For Consideration by the Health Policy Committee
SUBJECT:	Program of All-Inclusive Care for the Elderly
DATE:	March 27, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**

I. Summary:

SPB 7124 creates the Program of All-Inclusive Care for the Elderly (PACE) in statute. The bill establishes definitions for the PACE program, authorizes the Department of Elder Affairs (DOEA), in consultation with the Agency for Health Care Administration (AHCA), to contract for services and creates a two-step selection process for providers.

The bill establishes an eligibility confirmation status requirement for both new providers and those in existence as of May 1, 2014. Documentation of compliance with federal requirements, accreditation status, financial stability, fidelity bond, insurance coverage, prior experience and a business plan of operation is required to achieve eligibility confirmation status. Each provider must serve a unique and defined service area without duplication of services or target populations.

The PACE providers will be selected on a regional basis using the regions under s. 409.966, F.S., and no more than one provider can be selected per 3,000 potential eligible enrollees in a region.

Annually, the AHCA and the DOEA will review the list of existing providers, the projected enrollment and costs for existing providers, and the list of entities with a confirmed eligibility status. The AHCA and the DOEA shall develop an annual funding priority list by January 1 for submission to the President of the Senate and the Speaker of the House of Representatives. Besides enrollment and cost projections, the priority funding list must also include recommendations for any discontinuation of providers or policy changes that require statute modifications. The AHCA and DOEA are also directed to take into consideration several factors when developing their recommendations, such as the services being offered, the proposed plan of operation, the outreach plan, the anticipated costs and enrollment and any supplemental benefits.

All PACE providers will be required to meet quality and performance standards developed by the AHCA and DOEA, as well as unique standards mutually developed between the provider and the DOEA.

Enrollment in PACE is voluntary and on a first-come, first served basis. Based on the General Appropriations Act (GAA), the AHCA shall define a cap on the number of PACE slots; however, the number available statewide may not exceed 3 percent of the total enrollees in the long-term care managed care program.

The bill provides for the negotiation of rates between the PACE provider and the AHCA as part of the application and contract renewal process. Capitation rates and enrollment caps are subject to the GAA. Payment rates will reflect historic utilization and case mix of PACE enrollees.

SPB 7124 requires the contract between the PACE provider and the AHCA include a lock-in provision that holds the PACE provider financially responsible for a designated period of time if an enrollee disenrolls and subsequently enrolls or transfers to a nursing home.

Annual capitation rates to a PACE provider may not result in an increase to the capitation rate paid under the Statewide Medicaid Managed Care Program - Long-Term Care (SMMC - LTC) by more than 3 percent over the prior fiscal year, as certified by the AHCA's chief financial officer.

II. Present Situation:

Program of All-Inclusive Care for the Elderly (PACE)

The PACE is a capitated benefit model authorized by the federal Balanced Budget Act of 1997 (BBA), that features a comprehensive service delivery system and integrated federal Medicare and state Medicaid financing. The model, which was tested through Centers for Medicaid and Medicare (CMS) demonstration projects beginning in the mid-1980s,[1] was developed to address the needs of long-term care clients, providers, and payers.

A PACE organization is a not-for-profit, private or public entity that is primarily engaged in providing PACE services and must:

- Have a governing board that includes community representation;
- Be able to provide the complete service package regardless of frequency or duration of services;
- Have a physical site to provide adult day services;
- Have a defined service area;
- Have safeguards against conflicts of interest;
- Have a demonstrated fiscal soundness; and,
- Have a formal participant bill of rights.

The PACE participants must be at least 55 years of age, live in the PACE service area, and be certified eligible for nursing home care, but able to live safely in the community. The PACE program becomes the sole source of services for these Medicare and Medicaid eligible enrollees.

Under the PACE program, an interdisciplinary team consisting of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all services,

[1]CMS Manual *available at* http://www.cms.gov/Medicare/Health-Plans/pace/downloads/r1so.pdf (last visited Mar. 27, 2014)

including acute care and nursing facility services when necessary, which are integrated to provide a seamless delivery model. A PACE program provides social and medical services primarily in an adult day health center, which are supplemented by in-home and referral services as necessary. The PACE service package must include all Medicare and Medicaid covered services, and other services determined necessary by the multidisciplinary team for the care of the PACE participant. The PACE enrollee must accept the PACE center physician as their new Medicare primary care physician, if enrolled in Medicare.[2]

The BBA established the PACE model of care as a permanent entity within the Medicare program and enabled states to provide the PACE services to Medicaid beneficiaries as an optional state plan service without a Medicaid waiver. The state plan must include PACE as an optional Medicaid benefit before the state and the Secretary of the Department of Health and Human Services can enter into program agreements with PACE providers.

The PACE project is a unique federal/state partnership. The federal government establishes the PACE organization requirements and application process. The state Medicaid agency or other state agency is responsible for oversight of the entire application process, which includes reviewing the initial application and providing an on-site readiness review before a PACE organization can be authorized to serve patients. An approved PACE organization must sign a contract with CMS and the state Medicaid agency. Rates for PACE providers are developed based on a county level actuarial analysis of the costs associated with the service population.

Florida PACE Project

The Florida PACE project was initially authorized in ch. 98-327, Laws of Florida, and is codified in s. 430.707(2), F.S., under the administration of the DOEA, operating in consultation with the AHCA.[3] The initial program was located in Miami-Dade County and began serving enrollees in February 2003 with a total of 150 slots. Since then, the Legislature has approved additional slots either as part of the GAA or general law. Currently, active PACE programs exist in 6 Florida counties: Lee, Charlotte, Collier, Miami-Dade, Palm Beach, and Pinellas.

The 2006 GAA contained proviso language authorizing an additional 150 slots in the Miami-Dade County program and 200 slots each at new programs in Martin/St. Lucie Counties, and Lee County.[4] In 2008, the Legislature reallocated equally 150 unused PACE slots to Miami-Dade, Lee, and Pinellas Counties.[5] In 2009, the Legislature authorized 100 slots for a program in Hillsborough County.[6] The 2010 GAA funded an additional 100 slots in Pinellas County and authorized and funded a new program with 100 slots in Hillsborough County.[7] That same year, the Legislature, by general law, authorized an additional 50 slots in Miami-Dade and 150 slots

[2] Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (Jan. 14, 2014), http://ahca.myflorida.com/docs/PACE_Evaluation_2014.pdf (last visited Mar. 27, 2014).
[3] Chapter 2011-135, s. 24, L.O.F, repeals s. 430.707, F.S., effective Oct 1, 2013, as part of the expansion of Medicaid managed care.
[4] Chapter 2006-25, L.O.F.
[5] Chapter 2008-152, L.O.F.
[6] Chapter 2009-55, s. 20, L.O.F.
[7] Chapter 2010-152, L.O.F.

for a program serving Polk, Hardee, Highlands, and Hillsborough Counties.[8] In 2011, the Legislature authorized a program with 150 slots in Palm Beach County,[9] and funded, through the GAA, 50 additional slots in Lee County and 150 slots for a program serving Polk, Hardee, and Highlands Counties.[10] In 2012, the Legislature authorized two new programs of up to 150 slots each for a program in Broward County and a program serving Manatee, Sarasota, and DeSoto Counties.[11] The 2012–2013 GAA funded 100 additional slots in Miami-Dade and 150 additional slots in Lee County.[12]

The Legislature appropriated $30,402,775 for PACE in the 2013-2014 GAA.[13] The appropriation proviso language included specific slot increases in Lee County by 100, in Hillsborough County by 75, in Palm Beach County by 100, and in Broward County by 50. The Governor vetoed the allocations in all counties, except Palm Beach, noting that the state's focus should be on the implementation of the SMMC-LTC and that effectiveness and the need for additional PACE slots should be re-evaluated after that transition is completed.[14]

Slots are authorized by the Legislature for a specific PACE program area; however, those slots may not always be fully funded in the same year as the program is authorized. Some PACE providers need additional time to complete the application process, obtain necessary licensures or to finalize operations.

PACE Organizations and Enrollee Counts[15]

PACE Organization Name	Year Began Operating	County	Current Enrollees Mar-2014	Total Slots Funded
Hope Select Care	2010	Charlotte	37	100
Hope Select Care	2010	Collier	17	50
(No Provider Currently)[16]	2011	Hillsborough	0	150
Hope Select Care	2010	Lee	220	250
Florida PACE	NA	Broward	Vetoed	Vetoed
Florida PACE	2003	Miami-Dade	395	450
Suncoast Neighborly	2012	Pinellas	161	225
Morse PACE	2013	Palm Beach	35	100
TBA	NA	Manatee, Sarasota, DeSoto	0	0
Total Enrollees - Statewide:			865	1,325

[8] Chapter 2010-156, ss. 14 and 15, L.O.F.
[9] Chapter 2011-61, s. 17, L.O.F.
[10] Chapter 2011-69, L.O.F.
[11] Chapter 2012-33, ss.18 and 19, L.O.F.
[12] Chapter 2012-118, L.O.F.
[13] Chapter 2013-40, L.O.F.
[14] Governor Rick Scott, *Veto Message - SB 1500* (May 20, 2013), p.28, http://www.flgov.com/wp-content/uploads/2013/05/Message1.pdf (last visited Mar. 27, 2014).
[15] Agency for Health Care Administration and Department of Elder Affairs, *SPB 7124 - Relating to the Program of All-Inclusive Care for the Elderly (PACE) Bill Analysis and Background Information* (Mar. 28, 2014) on file with the Senate Health Policy Committee.
[16] The Hillsborough PACE provider, Chapters PACE, discontinued services as of August 31, 2013. Enrollees were transitioned to other home or community based setting options.

The 2013 Legislature also directed the AHCA and DOEA to provide a comprehensive report describing PACE's organizational structure, scope of services, utilization, and costs; comparing those findings with similar information for managed long-term care, and evaluating alternative methods for integrating PACE with SMMC-LTC.[17] The report's findings noted a difference in the average age (81.1 years in SMMC versus 75.5 in PACE),[18] prevalence of severe emotional problems (PACE enrollees are more likely to report) and affliction with cognitive impairments such as dementia (higher with SMMC-LTC).[19]

An entity that seeks to become a PACE provider must submit a comprehensive PACE application to the AHCA, which sets forth details about the adult day health care center, staffing, provider network, financial solvency and pro forma financial projections, and policies and procedures, among other elements. The application is similar in detail level to the provider applications submitted by managed care plans seeking to provide medical care to Medicaid recipients. Providers operating in the same geographic region must establish that there is adequate demand for services so that each provider will be viable. The application requires that documentation be submitted demonstrating that neither provider is competing for the same potential enrollees.

The AHCA and the DOEA review the application and, when the entity has satisfied all requirements, conduct an on-site survey of the entity's readiness to serve PACE enrollees. Once all requirements are met, including full licensure of the center, staffing for key positions, and signed provider network contracts, the AHCA certifies to CMS that the PACE site is ready. At that time, CMS reviews the application and readiness certification and, if all requirements are satisfied, executes a three-way agreement with the PACE provider and the AHCA. The PACE provider may then begin enrolling members, subject to an appropriation to fund the slots.

In 2011, the Legislature moved administrative responsibility for the PACE program from DOEA to AHCA as part of the expansion of Medicaid managed care.[20] Participation by PACE is not subject to the procurement requirements or regional plan number limits applicable to the statewide Medicaid Managed Care program. Instead, PACE plans may continue to provide services to individuals at such levels and enrollment caps as authorized by the GAA.[21]

Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid serves approximately 3.3 million people in Florida, with over half of those being children and adolescents 19 years of age or younger. Medicaid is a partnership between the federal and state governments where the federal government establishes the structure for the program and pays a share of the cost. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services or CMS. The plan outlines current Medicaid eligibility standards, policies and reimbursement methodologies.

[17] Chapter 2013-40, L.O.F., line 424.
[18] Department of Elder Affairs, *Supra* note 2 at 20.
[19] *Id* at 19.
[20] Chapter 2011-135, s. 24, L.O.F., repeals Section 430.707, F.S., effective Oct. 1, 2013.
[21] Section 409.981(4), F.S.

In Florida, the program is administered by the AHCA. The AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Agency for Persons with Disabilities (APD), and the DOEA. The AHCA has overall responsibility for the program and qualifies providers, sets payment levels, and pays for services. The DCF is responsible for determining financial eligibility for Medicaid recipients. The APD operates one of the larger waiver programs under Medicaid, the Home and Community Based Waiver program serving individuals with disabilities. The DOEA assesses Medicaid recipients to determine if they require nursing home care. Specifically, the DOEA determines whether an individual:

- Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and requires medically complex care to be performed on a daily basis under the direct supervision of a health professional because of mental or physical incapacitation;
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires care to be performed on a daily basis under the supervision of a health professional because of mental or physical incapacitation; or,
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires limited care to be performed on a daily basis under the supervision of a health professional because of mild mental or physical incapacitation.

Floridians who need nursing home care, but do not qualify for Medicaid, must pay from their own funds or through insurance. According to the 2012 MetLife Market Survey of Nursing Home, Assisted Living, Adult Day Services, and Home Care Costs, the national average cost of a nursing home was $81,030 per year for a semi-private room in 2012.[22] Persons needing nursing home care are determined to be eligible for Medicaid based on financial assets and monthly income.

Long-Term Managed Care

In 2011, the Legislature passed and the Governor signed into law HB 7107[23] to increase the use of managed care in Medicaid. The law requires both long-term care services and Medicaid medical assistance to be provided through managed care plans. The Long-term Care Managed Care component was implemented first. Enrollment began in Region 7 effective August 1, 2013, and concluded with Regions 1, 3, and 4 on March 1, 2014.[24]

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[22] 2012 MetLife Market Survey of Nursing Home, Assisted Living, Adult Day Services, and Home Care Costs, https://www.metlife.com/assets/cao/mmi/publications/highlights/mmi-market-survey-long-term-care-costs-highlights.pdf (last visited Mar. 27, 2014).

[23] Chapter 2011-134, L.O.F.

[24] Agency for Health Care Administration, *Medicaid - Long Term Care Home*, http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#LTCMC (last visited Mar. 27, 2014). Region 1 includes Escambia, Okaloosa, Santa Rosa, and Walton. Region 3 includes Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, and Union. Region 4 includes Baker, Clay, Duval, Flagler, Nassau, St. Johns, and Volusia. Region 7 includes Brevard, Orange, Osceola and Seminole.

The AHCA procured the long-term managed care plans through a competitive bid process. The AHCA considered many factors when selecting plans. The AHCA chose a certain number of long-term care managed care plans for each region to ensure that recipients have a choice between plans. PACE organizations were eligible to bid to become comprehensive long-term care program plans, but no PACE organizations elected to bid.[25] However, pursuant to s. 409.981, F.S., PACE plans are authorized to continue to provide services to individuals as authorized annually in the General Appropriations Act through a contract with the AHCA. Following the procurement process, seven different contracts were awarded and each region has at least two SMMC-LTC plans.

Participating managed care plans are required to provide minimum benefits that include nursing home as well as home and community based services. Plans were free to customize and offer additional services. The minimum benefits include:

- Nursing home
- Services provided in assisted living facilities
- Hospice
- Adult day care
- Medical equipment and supplies, including incontinence supplies
- Personal care
- Home accessibility adaptation
- Behavior management
- Home delivered meals
- Case management
- Therapies: physical, respiratory, speech, and occupational
- Intermittent and skilled nursing
- Medication administration
- Medication management
- Nutritional assessment and risk reduction
- Caregiver training
- Respite care
- Transportation
- Personal emergency response system

On February 1, 2013, the Federal Centers for Medicare and Medicaid Services, approved AHCA's request for a Home and Community Based Care Services waiver for individuals 65 and older and individuals with physical disabilities ages 18 through 64 years of age. This approval allows Florida to implement managed care for long-term care services under Medicaid.

III. Effect of Proposed Changes:

Section 1 creates s. 430.84, F.S., and establishes, in statute, the Program of All-Inclusive Care for the Elderly (PACE). Currently, the program does not have a specific implementing statute and has been operationalized through annual appropriations, proviso and implementing bill language. The bill creates the following definitions for the PACE program:

[25] Department of Elder Affairs, *See Supra* note 2, at 7.

- Agency;
- Applicant;
- Department;
- Eligible entity;
- Enrollee; and
- Provider.

The DOEA is authorized to contract, in consultation with the AHCA, with entities that have submitted applications to provide benefits pursuant to PACE under 42 U.S.C. s. 1395eee and that have met specific requirements. Provider selection is to be conducted through a two-step process developed by the AHCA and the DOEA for both new and existing PACE sites. A PACE provider is exempt from the requirements of chapter 641, requirements relating to health maintenance organizations, prepaid health clinics, and prepaid provider service networks.

Applications will be reviewed by the AHCA on an ongoing basis, in consultation with the DOEA. To be considered for funding, an applicant must receive an eligibility confirmation status and be placed on the annual funding priority list by the AHCA, in consultation with the DOEA. For PACE providers in existence as of May 1, 2014, the agency must document the provider's continued eligibility confirmation status in the provider's contract file by the provider's next contract renewal date, but no later than January 1, 2015.

The minimum components for an eligibility confirmation status are documentation by the applicant of the following:

- Ability to meet all federal requirements for participation as a PACE provider by the proposed implementation date;
- Confirmation of accreditation status or ability to attain the status within 1 year of the proposed implementation date;
- Evidence of financial stability, including insurance at a level determined by the AHCA or evidence that such level will be attained before the proposed implementation date;
- Evidence of a fidelity bond in the PACE provider's own name and in the name of its officers and employees in an amount to be established by the AHCA and the DOEA, or ability to acquire such coverage before the proposed implementation date;
- At least 20 years' prior experience in providing similar services to the frail elderly population; and
- Evidence of a business plan of operation, including pro forma financial statements and projections, based on the proposed implementation date.

If applications are received from more than one entity, the AHCA may notify the applicants and request that the parties collaborate on a single application if the region cannot support more than one PACE provider. Each provider must serve a unique and defined area without duplication of services or target population.

The AHCA will notify an applicant of their status and may request additional information for updates or to support its annual report. Providers will be selected based on the 11 regions under s. 409.966, F.S., and no more than one PACE provider per 3,000 eligible enrollees will be selected in a particular region.

The AHCA and DOEA must review the list of providers annually along with the projected enrollment and costs of existing providers and the list of entities with confirmed statuses seeking implementation. To remain on the priority funding list, a provider must continuously maintain its status. The AHCA and DOEA shall develop recommendations for the President of the Senate and Speaker of the House of Representatives no later than January 1 each year. The report must include, at a minimum, the following:

- Existing providers recommended for continuation;
- The estimated or proposed capitation rates and enrollment by existing provider for the next state fiscal year, including recommendations for discontinuation of any providers;
- A priority funding list for implementation of any new providers which includes, in priority order, all eligible entities with the estimated or proposed capitation rates and enrollment for each site; and
- Any recommended policy changes that require statutory modifications;

In developing the recommendations, the AHCA and DOEA are directed to take into consideration the following factors:

- The services being offered or proposed to be offered to the frail elderly population;
- The proposed plan of operation for implementation or continuation of services;
- An outreach plan to potentially eligible enrollees;
- The anticipated costs and enrollment projections; and,
- Any supplemental benefits offered to enrollees.

Every PACE provider will be required to meet specific quality and performance standards established by the DOEA. Each site will be monitored and additional quality standards unique to each site will be mutually developed.

The provisions of ss. 409.967 and 409.983, F.S., relating to Medicaid managed care accountability and long-term care plan payment are applicable to the PACE program, except to the extent that subsections (3) on the unique PACE selection process, (6) on the voluntary PACE plan enrollment process, and (7) on the PACE plan payment process have modified those requirements.

Enrollment in PACE is voluntary and will be based on a first-come, first-served basis until any enrollment cap is reached. The AHCA shall define any cap on PACE slots; however, the statewide cap shall not exceed 3 percent of the total number of enrollees in the SMMC-LTC program.

The PACE plan payments shall be negotiated between the provider and the AHCA as part of the negotiation and contract renewal process. Rates will be re-negotiated each year. Both capitation rates and enrollment caps are subject to the GAA. Payment rates must reflect historic utilization and spending for covered services and be adjusted based on the case mix of enrollees in each plan.

The contract between the AHCA and the PACE provider must include a lock-in provision that holds the provider financially responsible for a designated period of time for any PACE enrollee

that disenrolls and transfers to nursing home care within 6 months of disenrollment. The terms of the lock-in provision are to be negotiated between the AHCA and each provider.

Annual capitation rates paid under PACE may not result in a corresponding increase of more than 3 percent over the prior fiscal year in the SMMC-LTC program, as certified by the AHCA's chief financial officer.

Section 2 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Subject to the availability of funds and slots, additional private sector providers that meet the criteria to be a PACE provider and achieve eligibility confirmation status could be approved as a PACE site. Expansion of PACE sites would also mean additional individuals in the community would have access to these services.

C. Government Sector Impact:

The potential expansion of the PACE program may result in an increased workload for the AHCA and the DOEA. The bill requires both entities to review applications, monitor performance and make annual recommendations to the Legislature.

The AHCA estimates that at least one additional FTE would be required to manage the new contracts with the PACE providers. The FTE requested by the AHCA has a fiscal impact, for salary only, of $40,948.18.

VI. Technical Deficiencies:

The bill references a contract with the PACE provider in several provisions but varies with whom the contract is with, either the AHCA or the DOEA. On Lines 41-42, the provision references a contract between the DOEA and the eligible entities, but on Line 151, the reference is to a contract between the AHCA and the provider. The bill should be consistent and since the AHCA is the lead agency for Medicaid and the SMMC-LTC, the contracting entity should be the AHCA.

VII. Related Issues:

The bill extends and potentially expands an existing long-term care services program separate from the SMMC-LTC program in an environment where the Legislature has sought to combine similar programs and eliminate waivers and carve outs. The SMMC-LTC program is expected to have an enrollment of over 90,000 once fully implemented while the PACE program currently has less than 800 enrollees statewide.

VIII. Statutes Affected:

This bill creates the following section of the Florida Statutes: 430.54.

IX. Additional Information:

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

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: FAV	.	
04/02/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 41 - 42
and insert:
(2) PROGRAM CREATION.—The agency, in consultation with the department, may contract with entities that have submitted an

Delete lines 129 - 130
and insert:
(4) ACCOUNTABILITY.—All PACE providers must meet specific quality and performance standards established by the agency, in

646564

consultation with the department,

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

And the title is amended as follows:

Delete lines 4 - 6

and insert:

terms; authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to contract with specified entities to

FOR CONSIDERATION By the Committee on Health Policy

588-03128A-14 20147124__

A bill to be entitled

An act relating to the Program of All-Inclusive Care for the Elderly; creating s. 430.84, F.S.; defining terms; authorizing the Department of Elderly Affairs, in consultation with the Agency for Health Care Administration, to contract with specified entities to provide benefits pursuant to the Program of All-Inclusive Care for the Elderly (PACE); establishing a selection process for PACE providers; requiring an annual review by the department and the agency and the development of legislative recommendations; providing requirements for such review and recommendations; providing for accountability for PACE providers; providing applicability; providing that enrollment in PACE is voluntary; establishing PACE plan payments and financial responsibility requirements; providing an effective date.

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

Section 1. Section 430.84, Florida Statutes, is created to read:

430.84 Program of All-Inclusive Care for the Elderly.—

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Applicant" means an entity that has filed an application with the agency for consideration as a Program of All-Inclusive Care for the Elderly (PACE) provider.

588-03128A-14 20147124__

(c) "Department" means the Department of Elderly Affairs.

(d) "Eligible entity" means a not-for-profit organization that is a PACE provider as of May 1, 2014, or an entity licensed as a nursing home diversion program provider or a not-for-profit hospice provider which meets the requirements for participation established by this section and the agency.

(e) "Enrollee" means an individual receiving services from a PACE provider who is eligible under the Medicaid long-term managed care program or another health care services program.

(f) "Provider" means an eligible entity under contract with the department to deliver PACE services.

(2) PROGRAM CREATION.—The department, in consultation with the agency, may contract with entities that have submitted an application to provide benefits pursuant to PACE as established in 42 U.S.C. s. 1395eee in accordance with the requirements of this section.

(3) PROVIDER SELECTION.—Provider eligibility and enrollment for PACE shall be conducted through a two-step process developed by the agency and the department consistent with the requirements of this section for new and existing sites. A PACE provider is exempt from the requirements of chapter 641.

(a) *Eligibility confirmation status.*—Applications for eligibility confirmation status shall be considered on an ongoing basis by the agency, in consultation with the department. To be considered for funding as a PACE site, an eligible entity must receive an eligibility confirmation status and be placed on the annual funding priority list by the agency, in consultation with the department. For providers in existence as of May 1, 2014, the agency shall document the provider's

continued eligibility confirmation status in the provider's contract by the provider's next contract renewal date, but no later than January 1, 2015.

1. To receive eligibility confirmation status, an applicant or eligible entity must document to the agency all of the following minimum components:

a. Ability to meet all federal requirements for participation as a PACE provider by the proposed implementation date;

b. Confirmation of accreditation status or ability to attain status within 1 year of the proposed implementation date;

c. Documentation of financial stability, including evidence of insurance at a level determined by the agency or evidence that such level will be attained before the proposed implementation date;

d. Evidence of a fidelity bond in its own name and in the names of its officers and employees in an amount established by the agency and department, or documentation of ability to acquire such coverage before the proposed implementation date;

e. At least 20 years' prior experience in providing similar services to the frail elderly population; and

f. Documentation of a business plan of operation, including pro forma financial statements and projections, based on the proposed implementation date.

2. If applications are received from more than one entity within a region as described in s. 409.966, the agency may notify the applicants and request that they collaborate on a single application if the region cannot support more than one provider. Each provider must serve a unique and defined area

without duplication of services or target populations.

3. Upon approval of documentation, the agency shall provide notification of the entity's confirmed status. The agency may request additional or updated data to support its annual report and to develop its funding priorities.

(b) *Selection process.*—The selection of PACE providers shall be based on the regions described in s. 409.966, and no more than one PACE provider shall be selected per 3,000 estimated eligible enrollees in a particular region.

(c) *Annual review.*—

1. The agency and department shall review annually the list of existing providers, the projected enrollment and costs for existing providers, and the list of entities with a confirmed eligibility status. For ongoing placement on the agency's priority funding list or recommended continuation list, an applicant or eligible entity must maintain its eligibility confirmation status. The agency and department shall develop and provide recommendations for the President of the Senate and the Speaker of the House of Representatives no later than January 1 each year which include, at a minimum, the following:

a. The providers recommended for continuation for the next state fiscal year;

b. For existing providers, the estimated or proposed capitation rates and enrollment by provider for the next state fiscal year, including any recommendations for the discontinuation of any providers;

c. A priority funding list for implementation of new providers which includes, in priority order, all eligible entities with the estimated or proposed capitation rates and

enrollment for each entity; and

d. The recommended policy changes to the program which require statutory modifications.

2. In developing the recommendations, the agency and department shall consider the following factors:

a. The services being offered or proposed to be offered to the frail elderly population by the provider;

b. The proposed plan of operation for implementation or continuation of PACE services;

c. An outreach plan to potentially eligible enrollees;

d. The anticipated costs and enrollment projections; and

e. Any supplemental benefits offered to enrollees.

(4) ACCOUNTABILITY.—All PACE providers must meet specific quality and performance standards established by the department for PACE. The department shall monitor each PACE site individually and shall mutually develop with each provider additional quality and performance standards.

(5) APPLICABILITY OF LAWS RELATING TO MEDICAID.—Except as modified by subsections (3), (6), and (7), ss. 409.967 and 409.983 apply to the administration of PACE.

(6) ENROLLMENT.—Enrollment in PACE is voluntary and shall be on a first-come, first-served basis until the enrollment cap for a provider or region is reached. The agency shall define a cap on the number of PACE slots; however, the number of slots available statewide may not exceed 3 percent of the total number of enrollees in the long-term managed care program.

(7) PLAN PAYMENTS.—Prepaid payment rates shall be negotiated between the PACE provider and the agency as part of the application and contract renewal process and shall be

renegotiated each year. Capitation rates and enrollment caps are subject to the General Appropriations Act.

(a) Payment rates must reflect historic utilization and spending for covered services projected forward and adjusted to reflect the level of care profile for enrollees in each plan.

(b) The contract between the agency and provider must include a lock-in provision that holds the provider financially responsible for a designated period of time for any enrollee who disenrolls from PACE and subsequently enrolls or transfers to nursing home care within the first 6 months after disenrollment.

(c) Annual capitation rates to providers under PACE may not result in an increase to the capitation rate paid under s. 409.983 to long-term care managed care plans by more than 3 percent over the prior fiscal year, as certified by the agency's chief financial officer.

Section 2. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic PACE Program

Bill Number SPB 7124 *(if applicable)*

Name Cliff Bauer

Amendment Barcode *(if applicable)*

Job Title Sr VP - COO

Address 5200 NE 2nd
Street
Miami
City *State* *Zip*

Phone 305-762-1386

E-mail cbauer

Speaking: ☐ For ☒ Against ☐ Information

Representing Fl. Pace Centers Inc. / Miami Jewish Health System In

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic PACE

Bill Number 7124 *(if applicable)*

Name Stephanie Sessions RN

Amendment Barcode _____ *(if applicable)*

Job Title Executive Director

Address 485 Hickorynut Ave
Street
Oldsmar FL 34677
City *State* *Zip*

Phone 727-773-7184

E-mail StephanieSessions@Suncoastpace.org

Speaking: ☐ For ☒ Against ☐ Information

Representing Suncoast PACE

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Senate Bill 7124 / PACE Bill Number 7124 *(if applicable)*

Name Samira K. Beckwith Amendment Barcode *(if applicable)*

Job Title President / Hope PACE / and Florida PACE Association

Address 9470 HealthPark Circle Phone 239.489.9
Street

Ft. Myers, FL. 33908 E-mail Samira.Beckwith@hopehcs.org
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing

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

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic All-Inclusive Care for the Elderly

Bill Number SPB 7124 *(if applicable)*

Name Richard Polanglh

Amendment Barcode _____ *(if applicable)*

Job Title Director of Government Affairs

Address 1300 N Duval St

Phone 850 224-4206

Street Tallahassee FL 32303

E-mail richardpolangin@hotmail.com

City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Alliance for Retired Americans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1700
INTRODUCER:	Senator Bean
SUBJECT:	Public Records/Personal Identifying Information/Compassionate Use Registry
DATE:	March 27, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.			GO	
3.			RC	

I. Summary:

SB 1700 makes patient and physician personal identifying information held by the Department of Health (DOH) in the compassionate use registry[1] (registry) confidential and exempt from the public records requirements of section 119.07(1), F.S., and article I, section 24(a) of the Florida Constitution. The bill allows law enforcement agencies, low-THC marijuana dispensing organizations, physicians, the DOH's relevant health care regulatory boards, and persons engaged in bona fide research to access the information in the registry under certain circumstances. The bill also requires that such confidential information remain confidential once released from the registry and provides penalties for violating the provisions of the exemption.

Since this bill creates a new public records exemption, a two-thirds vote of the members present and voting in each house of the Legislature is required for its passage.[2]

II. Present Situation:

Public Records Laws

The Florida Constitution provides every person the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or of persons acting on their behalf.[3] The records of the legislative, executive, and judicial branches are specifically included.[4]

[1] That will be established under s. 456.60, F.S., if SB 1030 passes.
[2] FLA. CONST., art. I, s. 24(c).
[3] FLA. CONST., art. I, s. 24(a).
[4] *Id*.

The Florida Statutes also specify conditions under which public access must be provided to government records. The Public Records Act[5] guarantees every person's right to inspect and copy any state or local government public record[6] at any reasonable time, under reasonable conditions, and under supervision by the custodian of the public record.[7]

Only the Legislature may create an exemption to public records requirements.[8] Such an exemption must be created by general law and must specifically state the public necessity justifying the exemption.[9] Further, the exemption must be no broader than necessary to accomplish the stated purpose of the law. A bill enacting an exemption may not contain other substantive provisions[10] and must pass by a two-thirds vote of the members present and voting in each house of the Legislature.[11]

The Open Government Sunset Review Act (the Act) prescribes a legislative review process for newly created or substantially amended public records or open meetings exemptions.[12] It requires the automatic repeal of such exemption on October 2 of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.[13] The Act provides that a public records or open meetings exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary to meet such public purpose.[14]

The Compassionate Use Registry

SB 1030, if passed, will require the DOH to create a compassionate use registry that will be a secure, electronic, and online registry of physicians and patients who order and use low-THC

[5] Chapter 119, F.S.
[6] Section 119.011(12), F.S., defines "public records" 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." Section 119.011(2), F.S., defines "agency" to mean as "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 this chapter, 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." The Public Records Act does not apply to legislative or judicial records (*see Locke v. Hawkes*, 595 So.2d 32 (Fla. 1992)).
[7] Section 119.07(1)(a), F.S.
[8] 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 (s*ee WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48 (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 2004); and *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 the statutory exemption (*see* Attorney General Opinion 85-62, August 1, 1985).
[9] FLA. CONST., art. I, s. 24(c).
[10] The bill may, however, contain multiple exemptions that relate to one subject.
[11] FLA. CONST., art. I, s. 24(c).
[12] Section 119.15, F.S. An exemption is substantially amended if the amendment expands the scope of the exemption to include more records or information or to include meetings as well as records (s. 119.15(4)(b), F.S.). The requirements of the Act do not apply to an exemption that is required by federal law or that applies solely to the Legislature or the State Court System (s. 119.15(2), F.S.).
[13] Section 119.15(3), F.S.
[14] Section 119.15(6)(b), F.S.

marijuana. The registry must be able to be accessed by law enforcement and the dispensing organization in order to verify patient orders. Also, dispensing organizations must be able to record the low-THC marijuana dispensed and the registry must prevent an active registration of a patient by multiple physicians.

III. Effect of Proposed Changes:

Section 1 of the bill creates s. 456.61, F.S., to make confidential and exempt from the public records requirements of s. 119.07(1), F.S., and article I, section 24(a) of the Florida Constitution any patient and physician personal identifying information in the compassionate use registry. The bill specifically excludes a registered patient's and physician's name, address, telephone number, government issued identification number; the physician's Drug Enforcement Administration (DEA) number; and all information pertaining to the physician's order for low-THC marijuana.

Access to the registry, including excluded information, is allowed for:

- A law enforcement agency that is investigating a violation of law regarding cannabis in which the subject of the investigation claims an exception established under s. 456.60, F.S.;
- A dispensing organization approved by the DOH under s. 456.60, F.S., which is attempting to verify the authenticity of a physician's order for low-THC marijuana;
- A physician, for his or her patient only:
  - Before issuing an order for low-THC marijuana, for the purpose of determining whether another physician has ordered that patient low-THC marijuana; and
  - After issuing an order for low-THC marijuana, to monitor the patient's use of the marijuana.
- The DOH for the purpose of maintaining the registry and periodic reporting or disclosure of information that has been redacted so as not to include personal identifying information.
- The DOH's relevant health care regulatory boards when specifically investigating a physician for a violation of s. 456.60, F.S. If the board uncovers criminal activity, the board may provide relevant information to the appropriate law enforcement agency; and
- Persons engaged in bona fide research who agree to:
  - Submit a research plan to the department;
  - Maintain the confidentiality of the information;
  - Destroy confidential information when the research is concluded; and
  - Not to contact a patient or physician whose information is in the registry.

The bill states that all information that is released from the registry remains confidential and exempt and requires any person receiving information from the registry to maintain the confidentiality of that information. Any person who willingly and knowingly violates the provision of the exemption commits a third degree felony.

The bill also provides for the automatic repeal of the exemption on October 2, 2019, unless reenacted by the Legislature.

Section 2 of the bill provides legislative findings. The bill states that the Legislature finds it is a public necessity to protect the information in the compassionate use registry in order to protect the privacy of patients who choose to use low-THC marijuana and physicians who choose to

order it. The Legislature finds that the public availability of the registry information could make the public aware of a patient's medical diseases or conditions and may also open patients and physicians up to discrimination for their use or ordering of low-THC marijuana.

Section 3 of the bill establishes an effective date that is the same as the effective date of SB 1030 or similar legislation passed in the same legislative session. The bill only takes effect if SB 1030, or similar legislation, is passed and becomes law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

Vote Requirement
Article I, section 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. As such, this bill requires a two-thirds vote for passage.

Public Necessity Statement
Article I, section 24(c) of the Florida Constitution requires a public necessity statement for a newly-created or expanded public records or public meetings exemption. As such, this bill includes a public necessity statement.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 456.61 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Bean

4-02537B-14 20141700__

A bill to be entitled

An act relating to public records; creating s. 456.61, F.S.; exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry; exempting information related to ordering and dispensing low-THC marijuana; authorizing specified persons and entities access to the exempt information; requiring that information released from the registry remain confidential; providing a criminal penalty; providing for future legislative review and repeal; providing a statement of public necessity; providing a contingent effective date.

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

Section 1. Section 456.61, Florida Statutes, is created to read:

456.61 Public records exemption for personal identifying information in the compassionate use registry.—

(1) A patient's personal identifying information held by the department in the compassionate use registry established under s. 456.60, including, but not limited to, the patient's name, address, telephone number, and government-issued identification number, and all information pertaining to the physician's order for low-THC marijuana and the dispensing thereof are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

4-02537B-14 20141700__

(2) A physician's identifying information held by the department in the compassionate use registry established under s. 456.60, including, but not limited to, the physician's name, address, telephone number, government-issued identification number, and Drug Enforcement Administration number, and all information pertaining to the physician's order for low-THC marijuana and the dispensing thereof are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(3) The department shall allow access to the registry, including access to confidential and exempt information, to:

(a) A law enforcement agency that is investigating a violation of law regarding cannabis in which the subject of the investigation claims an exception established under s. 456.60.

(b) A dispensing organization approved by the department pursuant to s. 456.60(3)(b) which is attempting to verify the authenticity of a physician's order for low-THC marijuana, including whether the order had been previously filled and whether the order was written for the person attempting to have it filled.

(c) A physician who has written an order for low-THC marijuana for the purpose of monitoring the patient's use of such marijuana or for the purpose of determining, before issuing an order for low-THC marijuana, whether another physician has ordered the patient's use of low-THC marijuana. The physician may access the confidential and exempt information only for the patient for whom he or she has ordered or is determining whether to order the use of low-THC marijuana pursuant to s. 456.60.

(d) An employee of the department for the purposes of

maintaining the registry and periodic reporting or disclosure of information that has been redacted to exclude personal identifying information.

(e) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a physician if he or she is involved in a specific investigation of a violation of s. 456.60. If a health care regulatory board's investigation reveals potential criminal activity, the board may provide any relevant information to the appropriate law enforcement agency.

(f) A person engaged in bona fide research if the person agrees:

1. To submit a research plan to the department which specifies the exact nature of the information requested and the intended use of the information;

2. To maintain the confidentiality of the records or information if personal identifying information is made available to the researcher;

3. To destroy any confidential records or information obtained after the research is concluded; and

4. Not to contact, directly or indirectly, for any purpose, a patient or physician whose information is in the registry.

(4) All information released from the registry under subsection (3) remains confidential and exempt, and a person who receives access to such information must maintain the confidential status of the information received.

(5) A person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that identifying information of patients and physicians held by the Department of Health in the compassionate use registry established under s. 456.60, Florida Statutes, be made confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. Specifically, the Legislature finds that it is a public necessity to make confidential and exempt from public records requirements the names, addresses, telephone numbers, and government-issued identification numbers of patients and physicians and any other information on or pertaining to a physician's order for low-THC marijuana written pursuant to s. 456.60, Florida Statutes, which are held in the registry. The choice made by a physician and his or her patient to use low-THC marijuana to treat that patient's medical condition or symptoms is a personal and private matter between those two parties. The availability of such information to the public could make the public aware of both the patient's use of low-THC marijuana and the patient's diseases or other medical conditions for which the patient is using low-THC marijuana. The knowledge of the patient's use of low-THC marijuana, the knowledge that the physician ordered the use of low-THC marijuana, and the knowledge of the patient's medical condition could be used to embarrass, humiliate, harass, or discriminate against the patient and the physician. This information could be used as a

discriminatory tool by an employer who disapproves of the patient's use of low-THC marijuana or of the physician's ordering such use. However, despite the potential hazards of collecting such information, maintaining the compassionate use registry established under s. 456.60, Florida Statutes, is necessary to prevent the diversion and nonmedical use of any low-THC marijuana as well as to aid and improve research done on the efficacy of low-THC marijuana. Thus, the Legislature finds that it is a public necessity to make confidential and exempt from public records requirements the identifying information of patients and physicians held by the Department of Health in the compassionate use registry established under s. 456.60, Florida Statutes.

Section 3. This act shall take effect on the same date that SB 1030, or similar legislation establishing an electronic system to record a physician's orders for, and a patient's use of, low-THC marijuana takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Compassionate Registry

Bill Number SB 1700 *(if applicable)*

Name Jodi James

Amendment Barcode *(if applicable)*

Job Title Executive Director

Address 375 Cypress Ave *Street*

Phone 321 890 7302 (C) 321 253 3673

Melbourne FL 32935 *City* *State* *Zip*

E-mail JJamesFlorida@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Cannabis Action Network

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/CS/SB 836
INTRODUCER:	Health Policy Committee; Regulated Industries Committee; and Senator Bean
SUBJECT:	Medical Gas
DATE:	April 1, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Niles	Imhof	RI	**Fav/CS**
2.	Looke	Stovall	HP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 836 removes the regulation of medical gas from part I of the "Florida Drug and Cosmetic Act," and creates a new part III of chapter 499, F.S., consisting of sections 499.81 - 499.94, F.S., entitled "Medical gas."

The bill provides permit application procedures and permit requirements for medical gas wholesale distributors, medical gas manufacturers, and medical oxygen retail establishments. The bill grants the Department of Business and Professional Regulation (department), the authority to adopt rules and take the full breadth of regulatory actions regarding the new part III.

The bill requires specific storage and security procedures related to medical gas. The bill requires permitted distributors of medical gas to examine medical gas containers, act in due diligence, establish and maintain records regarding receipt and distribution of medical gas, and to establish specific policies and procedures to deal with normal business activity as well as emergency and theft situations. The bill also lays out prohibited and criminal acts in relation to medical gas and enforcement regarding these acts and this part.

II. Present Situation:

Currently, ch. 499, F.S., consists of two parts that cover drug, cosmetic, and household products and ether. Medical gas is covered in the first part under drug, cosmetic and household products of the "Florida Drug and Cosmetic Act," found in ss. 499.001 - 499.079, F.S.

Definitions

Section 499.003(11), F.S., defines "compressed medical gas" as any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

Section 499.003(46), F.S., defines "prescription medical oxygen" as oxygen USP[1] which is a drug that can only be sold by the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

Section 499.003(55), F.S., defines a "wholesale distributor" as any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 409.9201(1), F.S., describes medical fraud with s. 409.9201(1)(a), F.S., defining "prescription drug" as any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described in the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(46) or (53) or s. 499.007(13), F.S.

Permits

Section 499.01, F.S., lists the entities that require permits under the Florida Drug and Cosmetics Act and describes them in detail. These permitted entities include medical oxygen retail establishments, compressed medical gas wholesale distributors, and compressed medical gas manufacturers, among others.

A compressed medical gas wholesale distributor is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient.[2] A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.[3] A medical gas retail establishment permit is required for any person who sells medical oxygen to patients only.[4] Permit holders are overseen by the department under the Division of Drugs, Devices and Cosmetics.

[1] The United States Pharmacopoeia (USP) is a list of drugs licensed for use in the U.S. with standards necessary to determine purity suitable for persons.
[2]Florida Department of Business and Professional Regulation, *Compressed Medical Gas Wholesale Distributor*, www.myfloridalicense.com/department/ddc/CompressedMedicalGasesWholesaleDistributor.html (Last visited Mar. 21, 2014).
[3] Florida Department of Business and Professional Regulation, *Compressed Medical Gas Manufacturer*, www.myfloridalicense.com/department/ddc/CompressedMedicalGasesManufacturer.html (Last visited Mar. 21, 2014).
[4] Florida Department of Business and Professional Regulation, *Medical Oxygen Retail Establishment*, http://www.myfloridalicense.com/department/ddc/MedicalOxygenRetail.html (Last visited Mar. 21, 2014).

Drug Wholesale Distributor Advisory Council

Section 499.01211, F.S., creates the Drug Wholesale Distributor Advisory Council (council). The council meets each calendar quarter to review part I of ch. 499, F.S., and the rules adopted to administer that part, to annually provide input to the department, and to make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health. The council consists of 11 members including the Secretary of the Department of Business and Professional Regulation, or his or her designee, and the Secretary of the Agency for Health Care Administration, or his or her designee. The remaining nine members are appointed by the Secretary of the Department of Business and Professional Regulation to a term of 4 years each, as follows:

- Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47), F.S.;
- One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52), F.S.;
- One person employed by a retail pharmacy chain located in this state;
- One person who is a member of the Board of Pharmacy and is a pharmacist licensed under ch. 465, F.S.;
- One person who is a physician licensed under ch. 458, F.S., or ch. 459, F.S.;
- One person who is an employee of a hospital licensed under ch.395, F.S., and is a pharmacist licensed under ch.465, F.S.; and,
- One person who is an employee of a pharmaceutical manufacturer.

Compressed Gas Association

The Compressed Gas Association (association) has been dedicated to the development and promotion of safety standards and safe practices in the industrial gas industry since 1913.[5] Their mission is to promote safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers.[6] Their activities include the manufacture, transportation, storage, transfilling, and disposal of compressed gas and the containers and valves which hold the compressed gases. Their scope includes related apparatus if such apparatus is necessary for the safe dispensing or delivery of the gases in a commercial, industrial, research, or medical application along with providing safety information or warnings about the chemical or physical properties of gases and their containers.[7] The association defines industrial and medical gases as liquefied, nonliquefied, dissolved, or cryogenic gases.[8]

III. Effect of Proposed Changes:

The bill creates part III of ch. 499, F.S., entitled "Medical Gas," ss. 499.81-499.94, F.S. The regulation of medical gases is separated from the regulation of other types of prescription drugs

[5] Compressed Gas Association, *About Us*, http://www.cganet.com/about.php (Last visited April 2, 2014).
[6] Compressed Gas Association, *CGA Mission*, http://www.cganet.com/mission.php (last visited April 2, 2014).
[7] *Id.*
[8] *Id*.

in order to reduce the regulatory impact while more specifically regulating activities related to medical gases.

Definitions

The bill deletes s. 499.003(11), F.S., defining "compressed medical gas," and s. 499.003(46), F.S., defining "prescription medical oxygen." The bill adds a new definition to s. 499.003(32), F.S., for "medical gas," which is defined "in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases." The bill creates a number of new definitions related to medical gas in s. 499.82, F.S.[9] The bill deletes cross-references to the old sections and adds the new section throughout the bill where necessary.

Permits

The bill deletes medical oxygen retail establishment, compressed medical gas wholesale distributor, and compressed medical gas manufacturer as entities requiring permits under s. 499.01(1), F.S. The bill reestablishes these permits as wholesale distributor, manufacturer, and medical oxygen retail establishment permits in s. 499.83, F.S. A person or entity intending to distribute medical gas within or into this state must obtain the applicable permit before operating.

A *medical gas wholesale distributor permit* is required for wholesale distribution within or into Florida. The permit:

- Does not authorize distribution to a consumer or patient;
- Requires medical gas to be in the same container as obtained with no further manufacturing operations performed, unless the wholesale distributor is also permitted as a manufacturer; and,
- Prohibits a distributor from possessing or engaging in the wholesale distribution of other prescription drugs unless otherwise authorized under ch. 499, F.S.

The bill also establishes requirements for wholesale distributors including:

- Wholesale distributors may not operate from a residence, except for the on-call delivery of home care oxygen if the wholesale distributor also maintains a medical oxygen retail establishment permit;
- Each separate location must be permitted individually; and,
- Out-of-state wholesale distributors must be legally authorized to operate as a wholesale distributor in their state of residence to provide services in Florida.

A *medical gas manufacturer permit* is required for a person manufacturing[10] medical gas and distributing such medical gas within this state. A medical gas manufacturer:

[9] Section 499.81, F.S., defines the terms "adulterated," "department," "distribute" or "distribution," "emergency medical reasons," "emergency use oxygen," "federal act," "medical gas," "medical gas-related equipment," "misbranded," "medical oxygen," "product labeling," "USP," "USP-NF," "wholesale distribution," and "wholesale distributor." Some of the definitions duplicate those in s. 499.003, F.S.

[10] Manufacturing can be done by physical air separation, chemical action, purification, or filling containers using a liquid-to-liquid, liquid-to-gas, or gas-to-gas process.

- May not manufacture or possess another prescription drug unless otherwise authorized under ch. 499, F.S.;
- May engage in the wholesale distribution of medical gas it manufactured without obtaining a wholesale distributor permit if it complies with the requirements of the part and applicable rules; and,
- Must comply with all the requirements of a wholesale distributor and any appropriate good manufacturing practices.

A *medical oxygen retail establishment permit* is required for a person, except a pharmacy under ch. 465, F.S., who dispenses medical oxygen directly to patients. Sales and delivery must be based upon an order or prescription. A medical oxygen retail establishment:

- May not possess, purchase, sell, or trade a prescription drug other than medical oxygen unless otherwise authorized by ch. 499, F.S.;
- May not receive back into its inventory any prescription medical oxygen sold pursuant to a licensed practitioner's order;
- May fill and deliver medical oxygen to an individual based on an authorized order or prescription, and shall comply with all appropriate good manufacturing practices if doing so; and
- Must comply with all of the requirements in the part that are applicable to a wholesale distributor except for the requirements specifically related to nitrous oxide.

The bill creates s. 499.831, F.S., requiring the department to adopt rules to establish the form and content of medical gas permit applications and describing the application requirements and fees[11] for permits listed in s. 499.83, F.S. Section 499.832, F.S., provides that permits expire after 2 years, establishes renewal procedures, and requires the department to adopt rules and a reasonable fee for renewal.[12]

The bill creates s. 499.833, F.S., restricting permit use to the person or entity granted but allowing specific changes to be made upon approval of the department. The bill grants the department authority to approve:

- *A change of location*. The department must approve the change before the permit holder effectuates the change and the department may charge a change of location fee of up to $100;
- *A change in ownership*. The department must approve the change of ownership before the permitted entity changes owners. An exception is made if the new owner has held a permit that allows the wholesale distribution of medical gas for the preceding 18 months without any violations. In such a case the new owner must notify the department no later than one business day after the change in ownership.

Permit holders who are changing the permitted entity's name or closing must notify the department before the change in the status of the permit takes place. If a permit holder is closing he or she must also provide the department with an indication of the disposition of any medical

[11] The fee for initial and renewal permits are removed from s. 499.041, F.S., and added to s. 499.831(5), F.S. The fees may be between $200 and $300 annually for medical gas wholesale distributors and medical oxygen retail establishments between $400 and $500 annually for medical gas manufacturers. Fees collected will be deposited in the Professional Regulation Trust Fund and be used to administer the part.
[12] *Id*.

gas that was authorized to be distributed or dispensed under the permit. The department must also be notified of any other unspecified changes affecting the permit within 30 days after such a change is made. A permit holder in good standing may also change the type of permit held by submitting a new application and paying the difference in the permitting fees between the two permit types.

The bill creates s. 499.834, F.S., requiring the department to consider relevant factors when determining eligibility for, and renewal of, a permit application. Such factors include the applicant's past experience, previous noncompliance, felony convictions, and other qualifications that the department considers relevant to and consistent with public health and safety.

Medical Gas Storage and Security Measures

The bill creates s. 499.84, F.S., setting out the minimum requirements for storage and handling of medical gas and mandating that medical gas be stored in accordance to manufacturers' recommendations, or in their absence, according to applicable industry standards. Medical gas must be packaged in accordance with official compendium standards such as the United States Pharmacopeia and The National Formulary (USP-NF).[13]

The bill creates s. 499.85, F.S., requiring security measures for medical gas distribution and retailing facilities and vehicles used for delivering oxygen and oxygen-related equipment. Under this section, the department is required to adopt rules governing distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen so long as the rules are consistent with federal rules, unless state law specifically directs otherwise.

Wholesale Distributor Requirements

The bill creates s. 499.86, F.S., which requires examination of medical gas containers by wholesale distributors and review of records documenting the acquisition of the medical gas. The bill also creates s. 499.87, F.S., that provides procedures to handle defective gas or containers, and requires damaged, misbranded or adulterated medical gas to be quarantined until returned to the manufacturer or wholesale distributor, or until it is destroyed. If medical gas is adulterated or misbranded, or suspected as such, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

The bill creates s. 499.88, F.S., to require wholesale distributors to act with due diligence, obtaining appropriate documentation of registration from the wholesale distributor or manufacturer before an initial acquisition of medical gas from that distributor or manufacturer, except from a manufacturer that is registered with the United States Food and Drug Administration (FDA) and proof of the registration is provided along with proof of inspection within the last 3 years or proof of substantial compliance with current good manufacturing practices applicable to medical gases.

[13] The USP–NF is a book of public pharmacopeial standards. See U.S. Pharmacopial Convention, USP-NF, http://www.usp.org/usp-nf (Last visited Mar. 21, 2014).

The bill creates s. 499.89, F.S., which requires wholesale distributors to establish and maintain a record of transactions regarding the receipt and distribution, or other disposition, of medical gases, and the information to be included. These records constitute an audit trail and must contain information sufficient to perform a recall of medical gas. A record containing all required elements related to the receipt of medical gas or a separate record containing all required elements related to the distribution of medical gas must be maintained for each transaction as applicable. A pedigree paper is not required for the distribution, or other disposition, of medical gas.

The bill creates s. 499.90, F.S., that requires wholesale distributors to establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and for maintaining inventory and correcting all errors in inventory associated with nitrous oxide. Procedures are required for handling recalls and withdrawals, preparing for and responding to natural disasters or other crisis-events, and reporting criminal activity involving nitrous oxide.

Medical oxygen retail establishments and medical gas manufacturers must also comply with all requirements that apply to wholesale distributors except that medical oxygen retail establishments need not comply with requirements that pertain solely to nitrous oxide.

Prohibited and Criminal Acts

The bill creates s. 499.91, F.S., which prohibits a person from performing or aiding the performance of the following:

- Manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution;
- Adulterating or misbranding of medical gas;
- The receipt of adulterated or fraudulently obtained medical gas;
- Altering, mutilating, destroying, obliterating, or removing the whole or any part of the product labeling of medical gas or the willful commission of any other act of misbranding;
- Purchasing or receiving medical gas from a person who is not authorized by permit to distribute or dispense medical gas or who is exempted from permitting requirements to wholesale distribute medical gas to such purchaser or recipient;
- Knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except when a wholesale distributor provides oxygen to a retail establishment that is only out of compliance with the change of location requirements if the wholesale distributor notifies the department by the next business day;
- Failing to maintain or provide records required under this part;
- Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations;
- Distributing or dispensing medical gas that was purchased by a health care entity without an authorized recipient, donated or supplied at a reduced price to a charitable organization, or, stolen or obtained by fraud or deceit;
- Operating without a valid permit;

- Obtaining of medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas;
- Except for emergency use oxygen, the distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe;
- Distributing or dispensing medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe;
- Distributing or dispensing medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas;
- Failing to report an act prohibited under this part and its implementing regulations; and,
- Failing to exercise due diligence as provided in s. 499.88, F.S.

The bill creates s. 499.92, F.S., that provides that a person commits a felony in the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S., if he or she:

- With intent to defraud or deceive adulterates or misbrands medical gas;
- Knowingly purchases or receives, medical gas from a person not legally authorized to distribute or dispense medical gas;
- Knowingly engages in the wholesale distribution of, sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas. However, a violation is not committed by a wholesale distributor that provides oxygen to a permitted medical oxygen retail establishment retail establishment is out of compliance with only the change of location notice requirement and the wholesale distributors notifies the department no later than the next business day.
- Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

A person who is found guilty of one of the listed offenses in this section must forfeit to the state real or personal property used or intended to be used to commit such an offense and that is related to the gross proceeds gained as a result of the violation. The department and agencies involved in the investigation and prosecution that led to the conviction shall share equitably in the forfeiture proceeds. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Drug Wholesale Distributor Advisory Council

The bill adds an additional position on the council, now 12 members, recommended by the *Compressed Gas Association* who is an employee of a permitted medical gas wholesale distributor or manufacturer.

Inspections

The bill creates s. 499.93, F.S., which allows the department to require a facility engaged in the manufacturing, retail sale, or wholesale distribution of medical gas to undergo an inspection, including initial permitting, permit renewal, and change of location inspections. The department may recognize other state inspections if that state's laws are determined to be substantially

equivalent with this state's laws or may use a third party to inspect. A manufacturing facility registered with the FDA and verified as such and providing proof of an inspection with substantial compliance with current good manufacturing practices applicable to medical gas within the past 3 years is exempt from routine inspection.

The bill requires a wholesale distributor to have readily available its state permits and its most recent inspection report administered by the department.

The bill requires the department to ensure that information identified as a trade secret, as defined in s. 812.081, F.S., is maintained and remains confidential as required under s. 499.051, F.S., while it is retained by the department.

Rules, Enforcement and Additional Changes

The bill also makes numerous conforming changes and extends the department's rulemaking and regulatory authority in part I of ch. 499, F.S., to the whole chapter.

The bill establishes an effective date of October 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/CS SB 836 may have an indeterminate fiscal impact on private sector entities that are affected by the regulations implemented by the bill.

C. Government Sector Impact:

Expenses associated with the additional Drug Wholesale Distributor Advisory Council member are indeterminate but are expected to be minimal and can be funded with existing resources.[14]

The bill provides that fees collected under part III are to be used to administer "this part," which limits the fees and monies collected to use for administering only part III. The bill also requires the department to maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program. It is unclear at this time what the estimated fees and costs associated with medical gas regulation would be, and this is a change from the way the division currently operates.[15]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The definition of "adulteration" in the bill does not include transfer or possession by an unauthorized source.[16] Generally under the current law, if an unauthorized person holds, transfers, purchases, or sells a prescription drug, that drug becomes adulterated.[17] Currently, if medical oxygen is delivered to a patient who does not have a current, valid prescription for medical oxygen, then the medical oxygen could be deemed adulterated and thus unfit for consumption.[18] The bill may reduce the incentive of providers to verify current prescriptions before making deliveries.[19]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 499.001, 499.003, 499.01, 499.0121, 499.01211, 409.9201, 499.041, 499.05, 499.051, 499.066, 499.0661, 499.067, 460.403, 465.0265, 499.01212, 499.015, and 499.024.

This bill creates the following sections of the Florida Statutes: 499.81, 499.82, 499.83, 499.831, 499.832, 499.833, 499.834, 499.84, 499.85, 499.86, 499.87, 499.88, 499.89, 499.90, 499.91, 499.92, 499.93, 499.931, and 499.94.

IX. Additional Information:

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

CS/CS by Health Policy on April 1, 2014:
The CS makes numerous changes that provide greater clarity throughout the bill. The CS also amends the bill with changes that include:

[14] Department of Business and Professional Regulation, *Senate Bill 836 Legislative Bill Analysis* (Feb. 21, 2014) (on file with the Senate Committee on Health Policy).
[15] *Id.*

- Aligning the regulation of medical oxygen retail establishments and medical gas manufacturers with those for medical gas wholesale distributors in order to ensure they are responsible for security and recordkeeping;
- Changing the definition of "emergency" to "emergency medical reasons" and removing the requirement that the Governor declare an emergency in order to qualify as an "emergency medical reason" under the definition;
- Ensuring that the department has adequate rulemaking and enforcement authority to administer the provisions in the bill;
- Requiring that a permit holder receives prior approval from the department before changing their permitted location and ownership;
- Requiring that a permit holder notify department before changing the name of their business or closing and within 30 days after making any other change not listed that would affect their permit.

CS by Regulated Industries on March 6, 2014:
The CS adds that a permit holder under this section must notify the department 30 days prior to change in location, ownership, or name. The CS also adds a requirement that such permit holder notify the department within 30 days of change in information required under this part but not falling within one of those categories or closure.

The CS adds an exception under criminal acts, excluding as a violation a distributor providing oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement.

The CS adds a facility that engages in the retail sale of medical gas to the list of facilities that the department may require to undergo an inspection.

The CS removes the trade secret provisions created s. 499.93(5), F.S. The bill creates s. 499.931, F.S., which requires the department to maintain trade secrets as provided in s. 499.051, F.S., which provides that trade secrets must be confidential and exempt from disclosure under ch. 119, F.S., and section 24(a), Article I of the State Constitution. The department is allowed to use this information for regulatory and enforcement proceedings and to provide the information to law enforcement and regulatory agencies.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.94 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 2. Subsections (12) through (32) and subsections (47) through (55) of section 499.003, Florida Statutes, are


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renumbered as subsections (11) through (31) and subsections (46) through (54), respectively, and present subsections (11), (43), and (46) of that section are amended, to read:

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

(32) ~~(11)~~ "~~Compressed~~ Medical gas" means any liquefied or vaporized gas that is a prescription drug, whether ~~it is~~ alone or in combination with other gases, and as defined in the federal act.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal ~~Food, Drug, and Cosmetic~~ act or s. 465.003(8), s. 499.007(13), ~~or~~ subsection (32) ~~(11), subsection (46)~~, or subsection (52) ~~(53)~~, except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

~~(46) "Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.~~

Section 3. Subsection (1), paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2), and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—


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(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

(e) An out-of-state prescription drug wholesale distributor;

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

~~(m) A medical oxygen retail establishment;~~

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(m) ~~(p)~~ An over-the-counter drug manufacturer;

(n) ~~(q)~~ A device manufacturer;

(o) ~~(r)~~ A cosmetic manufacturer;

(p) ~~(s)~~ A third party logistics provider; or

(q) ~~(t)~~ A health care clinic establishment.

(2) The following permits are established:

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

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

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

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

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

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to

engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e) ~~s. 499.003(31)(e)~~.

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

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

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

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a) ~~s. 499.003(54)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized


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practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

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

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

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

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

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

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

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

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

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

~~(m) *Medical oxygen retail establishment permit.*—A medical~~


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~~oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.~~

~~1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.~~

~~2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.~~

~~3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.~~

~~4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.~~

~~(n) *Compressed medical gas wholesale distributor permit.*—A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription~~

~~medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.~~

~~(c) *Compressed medical gas manufacturer permit.* A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.~~

~~1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.~~

~~2. A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.~~

~~3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.~~

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s. 499.003(54)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the

repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

Section 4. Paragraph (b) of subsection (2) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(2) SECURITY.—

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers. ~~and establishments that only handle medical oxygen; and~~

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Section 5. Subsections (1) and (2) of section 499.01211, Florida Statutes, are amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(1) There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 ~~11~~ members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint 10 ~~nine~~ additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a) Three ~~different~~ persons, each of whom is employed by a different prescription drug wholesale distributor permitted


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~~licensed~~ under this part which operates nationally and is a primary wholesale distributor~~,~~ as defined in s. 499.003 ~~s. 499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor permitted ~~licensed~~ under this part which is a secondary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(52)~~.

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(h) One person who is an employee of a permitted medical gas manufacturer or medical gas wholesale distributor and who has been recommended by the Compressed Gas Association.

Section 6. Paragraph (e) of subsection (1), paragraph (b) of subsection (2), and paragraph (b) of subsection (3) of section 499.041, Florida Statutes, are amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established


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in this section for the specific type of manufacturer.

~~(c) The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.~~

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

~~(b) The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.~~

(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

~~(b) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.~~

Section 7. Section 499.05, Florida Statutes, is amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter ~~part~~ with respect to:

(a) The definition of terms used in this chapter ~~part~~, and used in the rules adopted under this chapter ~~part~~, when the use of the term is not its usual and ordinary meaning.

(b) Labeling requirements for drugs, devices, and cosmetics.

(c) The establishment of fees authorized in this chapter ~~part~~.

(d) The identification of permits that require an initial


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application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this chapter ~~part~~.

(e) The application processes and forms for product registration.

(f) Procedures for requesting and issuing certificates of free sale.

(g) Inspections and investigations conducted under s. 499.051 or s. 499.93 ~~s. 499.051~~, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).

(h) The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this chapter ~~part~~; and a process for the uncontested settlement of alleged violations.

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. or s. 499.82 ~~s. 499.003(54)(b)2~~.

(j) Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k) The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l) Information required from each retail establishment pursuant to s.499.012(3) or s 499.83(2)(c) ~~s. 499.012(3)~~, including requirements for prescriptions or orders.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in


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s. 499.003(53)(a)-(d) or s. 499.82(14) ~~s. 499.003(54)(a)-(d)~~.

(n) Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(o) Wholesale distributor reporting requirements of s. 499.0121(14).

(p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

(2) With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.

(3) The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

Section 8. Subsections (1) through (4) of section 499.051, Florida Statutes, are amended to read:

499.051 Inspections and investigations.—

(1) The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter ~~part~~ during business hours for the purpose of enforcing this chapter ~~part~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection


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(1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter ~~part~~ and rules adopted under this chapter ~~part~~ regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter ~~part~~ and rules adopted under this chapter ~~part~~ constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter ~~part~~ and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 or s. 499.831 and rules adopted under those sections ~~that section~~ constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter ~~part~~ and the rules adopted by the department to administer this chapter ~~part~~, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

Section 9. Subsections (1) through (4) of section 499.066, Florida Statutes, are amended to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1) The department may institute such suits or other legal


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proceedings as are required to enforce any provision of this chapter ~~part~~. If it appears that a person has violated any provision of this chapter ~~part~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this chapter ~~part~~ violates any provision of this chapter ~~part~~, any rule adopted under this chapter ~~part~~, or a cease and desist order as provided by this chapter ~~part~~, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and the orders of the department authorized by this chapter ~~part~~ or to mandate compliance with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and any order or permit issued by the department under this chapter ~~part~~.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund


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and are appropriated for the use of the department in administering this chapter ~~part~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this chapter ~~part~~, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter ~~part~~.

Section 10. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.0661, Florida Statutes, are amended to read:

499.0661 Cease and desist orders; removal of certain persons.—

(1) CEASE AND DESIST ORDERS.—

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon a ~~any~~ permittee or upon an ~~any~~ affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or


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trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of a ~~any~~ provision of this chapter ~~part~~;

3. A violation of a ~~any~~ rule of the department;

4. A violation of an ~~any~~ order of the department; or

5. A breach of a ~~any~~ written agreement with the department.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a) The department may issue and serve a complaint stating charges upon an ~~any~~ affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this chapter ~~part~~; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of a ~~any other~~ law involving fraud or moral turpitude which constitutes a felony;

4. A willful violation of a ~~any~~ rule of the department;

5. A willful violation of an ~~any~~ order of the department;

or

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

Section 11. Section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply with this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under ~~this part or~~ those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4. The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.


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5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of this chapter ~~ss. 499.005-499.0054~~.

(2) The department may deny, suspend, or revoke any registration required by ~~the provisions of~~ this chapter ~~part~~ for the violation of any provision of this chapter ~~part~~ or of any rules adopted under this chapter ~~part~~.

(3) The department may revoke or suspend a permit:

(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b) If the permit was procured, or attempted to be procured, for any other person by making or causing to be made any false representation; or

(c) If the permittee has violated ~~any provision of~~ this chapter ~~part~~ or rules adopted under this chapter ~~part~~.

(4) If a ~~any~~ permit issued under this chapter ~~part~~ is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for a ~~any~~ permit under this chapter ~~part~~ for a period of 1 year


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after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this part which authorizes the permittee to purchase prescription drugs if an ~~any~~ owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of a ~~any~~ violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under ~~this part or~~ those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of a ~~any~~ person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this chapter ~~part~~ will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.833, as applicable, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with

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the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 12. Part III of chapter 499, Florida Statutes, consisting of ss. 499.81-499.94, Florida Statutes, is created and entitled "Medical Gas."

Section 13. Section 499.81, Florida Statutes, is created to read:

499.81 Administration and enforcement.—

(1) This part is cumulative and shall be construed and applied as being in addition to, and not in substitution for or limiting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of medical gas, this part controls over any conflicting provisions.

(2) The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the manufacture and distribution of medical gases.

(3) For the purpose of an investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, subpoena witnesses, and compel the production of books, papers, documents, or other records. Challenges to, and enforcement of, subpoenas and orders shall be handled as provided in s. 120.569.

(4) Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports

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a violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and prosecuted as required by law.

(5) This part does not require the department to report, for the purpose of instituting proceedings under this part, minor violations of this part when the department believes that the public interest will be adequately served by a written notice or warning.

Section 14. Section 499.82, Florida Statutes, is created to read:

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

(1) "Adulterated," means a medical gas that:

(a) Consists, in whole or in part, of impurities or deleterious substances exceeding normal specifications;

(b) Is produced, prepared, packed, or held under conditions whereby the medical gas may have been contaminated causing it to be rendered injurious to health; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to ensure that the medical gas meets the requirements of this part as to safety and has the identity and strength and meets the quality and purity characteristics that the medical gas is represented to possess;

(c) Is held in a container with an interior that is composed in whole or in part of a poisonous or deleterious substance that may render the contents injurious to health; or

(d) Is represented as having a strength differing from, or quality or purity falling below, the standard set forth in the

USP-NF. A medical gas defined in USP-NF may not be deemed to be adulterated under this paragraph merely because it differs from the standard of strength, quality, or purity set forth in the USP-NF if its difference in strength, quality, or purity from that standard is plainly stated on its label. The determination as to strength, quality, or purity shall be made:

1. In accordance with the tests or methods of assay in the USP-NF or its validated equivalent; or

2. In the absence or inadequacy of such tests or methods of assay, in accordance with the tests or methods of assay prescribed under the federal act.

(2) "Department" means the Department of Business and Professional Regulation.

(3) "Distribute" or "distribution" means to sell; offer to sell; deliver; offer to deliver; transfer by either the passage of title, physical movement, or both; broker; or give away a medical gas. The term does not include:

(a) The dispensing or administration of a medical gas;

(b) The delivery of, or an offer to deliver, a medical gas by a common carrier in its usual course of business; or

(c) Sales activities taking place in a location owned, controlled, or staffed by persons employed by a person or entity permitted in this state to distribute a medical gas, if that location is not used to physically store or move a medical gas.

(4) "Emergency medical reasons" include:

(a) Transfers between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of a medical gas arising from a long-term delay or interruption of regular


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distribution schedules.

(b) Sales or transfers to licensed emergency medical services in this state, including ambulance companies and firefighting organizations.

(c) The provision of emergency supplies of medical gases to nursing homes during the hours of the day when necessary medical gases cannot normally be obtained from the nursing home's regular distributors.

(d) The transfer of medical gases between retail pharmacies to alleviate a temporary shortage.

(5) "Emergency use oxygen" means oxygen USP administered in emergency situations without a prescription for oxygen deficiency and resuscitation. The container must be labeled in accordance with requirements of the United States Food and Drug Administration.

(6) "Federal act" means the Federal Food, Drug, and Cosmetic Act.

(7) "Medical gas" means a liquefied or vaporized gas that is a prescription drug, whether alone or in combination with other gases, and as defined in the federal act.

(8) "Medical gas-related equipment" means a device used as a component part or accessory used to contain or control the flow, delivery, or pressure during the administration of a medical gas, such as liquid oxygen base and portable units, pressure regulators and flow meters, and oxygen concentrators.

(9) "Misbranded" means having a label that is false or misleading; a label without the name and address of the manufacturer, repackager, or distributor and without an accurate statement of the quantities of active ingredients; or a label


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without an accurate monograph for the medical gas, except in the case of mixtures of designated medical gases where the label identifies the component percentages of each designated medical gas used to make the mixture.

(10) "Medical oxygen" means oxygen USP which must be labeled in compliance with labeling requirements for oxygen under the federal act.

(11) "Product labeling" means the labels and other written, printed, or graphic matter upon an article, or the containers or wrappers that accompany an article, except for letters, numbers, and symbols stamped into the container as required by the federal Department of Transportation.

(12) "USP" means United States Pharmacopeial Convention.

(13) "USP-NF" means United States Pharmacopeia-National Formulary.

(14) "Wholesale distribution" means the distribution of medical gas to a person other than a consumer or patient. Wholesale distribution of medical gases does not include:

(a) The sale, purchase, or trade of a medical gas; an offer to sell, purchase, or trade a medical gas; or the dispensing of a medical gas pursuant to a prescription;

(b) Activities exempt from the definition of wholesale distribution in s. 499.003; or

(c) Other transactions excluded from the definition of wholesale distribution under the federal act or regulations implemented under the federal act related to medical gas.

(15) "Wholesale distributor" means any person or entity engaged in wholesale distribution of medical gas within or into this state, including, but not limited to, manufacturers; own-

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label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; and wholesale medical gas warehouses.

Section 15. Section 499.83, Florida Statutes, is created to read:

499.83 Permits.—

(1) A person or entity that intends to distribute medical gas within or into this state, unless exempted under this part, must obtain the applicable permit before operating as:

(a) A medical gas wholesale distributor;

(b) A medical gas manufacturer; or

(c) A medical oxygen retail establishment.

(2) The following permits are established:

(a) *Medical gas wholesale distributor permit.*—A medical gas wholesale distributor permit is required for wholesale distribution, whether within or into this state. A medical gas must remain in the original container obtained by the wholesale distributor and the wholesale distributor may not engage in further manufacturing operations unless it possesses a medical gas manufacturer permit. A medical gas wholesale distributor may not possess or engage in the wholesale distribution of a prescription drug that is not a medical gas or distribute a medical gas other than by wholesale distribution unless otherwise authorized.

(b) *Medical gas manufacturer permit.*—A medical gas manufacturer permit is required for a person or entity located in this state which engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid-to-liquid, liquid-to-gas, or gas-


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to-gas process and distributes those medical gases within this state.

1. A permitted medical gas manufacturer may not manufacture or possess a prescription drug other than a medical gas, unless otherwise authorized.

2. A permitted medical gas manufacturer may not distribute a medical gas without obtaining the applicable permit, except that it may engage in wholesale distribution of medical gases that it manufactured without obtaining a medical gas wholesale distributor permit if it complies with this part and the rules adopted under this part that apply to a wholesale distributor.

3. A permitted medical gas manufacturer shall comply with all of the requirements applicable to a wholesale distributor under this part and all appropriate state and federal good manufacturing practices.

(c) *Medical oxygen retail establishment permit.*—A medical oxygen retail establishment permit is required for an entity that is located in the state and that dispenses medical oxygen directly to patients in this state. The sale and delivery must be based on an order from a practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 does not require a permit as a medical oxygen retail establishment.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a medical gas other than medical oxygen, unless otherwise authorized.

2. A medical oxygen retail establishment may fill and deliver medical oxygen to an individual patient based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment must comply with all


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appropriate state and federal good manufacturing practices. Medical oxygen sold or delivered by a medical oxygen retail establishment pursuant to an order from a practitioner may not be returned into the retail establishment's inventory.

3. A medical oxygen retail establishment shall comply with all of the requirements applicable to a wholesale distributor under this part, except for those requirements that pertain solely to nitrous oxide.

(3) An out-of-state wholesale distributor that engages in wholesale distribution into this state must be legally authorized to engage in the wholesale distribution of medical gases as a wholesale distributor in the state in which it resides or is incorporated and provide proof of registration as set forth in s. 499.93(3), if required.

(4) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen for wholesale distributors that also maintain a medical oxygen retail establishment permit.

(5) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

Section 16. Section 499.831, Florida Statutes, is created to read:

499.831 Permit application.—

(1) The department shall adopt rules to establish the form and content of the application to obtain a permit and to renew a permit listed under this part.

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(2) An applicant must be at least 18 years of age or be managed, controlled, or overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(3) An application for a permit must be filed with the department and must include all of the following information:

(a) The trade or business name of the applicant, including a fictitious name, which may not be identical to a name used by an unrelated entity permitted in this state to dispense or distribute medical gas.

(b) The name or names of the owner and operator of the applicant, if not the same person or entity. The application must also include:

1. If the applicant is an individual, the applicant's name, business address, and date of birth.

2. If the applicant is a sole proprietorship, the business address of the sole proprietor and the name and federal employer identification number of the business entity.

3. If the applicant is a partnership, the name, business address, date of birth of each partner, the name of the partnership, and the partnership's federal employer identification number.

4. If the applicant is a limited liability company, the name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized.

5. If the applicant is a corporation, the name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, the federal

employer identification number, and, if applicable, the name and business address of the parent company.

(c) A list of disciplinary actions pertinent to wholesale distributors, manufacturers, and retailers of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and any such disciplinary actions against such applicant's principals, owners, directors, or officers.

(d) A complete disclosure of all of the applicant's past felony convictions.

(e) An address and description of each facility and warehouse, including all locations used for medical gas storage or wholesale distribution including a description of each facility's security system.

(4) An applicant shall attest in writing that the information contained in its application is complete and accurate.

(5) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit.

(a) The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(b) The fee for a medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(c) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

(6) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

Section 17. Section 499.832, Florida Statutes, is created


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to read:

499.832 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. Upon approval of a renewal application by the department and payment of the required renewal fee, the department shall renew a permit issued under this part pursuant to the rules adopted under this part.

(3) A renewal application may be accepted up to 60 days after the expiration date of the permit if, along with the permit renewal fee, the applicant submits an additional renewal delinquent fee of $100. A permit that expired more than 60 days before a renewal application was submitted or postmarked may not be renewed.

(4) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person, entity, or establishment holding the permit must cease all permit related activities. In order to engage in activities that require a permit the person, entity, or establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before engaging in an activity that requires a permit under this part.


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(5) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

Section 18. Section 499.833, Florida Statutes, is created to read:

499.833 Permitholder changes.—

(1) A permit issued under this part is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily.

(2) A permit issued under this part is not valid for an establishment other than the establishment for which it was originally issued.

(3) The department may approve the following permit changes:

(a) *Change of location.*—A person or entity permitted under this part must notify and receive approval from the department before changing location. The department shall set a change-of-location fee not to exceed $100.

(b) *Change in ownership.*—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. Such application must be submitted and approved by the department before the change of ownership takes place. However, if a permitted wholesale distributor or manufacturer is changing ownership and the new owner has held another permit that allows the wholesale distribution of medical


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gas under this chapter for the preceding 18 months without having been found in violation of the provisions of this chapter relating to medical gases, then the new owner may operate under the permit of the acquired entity if the new owner submits the application for a new permit by the first business day after ownership is transferred or assigned. A new owner operating under the original permit is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.

(c) *Change of name.*—A permitholder may make a change of business name without submitting a new permit application. However, the permitholder must notify the department before making the name change.

(d) *Closure.*—If an establishment permitted under this part closes, the owner must notify the department, in writing, before the effective date of the closure and must:

1. Return the permit to the department; and

2. Indicate the disposition of any medical gas authorized to be distributed or dispensed under the permit, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.

(e) *Change in information.*—Any change in the information required under this part, other than the changes in paragraphs (a)-(d), shall be submitted to the department within 30 days after such change occurs.


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(4) A permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, meeting the applicable permitting requirements for the new permit type, and paying any difference between the permit fees. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit. The new permit retains the expiration date of the original permit.

Section 19. Section 499.834, Florida Statutes, is created to read:

499.834 Minimum qualifications.—The department shall consider all of the following factors in determining eligibility for, and renewal of, a permit for a person or entity under this part:

(1) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to prescription drugs.

(2) Felony convictions of the applicant under a federal, state, or local law.

(3) The applicant’s past experience in the manufacture, retail, or distribution of medical gases.

(4) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing, retailing, or distribution of prescription drugs.

(5) Any suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding prescription drugs.

(6) Compliance with previously granted licenses or permits.


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(7) Compliance with the requirements that distributors or retailers of medical gases maintain records and make records available to the department licensing authority or federal, state, or local law enforcement officials.

(8) Other factors or qualifications the department considers relevant to and consistent with the public health and safety.

Section 20. Section 499.84, Florida Statutes, is created to read:

499.84 Minimum requirements for the storage and handling of medical gases.—

(1) A facility where a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported, to avoid any negative effect on the identity, strength, quality, or purity of the medical gas, must:

(a) Be of suitable construction to ensure that medical gases are maintained in accordance with the product labeling of the medical gas or in compliance with the USP-NF;

(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper permitted operations;

(c) Have adequate storage areas with appropriate lighting, ventilation, space, equipment, and security conditions.

(d) Have a quarantined area for storage of medical gases that are suspected of being misbranded, adulterated, or otherwise unfit for distribution;

(e) Be maintained in an orderly condition;

(f) Be located in a commercial location and not in a personal dwelling or residence location, except that a personal dwelling location used for on-call delivery of oxygen USP for

homecare use if the person providing on-call delivery is employed by or acting under a written contract with an entity that holds a medical oxygen retailer permit;

(g) Provide for the secure and confidential storage of patient information, if applicable, with restricted access and policies and procedures to protect the integrity and confidentiality of patient information; and

(h) Provide and maintain appropriate inventory controls to detect and document any theft of nitrous oxide.

(2) Medical gas shall be stored under appropriate conditions in accordance with the manufacturer's recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards.

(3) Medical gas shall be packaged in accordance with official compendium standards, such as the USP-NF.

Section 21. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A permitholder that has a facility used for the distribution or retailing of medical gases shall protect such gases from unauthorized access by implementing all of the following security measures:

(a) Keeping access from outside the premises well-controlled and to a minimum.

(b) Ensuring the outside perimeter of the premises is well lit.

(c) Limiting access into areas where medical gases are held to authorized personnel.

(d) Equipping all facilities with a fence or other system

to detect or deter entry after hours.

(2) A facility used for distributing or retailing medical gases shall be equipped with a system that provides suitable protection against theft, including if appropriate, protection against theft of computers or electronic records and the protection of the integrity and confidentiality of data and documents.

(3) A facility used for wholesale distribution of medical gases shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.

(4) If a wholesale distributor uses electronic distribution records, the wholesale distributor shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(5) Vehicles used for on-call delivery of oxygen USP and oxygen-related equipment for home care use by home care providers may be parked at a place of residence and must be locked and equipped with an audible alarm when not attended.

(6) The department shall adopt rules that govern the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such rules must be consistent with federal regulations, including the labeling requirements of oxygen under the federal act.

Section 22. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine a medical

gas container upon receipt from the manufacturer in order to identify the medical gas stored within and to determine if the container has been damaged or is otherwise unfit for distribution. Such examination must occur in a manner that would reveal damage to the container which could suggest possible adulteration or misbranding.

(2) A medical gas container that is found to be damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the stock of medical gas until a determination is made that the medical gas in question is not misbranded or adulterated.

(3) An outgoing shipment must be inspected to identify the medical gases in the shipment to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not distributed or dispensed.

(4) A wholesale distributor must review records documenting the acquisition of medical gas upon receipt for accuracy and completeness.

Section 23. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) A medical gas that has left the control of the wholesale distributor may be returned to the wholesale distributor or manufacturer from which it was acquired, but may not be resold as a medical gas unless it is reprocessed by a manufacturer using proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

(2) A medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may


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not be salvaged or reprocessed.

(3) A medical gas, including its container, which is damaged, misbranded, or adulterated must be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired. External contamination of a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damaged or adulterated for purposes of this subsection. If a medical gas is adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

(4) A medical gas container that has been opened or used but is not adulterated or misbranded is considered empty and must be quarantined from nonempty medical gas containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(5) A medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

Section 24. Section 499.88, Florida Statutes, is created to read:

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the United States Food and Drug Administration;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is legally authorized to distribute medical gas within or into the state;

(c) The name of the responsible facility contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer's or wholesale distributor's policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer, as required under subsection (1), if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration; and

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required by s. 499.89(1), as applicable.

Section 25. Section 499.89, Florida Statutes, is created to read:

499.89 Recordkeeping.—

(1) A permitholder under this part shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases, as applicable. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records must include all of the following information, which may be kept in two separate documents one related to the distribution of medical gas and the other related to the receipt of medical gas:

(a) The dates of receipt and distribution or other disposition of the medical gas.

(b) The name, address, license or permit number and its expiration date for the person or entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, license or permit number and its expiration date for the person or entity receiving the medical gas, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received, distributed, or dispensed.

(2) Such records shall be made available for inspection and copying by an authorized official of any federal, state, or local governmental agency for a period of:

(a) Three years following the distribution date of high pressure medical gases.

(b) Two years following the distribution date for cryogenic or refrigerated liquid medical gases.

(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) A pedigree paper is not required for distributing or dispensing medical gas.

(5) A wholesale distributor shall maintain records sufficient to aid in the mandatory reporting of any theft, suspected theft, or other significant loss of nitrous oxide to the department and other appropriate law enforcement agencies.

Section 26. Section 499.90, Florida Statutes, is created to read:

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and distribution of medical gases and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:

(a) Action initiated at the request of the United States

Food and Drug Administration or any federal, state, or local law enforcement or other government agency, including the department; or

(b) Voluntary action by a manufacturer of medical gases to remove defective or potentially defective medical gases from the market.

(2) A procedure that includes preparation for, protection against, and responding to a crisis that affects the security or operation of a facility that stores medical gases in the event of a strike; a fire, flood, or other natural disaster; or other local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

Section 27. Section 499.91, Florida Statutes, is created to read:

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts in this state:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of a medical gas that is adulterated, misbranded, or is otherwise unfit for distribution.

(2) The adulteration or misbranding of a medical gas.

(3) The receipt of a medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit, or the delivery or proffered delivery of such medical gas for pay or otherwise.


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(4) The alteration, mutilation, destruction, obliteration, or removal of all or any part of the product labeling of a medical gas, or the willful commission of any other act with respect to a medical gas that results in it being misbranded.

(5) The purchase or receipt of a medical gas from a person not authorized to distribute or dispense medical gas or who is not exempted from permitting requirements to wholesale distribute medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of a medical gas to a recipient who is not legally authorized to receive a medical gas, except that a violation does not exist if a permitted wholesale distributor provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with the notice of location change requirements of s. 499.834, provided that the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.

(7) The failure to maintain or provide records required under this part and the rules adopted under this part.

(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part or the rules adopted under this part.

(9) The distribution of a medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;

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

organization; or

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a license or permit or operating without a valid license or permit, if one is required.

(11) The obtaining of, or attempt to obtain, a medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a medical gas.

(12) Except for emergency use oxygen, the distribution of a medical gas to a patient without a prescription from a practitioner authorized by law to prescribe a medical gas.

(13) The distribution or dispensing of a medical gas that was previously dispensed by a pharmacy or a practitioner authorized by law to prescribe.

(14) The distribution or dispensing of a medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal the medical gas.

(15) Failure to report an act prohibited under this part or the rules adopted under this part.

(16) Failure to exercise due diligence as provided in s. 499.88.

Section 28. Section 499.92, Florida Statutes, is created to read:

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) Adulterates or misbrands a medical gas with intent to defraud or deceive;

(b) Knowingly purchases or receives a medical gas from a person not legally authorized to distribute or dispense medical gas;

(c) Knowingly engages in the wholesale distribution of, or sells, barters, brokers, or transfers, a medical gas to a person not legally authorized to purchase or receive medical gas in the jurisdiction in which the person receives the medical gas. A permitted wholesale distributor that, at its location, provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with only the change of location notice requirement under s. 499.834, does not commit a violation of this subsection if the wholesale distributor notifies the department of the transaction no later than the next business day; or

(d) Knowingly falsely creates a label for a medical gas or knowingly falsely misrepresents a factual matter contained in a label for a medical gas.

(2) A person found guilty of an offense under this section, under the authority of the court convicting and sentencing the person, shall be ordered to forfeit to the state any real or personal property:

(a) Used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized

by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the department and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution that led to the conviction.

Section 29. Section 499.93, Florida Statutes, is created to read:

499.93 Inspections.—

(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department, including inspections for initial permitting, permit renewal, and a permitholder’s change of location. The department may recognize a third party to inspect wholesale distributors in this state or other states pursuant to a schedule to be determined by the department.

(2) The department may recognize another state’s inspections of a manufacturer or wholesale distributor located in that state if such state’s laws are deemed to be substantially equivalent to the laws of this state by the department.

(3) A manufacturing facility of medical gases is exempt from inspection by the department if:

(a) The manufacturing facility is currently registered with


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the United States Food and Drug Administration under s. 510 of the federal act and can provide proof of registration, such as a copy of the Internet verification page; and

(b) The manufacturing facility can provide proof of inspection by the Food and Drug Administration, or if the facility is located in another state, inspection by the Food and Drug Administration or other governmental entity charged with regulation of good manufacturing practices related to medical gases in that state within the past 3 years, which demonstrates substantial compliance with current good manufacturing practices applicable to medical gases.

(4) A permitholder under this part shall exhibit or have readily available its state permits and its most recent inspection report administered by the department.

Section 30. Section 499.931, Florida Statutes, is created to read:

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081(1)(c) and designated as a trade secret by an applicant or permitholder must be maintained as required under s. 499.051.

Section 31. Section 499.94, Florida Statutes, is created to read:

499.94 Fees.—A fee collected for a permit under this part shall be deposited into the Professional Regulation Trust Fund. Moneys collected under this part shall be used for administering this part. The department shall maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program.

Section 32. Paragraph (a) of subsection (1) of section


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409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s. 499.003(52), ~~s. 499.003(46) or (53) or~~ s. 499.007(13), or s. 499.82(10).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 33. Paragraph (c) of subsection (9) of section 460.403, Florida Statutes, is amended to read:

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

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any


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surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.83(2)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic physician to prescribe medical oxygen as defined in chapter 499.

Section 34. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as described ~~set forth~~ in s. 465.026 or as a wholesale distribution as defined ~~set forth~~ in s. 499.003 ~~s. 499.003(54)~~.

Section 35. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following


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information:

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer as defined in s. 499.003(30)(e) ~~under s. 499.003(31)(e)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

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Section 36. Paragraph (a) of subsection (1) and subsection (3) of section 499.015, Florida Statutes, are amended to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

Section 37. Subsection (3) of section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(3) Any product that falls under the definition of drug in s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority

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of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

Section 38. This act shall take effect October 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to medical gas; amending s. 499.001, F.S.; conforming provisions to changes made by this act; amending s. 499.003, F.S.; revising terms; amending ss. 499.01 and 499.0121, F.S.; conforming provisions to changes made by this act; amending s. 499.01211, F.S.; adding a member of to the Drug Wholesale Distributor Advisory Council; authorizing the Compressed Gas Association to recommend one person to the council for appointment; amending ss. 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by this act; creating part III of ch. 499, F.S., entitled "Medical Gas"; creating s. 499.81, F.S.; providing for the administration and enforcement of this part; creating s. 499.82, F.S.; defining terms; creating s. 499.83, F.S.; requiring a person or entity that intends to distribute medical gas within or into this state to obtain an applicable permit before operating; establishing categories of permits and setting

requirements for each; creating s. 499.831, F.S.; requiring the Department of Business and Professional Regulation to establish the form and content of an application; authorizing the department to set fees within certain parameters; creating s. 499.832, F.S.; providing that a permit expires 2 years after the last day of the month in which the permit was originally issued; providing requirements for the renewal of a permit; requiring the department to adopt rules for the renewal of permits; creating s. 499.833, F.S.; authorizing the department to approve certain permitholder changes; creating s. 499.834, F.S.; authorizing the department to consider certain factors in determining the eligibility of an applicant; creating s. 499.84, F.S.; setting the minimum requirements for the storage and handling of medical gas; creating s. 499.85, F.S.; setting facility requirements for security purposes; authorizing a vehicle used for on-call delivery of oxygen USP and oxygen-related equipment to be parked at a place of residence; requiring the department to adopt rules governing the distribution of medical oxygen; creating s. 499.86, F.S.; requiring a wholesale distributor of medical gases to visually examine a medical gas container upon receipt in order to identify the medical gas stored within and to determine if the container has been damaged or is otherwise unfit for distribution; requiring a medical gas container that is damaged or otherwise unfit for distribution to be

quarantined; requiring outgoing shipments of medical gas to be inspected; requiring wholesale distributors to review certain records; creating s. 499.87, F.S.; authorizing the return of medical gas that has left the control of a wholesale distributor; requiring that medical gas that is damaged, misbranded, or adulterated be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired; creating s. 499.88, F.S.; requiring a wholesale distributor to obtain certain information before the initial acquisition of a medical gas; providing certain exemptions; creating s. 499.89, F.S.; requiring a permitholder under this part to establish and maintain transactional records; providing a retention period for certain records and requiring that such records be available for inspection during that period; creating s. 499.90, F.S.; requiring a wholesale distributor to establish, maintain, and adhere to certain written policies and procedures; creating s. 499.91, F.S.; prohibiting certain acts; creating s. 499.92, F.S.; establishing criminal penalties; authorizing property or assets subject to forfeiture to be seized pursuant to a warrant; creating s. 499.93, F.S.; authorizing the department to require a facility that engages in in the manufacture, retail sale, or wholesale distribution of medical to undergo an inspection; authorizing the department to authorize a third party to inspect such


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facilities; creating s. 499.931, F.S.; providing that trade secret information required to be submitted pursuant to this part must be maintained by the department; creating s. 499.94, F.S.; requiring fees collected pursuant to this part to be deposited into the Professional Regulation Trust Fund; amending ss. 409.9201, 460.403, 465.0265, 499.01212, 499.015, and 499.024, F.S.; conforming cross references; providing an effective date.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (181392)

Delete lines 789 - 1402
and insert:
otherwise authorized under this chapter.

(b) *Medical gas manufacturer permit.*—A medical gas manufacturer permit is required for a person or entity located in this state which engages in the manufacture of medical gases by physical air separation, chemical action, purification, or filling containers by a liquid-to-liquid, liquid-to-gas, or gas-to-gas process and distributes those medical gases within this

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state.

1. A permitted medical gas manufacturer may not manufacture or possess a prescription drug other than a medical gas, unless otherwise authorized under this chapter.

2. A permitted medical gas manufacturer may not distribute a medical gas without obtaining the applicable permit, except that it may engage in wholesale distribution of medical gases that it manufactured without obtaining a medical gas wholesale distributor permit if it complies with this part and the rules adopted under this part that apply to a wholesale distributor.

3. A permitted medical gas manufacturer shall comply with all of the requirements applicable to a wholesale distributor under this part and all appropriate state and federal good manufacturing practices.

(c) *Medical oxygen retail establishment permit.*—A medical oxygen retail establishment permit is required for an entity that is located in the state and that dispenses medical oxygen directly to patients in this state. The sale and delivery must be based on a prescription or an order from a practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 does not require a permit as a medical oxygen retail establishment.

1. A medical oxygen retail establishment may not possess, purchase, sell, or trade a medical gas other than medical oxygen, unless otherwise authorized under this chapter.

2. A medical oxygen retail establishment may fill and deliver medical oxygen to an individual patient based on an order from a practitioner authorized by law to prescribe. The medical oxygen retail establishment must comply with all

appropriate state and federal good manufacturing practices. Medical oxygen sold or delivered by a medical oxygen retail establishment pursuant to an order from a practitioner may not be returned into the retail establishment's inventory.

3. A medical oxygen retail establishment shall comply with all of the requirements applicable to a wholesale distributor under this part, except for those requirements that pertain solely to nitrous oxide.

(3) An out-of-state wholesale distributor that engages in wholesale distribution into this state must be legally authorized to engage in the wholesale distribution of medical gases as a wholesale distributor in the state in which it resides or is incorporated and provide proof of registration as set forth in s. 499.93(3), if required.

(4) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen for wholesale distributors that also maintain a medical oxygen retail establishment permit.

(5) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

Section 16. Section 499.831, Florida Statutes, is created to read:

499.831 Permit application.—

(1) The department shall adopt rules to establish the form and content of the application to obtain a permit and to renew a permit listed under this part.


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(2) An applicant must be at least 18 years of age or be managed, controlled, or overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(3) An application for a permit must be filed with the department and must include all of the following information:

(a) The trade or business name of the applicant, including a fictitious name, which may not be identical to a name used by an unrelated entity permitted in this state to dispense or distribute medical gas.

(b) The name or names of the owner and operator of the applicant, if not the same person or entity. The application must also include:

1. If the applicant is an individual, the applicant's name, business address, and date of birth.

2. If the applicant is a sole proprietorship, the business address of the sole proprietor and the name and federal employer identification number of the business entity.

3. If the applicant is a partnership, the name, business address, date of birth of each partner, the name of the partnership, and the partnership's federal employer identification number.

4. If the applicant is a limited liability company, the name, business address, and title of each company officer, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized.

5. If the applicant is a corporation, the name, business address, and title of each corporate officer and director, the corporate names, the state of incorporation, the federal


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employer identification number, and, if applicable, the name and business address of the parent company.

(c) A list of disciplinary actions pertinent to wholesale distributors, manufacturers, and retailers of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and any such disciplinary actions against such applicant's principals, owners, directors, or officers.

(d) A complete disclosure of all of the applicant's past felony convictions.

(e) An address and description of each facility and warehouse, including all locations used for medical gas storage or wholesale distribution including a description of each facility's security system.

(4) An applicant shall attest in writing that the information contained in its application is complete and accurate.

(5) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit.

(a) The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(b) The fee for a medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(c) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

(6) Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant pursuant to the rules adopted under this part.

Section 17. Section 499.832, Florida Statutes, is created

to read:

499.832 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. Upon approval of a renewal application by the department and payment of the required renewal fee, the department shall renew a permit issued under this part pursuant to the rules adopted under this part.

(3) A renewal application may be accepted up to 60 days after the expiration date of the permit if, along with the permit renewal fee, the applicant submits an additional renewal delinquent fee of $100. A permit that expired more than 60 days before a renewal application was submitted or postmarked may not be renewed.

(4) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person, entity, or establishment holding the permit must cease all permit related activities. In order to engage in activities that require a permit the person, entity, or establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before engaging in an activity that requires a permit under this part.


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(5) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

Section 18. Section 499.833, Florida Statutes, is created to read:

499.833 Permitholder changes.—

(1) A permit issued under this part is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily.

(2) A permit issued under this part is not valid for an establishment other than the establishment for which it was originally issued.

(3) The department may approve the following permit changes:

(a) *Change of location.*—A person or entity permitted under this part must notify and receive approval from the department before changing location. The department shall set a change-of-location fee not to exceed $100.

(b) *Change in ownership.*—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. Such application must be submitted and approved by the department before the change of ownership takes place. However, if a permitted wholesale distributor or manufacturer is changing ownership and the new owner has held another permit that allows the wholesale distribution of medical

gas under this chapter for the preceding 18 months without having been found in violation of the provisions of this chapter relating to medical gases, then the new owner may operate under the permit of the acquired entity if the new owner submits the application for a new permit by the first business day after ownership is transferred or assigned. A new owner operating under the original permit is responsible for compliance with all laws and regulations governing medical gas. If the application is denied, the new owner shall immediately cease operation at the establishment until a permit is issued to the new owner.

(c) *Change of name.*—A permitholder may make a change of business name without submitting a new permit application. However, the permitholder must notify the department before making the name change.

(d) *Closure.*—If an establishment permitted under this part closes, the owner must notify the department, in writing, before the effective date of the closure and must:

1. Return the permit to the department; and

2. Indicate the disposition of any medical gas authorized to be distributed or dispensed under the permit, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.

(e) *Change in information.*—Any change in the information required under this part, other than the changes in paragraphs (a)-(d), shall be submitted to the department within 30 days after such change occurs.

(4) A permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, meeting the applicable permitting requirements for the new permit type, and paying any difference between the permit fees. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit. The new permit retains the expiration date of the original permit.

Section 19. Section 499.834, Florida Statutes, is created to read:

499.834 Minimum qualifications.—The department shall consider all of the following factors in determining eligibility for, and renewal of, a permit for a person or entity under this part:

(1) A finding by the department that the applicant has violated or been disciplined by a regulatory agency in any state for violating a federal, state, or local law relating to prescription drugs.

(2) Felony convictions of the applicant under a federal, state, or local law.

(3) The applicant’s past experience in the manufacture, retail, or distribution of medical gases.

(4) False or fraudulent material provided by the applicant in an application made in connection with the manufacturing, retailing, or distribution of prescription drugs.

(5) Any suspension, sanction, or revocation by a federal, state, or local government against a license or permit currently or previously held by the applicant or its owners for violations of a federal, state, or local law regarding prescription drugs.

(6) Compliance with previously granted licenses or permits.

(7) Compliance with the requirements that distributors or retailers of medical gases maintain records and make records available to the department licensing authority or federal, state, or local law enforcement officials.

(8) Other factors or qualifications the department considers relevant to and consistent with the public health and safety.

Section 20. Section 499.84, Florida Statutes, is created to read:

499.84 Minimum requirements for the storage and handling of medical gases.—

(1) A facility where a medical gas is received, stored, warehoused, handled, held, offered, marketed, displayed, or transported, to avoid any negative effect on the identity, strength, quality, or purity of the medical gas, must:

(a) Be of suitable construction to ensure that medical gases are maintained in accordance with the product labeling of the medical gas or in compliance with the USP-NF;

(b) Be of suitable size and construction to facilitate cleaning, maintenance, and proper permitted operations;

(c) Have adequate storage areas with appropriate lighting, ventilation, space, equipment, and security conditions.

(d) Have a quarantined area for storage of medical gases that are suspected of being misbranded, adulterated, or otherwise unfit for distribution;

(e) Be maintained in an orderly condition;

(f) Be located in a commercial location and not in a personal dwelling or residence location, except that a personal dwelling location used for on-call delivery of oxygen USP for

homecare use if the person providing on-call delivery is employed by or acting under a written contract with an entity that holds a medical oxygen retailer permit;

(g) Provide for the secure and confidential storage of patient information, if applicable, with restricted access and policies and procedures to protect the integrity and confidentiality of patient information; and

(h) Provide and maintain appropriate inventory controls to detect and document any theft of nitrous oxide.

(2) Medical gas shall be stored under appropriate conditions in accordance with the manufacturer's recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards.

(3) Medical gas shall be packaged in accordance with official compendium standards, such as the USP-NF.

Section 21. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A permitholder that has a facility used for the distribution or retailing of medical gases shall protect such gases from unauthorized access by implementing all of the following security measures:

(a) Keeping access from outside the premises well-controlled and to a minimum.

(b) Ensuring the outside perimeter of the premises is well lit.

(c) Limiting access into areas where medical gases are held to authorized personnel.

(d) Equipping all facilities with a fence or other system

to detect or deter entry after hours.

(2) A facility used for distributing or retailing medical gases shall be equipped with a system that provides suitable protection against theft, including if appropriate, protection against theft of computers or electronic records and the protection of the integrity and confidentiality of data and documents.

(3) A facility used for wholesale distribution of medical gases shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.

(4) If a wholesale distributor uses electronic distribution records, the wholesale distributor shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(5) Vehicles used for on-call delivery of oxygen USP and oxygen-related equipment for home care use by home care providers may be parked at a place of residence and must be locked and equipped with an audible alarm when not attended.

(6) The department shall adopt rules that govern the distribution of medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such rules must be consistent with federal regulations, including the labeling requirements of oxygen under the federal act.

Section 22. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine a medical

gas container upon receipt from the manufacturer in order to identify the medical gas stored within and to determine if the container has been damaged or is otherwise unfit for distribution. Such examination must occur in a manner that would reveal damage to the container which could suggest possible adulteration or misbranding.

(2) A medical gas container that is found to be damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the stock of medical gas until a determination is made that the medical gas in question is not misbranded or adulterated.

(3) An outgoing shipment must be inspected to identify the medical gases in the shipment to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not distributed or dispensed.

(4) A wholesale distributor must review records documenting the acquisition of medical gas upon receipt for accuracy and completeness.

Section 23. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) A medical gas that has left the control of the wholesale distributor may be returned to the wholesale distributor or manufacturer from which it was acquired, but may not be resold as a medical gas unless it is reprocessed by a manufacturer using proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas.

(2) A medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may

not be salvaged or reprocessed.

(3) A medical gas, including its container, which is damaged, misbranded, or adulterated must be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired. External contamination of a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damaged or adulterated for purposes of this subsection. If a medical gas is adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

(4) A medical gas container that has been opened or used but is not adulterated or misbranded is considered empty and must be quarantined from nonempty medical gas containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(5) A medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

Section 24. Section 499.88, Florida Statutes, is created to read:

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:


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(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the United States Food and Drug Administration;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is legally authorized to distribute medical gas within or into the state;

(c) The name of the responsible facility contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer's or wholesale distributor's policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer, as required under subsection (1), if the manufacturer is registered with the United States Food and Drug Administration in accordance with s. 510 of the federal act and the manufacturer provides:

(a) Proof of such registration; and

(b) Proof of inspection by the United States Food and Drug Administration or other regulatory body within the past 3 years demonstrating substantial compliance with current good manufacturing practices applicable to medical gases.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required by s. 499.89(1), as applicable.

Section 25. Section 499.89, Florida Statutes, is created to read:

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499.89 Recordkeeping.—

(1) A permitholder under this part shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases, as applicable. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records must include all of the following information, which may be kept in two separate documents one related to the distribution of medical gas and the other related to the receipt of medical gas:

(a) The dates of receipt and distribution or other disposition of the medical gas.

(b) The name, address, license or permit number and its expiration date for the person or entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, license or permit number and its expiration date for the person or entity receiving the medical gas, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received, distributed, or dispensed.

(2) Such records shall be made available for inspection and copying by an authorized official of any federal, state, or local governmental agency for a period of:

(a) Three years following the distribution date of high pressure medical gases.

(b) Two years following the distribution date for cryogenic or refrigerated liquid medical gases.


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(3) Records kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules.

(4) A pedigree paper is not required for distributing or dispensing medical gas.

(5) A wholesale distributor shall maintain records sufficient to aid in the mandatory reporting of any theft, suspected theft, or other significant loss of nitrous oxide to the department and other appropriate law enforcement agencies.

Section 26. Section 499.90, Florida Statutes, is created to read:

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and distribution of medical gases and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:

(a) Action initiated at the request of the United States

Food and Drug Administration or any federal, state, or local law enforcement or other government agency, including the department; or

(b) Voluntary action by a manufacturer of medical gases to remove defective or potentially defective medical gases from the market.

(2) A procedure that includes preparation for, protection against, and responding to a crisis that affects the security or operation of a facility that stores medical gases in the event of a strike; a fire, flood, or other natural disaster; or other local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

Section 27. Section 499.91, Florida Statutes, is created to read:

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of a medical gas that is adulterated, misbranded, or is otherwise unfit for distribution.

(2) The adulteration or misbranding of a medical gas.

(3) The receipt of a medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit, and the delivery or proffered delivery of such medical gas for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of all or any part of the product labeling of a medical gas, or the willful commission of any other act with respect to a medical gas that results in it being misbranded.

(5) The purchase or receipt of a medical gas from a person not authorized to distribute or dispense medical gas or who is not exempted from permitting requirements to wholesale distribute medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of a medical gas to a recipient who is not legally authorized to receive a medical gas, except that a violation does not exist if a permitted wholesale distributor provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with the notice of location change requirements of s. 499.834, provided that the wholesale distributor with knowledge of the violation notifies the department of the transaction by the next business day.

(7) The failure to maintain or provide records required under this part and the rules adopted under this part.

(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part or the rules adopted under this part.

(9) The distribution of a medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;

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

organization; or

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a license or permit or operating without a valid license or permit, if one is required.

(11) The obtaining of, or attempt to obtain, a medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a medical gas.

(12) Except for emergency use oxygen, the distribution of a medical gas to a patient without a prescription from a practitioner authorized by law to prescribe a medical gas.

(13) The distribution or dispensing of a medical gas that was previously dispensed by a pharmacy or a practitioner authorized by law to prescribe.

(14) The distribution or dispensing of a medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of the medical gas.

(15) Failure to report an act prohibited under this part or the rules adopted under this part.

(16) Failure to exercise due diligence as provided in s. 499.88.

Section 28. Section 499.92, Florida Statutes, is created to read:

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) Adulterates or misbrands a medical gas with intent to defraud or deceive;


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(b) Knowingly purchases or receives a medical gas from a person not legally authorized to distribute or dispense medical gas;

(c) Knowingly engages in the wholesale distribution of, or sells, barters, brokers, or transfers, a medical gas to a person not legally authorized to purchase or receive medical gas in the jurisdiction in which the person receives the medical gas. A permitted wholesale distributor that, at its location, provides oxygen to a permitted medical oxygen retail establishment that is out of compliance with only the change of location notice requirement under s. 499.834, does not commit a violation of this subsection if the wholesale distributor notifies the department of the transaction no later than the next business day; or

(d) Knowingly falsely creates a label for a medical gas or knowingly falsely misrepresents a factual matter contained in a label for a medical gas.

(2) A person found guilty of an offense under this section, under the authority of the court convicting and sentencing the person, shall be ordered to forfeit to the state any real or personal property:

(a) Used or intended to be used to commit, to facilitate, or to promote the commission of such offense; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the offense.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized

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by law, and held until the case against a defendant is adjudicated. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited, shall be equitably divided between the department and other agencies involved in the investigation and prosecution that led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution that led to the conviction.

Section 29. Section 499.93, Florida Statutes, is created to read:

499.93 Inspections.—

(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department, including inspections for initial permitting, permit renewal, and a permitholder’s change of location. The department may recognize a third party to inspect wholesale distributors in this state or other states pursuant to a schedule to be determined by the department.

(2) The department may recognize another state’s inspections of a manufacturer or wholesale distributor located in that state if such state’s laws are deemed to be substantially equivalent to the laws of this state by the department.

(3) A manufacturing facility of medical gases is exempt from routine inspection by the department if:

By the Committee on Regulated Industries; and Senator Bean

580-02206-14 2014836c1

A bill to be entitled

An act relating to medical gas; creating part III of ch. 499, F.S., entitled "Medical Gas"; creating s. 499.81, F.S.; defining terms; creating s. 499.82, F.S.; requiring a person or establishment located inside or outside the state which intends to distribute medical gas within or into this state to obtain an applicable permit before operating; listing the people or entities that are legally authorized to receive medical gas; establishing categories of permits and setting requirements for each; creating s. 499.821, F.S.; requiring the Department of Business and Professional Regulation to establish the form and content of an application; stating that an applicant who is denied a permit has a right of review pursuant to ch. 120, F.S.; authorizing the department to set fees within certain parameters; creating s. 499.822, F.S.; requiring a permit to expire 2 years after the last day of the month in which the permit was issued; providing requirements for the renewal of a permit; requiring the department to adopt rules for the renewal of permits; creating s. 499.823, F.S.; authorizing the department to consider certain factors in determining the eligibility of an applicant; creating s. 499.824, F.S.; authorizing the department to approve certain permitholder changes; authorizing the department to revoke the permit of a person that fails to comply with this section; creating s. 499.83, F.S.; requiring an applicant for or a holder of a

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permit as a wholesale distributor of medical gas or as a medical oxygen retailer to designate a registered agent; creating s. 499.84, F.S.; setting the minimum requirements for the storage and handling of medical gas; creating s. 499.85, F.S.; requiring a wholesale distributor of medical gas to implement measures to secure the location from unauthorized entry; setting facility requirements for security purposes; authorizing a vehicle used for on-call delivery of oxygen USP and oxygen-related equipment to be parked at a place of residence; requiring the department to adopt rules governing the wholesale distribution of prescription medical oxygen; creating s. 499.86, F.S.; requiring a wholesale distributor of medical gases to visually examine an immediate container upon receipt for identity and to determine if the medical gas container has been damaged or is otherwise unfit for distribution; requiring a medical gas container that is damaged or otherwise unfit for distribution to be quarantined; requiring outgoing shipments to be inspected; requiring wholesale distributors to review certain records; creating s. 499.87, F.S.; authorizing the return of medical gas that has left the control of the wholesale distributor; requiring that medical gas that is damaged, misbranded, or adulterated be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired; creating s. 499.88, F.S.; requiring a wholesale distributor to

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

obtain certain information before the initial acquisition of the medical gas; providing certain exemptions; creating s. 499.89, F.S.; requiring a wholesale distributor to establish and maintain transactional records; providing a retention period for certain records and requiring that the records be available for inspection during that period; creating s. 499.90, F.S.; requiring a wholesale distributor to establish, maintain, and adhere to certain written policies and procedures; creating s. 499.91, F.S.; prohibiting certain acts; creating s. 499.92, F.S.; establishing criminal penalties; authorizing property or assets subject to forfeiture to be seized pursuant to a warrant; creating s. 499.93, F.S.; authorizing the department to require a facility that engages in wholesale distribution to undergo an inspection; authorizing the department to authorize a third party to inspect wholesale distributors; creating s. 499.931, F.S.; providing that trade secret information required to submitted pursuant to this part must be maintained by the department; creating s. 499.94, F.S.; requiring fees collected pursuant to this part to be deposited into the Professional Regulation Trust Fund; creating s. 499.95, F.S.; authorizing the department for the purpose of initiating an investigation or proceeding under this part to administer oaths, take depositions, issue and serve subpoenas, and compel attendance of witnesses and the production of books, papers, documents or other

evidence; requiring an attorney to whom the department reports a violation of this part to timely institute proceedings in the court of competent jurisdiction; exempting minor violations from reporting requirements at the department's discretion; providing that this part is cumulative and does not repeal or affect the power, duty, or authority of the department; amending ss. 409.9201, 460.403, and 465.0265; conforming provisions to changes made by the act; amending s. 499.001, F.S.; conforming a provision to changes made by the act; amending s. 499.003, F.S.; conforming terminology, deleting a definition, and defining the term "medical gas"; amending ss. 499.01 and 499.0121, F.S.; conforming provisions to changes made by the act; amending s. 499.01211, F.S.; changing the membership of the Drug Wholesale Distributor Advisory Council; requiring the Compressed Gas Association to appoint one person to the council; amending ss. 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Part III of chapter 499, Florida Statutes, consisting of ss. 499.81-499.95, Florida Statutes, is created and is entitled "Medical Gas."

Section 2. Section 499.81, Florida Statutes, is created to

read:

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

(1) "Adulterated" with respect to medical gas means medical gas that:

(a) Consists, in whole or in part, of impurities or deleterious substances that exceed normal specifications;

(b) Has been produced, prepared, packed, or held under conditions whereby the gas may have been contaminated, causing it to be rendered injurious to health; or was manufactured, processed, packed, or held using methods, facilities, or controls that do not conform to or are not operated or administered in conformity with current good manufacturing practices;

(c) Has a container interior that is composed, in whole or in part, of a poisonous or deleterious substance that may render the container contents injurious to health; or

(d) Has a strength that differs from, or that is of a quality or purity that fails to meet, the standards established in the USP-NF, if the gas is purported to be, or is represented as, medical gas as recognized in the USP-NF. Such a determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in the USP-NF or a validated equivalent, or, in the absence or inadequacy of these tests or methods of assay, those prescribed under the authority of the federal act shall be used. However, a gas that is purported to be, or is represented as, medical gas as recognized in the USP-NF but that differs in strength, quality, or purity from the standards established in the USP-NF may not be deemed adulterated for purposes of this paragraph if

the difference is plainly stated on its label.

(2) "Department" means the Department of Business and Professional Regulation.

(3) "Distribute" or "distribution" means to sell or offer to sell, deliver or offer to deliver, broker, give away, or transfer medical gas, by passage of title or by physical movement. The term does not include:

(a) Dispensing or administering medical gas;

(b) Delivering or offering to deliver medical gas by a common carrier in its usual course of business; or

(c) A sales activity that takes place in an establishment that is owned or controlled by a person or business entity authorized to distribute medical gas within or into this state or staffed by persons employed by such person, if the location where the sales activity takes place does not physically store or transport medical gas.

(4) "Emergency use oxygen" means oxygen USP that is administered without a prescription for an emergency situation concerning oxygen deficiency or resuscitation and that is in a container labeled in accordance with FDA standards.

(5) "FDA" means the federal Food and Drug Administration.

(6) "Federal act" means the federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.

(7) "Health care entity" means a person, including an organization business entity, which provides diagnostic, medical, surgical, or dental treatment or rehabilitative care. The term includes a home respiratory care provider or a person or entity authorized to administer emergency use oxygen, but does not include a retail pharmacy or wholesale distributor.

(8) "Immediate container" means a compressed gas cylinder or liquid container that contains medical gas. The term does not include a large-bulk liquid or high pressure container, such as a storage tank, vehicle-mounted vessel, trailer, or railcar.

(9) "Intracompany transaction" means a transaction between divisions, subsidiaries, parents, or affiliated or related companies under the common ownership and control of a single corporate entity.

(10) "Label" means a display of a written, printed, or graphic matter upon an immediate container. The term does not include the letters, numbers, or symbols stamped onto a container as required by the United States Department of Transportation.

(11) "Manufacturer" means a person or entity that manufactures medical gas in bulk or that transfers the gas or liquefied gas product from one container to another.

(12) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

(13) "Medical gas-related equipment" means a device used as an accessory or component part to contain or control flow, delivery, or pressure during the administration of medical gas, such as liquid-oxygen base and portable units, pressure regulators, flow meters, and oxygen concentrators.

(14) "Misbranded" means medical gas that has a label that is false or misleading or a label that does not:

(a) Display the name and address of the manufacturer, packer, or distributor;

(b) Provide an accurate statement of the quantity of active ingredients or show an accurate monograph for the medical gas; or

(c) In the case of mixtures of designated medical gases, identify the component percentages of each designated medical gas used to make the mixture.

(15) "Prescription medical oxygen" means oxygen USP, a drug that may be sold only by the order or prescription of a licensed practitioner authorized by law to prescribe.

(16) "USP-NF" or "USP" means the standards published in the official book, "The United States Pharmacopeia and the National Formulary."

(17) "Wholesale distribution" means the distribution of medical gas by a wholesale distributor of medical gas to a person other than a consumer or patient. The term does not include:

(a) The sale, purchase, or trade of a medical gas, an offer to sell, purchase, or trade a prescription drug or device, or the dispensing of medical gas pursuant to a prescription;

(b) The sale, purchase, or trade of a medical gas or an offer to sell, purchase, or trade medical gas for an emergency medical reason that includes, but is not limited to:

1. A transfer of a medical gas between wholesale distributors or between a wholesale distributor and a retail pharmacy or health care entity to alleviate a temporary shortage of medical gas resulting from a delay in or an interruption of a regular distribution schedule;

2. Sales to a licensed emergency medical service provider, such as an ambulance company, a firefighting organization, or a

licensed practitioner authorized to prescribe medical gases;

3. Provision of minimal emergency supplies of medical gas to a nursing home for use in an emergency or during the hours of the day when necessary medical gas cannot be obtained; or

4. Transfers of medical gases to alleviate a temporary shortage between retail pharmacies;

(c) An intracompany transaction;

(d) The sale, purchase, or trade of medical gas or an offer to sell, purchase, or trade medical gas among hospitals, pharmacies, or other health care entities that are under common control;

(e) The sale, purchase, or trade of medical gas, or the offer to sell, purchase, or trade medical gas by a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization, to the extent otherwise permitted by law;

(f) The purchase or other acquisition of medical gas by a hospital or other similar health care entity that is a member of a group purchasing organization, for the hospital's or the health care entity's own use, from the group purchasing organization or from another hospital or similar health care entity that is a member of such organization;

(g) The return of residual medical gas that may be reprocessed in accordance with the manufacturer's procedures or the return of recalled, expired, damaged, or otherwise nonsalable medical gas, when returned by a hospital, health care entity, pharmacy, or charitable institution to a wholesale distributor;

(h) An activity that is exempt from the definition of the

term "wholesale distribution" as provided in s. 499.003; or

(i) A transaction that is excluded from the definition of the term "wholesale distribution" under the federal act or regulations implemented under the federal act related to medical gas.

(18) "Wholesale distributor" means a person or entity engaged in the wholesale distribution of medical gas within or into this state, including, but not limited to, a manufacturer, an own-label distributor, a private-label distributor, a warehouse, including a manufacturers' and distributors' warehouse, and a wholesale medical gas warehouse.

Section 3. Section 499.82, Florida Statutes, is created to read:

499.82 Permits.—

(1) A person or establishment, located inside or outside the state, which intends to distribute medical gas within or into this state must obtain the applicable permit before operating.

(2) All of the following are legally authorized to receive medical gas: permitted medical gas manufacturers or permitted wholesale distributors, licensed pharmacies or health care entities, people authorized to receive emergency use oxygen without a prescription, locations with automated external defibrillation machines where emergency use oxygen is intended to be used with such machines, or companies that need medical gas in the installation and refurbishment of piping and equipment used to contain or administer medical gas.

(3) An applicant who is a natural person must be at least 18 years of age or an applicant must be managed, controlled, or

overseen, directly or indirectly, by a natural person who is at least 18 years of age.

(4) An out-of-state wholesale distributor that provides services in this state must be legally authorized as a wholesale distributor in the state in which it resides or is incorporated.

(5) A wholesale distributor may not operate from a place of residence, and a place of residence may not be granted a permit or operate under this part, except for the on-call delivery of home care oxygen by a home respiratory care technician.

(6) If wholesale distribution is conducted at more than one location within this state or more than one location distributing into this state, each location must be permitted by the department.

(7) The following permits are established:

(a) Medical gas wholesale distributor permit.—A medical gas wholesale distributor permit is required for wholesale distribution within or into this state.

1. Such permit does not authorize distribution to a consumer or patient.

2. The medical gas must be in the container that was obtained by that wholesale distributor without further manufacturing operations being performed.

3. A wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than medical gas.

(b) Medical gas manufacturer permit.—A medical gas manufacturer permit is required for a person who engages in the manufacture of medical gas by physical air separation, chemical action, purification, or filling containers using a liquid-to-

liquid, liquid-to-gas, or gas-to-gas process and distributes such medical gas within or into this state. A medical gas manufacturer:

1. May not manufacture or possess a prescription drug other than medical gas unless the appropriate permit is obtained.

2. May engage in the wholesale distribution of medical gas that is manufactured at the permitted establishment without obtaining a medical gas wholesale distributor permit, but shall comply with this part and applicable rules.

3. Shall comply with all appropriate state and federal good manufacturing practices.

(c) Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for a person who sells prescription medical oxygen directly to patients. Such sales must be based upon an order or prescription from a licensed practitioner authorized by law to prescribe. A pharmacy licensed under chapter 465 is exempt from this paragraph. A medical oxygen retail establishment:

1. May not possess, purchase, sell, or trade a prescription drug other than medical oxygen unless other appropriate permits are obtained.

2. May refill a prescription medical oxygen container for a patient based on an order or prescription from a licensed practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills prescription medical oxygen shall comply with all appropriate state and federal good manufacturing practices.

3. Shall comply with the storage and handling requirements under s. 499.84.

4. May not receive back into its inventory any prescription medical oxygen that it sold pursuant to a licensed practitioner's order.

Section 4. Section 499.821, Florida Statutes, is created to read:

499.821 Permit application.—

(1) The department shall establish by rule the form and content of an application to obtain a permit listed under s. 499.82.

(a) An application for a permit must be filed with the department and must include the following information:

1. The trade or business names, including fictitious names, currently and formerly used by the applicant, which may not be identical to a name used by an unrelated wholesale distributor authorized in this state to purchase medical gas.

2. The name or names of the owner and operator of the permittee, if not the same person or entity. The application must also include the following if the applicant is:

a. An individual: the applicant's business address and date of birth.

b. A sole proprietorship: the business address of the sole proprietor and the name and federal employer identification number of the business entity.

c. A partnership: the business address and date of birth of each partner and the name and federal employer identification number of the partnership.

d. A limited liability company: the business address and title of each company officer, the name and federal employer identification number of the limited liability company, and the

state of incorporation.

e. A corporation: the business address and title of each corporate officer and director; the name, state of incorporation, and federal employer identification number of the corporation; and the name and business address of any parent company.

3. A list of disciplinary actions pertinent to wholesale distributors of prescription drugs or controlled substances by a state or federal agency against the applicant seeking to distribute into this state and against a principal, owner, director, or officer.

4. An address and description of each facility or warehouse, including a description of the security system for any location used for medical gas storage or wholesale distribution.

(b) The applicant shall attest in writing that the information contained in the application is complete and accurate, that the applicant has not been convicted of or disciplined for a criminal or prohibited act, and that the application contains complete disclosure of any past criminal convictions or violations of state or federal law relating to medical gases.

(2) An applicant that is denied a permit has the right to review of the department's decision pursuant to chapter 120.

(3) An applicant must submit a reasonable fee, to be determined by the department, in order to obtain a permit. The fee for a medical gas wholesale distributor permit may not be less than $200 or more than $300 annually. The fee for a medical gas manufacturer permit may not be less than $400 or more than

$500 annually. The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

Section 5. Section 499.822, Florida Statutes, is created to read:

499.822 Expiration and renewal of a permit.—

(1) A permit issued under this part automatically expires 2 years after the last day of the month in which the permit was originally issued unless the permit is suspended or revoked before the automatic expiration date.

(2) A permit issued under this part may be renewed by submitting an application for renewal on a form furnished by the department and paying the appropriate fee. The application for renewal must contain a statement by the applicant attesting that the information is true and correct. If a renewal application and renewal fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, within 60 days after the expiration date.

(3) Failure to renew a permit in accordance with this section precludes future renewal. If a permit has expired and cannot be renewed, the person or establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department before engaging in an activity that requires a permit under this part.

(4) The department shall adopt rules to administer this section, including setting a reasonable fee for a renewal application.

Section 6. Section 499.823, Florida Statutes, is created to

read:

499.823 Minimum qualifications.—The department may deny an application for a permit or refuse to renew a permit based upon:

(1) Whether the applicant has violated, or has been disciplined by a regulatory agency in any state for violating, a federal, state, or local law relating to wholesale distribution;

(2) The applicant's criminal convictions;

(3) The applicant's past experience in manufacturing or distributing medical gas;

(4) Any false or fraudulent material contained in an application;

(5) Suspension, sanction, or revocation of a permit currently or previously held by the applicant for violations of a state or federal law relating to medical gas;

(6) Compliance with previously granted permit requirements;

(7) Compliance with the requirements to maintain or make available to the department or permitting authority or to a federal, state, or local law enforcement official records required to be maintained by a wholesale distributor; and

(8) Any other factors or qualifications that the department considers relevant to and consistent with public health and safety.

Section 7. Section 499.824, Florida Statutes, is created to read:

499.824 Permitholder changes.—

(1) A permit issued by the department is valid only for the person or entity to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily, and is not valid for an establishment other than

the establishment for which it was originally issued, except as provided in this part. The department may approve the following changes, and a person or entity may continue to operate in the following manner:

(a) *Change of location.*—A person or entity permitted under this part must notify the department 30 days before changing location. The department shall set a change-of-location fee not to exceed $100.

(b) *Change in ownership.*—If a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or if a lessee agrees to undertake or provide services such that legal liability for operation of the establishment will rest with the lessee, an application for a new permit is required. The application for the new permit must be submitted 30 days before the change of ownership. However, if an applicant is a permitholder or is wholly owned by or wholly owns a permitholder under this part, the application for the new permit must be made by the date of the sale, transfer, assignment, or lease. Between the date of the change of ownership and the date of the application approval or denial by the department, an applicant may distribute under the permit number of the previous owner.

(c) *Change of name.*—A permitholder may change its name without submitting a new permit application. However, the permitholder must notify the department 30 days before changing its name. The permitholder may continue to operate the establishment while the notification is being processed.

(d) *Closure.*—If an establishment permitted under this part closes, the owner must notify the department, in writing, before

the effective date of the closure and must:

1. Return the permit to the department; and

2. If the permittee is authorized to distribute medical gas, indicate the disposition of such medical gas, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to the records that are required to be maintained under this part. Transfer of ownership of medical gas may be made only to persons authorized to receive medical gas pursuant to this part.

(e) *Change in information.*—Any change in information required under this part, other than a change of information as set forth in paragraphs (a)-(d), must be submitted to the department within 30 days after such change.

(2) Notwithstanding paragraph (1)(a), a permitholder in good standing may change the type of permit issued by completing a new application for the requested permit, paying the amount of the difference in the permit fees, and meeting the applicable permitting requirements for the new permit type. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit. The new permit expires on the expiration date of the original permit being changed.

(3) The department may revoke a permit for failure to comply with this section.

Section 8. Section 499.83 Florida Statutes, is created to read:

499.83 Registered agent.—An applicant for or a holder of a permit as a medical gas wholesale distributor or as a medical oxygen retail establishment shall designate a registered agent in this state for purposes of service of process. If an

applicant or a permitted wholesale distributor or medical oxygen retailer fails to designate a registered agent, the Secretary of State shall be deemed the true and lawful attorney of the applicant or the permitted wholesale distributor or medical oxygen retailer, and, in such case, the legal processes in any action or proceeding against an applicant or permitted wholesale distributor or medical oxygen retailer which grows out of or arising from wholesale distribution or retail may be served upon the Secretary of State. A copy of the service of process shall be mailed to the applicant or the permitted wholesale distributor or medical oxygen retailer by the department by certified mail, return receipt requested, postage prepaid, at the address of the applicant or the distributor or retailer as designated on the application for a permit in this state.

Section 9. Section 499.84, Florida Statutes, is created to read:

499.84 Minimum requirements for the storage and handling of medical gas.—

(1) A facility that receives, stores, warehouses, handles, holds, offers, markets, displays, or transports medical gas must avoid any negative effect on the identity, strength, quality, or purity of medical gas by:

(a) Being constructed in a way that ensures that medical gas is maintained in accordance with its product labeling recommendations or in compliance with official compendium standards, such as the USP-NF;

(b) Being of a suitable size and construction that facilitates cleaning, maintenance, and proper wholesale distribution;

(c) Having an adequate storage area with appropriate lighting, ventilation, space, equipment, and security conditions;

(d) Having a quarantine area for the storage of medical gas that is suspected of being misbranded, adulterated, or otherwise unfit for distribution;

(e) Being maintained in an orderly condition;

(f) Being in a commercial location, except if a personal dwelling location is used for the on-call delivery of oxygen USP for home care use and the person providing on-call delivery is employed by or acting under a written contract with a permittee;

(g) Providing for the secure storage of patient information, if applicable, by restricting access and implementing policies and procedures that protect the integrity and confidentiality of patient information; and

(h) Providing and maintaining appropriate inventory controls in order to detect and document any theft of nitrous oxide.

(2) Medical gas must be stored under appropriate conditions in accordance with the manufacturers' recommendations on product labeling and department rules or, in the absence of rules, in accordance with applicable industry standards. Medical gas must be packaged in accordance with official compendium standards, such as the USP-NF.

Section 10. Section 499.85, Florida Statutes, is created to read:

499.85 Security.—

(1) A facility that engages in wholesale distribution shall implement measures to secure its facility from unauthorized

entry. Such measures must include the following:

(a) Access from outside the premises must be well-controlled and kept to a minimum.

(b) The outside perimeter of the premises must be well-lighted.

(c) Areas in which medical gas is held must be restricted by a fence or other system that detects or deters entry after hours and limits access only to authorized personnel.

(2) A facility that engages in wholesale distribution must have:

(a) A security system that provides protection against theft and, if appropriate, theft that is enabled or obscured by tampering with computers or electronic records.

(b) A security system that protects the integrity and confidentiality of data and documents.

(3) If a wholesale distributor uses electronic distribution records, he or she must employ, train, and document the training of personnel for the proper use of the applicable technology and equipment.

(4) A vehicle used for on-call delivery of oxygen USP and oxygen-related equipment for home care use by a home care provider may be parked at a place of residence. Such vehicle while unattended must be locked and equipped with an audible alarm.

(5) The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use by persons authorized to receive emergency use oxygen. Unless the laws of this state specifically direct otherwise, such rules must be consistent with federal rules and

regulations, including the labeling requirements of oxygen under the federal act.

Section 11. Section 499.86, Florida Statutes, is created to read:

499.86 Examination of materials.—

(1) A wholesale distributor must visually examine an immediate container upon receipt from the manufacturer in order to identify the medical gas and to determine if the container has been damaged or is otherwise unfit for wholesale distribution. Such examination must occur in a manner that would reveal damage to the container which could suggest possible adulteration or misbranding.

(2) A medical gas container that is damaged or otherwise unfit pursuant to subsection (1) must be quarantined from the rest of the stock of medical gas until it is determined that the medical gas in question was not misbranded or adulterated.

(3) An outgoing shipment must be inspected for identity and to ensure that medical gas containers that have been damaged in storage or held under improper conditions are not delivered.

(4) A wholesale distributor must review records documenting the acquisition of medical gas upon receipt for accuracy and completeness.

Section 12. Section 499.87, Florida Statutes, is created to read:

499.87 Returned, damaged, and outdated medical gas.—

(1) Medical gas that has left the control of a wholesale distributor may be returned to the manufacturer or wholesale distributor from which it was acquired.

(2) Unless medical gas is reprocessed by a manufacturer

employing proper and adequate controls to ensure the identity, strength, quality, and purity of the reprocessed medical gas, the gas may not be resold as a medical gas even if its integrity was maintained.

(3) Medical gas that has been subjected to improper conditions, such as a fire, accident, or natural disaster, may not be salvaged or reprocessed.

(4) Medical gas, including its container, which is damaged, misbranded, or adulterated must be quarantined from other medical gases until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired. External contamination to a medical gas container or closure system which does not impact the integrity of the medical gas is not considered damage or adulteration for purposes of this subsection. If medical gas is adulterated or misbranded or suspected of being adulterated or misbranded, notice shall be provided to the manufacturer or wholesale distributor from which the medical gas was acquired and to the appropriate boards and federal regulatory bodies.

(5) A medical gas container that has been opened or used but is not adulterated or misbranded is considered empty and must be quarantined from nonempty medical gas containers and returned to the manufacturer or wholesale distributor from which it was acquired for destruction or reprocessing.

(6) Medical gas, its container, or its associated documentation or labeling that is suspected of being used in criminal activity must be retained until its disposition is authorized by the department or an applicable law enforcement agency.

Section 13. Section 499.88, Florida Statutes, is created to read:

499.88 Due diligence.—

(1) A wholesale distributor shall obtain, before the initial acquisition of medical gas, the following information from the supplying wholesale distributor or manufacturer:

(a) If a manufacturer is distributing to a wholesale distributor, evidence that the manufacturer is registered and the medical gas is listed with the FDA;

(b) If a wholesale distributor is distributing to a wholesale distributor, evidence that the wholesale distributor supplying the medical gas is permitted to distribute medical gas within or into the state;

(c) The name of the contact person for the supplying manufacturer or wholesale distributor; and

(d) Certification that the manufacturer's or wholesale distributor's policies and procedures comply with this part.

(2) A wholesale distributor is exempt from obtaining the information from a manufacturer as required under subsection (1) if the manufacturer is registered with the FDA in accordance with s. 510 of the federal act and provides:

(a) Proof of such registration; and

(b) Proof of inspection within the past 3 years by the FDA or other regulatory body or proof of conformance with industry standards or guidelines as identified by the department.

(3) A manufacturer or wholesale distributor that distributes to or acquires medical gas from another wholesale distributor shall provide to or obtain from the distributing or acquiring manufacturer or distributor the information required

by s. 499.89(1), as applicable.

Section 14. Section 499.89, Florida Statutes, is created to read:

499.89 Recordkeeping.—

(1) A wholesale distributor shall establish and maintain a record of transactions regarding the receipt and the distribution, or other disposition, of medical gases. Such records constitute an audit trail and must contain information sufficient to perform a recall of medical gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records must include all the following information, which need not appear in the same document:

(a) The dates of receipt and wholesale distribution, or other disposition, of the medical gas.

(b) The name, address, permit number, and permit expiration date for the entity purchasing the medical gas from the wholesale distributor.

(c) The name, address, permit number, and permit expiration date for the entity receiving the medical gas from the wholesale distributor, if different from the information required under paragraph (b).

(d) Information sufficient to perform a recall of all medical gas received or distributed.

(2) From the time of their creation, such records shall be kept for 3 years for high pressure medical gas and for 1 year for cryogenic or refrigerated liquid medical gas.

(3) During the retention period, such records shall be made available for inspection and photocopying by an authorized official of a state, federal, or local governmental agency. If

such records are kept at the inspection site or could be immediately retrieved by electronic means, they shall be made readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 business days of a request.

(4) A pedigree paper is not required for the wholesale distribution of medical gas.

Section 15. Section 499.90, Florida Statutes, is created to read:

499.90 Policies and procedures.—A wholesale distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, transport, shipping, and wholesale distribution of medical gas and shall establish, maintain, and adhere to procedures for maintaining inventories; for identifying, recording, and reporting losses or thefts; and for correcting all errors and inaccuracies in inventories associated with nitrous oxide. A wholesale distributor shall include in its written policies and procedures the following:

(1) A procedure for handling recalls and withdrawals of medical gas. Such procedure must deal with recalls and withdrawals due to:

(a) Action initiated at the request of the FDA or any federal, state, or local law enforcement or other government agency, including the department; or

(b) Voluntary action by the manufacturer of medical gas to remove defective or potentially defective medical gases from the market.

(2) A procedure preparing for, protecting against, and handling a crisis that affects the security or operation of a facility in the event of a strike, fire, flood, or other natural disaster or other situations of local, state, or national emergency.

(3) A procedure for reporting criminal or suspected criminal activity involving the inventory of nitrous oxide to the department and to applicable law enforcement agencies within 3 business days after becoming aware of the criminal or suspected criminal activity.

Section 16. Section 499.91, Florida Statutes, is created to read:

499.91 Prohibited acts.—A person may not perform or cause the performance of, or aid and abet in, any of the following acts in this state:

(1) The manufacture, sale, or delivery, or the holding or offering for sale, of medical gas that is adulterated, misbranded, or has otherwise been rendered unfit for distribution.

(2) The adulteration or misbranding of medical gas.

(3) The receipt of medical gas that is adulterated, misbranded, stolen, or obtained by fraud or deceit or the delivery or proffered delivery of such medical gas for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the product labeling of medical gas or the willful commission of any other act with respect to medical gas that results in it being misbranded.

(5) The purchase or receipt of medical gas from a person

who is not authorized by permit to distribute wholesale medical gas or who is exempted from permitting requirements to distribute wholesale medical gas to such purchaser or recipient.

(6) The knowing and willful sale or transfer of medical gas to a recipient who is not legally authorized to receive medical gas, except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(7) The failure to maintain or provide records required under this part and its implementing regulations.

(8) Providing the department or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding this part and its implementing regulations.

(9) The wholesale distribution of medical gas that was:

(a) Purchased by a public or private hospital or other health care entity, except for the physical distribution of such medical gas to an authorized recipient at the direction of a hospital or other health care entity;

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

(c) Stolen or obtained by fraud or deceit.

(10) The failure to obtain a permit or operating without a valid permit when a permit is required.

(11) The obtaining of or attempt to obtain medical gas by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of medical gas.

(12) Except for oxygen USP in emergency situations, the

distribution of medical gas to a patient without an order or prescription from a licensed practitioner authorized by law to prescribe.

(13) The distribution of medical gas that was previously dispensed by a pharmacy or a licensed practitioner authorized by law to prescribe.

(14) The distribution of medical gas or medical gas-related equipment to a patient, unless the patient has been provided with the appropriate information and counseling on the use, storage, and disposal of medical gas.

(15) The failure to report an act prohibited under this part and its implementing regulations.

(16) The failure to exercise due diligence as provided in s. 499.88.

Section 17. Section 499.92, Florida Statutes, is created to read:

499.92 Criminal acts.—

(1) A person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if he or she:

(a) With intent to defraud or deceive adulterates or misbrands medical gas.

(b) Engages in the wholesale distribution of, and knowingly purchases or receives, medical gas from a person not legally authorized to distribute medical gas.

(c) Engages in the wholesale distribution of, and knowingly sells, barters, brokers, or transfers, medical gas to a person not legally authorized to purchase medical gas in the jurisdiction in which the person receives the medical gas,

except that a violation does not exist as to a distributor that provides oxygen to a permitted medical oxygen retail establishment if the distributor is out of compliance with only the change of location notice requirement under s. 499.824.

(d) Knowingly, falsely creates a label for medical gas or knowingly, falsely represents a factual matter contained in a label for medical gas.

(2) A court that has authority over a person who violates this section and that convicts such person shall order him or her to forfeit to the state real or personal property or assets:

(a) Used or intended to be used to commit, facilitate, or promote the commission of such violation; and

(b) Constituting, derived from, or traceable to the gross proceeds that the defendant obtained as a result of the violation.

(3) Property or assets subject to forfeiture under subsection (2) may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise authorized by law and held until the case against the defendant is adjudicated. Moneys ordered to be forfeited or proceeds from the sale of assets ordered to be forfeited shall be equitably divided between the department and agencies involved in the investigation and prosecution that led to the conviction. Other property ordered to be forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution.

Section 18. Section 499.93, Florida Statutes, is created to read:

499.93 Inspections.—

(1) The department may require a facility that engages in the manufacture, retail sale, or wholesale distribution of medical gas to undergo an inspection in accordance with a schedule to be determined by the department.

(2) The department may recognize other state inspections of a manufacturer or wholesale distributor in another state if such state's laws are deemed to be substantially equivalent to the laws of this state.

(3) A manufacturing facility is exempt from inspection by the department if the facility:

(a) Is currently registered with the FDA in accordance with s. 510 of the federal act and can provide proof of such registration, such as a copy of the online verification page; and

(b) Can provide proof of inspection within the past 3 years by the FDA or, if the facility is located in another state, by another governmental entity charged with regulation of good manufacturing practices related to medical gas.

(4) A wholesale distributor must exhibit or have readily available its state permits and its most recent inspection report administered by the department. The department may authorize a third party to inspect wholesale distributors who distribute within or into this state.

Section 19. Section 499.931, Florida Statutes, is created to read:

499.931 Trade secret information.—Information required to be submitted under this part which is a trade secret as defined in s. 812.081(1)(c) and designated as a trade secret by an

applicant or permit holder must be maintained as required under s. 499.051.

Section 20. Section 499.94, Florida Statutes, is created to read:

499.94 Fees.—A fee collected for a permit under this part shall be deposited into the Professional Regulation Trust Fund. Moneys collected under this part shall be used for administering this part. The department shall maintain a separate account in the trust fund for the Drugs, Devices, and Cosmetics program.

Section 21. Section 499.95, Florida Statues, is created to read:

499.95 Enforcement and construction of this part.—

(1) For the purpose of initiating an investigation or proceeding under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. Challenges to, and enforcement of, a subpoena and an order shall be conducted in accordance with s. 120.569.

(2) A state, county, or municipal attorney to whom the department or its designated agent reports a violation of this part shall timely institute proceedings in the court of competent jurisdiction and shall prosecute in the manner required by law.

(3) The department is not required to report minor violations to a state, county, or municipal attorney if the department determines that the public interest is best served by issuance of a written notice or warning to the violator.

(4) This part is cumulative and does not repeal or affect

the power, duty, or authority of the department. However, relating to the regulation of medical gas, if this part conflicts with other law, this part controls.

Section 22. Section 499.001, Florida Statutes, is amended to read:

499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.95 ~~499.001-499.081~~ may be cited as the "Florida Drug and Cosmetic Act."

Section 23. Present subsections (11) through (32) and (46) through (55) of section 499.003, Florida Statutes, are amended, and a new subsection (32) is added to that section, to read:

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

~~(11) "Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.~~

(11)~~(12)~~ "Contraband prescription drug" means any adulterated drug, ~~as defined in s. 499.006,~~ any counterfeit drug, ~~as defined in this section,~~ and ~~also means~~ any prescription drug for which a pedigree paper does not exist~~,~~ or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

(12)~~(13)~~ "Cosmetic" means an article, with the exception of soap, that is:

(a) Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b) Intended for use as a component of any such article.

(13)~~(14)~~ "Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(14)~~(15)~~ "Department" means the Department of Business and Professional Regulation.

(15)~~(16)~~ "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof;~~,~~

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

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

and that does not achieve any of its principal intended purposes

through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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

(17)~~(18)~~ "Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

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

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

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

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

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and

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

(19)~~(20)~~ "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(20)~~(21)~~ "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(21)~~(22)~~ "Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(22)~~(23)~~ "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or

chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

(23)~~(24)~~ "Health care facility" means a health care facility licensed under chapter 395.

(24)~~(25)~~ "Hospice" means a corporation licensed under part IV of chapter 400.

(25)~~(26)~~ "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(26)~~(27)~~ "Immediate container" does not include package liners.

(27)~~(28)~~ "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(28)~~(29)~~ "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(29)~~(30)~~ "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(30)~~(31)~~ "Manufacturer" means:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b) The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c) A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d) A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e) A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s.

1504 of the Internal Revenue Code of 1986, as amended. The manufacturer must disclose the names of all of its affiliated group members to the department; or

(f) A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(31) ~~(32)~~ "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(32) "Medical gas" is defined in accordance with the federal act and means a liquefied or vaporized gas that is a prescription drug, regardless of whether it is alone or combined with other gases.

(46) ~~"Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.~~

~~(47)~~ "Primary wholesale distributor" means any wholesale distributor that:

(a) Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from

manufacturers in the previous year; and

(b)1. Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2. Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c) For purposes of this subsection, "directly from manufacturers" means:

1. Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2. Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a. The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

b. The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(47) ~~(48)~~ "Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be

purchased without a prescription.

(48) ~~(49)~~ "Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(49) ~~(50)~~ "Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(50) ~~(51)~~ "Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(51) ~~(52)~~ "Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(52) ~~(53)~~ "Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(53) ~~(54)~~ "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the

group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f. In addition to the departmental inspection authority described ~~set forth~~ in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this

subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3. The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

5. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

6. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person

licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c) The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d) The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e) The lawful dispensing of a prescription drug in accordance with chapter 465.

(f) The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or

consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(54)~~(55)~~ "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 24. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

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

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s. 499.003(52), ~~s. 499.003(46) or (53) or~~ s. 499.007(13), or s. 499.81(15).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 25. Paragraph (c) of subsection (9) of section

460.403, Florida Statutes, is amended to read:

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

(9)

(c)1. Chiropractic physicians may adjust, manipulate, or treat the human body by manual, mechanical, electrical, or natural methods; by the use of physical means or physiotherapy, including light, heat, water, or exercise; by the use of acupuncture; or by the administration of foods, food concentrates, food extracts, and items for which a prescription is not required and may apply first aid and hygiene, but chiropractic physicians are expressly prohibited from prescribing or administering to any person any legend drug except as authorized under subparagraph 2., from performing any surgery except as stated herein, or from practicing obstetrics.

2. Notwithstanding the prohibition against prescribing and administering legend drugs under subparagraph 1. or s. 499.82(7)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule chiropractic physicians may order, store, and administer, for emergency purposes only at the chiropractic physician's office or place of business, prescription medical oxygen and may also order, store, and administer the following topical anesthetics in aerosol form:

a. Any solution consisting of 25 percent ethylchloride and 75 percent dichlorodifluoromethane.

b. Any solution consisting of 15 percent dichlorodifluoromethane and 85 percent trichloromonofluoromethane.

However, this paragraph does not authorize a chiropractic

physician to prescribe medical oxygen as defined in chapter 499.

Section 26. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section may ~~shall~~ not be construed as the filling of a transferred prescription as described ~~set forth~~ in s. 465.026 or as a wholesale distribution as defined ~~set forth~~ in s. 499.003 ~~s. 499.003(54)~~.

Section 27. Subsection (1), paragraphs (a), (c), (g), (m), (n), and (o) of subsection (2), and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(1) Before ~~Prior to~~ operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A prescription drug wholesale distributor;

(e) An out-of-state prescription drug wholesale distributor;

(f) A retail pharmacy drug wholesale distributor;

(g) A restricted prescription drug distributor;

(h) A complimentary drug distributor;

(i) A freight forwarder;

(j) A veterinary prescription drug retail establishment;

(k) A veterinary prescription drug wholesale distributor;

(l) A limited prescription drug veterinary wholesale distributor;

~~(m) A medical oxygen retail establishment;~~

~~(n) A compressed medical gas wholesale distributor;~~

~~(o) A compressed medical gas manufacturer;~~

(m) ~~(p)~~ An over-the-counter drug manufacturer;

(n) ~~(q)~~ A device manufacturer;

(o) ~~(r)~~ A cosmetic manufacturer;

(p) ~~(s)~~ A third party logistics provider; or

(q) ~~(t)~~ A health care clinic establishment.

(2) The following permits are established:

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

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

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

3. A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

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

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e) ~~s. 499.003(31)(c)~~.

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

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

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

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(53)(a) ~~s. 499.003(54)(a)~~.

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

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

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

(III) Drugs that are blood derivatives, or a recombinant or

synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

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

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those described ~~set forth~~ in s. 499.01212 if

the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

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

~~(m) *Medical oxygen retail establishment permit.* A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.~~

~~1. A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.~~

~~2. A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.~~

~~3. A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.~~

~~4. Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.~~

~~(n) *Compressed medical gas wholesale distributor permit.* A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.~~

~~(o) *Compressed medical gas manufacturer permit.* A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.~~

~~1. A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.~~

~~2. A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a~~

~~wholesale distributor.~~

~~3. A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.~~

(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s. 499.003(54)(a)3.~~, if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

Section 28. Paragraph (b) of subsection (2) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(2) SECURITY.—

(b) An establishment that is used for wholesale drug distribution must be equipped with:

1. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers ~~and establishments that only handle medical oxygen~~; and

2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Section 29. Section 499.01211, Florida Statutes, is amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.—

(1) There is created the Drug Wholesale Distributor

Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 12 ~~11~~ members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2) The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(47)~~.

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003 ~~s. 499.003(52)~~.

(c) One person employed by a retail pharmacy chain located in this state.

(d) One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e) One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f) One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g) One person who is an employee of a pharmaceutical manufacturer.

(3) The Compressed Gas Association shall appoint one person to the council who is an employee of a permitted medical gas wholesale distributor or manufacturer.

(4) ~~(3)~~ The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.

Section 30. Paragraph (b) of subsection (2) of section 499.01212, Florida Statutes, is amended to read:

499.01212 Pedigree paper.—

(2) FORMAT.—A pedigree paper must contain the following information:

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs.

2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.

4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5. An invoice number, a shipping document number, or

another number uniquely identifying the transaction.

6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer as defined in s. 499.003(30)(e) ~~under s. 499.003(31)(c)~~, information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

Section 31. Paragraph (a) of subsection (1) and subsection (3) of section 499.015, Florida Statutes, are amended to read:

499.015 Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time

of registration.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

Section 32. Subsection (3) of section 499.024, Florida Statutes, is amended to read:

499.024 Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(3) Any product that falls under the definition of drug in s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

Section 33. Paragraph (e) of subsection (1), paragraph (b) of subsection (2), and paragraph (b) of subsection (3) of section 499.041, Florida Statutes, are amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

~~(c) The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.~~

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

~~(b) The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.~~

(3) The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

~~(b) The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.~~

Section 34. Paragraphs (i) and (m) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this chapter ~~part~~ with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s. 499.003(53)(b)2. ~~s. 499.003(54)(b)2~~.

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(53)(a)-(d) ~~s. 499.003(54)(a)-(d)~~.

Section 35. Subsections (1) through (4) of section 499.051, Florida Statutes, are amended to read:

499.051 Inspections and investigations.—

(1) The agents of the department and of the Department of

Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this chapter ~~part~~ during business hours for the purpose of enforcing this chapter ~~part~~, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and rules adopted under this chapter ~~part~~ regarding any drug, device, or cosmetic product.

(3) Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this chapter ~~part~~ and rules adopted under this chapter ~~part~~ constitutes permission for any entry or inspection of the premises in order to verify compliance with this chapter ~~part~~ and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4) Any application for a permit made pursuant to s. 499.012 or s. 499.821 and rules adopted under those sections ~~that section~~ constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this chapter ~~part~~ and the rules adopted by the department to administer this chapter ~~part~~, in order to discover, investigate,

and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

Section 36. Section 499.066, Florida Statutes, is amended to read:

499.066 Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1) The department may institute such suits or other legal proceedings as are required to enforce any provision of this chapter ~~part~~. If it appears that a person has violated any provision of this chapter ~~part~~ for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2) If any person engaged in any activity covered by this chapter ~~part~~ violates any provision of this chapter ~~part~~, any rule adopted under this chapter ~~part~~, or a cease and desist order as provided by this chapter ~~part~~, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and the orders of the department authorized by this chapter ~~part~~ or to mandate compliance with this chapter ~~part~~, the rules adopted under this chapter ~~part~~, and any order or permit issued by the department under this chapter ~~part~~.

(3) The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this chapter ~~part~~. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a) The severity of the violation;

(b) Any actions taken by the person to correct the violation or to remedy complaints; and

(c) Any previous violations.

(4) The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this chapter ~~part~~, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this chapter ~~part~~.

(5) The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6) The department may issue an emergency order to immediately remove from commerce and public access any drug,

device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7) Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

Section 37. Paragraph (a) of subsection (1) and paragraph (a) of subsection (2) of section 499.0661, Florida Statutes, are amended to read:

499.0661 Cease and desist orders; removal of certain persons.—

(1) CEASE AND DESIST ORDERS.—

(a) In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A violation of any provision of this chapter ~~part~~;

3. A violation of any rule of the department;

4. A violation of any order of the department; or

5. A breach of any written agreement with the department.

(2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a) The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1. An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this chapter ~~part~~, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2. A willful violation of this chapter ~~part~~; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3. A violation of any other law involving fraud or moral turpitude which constitutes a felony;

4. A willful violation of any rule of the department;

5. A willful violation of any order of the department; or

6. A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

Section 38. Section 499.067, Florida Statutes, is amended to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a) The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply

with this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, the rules adopted under this chapter ~~part~~ or those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b) The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1. The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2. The applicant has not met the requirements for the permit or certification.

3. The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4. The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5. The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054.

(2) The department may deny, suspend, or revoke any registration required by the provisions of this chapter ~~part~~ for the violation of any provision of this chapter ~~part~~ or of any rules adopted under this chapter ~~part~~.

(3) The department may revoke or suspend a permit:

(a) If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b) If the permit was procured, or attempted to be

procured, for any other person by making or causing to be made any false representation; or

(c) If the permittee has violated any provision of this chapter ~~part~~ or rules adopted under this chapter ~~part~~.

(4) If any permit issued under this chapter ~~part~~ is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under this chapter ~~part~~ for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5) The department may deny, suspend, or revoke a permit issued under this chapter ~~part~~ which authorizes the permittee to purchase prescription drugs if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this chapter ~~part~~ or chapter 465, chapter 501, or chapter 893, any rules adopted under this chapter ~~part~~ or those chapters, or any federal or state drug law, regardless of whether the person has

been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6) The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this chapter ~~part~~ will avoid an administrative penalty, civil action, or criminal prosecution.

(7) Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6) or s. 499.83, as applicable, the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit under this part if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 39. This act shall take effect October 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic Medical Gas Regulation

Bill Number CS/SB 836 *(if applicable)*

Name Mark Delegal

Amendment Barcode 181392 *(if applicable)*

Job Title Retained Counsel

Address 315 S. Calhoun St. #600
Street

Phone 850 224-7000

TLH FL 32301
City *State* *Zip*

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing Compressed Gas Assn

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 918
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Termination of Pregnancies
DATE:	April 2, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			JU	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 918 amends the statutes relating to termination of pregnancies to prohibit an abortion if the physician determines that, in reasonable medical judgment, the fetus has achieved viability. The bill defines reasonable medical judgment as a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and treatment possibilities with respect to the medical conditions involved. Medical exceptions are provided if the termination of 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. The exceptions allowing a physician to terminate a pregnancy during the third trimester are revised to reflect this same standard.

Before performing an abortion, a physician must determine if the fetus is viable. Viability is redefined to mean the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures. The bill also defines standard medical measures.

The bill provides a parallel structure for abortions during the third trimester and once a fetus has achieved viability, including efforts to preserve the life and health of the fetus, requiring a lawful abortion to be performed in a hospital after these milestones, and criminal penalties for an unlawful abortion.

The bill provides a severability clause but provides that if the new section of law relating to termination of pregnancy during viability is held unconstitutional, then the other amendments in this act are repealed and these sections of law revert to the law as it existed on January 1, 2014.

II. Present Situation:

Case Law on Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*, was decided by the U.S. Supreme Court.[1] Using strict scrutiny, the court determined that a woman's right to terminate a pregnancy is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution.[2] 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.[3] The court established the trimester framework for the regulation of termination – holding that in the third trimester, a state could prohibit termination to the extent that the woman's life or health was not at risk.[4]

In *Planned Parenthood v. Casey*, the U.S. Supreme Court, while upholding the fundamental holding of *Roe*, recognized that medical advancement could shift determinations of fetal viability away from the trimester framework.[5]

Abortion in Florida

Article I, section 23 of the State Constitution provides an express right to privacy. The Florida Supreme Court has recognized the Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[6]

In *In re T.W.*, the Florida Supreme Court determined 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.

[1] 410 U.S. 113 (1973).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] 505 U.S. 833 (1992).
[6] *See In re T.W.*, 551 So. 2d 1186, 1192 (Fla. 1989)(holding that a parental consent statute was unconstitutional because it intrudes on a minor's right to privacy).

The Florida Supreme Court recognized that after viability, the state can regulate termination in the interest of the unborn child so long as the mother's health is not in jeopardy.[7]

Under Florida law, 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.[8] A termination of pregnancy must be performed by a physician[9] 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.[10]

A termination of pregnancy may not be performed in the third trimester unless there is a medical necessity. Florida law defines the third trimester to mean the weeks of pregnancy after the 24th week.[11] Specifically, an abortion may not be performed within the third trimester unless two physicians certify in writing that, to a reasonable degree of medical probability, the termination of pregnancy is necessary to save the life or preserve the health of the pregnant woman. If a second physician is not available, one physician may certify in writing to the medical necessity for legitimate emergency medical procedures for termination of the pregnancy.

Section 390.0111(4), F.S., provides that if a termination of pregnancy is performed during viability, the person who performs or induces the termination of pregnancy must use that degree of professional skill, care, and diligence to preserve the life and health of the fetus, which such person would be required to exercise in order to preserve the life and health of any fetus intended to be born and not aborted. Viability is defined in this provision to mean that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb. However, the woman's life and health constitute an overriding and superior consideration to the concern for the life and health of the fetus when such concerns are in conflict.

A termination of pregnancy in the third trimester must be performed in a hospital.[12]

Viability

Current law defines "viability" to mean that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb.[13]

The gestational age of a viable fetus has become earlier in the pregnancy over the years. In 1935, the American Academy of Pediatrics defined a premature infant as one who weighed <2500 g at birth regardless of gestational age. Although no minimum weight for viability was established, 1250 g was frequently used and corresponded to an estimated gestational age of 28 weeks. As continuous positive airway pressure and neonatal total parenteral nutritional therapy became increasingly mainstream, the medical definition of viability continued to evolve as well. By the

[7] *Id.*
[8] Section 390.011(1), F.S.
[9] Section 390.0111(2), F.S.
[10] Section 390.011(8), F.S.
[11] Section 390.011(7), F.S.
[12] Section 797.03(3), F.S.
[13] Section 390.0111(4), F.S.

1980s, survival of infants who were born weighing 500 to 700 g or were of 24 to 26 weeks' gestation became an expected possibility in regional NICUs. The 1980s and 1990s brought new waves of neonatal biomedical advances, led by tracheal instillation of surfactant for respiratory distress syndrome and the use of antenatal corticosteroids in women with imminent delivery of a preterm infant at 24 to 34 weeks' gestation. With these changes, survival of infants born at 23 and 24 weeks' estimated gestational age became increasingly frequent.[14]

The determination of viability is not an exact science and the stage at which a fetus is viable is an individual determination based on each pregnant woman and fetus. Gestational age, weight, sex, plurality or whether it is a single fetus, as well as other factors, may be considered in the determination of viability now and in the future as neonatal and medical care advances.[15,16]

Twenty-one states place limits on abortions after the fetus is viable. Generally, exceptions are made when the life and health of the women is at risk.[17]

Documenting Gestational Age

The Agency for Health Care Administration (agency) is responsible for regulating abortion clinics under ch. 390, F.S., and part II of ch. 408, F.S. Section 390.012, F.S., requires the agency to adopt rules[18] for, among other things, clinics that perform abortions after the first trimester of pregnancy. These rules must address physical facilities, supplies and equipment standards, personnel, medical screening and evaluation of patients, abortion procedures, recovery room standards, follow-up care, and adverse incident reporting. The statutes further prescribe specific components to be included within the rules relating to each of these subject areas.

Within rules relating to medical screening and evaluation of patients, the rules must, among other things, require that the physician is responsible for estimating the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age and shall write the estimate in the patient's medical history. The physician is also required to keep original prints of each ultrasound examination in the patient's medical history file.

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[14] *See Limits of Human Viability in the United States: A Medicolegal Review*, Bonnie Hope Arzuaga, MD and Ben Hokew Lee, MD, MPH, MSCR, Pediatrics Perspectives, published online November 1, 2011, available at: http://pediatrics.aappublications.org/content/128/6/1047.full (Last visited Feb. 26, 2014)

[15] Wolters Kluwer Health, UpToDate, available at: http://www.uptodate.com/contents/limit-of-viability#H8144843, (Last visited Feb. 26, 2014).

[16] The U.S. Department of Health and Human Services, National Institutes of Health *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, Pregnancy and Perinatology Branch-supported researchers developed a tool using data from the Neonatal Research Network (NRN) that shows outcome trends for infants born at extremely preterm gestations. Found at:http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx, (Last visited Feb. 26, 2014).

[17] These states include Arizona, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Kentucky, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Ohio, Tennessee, Utah, Washington, Wisconsin, and Wyoming. *See* Guttmacher Institute State Policies in Brief *State Policies on Later Abortions*, as of February 1, 2014, found at: http://www.guttmacher.org/statecenter/spibs/spib_PLTA.pdf (Last visited Feb. 25, 2014).

[18] These rules are found in Rule Chapter 59A-9, Florida Administrative Code.

III. Effect of Proposed Changes:

The bill prohibits abortions once a physician has determined that, in reasonable medical judgment, a fetus is viable in the same manner as abortions are prohibited during the third trimester of pregnancy. This provides for comparable treatment as medical advances allow the life of a fetus to be sustainable outside the womb at an earlier point of gestation than the third trimester. The bill leaves in place the current prohibition on performing abortions during the third trimester.

Definitions

Section 1 of the bill
The bill defines the term "reasonable medical judgment" as a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and treatment possibilities with respect to the medical conditions involved.

The term "viable" or "viability" is redefined and moved from another section of law[19] into the definitions section for applicability to the entire ch. 390, F.S. Under the bill, "viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

"Standard medical measure" is defined in the bill to mean the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, F.S., with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

Termination of Pregnancy in the Third Trimester and During Viability

Sections 2 and 3 of the bill
The bill establishes the same prohibitions and conditions for performing an abortion in the third trimester of pregnancy and once a fetus has achieved viability. The medical exceptions that allow a physician to perform an abortion in the third trimester of pregnancy are modified and are consistent with the medical exceptions established during viability.

The bill authorizes a termination of pregnancy in the third trimester or during viability when two physicians certify in writing that, in reasonable medical judgment, the termination 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. If a second physician is not available, the physician may certify in writing to the 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.

[19] Section 390.0111(4), F.S.

The bill specifies a standard of care when a termination of pregnancy occurs during viability that parallels the standard of care required when a termination of pregnancy occurs in the third trimester. The physician performing the abortion 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 and not aborted. Further, if preserving the life and health of the fetus conflicts with preserving the life and health of the woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Section 4 of the bill amends s. 797.03, F.S., to prohibit a person performing an abortion on a person during viability other than in a hospital. A person who wilfully violates this provision is guilty of a misdemeanor of the second degree, punishable by a definite term of imprisonment not exceeding 60 days and subject to a fine of up to $500.

Determination of Viability

Section 3 of the bill
Before terminating a pregnancy, a physician must determine, in reasonable medical judgment, whether the fetus has achieved viability. At a minimum, the physician must perform a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound,[20] an examination of the fetus. The physician must document in the pregnant woman's medical file his or her determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

Penalties

Section 2 of the bill
The penalties for violating the bill's provisions pertaining to termination of pregnancies during viability in s. 390.01112, F.S., are similar to those for violating the provisions pertaining to termination of pregnancies during the third trimester in s. 390.0111, F.S.

Specifically, the bill provides that a person who willfully performs, or actively participates in, a termination of pregnancy in violation of the requirements of s. 390.01112, F.S., commits a felony of the third degree. If the woman dies as a result of this act, the person commits a felony of the second degree. A felony of the third degree is punishable by a term of imprisonment not exceeding 5 years and may incur a fine of up to $5,000. A felony of the second degree is punishable by a term of imprisonment not exceeding 15 years and may incur a fine of up to $10,000.

Section 5 of the bill provides for severability and reversion. If any provision of this act or its application to any person or circumstance is held invalid, then other provisions which can be given effect are to be given effect. Notwithstanding that, if s. 390.01112, F.S., governing the termination of pregnancies during viability, is held unconstitutional and severed, then the

[20] Current law requires an ultrasound to be performed before an abortion may be performed. *See* s. 390.0111(3)(a)1.b., F.S.

amendments in this act to the other provisions of law are repealed and will revert to the law as it existed on January 1, 2014.

The effective date of this act is July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Roe v. Wade, was decided by the U.S. Supreme Court in 1973.[21] Using strict scrutiny, the court determined that a woman's right to terminate a pregnancy is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution.[22] 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.[23] The court established the trimester framework for the regulation of termination – holding that in the third trimester, a state could prohibit termination to the extent that the woman's life or health was not at risk.[24]

Later, in 1992, in *Planned Parenthood v. Casey*, the U.S. Supreme Court, while upholding the fundamental holding of *Roe*, recognized that medical advancement could shift determinations of fetal viability away from the trimester framework.[25]

Article I, Section 23 of the State Constitution provides an express right to privacy. The Florida Supreme Court has recognized the Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."[26]

In *In re T.W.*, the Florida Supreme Court determined that:

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[21] 410 U.S. 113 (1973).
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] 505 U.S. 833 (1992).
[26] *See In re T.W.*, 551 So. 2d 1186, 1192 (Fla. 1989)(holding that a parental consent statute was unconstitutional because it intrudes on a minor's right to privacy).

> [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.
>
> The Florida Supreme Court recognized that after viability, the state can regulate termination in the interest of the unborn child so long as the mother's health is not in jeopardy.[27]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Indeterminate.

C. Government Sector Impact:

Indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 390.011, 390.0111, and 797.03.
This bill creates section 390.01112 of the Florida Statutes.
This bill creates an unnumbered section of the Florida Statutes.

[27] *Id.*

IX. Additional Information:

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

CS by Health Policy on April 1, 2014:
The CS defines the term "reasonable medical judgment." The CS requires a physician to use reasonable medical judgment, as defined, when determining:

- Whether a fetus is viable, in lieu of "good faith medical judgment"; and,
- Whether a woman's life and health is in sufficient danger to require a termination of pregnancy in either the third trimester or after the fetus is viable, in lieu of a reasonable degree of medical probability.

B. Amendments:

None.

791524

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
	.	
	.	
	.	

The Committee on Health Policy (Flores) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Present subsection (9) of section 390.011, Florida Statutes, is redesignated as subsection (11), and new subsections (9), (10) and (12) are added to that section, to read:

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

(9) "Reasonable medical judgment" means a medical judgment

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that would be made by a reasonably prudent physician, knowledgeable about the case and treatment possibilities with respect to the medical conditions involved.

(10) "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

(12) "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

Section 2. Subsections (1), (4), (10), and (13) of section 390.0111, Florida Statutes, are amended to read:

390.0111 Termination of pregnancies.—

(1) TERMINATION IN THIRD TRIMESTER; WHEN ALLOWED.—No termination of pregnancy shall be performed on any human being in the third trimester of pregnancy unless one of the following conditions is met:

(a) Two physicians certify in writing ~~to the fact~~ that, in reasonable medical judgment ~~to a reasonable degree of medical probability~~, 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 preserve the health of the pregnant woman; or~~

(b) The physician certifies in writing that, in reasonable


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medical judgment, there is a ~~to the~~ 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 ~~in the third trimester~~, and another physician is not available for consultation.

(4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER ~~DURING VIABILITY~~.—If a termination of pregnancy is performed in the third trimester, the physician performing ~~during viability, no person who performs or induces~~ the termination of pregnancy must exercise the same ~~shall fail to use that~~ degree of professional skill, care, and diligence to preserve the life and health of the fetus which the physician ~~such person~~ would be required to exercise in order to preserve the life and health of a ~~any~~ fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the pregnant woman, the physician must consider preserving the woman's life and health the overriding and superior concern ~~"Viability" means that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb~~. ~~Notwithstanding the provisions of this subsection, the woman's life and health shall constitute an overriding and superior consideration to the concern for the life and health of the fetus when such concerns are in conflict.~~

(10) PENALTIES FOR VIOLATION.—Except as provided in subsections (3), (7), and (12):

(a) Any person who willfully performs, or actively


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participates in, a termination of pregnancy ~~procedure~~ in violation of the requirements of this section or s. 390.01112 commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in, a termination of pregnancy ~~procedure~~ in violation of ~~the provisions of~~ this section or s. 390.01112 which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(13) FAILURE TO COMPLY.—Failure to comply with the requirements of this section or s. 390.01112 constitutes grounds for disciplinary action under each respective practice act and under s. 456.072.

Section 3. Section 390.01112, Florida Statutes, is created to read:

390.01112 Termination of pregnancies during viability.—

(1) No termination of pregnancy shall be performed on any human being if the physician determines that, in reasonable medical judgment, the fetus has achieved viability, unless:

(a) 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

(b) The 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.

(2) Before performing a termination of pregnancy, a physician must determine if the fetus is viable by, at a minimum, performing a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound required under s. 390.0111(3), an examination of the fetus. The physician must document in the pregnant woman's medical file the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

(3) If a termination of pregnancy is performed during viability, 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 that the physician would be required to exercise in order to preserve the life and health of a fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Section 4. Subsection (3) of section 797.03, Florida Statutes, is amended to read:

797.03 Prohibited acts; penalties.—

(3) It is unlawful for any person to perform or assist in performing an abortion on a person during viability or in the third trimester other than in a hospital.

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Section 5. Severability and reversion.—

(1) If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

(2) Notwithstanding subsection (1), if s. 390.01112, Florida Statutes, is held unconstitutional and severed by a court having jurisdiction, the amendments made by this act to s. 390.011, Florida Statutes, and subsections (4), (10), and (13) of s. 390.0111, Florida Statutes, will be repealed and will revert to the law as it existed on January 1, 2014.

Section 6. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the termination of pregnancies; amending s. 390.011, F.S.; defining the terms "reasonable medical judgment" and "standard medical measure" and redefining the term "viability"; amending s. 390.0111, F.S.; revising the circumstances under which a pregnancy in the third trimester may be terminated; providing the standard of medical care for the termination of a pregnancy during the third trimester; providing criminal penalties for a violation of s. 390.01112, F.S.; authorizing

administrative discipline for a violation of s. 390.01112, F.S., by certain licensed professionals; creating s. 390.01112, F.S.; prohibiting the termination of a viable fetus; providing exceptions; requiring a physician to perform certain examinations to determine the viability of a fetus; providing the standard of care for the termination of a viable fetus; amending s. 797.03, F.S.; prohibiting an abortion of a viable fetus outside of a hospital; providing for severability; providing for a contingent future repeal and reversion of law; providing an effective date.

By Senator Flores

37-01090C-14 2014918__

A bill to be entitled

An act relating to the termination of pregnancies; amending s. 390.011, F.S.; defining the term "standard medical measure" and redefining the term "viability"; amending s. 390.0111, F.S.; revising the circumstances under which a pregnancy in the third trimester may be terminated; providing the standard of medical care for the termination of a pregnancy during the third trimester; providing criminal penalties for a violation of s. 390.01112, F.S.; authorizing administrative discipline for a violation of s. 390.01112, F.S., by certain licensed professionals; creating s. 390.01112, F.S.; prohibiting the termination of a viable fetus; providing exceptions; requiring a physician to perform certain examinations to determine the viability of a fetus; providing the standard of care for the termination of a viable fetus; amending s. 797.03, F.S.; prohibiting an abortion of a viable fetus outside of a hospital; providing for severability; providing for a contingent future repeal and reversion of law; providing an effective date.

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

Section 1. Present subsection (9) of section 390.011, Florida Statutes, is redesignated as subsection (10), and new subsections (9) and (11) are added to that section, to read:

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

37-01090C-14 2014918__

(9) "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

(11) "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

Section 2. Subsections (1), (4), (10), and (13) of section 390.0111, Florida Statutes, are amended to read:

390.0111 Termination of pregnancies.—

(1) TERMINATION IN THIRD TRIMESTER; WHEN ALLOWED.—No termination of pregnancy shall be performed on any human being in the third trimester of pregnancy unless one of the following conditions is met:

(a) Two physicians certify in writing ~~to the fact~~ that, to a reasonable degree of medical probability, 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 preserve the health of the pregnant woman; or~~

(b) The physician certifies in writing to the 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 ~~in the third trimester~~, and another physician is not available for consultation.

(4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER ~~DURING VIABILITY~~.—If a termination of pregnancy is performed in the third trimester, the physician performing ~~during viability, no person who performs or induces~~ the termination of pregnancy must exercise the same ~~shall fail to use that~~ degree of professional skill, care, and diligence to preserve the life and health of the fetus which the physician ~~such person~~ would be required to exercise in order to preserve the life and health of a ~~any~~ fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the pregnant woman, the physician must consider preserving the woman's life and health the overriding and superior concern ~~"Viability" means that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb. Notwithstanding the provisions of this subsection, the woman's life and health shall constitute an overriding and superior consideration to the concern for the life and health of the fetus when such concerns are in conflict.~~

(10) PENALTIES FOR VIOLATION.—Except as provided in subsections (3), (7), and (12):

(a) Any person who willfully performs, or actively participates in, a termination of pregnancy ~~procedure~~ in violation of the requirements of this section or s. 390.01112 commits a felony of the third degree, punishable as provided in

s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in, a termination of pregnancy ~~procedure~~ in violation of ~~the provisions of~~ this section or s. 390.01112 which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(13) FAILURE TO COMPLY.—Failure to comply with the requirements of this section or s. 390.01112 constitutes grounds for disciplinary action under each respective practice act and under s. 456.072.

Section 3. Section 390.01112, Florida Statutes, is created to read:

390.01112 Termination of pregnancies during viability.—

(1) No termination of pregnancy shall be performed on any human being if the physician reasonably determines that, in the physician's good faith medical judgment, the fetus has achieved viability, unless:

(a) Two physicians certify in writing that, to a reasonable degree of medical probability, 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

(b) The physician certifies in writing to the 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.

(2) Before performing a termination of pregnancy, a physician must determine if the fetus is viable by, at a minimum, performing a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound required under s. 390.0111(3), an examination of the fetus. The physician must document in the pregnant woman's medical file the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

(3) If a termination of pregnancy is performed during viability, 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 that the physician would be required to exercise in order to preserve the life and health of a fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Section 4. Subsection (3) of section 797.03, Florida Statutes, is amended to read:

797.03 Prohibited acts; penalties.—

(3) It is unlawful for any person to perform or assist in performing an abortion on a person during viability or in the third trimester other than in a hospital.

Section 5. Severability and reversion.—

(1) If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not

affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

(2) Notwithstanding subsection (1), if s. 390.01112, Florida Statutes, is held unconstitutional and severed by a court having jurisdiction, the amendments made by this act to s. 390.011, Florida Statutes, and subsections (4), (10), and (13) of s. 390.0111, Florida Statutes, will be repealed and will revert to the law as it existed on January 1, 2014.

Section 6. This act shall take effect July 1, 2014.

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 14, 2014

I respectfully request that **Senate Bill #918**, relating to Termination of Pregnancy, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 37

File signed original with committee office

S-020 (03/2004)

ENTERED

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Termination of Pregnancies

Bill Number SB 918 *(if applicable)*

Name Barbara DeVane

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 1625 E. Brevard St
Street
Tallahassee FL 32308
City *State* *Zip*

Phone 850-222-3969

E-mail barbaradevane1@yahoo.com

Speaking: ☐ For ☑ Against ☐ Information

Representing FL NOW

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic Termination of Pregnancies

Bill Number SB 918 *(if applicable)*

Name Richard Polangin

Amendment Barcode _____ *(if applicable)*

Job Title —

Address 1300 N Duval St
Street
Tallahassee FL 32303
City *State* *Zip*

Phone 850 224-4206

E-mail richardpolangin@hotmail.com

Speaking: ☐ For ☒ Against ☐ Information

Representing League of Women Voters of Florida

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic TERMINATION of PREGNANCIES

Bill Number 918 *(if applicable)*

Name BILL BUNKLEY

Amendment Barcode _____ *(if applicable)*

Job Title PRESIDENT

Address PO Box 381644 *Street*

Phone 813.264.2977

TAMPA FL 33694 *City* *State* *Zip*

E-mail _____

Speaking: ☑ For ☐ Against ☐ Information

Representing FLORIDA ETHICS AND RELIGIOUS LIBERTY COMMISSION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Termination of Pregnancies Bill Number 918 *(if applicable)*

Name Ingrid Delgado Amendment Barcode *(if applicable)*

Job Title Associate for Social Concerns and Respect Life

Address 201 W Park AV Phone
Street

Tallahassee FL 32301 E-mail
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Conference of Catholic Bishops

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Relating to Pregnancy

Bill Number SB 918
(if applicable)

Name Matthew Van Name

Amendment Barcode
(if applicable)

Job Title Legislative Director

Address
Street

Phone 786-459-1798

E-mail

City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing SEIU

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic _____ Bill Number SB 918 *(if applicable)*

Name Stephanie Kunkel Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 1143 Albritton Dr Phone 850-320-4208
Street

Tallahassee FL 32301 E-mail Stef.Kunkel@gmail.com
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing Business and Professional Women, Inc

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic Relating to Pregnancy

Bill Number SB 918 *(if applicable)*

Name Moni Holder

Amendment Barcode _____ *(if applicable)*

Job Title Policy Director

Address 8330 Biscayne Blvd. Suite 1
Street

Miami FL 33138
City *State* *Zip*

Phone 305-321-4573

E-mail moni@thenewmajority.org

Speaking: ☐ For ☒ Against ☐ Information

Representing Florida New Majority

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Termination & Pregnancy

Bill Number SB 918 *(if applicable)*

Name Mallory Garner-Wells

Amendment Barcode _____ *(if applicable)*

Job Title Public Policy Director

Address 737 NW 24th Ave
Street

Phone _____

Gville FL
City *State* *Zip*

E-mail _____

Speaking: ☐ For ☑ Against ☐ Information

Representing Equality Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Termination of Pregnancy

Bill Number SB918 *(if applicable)*

Name Beth Swickard

Amendment Barcode _____ *(if applicable)*

Job Title Legislative Director

Address 2300 N. Florida Mango Road
Street
West Palm Beach, FL 33435
City *State* *Zip*

Phone 561-472-9934

E-mail beth.swickard@ppsofl.org

Speaking: ☐ For ☒ Against ☐ Information

Representing Florida Alliance of Planned Parenthood Affiliates

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Termination of Pregnancy

Bill Number 918 *(if applicable)*

Name Pamela Burch Fort

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 104 S. Monroe Street
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-425-1344

E-mail TcgLobby@aol.com

Speaking: ☐ For ☑ Against ☐ Information

Representing ACLU of Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1 Apr 14
Meeting Date

Topic Termination of Pregnancy

Bill Number SB918 *(if applicable)*

Name Benjamin Dowd-Arrow

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 1010 Sharer Ct 19
Street

Tallahassee FL 32312
City *State* *Zip*

Phone 850 321 0660

E-mail bjh12f@my.fsu.edu

Speaking: ☐ For ☒ Against ☐ Information

Representing Unite Women

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

April 1
Meeting Date

Topic Fetal Viability

Bill Number 918 *(if applicable)*

Name Sara Johnson

Amendment Barcode *(if applicable)*

Job Title Legislative Assistant to the President

Address 4853 S. Orange Ave
Street

Orlando FL 32806
City *State* *Zip*

Phone 850-567-8143

E-mail saraj@flfamily

Speaking: ☑ For ☐ Against ☐ Information

Representing Florida Family Action

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1160
INTRODUCER:	Environmental Preservation and Conservation Committee and Senator Evers
SUBJECT:	Onsite Sewage Treatment and Disposal Systems
DATE:	March 31, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Gudeman	Uchino	EP	**Fav/CS**
2.	Peterson	Stovall	HP	**Favorable**
3.			AG	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1160 extends the effective date of the ban on land application of septage to January 1, 2017 and requires the Department of Environmental Protection (DEP), in consultation with others, to examine and report to the Governor and Legislature on options for disposing of or reusing septage, and the contents of portable toilets, grease inceptors, and holding tanks.

II. Present Situation:

The Department of Health (DOH) oversees the administration of onsite sewage treatment and disposal systems (OSTDSs, septic systems) in order to detect and prevent disease caused by natural and manmade factors in the environment.[1] The DOH estimates there are approximately 2.6 million septic tanks in use statewide.[2] An onsite sewage treatment and disposal system is:[3]

> a system that contains a standard subsurface, filled, or mound drainfield system; an aerobic treatment unit; a graywater system tank; a laundry wastewater system tank; a septic tank; a grease interceptor; a pump tank; a solids or effluent pump; a waterless, incinerating, or organic waste-composting toilet; or a sanitary pit privy that is installed or proposed to be installed beyond the building sewer on land of the owner or on other land to which the owner has the legal right to install a system. The term

[1] *See* s. 381.006(7), F.S.
[2] Fla. Dept. of Health, *Onsite Sewage*, http://www.floridahealth.gov/healthy-environments/onsite-sewage/index.html (last visited Mar. 29, 2014).
[3] Section 381.0065(2)(k), F.S.

> includes any item placed within, or intended to be used as a part of, or in conjunction with, the system. The term does not include package sewage treatment facilities and other treatment works regulated under ch. 403, F.S.

The systems operate by allowing sewage to flow from a home or business through a pipe into the first chamber, where solids settle out. The liquid then flows into the second chamber where anaerobic bacteria, which do not require oxygen, in the sewage break down the organic matter, allowing cleaner water to flow out of the second chamber into a drainfield.[4]

The DOH's Onsite Sewage Program, in the Bureau of Environmental Health (bureau), develops statewide rules and provides training and standardization for county health department employees responsible for permitting the installation and repair of OSTDSs. The bureau also licenses septic system contractors, approves continuing education courses and courses provided for septic system contractors, funds a hands-on training center, and mediates septic system contracting complaints. The bureau also manages a state-funded research program, prepares research grants, and reviews and approves innovative products and OSTDS designs.[5]

The majority of septage is regulated by the DOH; however, the DEP permits OSTDSs when the estimated domestic sewage flow from the establishment is over 10,000 gallons per day or the commercial sewage flow is over 5,000 gallons per day. The DEP also has jurisdiction over OSTDSs where there is a likelihood that the system will receive toxic, hazardous or industrial wastes, where a sewer system is available, or if any system or flow from the establishment is currently regulated by the DEP. Variances can be granted by either agency as needed.[6]

Land Application of Septage

The land application of septage from OSTDSs is an approved method of disposal in Florida, and is common in rural areas.[7] Septage is defined as a mixture of sludge, fatty materials, human feces, and wastewater removed during the pumping of an OSTDS.[8] Approximately 100,000 septic tanks are pumped each year, generating 100 million gallons of septage requiring treatment and disposal.[9] When used for land application, the septage is stabilized by raising the pH to 12 for at least 2 hours or to a pH of 12.5 for 30 minutes.[10] The treated septage is then spread over the land at DOH-regulated land application sites.[11] In addition to septage, onsite systems serving restaurants include tanks that separate grease from the sewage stream. The grease is collected, hauled, treated, and land applied similarly to septage. There are 92 land application sites

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[4] Environmental Protection Agency, *Primer for Municipal Wastewater Treatment Systems*, 2004, p. 22, *available at* http://water.epa.gov/aboutow/owm/upload/2005_08_19_primer.pdf (last visited Mar. 29, 2014).
[5] Fla. Dept. of Health, *Resource Manual*, 169 (FY 2012 – 2013) (on file with the Senate Health Policy Committee).
[6] Fla. Dept. of Environmental Protection, *Septic Systems*, http://www.dep.state.fl.us/water/wastewater/dom/septic.htm (last visited Mar. 29, 2014).
[7] Fla. Dept. of Health, Bureau of Onsite Sewage Programs, *Report on Alternative Methods for the Treatment and Disposal of Septage*, 1 (Feb. 1, 2011), *available at* http://pk.b5z.net/i/u/6019781/f/FINAL_REPORT_ON_ALTERNATIVE_METHODS_FOR_THE_TREATMENT_AND_DISPOSAL_OF_SEPTAGE_03282011__2_.pdf (last visited Mar. 29, 2014).
[8] Section 381.0065(2)(n), F.S.
[9] *Supra* note 6, at 1.
[10] Rule 64E-6.010(7)(a), F.A.C.
[11] *See* Rule 64E-6.010, F.A.C.

receiving septage from 108 treatment facilities. The land application of septage accounts for approximately 40 percent of disposal in Florida. The rest is either managed at a wastewater treatment facility or a municipal landfill.[12]

In 2010, the Legislature passed SB 550, which created a 5-year OSTDS inspection program to be fully implemented by the DOH by January 2016, and banned the land application of septage by January 1, 2016.[13] The law required the DOH to adopt rules and begin initial inspections of OSTDSs by January 1, 2011.[14]

During the November 2010 Special Session, the Legislature acted to extend the implementation date of the inspection program to July 1, 2011, so it could take up the issue during the 2011 Regular Session.[15] Several bills were introduced in 2011 to address the inspection program and repeal the ban on land application of septage. Although none passed, provisions were included in the implementing act for the 2011-2012 General Appropriations Act that prohibited the DOH from expending funds to move forward with an inspection program until it submits a plan for approval by the Legislative Budget Committee.[16]

In 2012, the statewide inspection program and the DOH's rulemaking authority were repealed. A county or municipality with a first magnitude spring[17] was required to adopt a local ordinance for an OSTDS evaluation and assessment program, unless the county or municipality opted out. All other counties were given the option to opt in.[18] All counties required to opt out of the inspection program have done so, and no county or municipality has opted in.

Department of Health Requirements

The DOH regulates the land application of septage pursuant to Rule 64E-6.010, F.A.C., which requires land application of septage be applied at least:

- 3000 feet from a Class I water body or Outstanding Florida Waters;
- 300 feet from any surface water bodies, except canals or bodies of water that are used for irrigation;
- 500 feet from any public water supply wells;
- 300 feet from any private drinking water supply well;
- 300 feet from a habitable building; and
- 75 feet from property lines and drainage ditches.

The following provisions are required for the land application site and timing of land application:

- A minimum of 24 inches of unsaturated soil above the ground water table at the time of septage or sludge application;

[12] *Supra* note 6 at 1.
[13] Chapter 2010-205, s. 35, Laws of Fla.
[14] *Id*.
[15] Chapter 2010-283, Laws of Fla.
[16] Chapter 2011-47, s. 13, Laws of Fla.
[17] "First magnitude spring" is a spring that has a median water discharge of greater than or equal to 100 cubic feet per second for the period of record, as determined by the DEP. (s. 381.00651(1), F.S.)
[18] Chapter 2012-184, s. 33, Laws of Fla.

- If the wet season high ground water table is within 2 feet of the surface or is not determined in the Agricultural Use Plan, then the water table at the time of application must be determined using a monitoring well;
- Land application is prohibited during rain events that are significant enough to cause runoff, or when the soil is saturated;
- The application area must have sufficient buffer areas or stormwater management structures to retain the run-off from a 10-year, 1-hour storm;
- The topographic grade shall not exceed 8 percent;
- A layer of permeable soil at least 2 feet thick must cover the surface of the land application area; and
- The land application area and an area 200 feet wide adjacent to the site must not contain:
  - Subsurface fractures,
  - Solution cavities;
  - Sink holes;
  - Excavation core holes;
  - Abandoned holes; or
  - Other natural or manmade conduits.

Sufficient storage capacity for the septage or sludge is required during periods of equipment failure. All facilities must be designed, located, and operated to prevent nuisance conditions and runoff.

Groundwater quality criteria for groundwater and surface water cannot be violated as a result of land application of septage or sludge and the DOH may require water quality testing. The site owner must suspend activities if water quality is violated.

Application rates of septage and food establishment sludge are limited by nitrogen content of the waste and not phosphorus content, unless otherwise provided. For the application rate limited by nitrogen:

- The maximum annual surface application rate is 500 pounds per acre in a 12-month period (equates to six dry tons or 40,000 gallons of typical septage per acre per year);
- Septage must be applied as evenly as possible to ensure maximum uptake of nitrogen;
- The annual application rate of nitrogen (AAR) can be calculated using the following formula: AAR = N ÷ 0.0026, where N is the amount of nitrogen in pounds per acre per 365 day period needed by the crop or vegetation.

Where the application rate is limited by phosphorus:

- The maximum annual surface application rate is 40 pounds per acre in a 12-month period (equates to two dry tons or 12,000 gallons of typical septage per year);
- The formulas to calculate AAR of phosphorus are:
  - AAR = P ÷ 0.0076 (if crop demand is calculated for P_2O_5); and
  - AAR = P ÷ 0.0033 (if crop demand is calculated P).

The rule requires permanent records be kept of the application areas and rates. The records are to be maintained by the site owner, lessee, or the land applicator for 5 years and must be available

for inspection by the DOH. The annual summary of total septage or sludge must be included in the annual update to the Agricultural Use Plan. The records must include the:

- Location of the septage treatment facility where each load of treated septage is obtained;
- Date and time the treated septage was obtained from the treatment facility;
- Dates of septage or sludge land application;
- Weather conditions when applied;
- Location of septage or sludge application site;
- Amounts of septage or sludge applied;
- Specific area of the site where septage or sludge was applied;
- pH of stabilized septage or sludge;
- Soil groundwater table when septage was applied; and,
- Vegetational status of application area.[19]

Alternatives to Land Application of Septage

There are two current practices in Florida that serve as alternatives to land application of septage. Neither is available in every part of the state. Typically, septage that is not land applied is either treated at wastewater treatment facilities or is dewatered and then disposed of in landfills. There are other alternatives that process small quantities of septage, but they are not yet commercially available in Florida.[20]

Wastewater Treatment Facilities

There are approximately 2,100 domestic wastewater treatment facilities in Florida.[21] Only 60 have permitted capacities greater than 10 million gallons per day, resulting in less than 30 percent of counties that have a facility this large. The DOH has determined the capacity of the facility is directly related to its ability to accept septage.[22]

Disposing septage at a wastewater treatment facility centralizes the waste treatment process, however, the high strength septage from septic tanks leads to increased operational costs. High strength septage is produced from properly functioning OSTDSs, which separate the liquids from the solids, concentrating the solids at the bottom of the tank. The result is high strength septage with a higher concentration of solid to liquid than wastewater treatment plants typically receive.[23]

There are two current methods facilities use to assimilate septage into the waste stream. The less desirable of the two is allowing septage haulers to discharge the entire load in one "slug" into the main lift station or headworks. This method has the potential to upset the process because of the high concentration of solids entering the system quickly. A more desirable method is to discharge the slug load into a holding tank and then slowly release the septage into any of

[19] Rule 64E—6.010, F.A.C.
[20] *Supra* note 6 at 2-4.
[21] Fla. Dept. of Environmental Protection, *General Facts and Statistics about Wastewater in Florida*, http://www.dep.state.fl.us/WATER/wastewater/facts.htm (last visited Mar 29, 2014).
[22] *Supra* note 6 at 2-3.
[23] *Supra* note 6 at 2-3.

various treatment points in the system as capacity allows.[24] The average rate for this disposal method is 6 to 12 cents per gallon.[25]

Disposal in Landfills

A second option for septage disposal is at Class I landfills. There are 48 active Class 1 landfills in Florida. This method also has benefits and drawbacks. The main benefits are:

- It increases microbial activity within the landfill resulting in faster decomposition and waste stabilization;
- It requires less acreage than land application sites; and,
- Purchasing additional land is not required for disposal at existing Class I landfills.

However, disposal of dewatered septage can lead to some instability, as well as slick working conditions for compaction equipment. Septage also needs to be covered quickly to avoid health hazards for workers from pathogen exposure and to avoid attracting birds, insects, and rodents.[26]

Landfills follow state rules based on an Environmental Protection Agency Paint Filter test when accepting septage. Typically, septage is 2 to 3 percent solids and must be dewatered to achieve 12 percent solids before it passes the paint filter test. The dewatering process releases effluent that must be disposed of properly. Alternatively, some landfill operators add dry solids to septage to meet the paint filter test requirements. In either scenario, septage must be processed before it can be landfilled. The average cost of landfilling septage is 10 cents per gallon.[27]

III. Effect of Proposed Changes:

The bill amends s. 381.0065, F.S., to extend the effective date of the ban on the land application of septage from January 1, 2016, to January 1, 2017.

The bill requires the DEP, in consultation with the Department of Agriculture and Consumer Services, the Department of Economic Opportunity, the University of Florida Institute of Food and Agricultural Sciences, local governments, and other stakeholders, to examine and report on the options for disposing of or reusing septage, and the contents of portable toilets, grease inceptors, and holding tanks. The report is to include:

- An inventory of domestic wastewater utilities and solid waste management facilities that receive and treat septage, and the contents of portable toilets, grease inceptors, and holding tanks;
- An inventory of permitted septage land application sites;
- An analysis of nutrient concentrations of septage;
- An analysis of the technical limitations for domestic wastewater utilities and solid waste management facilities to receive and treat septage, and the contents of portable toilets, grease inceptors, and holding tanks;

[24] *Supra* note 6, at 2-3.
[25] *Supra* note 6, at 3.
[26] *Supra* note 6, at 3.
[27] *Supra* note 6, at 3-4.

- An analysis of the sufficiency of Rule 64E-6, F.A.C., in managing nutrient loading from application sites. The analysis must emphasize high recharge areas and sensitive surface waters or groundwaters;
- An analysis of compliance rates with Rule 64E-6, F.A.C., and the sufficiency of operator oversight;
- An analysis of the sufficiency of penalties for noncompliance;
- An analysis of the transfer of regulatory authority over the land application of septage from the DOH to the DEP. This analysis must include:
  - The environmental benefits of applying nutrient management plan requirements;
  - Setbacks;
  - Site-monitoring requirements; and
  - Provisions of Rule 62-640, F.A.C.

The bill requires the DEP to submit a report of its findings and recommendations to the Governor, the Senate President, and the Speaker of the House of Representatives by February 1, 2015.

The bill provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

C. Government Sector Impact:

The DEP will incur a cost to conduct the study; however, the DEP did not provide this information, therefore the amount is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0065 of the Florida Statutes.

IX. Additional Information:

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

CS by Environmental Preservation and Conservation on March 26, 2014:
The CS for SB 1160:

- Extends the effective date of the ban on land application of septage to January 1, 2017; and,
- Requires the DEP to submit a report to the Governor, the Senate President, and the Speaker of the House of Representatives by February 1, 2015.

B. Amendments:

None.

By the Committee on Environmental Preservation and Conservation; and Senator Evers

592-03286-14 20141160c1

A bill to be entitled

An act relating to onsite sewage treatment and disposal systems; amending s. 381.0065, F.S.; delaying the effective date of the prohibition against the land application of septage from onsite sewage treatment and disposal systems; requiring the Department of Environmental Protection to examine and report on potential options for safely and appropriately disposing or reusing septage; requiring the department to submit a report of its findings and recommendations; providing an effective date.

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

Section 1. Subsection (6) of section 381.0065, Florida Statutes, is amended to read:

381.0065 Onsite sewage treatment and disposal systems; regulation.—

(6) LAND APPLICATION OF SEPTAGE PROHIBITED.—

(a) Effective January 1, 2017 ~~2016~~, the land application of septage from onsite sewage treatment and disposal systems is prohibited.

(b) The Department of Environmental Protection, in consultation with the Department of Health, the Department of Agriculture and Consumer Services, the Department of Economic Opportunity, the University of Florida Institute of Food and Agricultural Sciences, local governments, and other stakeholders, shall examine and report on the potential options for safely and appropriately disposing of or reusing septage and

592-03286-14 20141160c1

the contents of portable toilets, grease interceptors, and holding tanks, including, but not limited to:

1. An inventory of domestic wastewater utilities and solid waste management facilities that are known to receive and treat septage or the contents of portable toilets, grease interceptors, and holding tanks.

2. An inventory of permitted septage land application sites.

3. An analysis of the nutrient concentrations of septage.

4. An analysis of the technical limitations for domestic wastewater utilities and solid waste management facilities to receive and treat septage or the contents of portable toilets, grease interceptors, and holding tanks.

5. An analysis of the sufficiency of chapter 64E-6, Florida Administrative Code, in managing nutrient loading from land application sites, with emphasis on high recharge areas of the aquifer and other sensitive surface waters or groundwaters.

6. An analysis of compliance rates with chapter 64E-6, Florida Administrative Code, and the sufficiency of operator oversight to ensure compliance.

7. An analysis of the sufficiency of penalties for noncompliance.

8. The transfer of regulatory authority over the land application of septage or the contents of portable toilets, grease interceptors, and holding tanks from the Department of Health to the Department of Environmental Protection, including the environmental benefits of applying the nutrient management plan requirements, setbacks, site-monitoring requirements, and provisions of chapter 62-640, Florida Administrative Code, to

the land application of septage.

(c) The Department of Environmental Protection shall submit a report of its findings and recommendations, pursuant to paragraph (b), to the Governor, the President of the Senate, and the Speaker of the House of Representatives by February 1, 2015.

Section 2. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Criminal Justice, *Chair*
Appropriations Subcommittee on Finance and Tax
Appropriations Subcommittee on Transportation, Tourism, and Economic Development
Communications, Energy, and Public Utilities
Military and Veterans Affairs, Space, and Domestic Security
Transportation

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GREG EVERS
2nd District

March 26, 2014

Honorable Senator Bean
Senate Health Policy Committee
302 SOB
404 S. Monroe St.
Tallahassee, FL 32399

RE: SB 1160

Dear Chairman Bean:

Please allow this letter to serve as my respectful request to include SB 1160 regarding Onsite Sewage Treatment and Disposal Systems on the agenda for your next Health Policy Committee meeting.

Your kind consideration of this request is greatly appreciated. Please feel free to contact my office for any additional information.

Sincerely,

Greg Evers

Greg Evers
State Senator, District 2

REPLY TO:
☐ 209 East Zaragoza Street, Pensacola, Florida 32502-6048 (850) 595-0213 FAX: (888) 263-0013
☐ 308 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5002

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

DON GAETZ
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-1-14
Meeting Date

Topic Onsite Septic Disposal

Bill Number 1160 *(if applicable)*

Name Chris Doolin

Amendment Barcode *(if applicable)*

Job Title Consultant

Address 1118-B Thomasville Rd. *Street*

Phone 850-508-5492

Tallahassee, Fla. 32303 *City State Zip*

E-mail

Speaking: ☑ For ☐ Against ☐ Information

Representing Small County Coalition

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Land App. Septage

Bill Number 1160 *(if applicable)*

Name Jeff Mann

Amendment Barcode *(if applicable)*

Job Title Owner Mann Septic

Address 4257 Old Eagle Lk Rd
Street
Barton
City *State* *Zip*

Phone (863)-533-8383

E-mail Mannseptic@Yahoo.com

Speaking: ☐ For ☐ Against ☐ Information

Representing F.O.W.A

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1 April 2014
Meeting Date

Topic LAND APPLICATION

Bill Number 1160 *(if applicable)*

Name Roxanne L. GROOVER

Amendment Barcode *(if applicable)*

Job Title EXECUTIVE DIRECTOR

Address 5115 SR 557
Street
LAKE ALFRED FL 33850
City *State* *Zip*

Phone 8639565540

E-mail rgroover@fowaonsite.com

Speaking: ☒ For ☐ Against ☒ Information

Representing FLORIDA ONSITE WASTEWATER ASSOC

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/1/2014
Meeting Date

Topic onsite treatment & disposal systems

Bill Number 1160 *(if applicable)*

Name Darla Huntley

Amendment Barcode *(if applicable)*

Job Title Owner

Address 7010 NE 150th Ave
Street
Williston, FL 32696
City *State* *Zip*

Phone 352-317-2527

E-mail prettypottys@yahoo.com

Speaking: ☐ For ☐ Against ☒ Information

Representing FOWA, self

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 992
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Infectious Disease Control
DATE:	April 2, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 992 directs the Department of Health (DOH) to convene a study group of affected stakeholders to assess the efficacy of the state's current system of surveillance, reporting, public notification, prevention, and response activities related to antibiotic-resistant bacteria. The bill requires the study group to submit a report of its findings, an action plan for implementation, and recommendations for necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.

The bill also updates a reference in statute to the pneumococcal vaccine that is provided to nursing home residents upon admission.

II. Present Situation:

Antibiotic-Resistance

Antibiotic-resistance is a natural phenomenon that occurs when an antibiotic has lost its ability to effectively control or kill bacterial growth. When an antibiotic is used, bacteria which can resist that antibiotic have a greater chance of survival than those that are "susceptible." When susceptible bacteria are killed or inhibited by an antibiotic, this creates selective pressure for the

resistant strains to survive.[1] Some resistance occurs naturally. But the increasingly higher-levels now occurring are the result of the overuse and misuse of antibiotics both by humans, most commonly when prescribed to treat a viral infection or prescribed in the wrong dose or for the incorrect amount of time, and in livestock production to promote growth.[2]

The Centers for Disease Control and Prevention (CDC) estimates that more than 2 million people become ill each year due to antibiotic-resistant infections, resulting in the death of at least 23,000. *Clostridium difficile (C.diff.)* infections are not yet drug resistant, but most are directly related to antibiotic use. These infections result in an estimated additional 250,000 hospitalizations.[3]

In most cases, antibiotic–resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional physician visits, and result in greater disability and death than treatable infections. The total economic cost of antibiotic-resistance to the U.S. economy has been estimated as high as $20 billion in health care system costs, and $35 billion in societal costs resulting from lost productivity.[4]

In a report released in 2013, the CDC prioritized the threat posed by bacteria into three categories: urgent, serious, and concerning. The threat was assessed according to seven factors associated with resistant infections:[5]

- Clinical impact.
- Economic impact.
- 10-year projection of incidence.
- Transmissibility.
- Availability of effective antibiotics.
- Barriers to transmission.

The threat analysis resulted in a priority list of 17 bacteria and one fungus: three urgent threats; 12 serious threats; and three concerning threats.[6]

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[1] Alliance for the Prudent Use of Antibiotics, *General Background: About Antibiotic Resistance,*, http://www.tufts.edu/med/apua/about_issue/about_antibioticres.shtml (last visited Mar. 27, 2014).
[2] Alliance for the Prudent Use of Antibiotics, *General Background: What can be done about Antibiotic Resistance?*, http://www.tufts.edu/med/apua/about_issue/what_can_be_done.shtml (last visited Mar. 27, 2014).
[3] Centers for Disease Control and Prevention, *Antibiotic Resistant Threats in the United States, 2013*, 11 (Sept. 2013), *available at* *http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&sqi=2&ved=0CCYQFjAA&url=http%3A%2F%2Fwww.cdc.gov%2Fdrugresistance%2Fthreat-report-2013%2Fpdf%2Far-threats-2013-508.pdf&ei=I0o0U5qAH6jA0QG5zYGQBQ&usg=AFQjCNHv-BZapjIjn8KobhkrFT3ngVUtXg* (last visited Mar. 27, 2014). Due to limitations in available research, the numbers used by the CDC are approximations which underestimate the actual impact of the infections. Centers for Disease Control and Prevention, *Antibiotic Resistant Threats in the United States, 2013*, 18.
[4] *Id.* at 11.
[5] *Id.* at 20.
[6] *Id.* at 7.

To combat the threats, the CDC has recommended a four-part strategy of prevention, tracking, improving antibiotic use, and developing more resistant antibiotics.[7] The President's budget request for the 2015 fiscal year includes $30 million, the first year of a 5-year funding plan, to fund the strategy. The Detect and Protect Against Antibiotic Resistance initiative targets five of the bacteria on the threat list: C.*diff*, CRE, *MRSA*, and drug resistant Pseudomonas, drug resistant *Salmonella*—with targeted reductions in associated infections of up to 50 percent.[8]

Communicable Diseases

The DOH is responsible for implementing a communicable disease[9] prevention and control program.[10] It has broad authority to adopt rules for the prevention and control of communicable diseases, including procedures for investigation, timeframes for reporting, definitions, procedures for managing, required follow up related to suspected exposures, and procedures for providing access to confidential information.[11]

The DOH is also granted authority to conduct epidemiological studies of diseases of public health significance.[12] The rules implementing this function are set forth in Rule 64D-3, F.A.C. In general, the DOH rules require physicians, chiropractors, naturopaths, nurses, midwives, veterinarians, and medical examiners who treat or suspect a case or occurrence of a notifiable disease or condition to report to the DOH.[13] Likewise, a laboratory must report to the DOH when a test suggests or diagnoses a notifiable disease or condition.[14] Information submitted in reports is confidential and exempt from the public records laws and may be disclosed only when necessary to public health.[15]

The DOH rule contains a Table of Notifiable Diseases and Conditions, which specifies reporting timeframes by disease or condition type and covers an extensive list of specific diseases, including when a case, cluster of cases, or outbreak of a disease or condition found in the general

[7] Centers for Disease Control, CDC Newsroom, *Untreatable: Report by CDC details today's drug-resistant health threats*,(Sept. 16, 2013), http://www.cdc.gov/media/releases/2013/p0916-untreatable.html (last visited March 27, 2014).
[8] Centers for Disease Control and Prevention, *CDC—Detect and Protect Against Antibiotic Resistance*, available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCYQFjAA&url=http%3A%2F%2Fwww.cdc.gov%2Ffmo%2Ftopic%2Fbudget%2520information%2FFY-2015-Fact-Sheets%2FDetect-and-Protect-Against-Antibiotic-Resistance.pdf&ei=XFc0U9iKPOjjsASqm4HwBQ&usg=AFQjCNFz-uyFsgpL6Db3jGW951Xv2mWWVA (last visited Mar. 27, 2014).
[9] "Communicable disease" is defined as any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indicated. (s. 381.003(1), F.S.; *See, also* Rule 64D-3.028, F.A.C.) Communicable diseases include all infectious diseases, as well as diseases such as botulism, ricin intoxication and saxitoxin. These three are examples of communicable, but not infectious, diseases now reportable in Florida. (Fla. Dept. of Health, *Senate Bill 992 Bill Analysis* (Jan. 23, 2014) (on file with the Senate Health Policy Committee).
[10] Section 381.003(1), F.S.
[11] Section 381.003(8), F.S.
[12] Section 381.0031(1), F.S.
[13] Rule 64D-3.030, F.A.C.
[14] Rule 64D-3.030, F.A.C.
[15] Section 381.0031(6), F.S.

population or an institution is of urgent public health significance.[16,17] The list is based on the notifiable diseases recommended by the Council of State and Territorial Epidemiologists[18] and the CDC. but may be expanded by the DOH.[19] Currently the table includes five of the 18 threats identified by the CDC in its 2013 report.[20] The DOH has initiated rulemaking to add four additional bacteria[21] that appear on the CDC threat list and to require laboratories to report drug resistant tuberculosis bacteria, which also appears as a threat on the CDC list.[22] As part of its surveillance program, the DOH produces weekly tables and annual summaries that include data summaries of antimicrobial resistance of the organisms under surveillance and makes these data available to the public on an internet website.[23]

The DOH, in coordination with the county health departments, conducts activities to prevent and control diseases of public health significance. The DOH has epidemiologists, statisticians, and clinicians who utilize the data reported under the surveillance program to investigate disease cases and outbreaks; document outbreaks; and make infection control recommendations to control the spread of disease. The DOH also has emergency response teams to control disease outbreaks and processes and protocols that integrate with existing systems for reporting to the CDC.[24]

The State Surgeon General has specific responsibility for declaring public health emergencies and issuing public health advisories.[25] Before issuing an advisory, the State Surgeon General must consult with affected state agencies or local governments regarding areas of responsibility.[26] A public health emergency is an occurrence or threat that results or may result in substantial injury or harm to the public from infectious disease, among other agents and events.[27] Before declaring a public health emergency, the State Surgeon General must consult with the Governor and the Chief of Domestic Security.[28]

Infection Reporting and Prevention Initiatives

As a condition of receiving payment, hospitals participating in the Medicare program are now required to report to the CDC's National Health Safety Network regarding certain hospital acquired infections. Infections that must be reported currently include: central line-associated bloodstream infections, catheter-associated urinary tract infections, surgical site infections, and

[16] Rule 64D-3.029(3), F.A.C.
[17] "Urgent public health significance" is a characteristic of a disease or condition that requires rapid public health response due to the potential to cause significant morbidity or mortality; potential to spread between or to humans; and the number of cases. (Rule 64D-3.028(28), F.A.C.)
[18] The list is available at: http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/CSTENotifiableConditionListA.pdf (last visited Mar. 27, 2014).
[19] Section 381.0031($), F.S.
[20] MRSA, multi-drug resistant Gonnorrhea, VRSA, and *Streptococcus pneumonia*.
[21] Carbapenem-resistant enterobacteriaceae, ESBLs, VRE, and Acinetobacter.
[22] E-mail from Marco T. Paredes, Jr., Director, Office of Legislative Planning, Fla. Dept. of Health (Mar. 28, 2014) (on file with the Senate Committee on Health Policy).
[23] Fla. Dept. of Health, *supra* note 11. *See* http://www.floridacharts.com/merlin/freqrpt.asp (last visited Mar. 27, 2014).
[24] *Id.*
[25] Section 381.00315, F.S.
[26] Section 381.00315(1)(a), F.S.
[27] Section 381.00315(1)(b), F.S.
[28] *Id.*

two of the infections appearing on the CDC threat list, MRSA Bacteremia, and C.*diff*.[29] This information is posted on the Hospital Compare website, which allows consumers to compare hospital performance on specific quality of care indicators.[30]

In addition, current law requires hospitals to report data about infections to the Agency for Health Care Administration (AHCA).[31]To implement the requirement, the AHCA is obtaining the data reported to the CDC and republishing it on HealthFinder.gov, which is Florida's publicly-accessible, health care facility comparison website.[32]

Pneumococcal Disease

Pneumococcal disease causes meningitis, bloodstream infections, and pneumonia. As many as 175,000 people are hospitalized due to pneumococcal pneumonia in the U.S. annually. In its worst form, the disease kills one in every four to five people over the age of 65 who contract it.[33]

In 1997, the CDC's Advisory Committee on Immunization Practices revised its recommendations for the use of pneumococcal vaccine, calling for vaccination of certain high risk groups, including persons over the age of 65.[34] There are two types of pneumococcal vaccines available for adults: a pneumococcal polysaccharide vaccine (PPSV23) and a pneumococcal conjugate vaccine (PCV13).[35]

Section 400.141, F.S., requires nursing homes to assess a resident's eligibility for vaccination against pneumococcal disease within 5 days after admission, but only references the pneumococcal polysaccharide vaccine.

III. Effect of Proposed Changes:

CS/SB 992 directs the DOH to convene a study group to assess the efficacy of state surveillance, mandatory reporting, public notification, prevention, and response activities related to antibiotic-resistant bacteria.

The study group must include representatives of facilities licensed under ch. 395, F.S. (hospitals, ambulatory surgical centers, and mobile surgical facilities), ch. 400, F.S. (nursing homes and related health care facilities), part I of ch. 483, F.S. (clinical laboratories), physicians, nurses,

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[29] Medicare.gov Hospital Compare, *Healthcare-associated infections*, http://www.medicare.gov/hospitalcompare/Data/Healthcare-Associated-Infections.html?AspxAutoDetectCookieSupport=1 (last visited Mar. 28, 2014).
[30] Medicare.gov Hospital Compare, *What Is Hospital Compare?*, http://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html (last visited Mar. 28, 2014).
[31] Section 408.0361(5)(a)2., F.S.
[32] E-mail from Joshua Spagnola, Legislative Affairs Director, Agency for Health Care Administration (March 28, 2014) (on file with the Senate Committee on Health Policy).
[33] National Foundation for Infectious Disease, *Pneumococcal Disease*, http://www.adultvaccination.com/pneumococcal_vaccine_vaccination_adult_immunization.htm (last visited April 2, 2014).
[34] Centers for Disease Control and Prevention, Office of Enterprise Communication, *CDC Recommends Pneumococcal Vaccination For All Senior Citizens and Others at High Risk* (May 1997), http://www.cdc.gov/media/pressrel/pneumovx.htm (last visited April 2, 2014).
[35] *Supra* note 33.

veterinarians, the AHCA, and the DOH. At least two members must be certified infection control practitioners. The DOH is authorized to reimburse travel.

The study group is directed to evaluate what types of bacteria are currently reported and how; how information is distributed to the public; the coordination of response activities between state and federal agencies, local government, school boards, affected facilities, and the public; and any other issues the study group determines are necessary and appropriate.

The study group must submit a report of its findings, an action plan for implementation, and recommendations for any necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.

In addition the bill changes the reference to the pneumococcal vaccine that must be provided to nursing home patients upon admission. The current law references one of two vaccination types that are currently recommended by the CDC. The bill changes the reference to "pneumococcal vaccination" to allow nursing homes options. The bill also revises the law to clarify that the assessment upon admission is for vaccination or revaccination.

The bill has an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Nursing homes, which are required to vaccinate eligible residents for pneumococcal disease, may benefit as a result of having additional vaccine options from which to choose.

C. Government Sector Impact:

The DOH will incur indeterminate expenses related to the administration of the study group and reimbursement of members' travel expenses as authorized by the bill. These amounts are not currently known and will vary depending on the size of the group, the location of the appointed representatives, and the frequency of in-person meetings.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.141 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on April 1, 2014:
The committee substitute:

- Deletes all provisions of the bill and substitutes new provisions.
- Requires the DOH to convene a study group of affected stakeholders to assess the effectiveness of the state's current system of surveillance and response to antibiotic-resistant bacteria.
- Requires the study group to submit a report of its findings and recommendations for necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives by July 1, 2015.
- Updates a reference in statute to the pneumococcal vaccine that is provided to nursing home residents upon admission.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. The Department of Health shall convene a study group to evaluate and make recommendations related to the efficacy of state surveillance, mandatory reporting, public notification, prevention, and response activities related to antibiotic-resistant bacteria. The study group must include, at a minimum, representatives of facilities licensed under chapter 395, chapter 400, and part I of chapter 483, health care

164560

practitioners licensed under chapter 458, chapter 459, chapter 464, and chapter 474, the Agency for Health Care Administration, and the Department of Health. At least two members of the work group must be certified infection control practitioners. Members of the study group may be reimbursed for travel expenses. The work group shall evaluate the list of currently reportable antibiotic-resistant bacteria; reporting procedures, including content and format of the reports; notification procedures, including the modes and the network of distribution; and response procedures, including coordination with other departments and agencies of state government, with county and municipal governments, school boards, the Centers for Disease Control and Prevention, facilities that may be affected by an outbreak, and the public. The work group may evaluate other issues it deems necessary and appropriate. The study group shall submit a report of its findings and an action plan for implementation, together with any recommendations of necessary legislation, to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than July 1, 2015.

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

400.141 Administration and management of nursing home facilities.—

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

(t) Assess all residents within 5 working days after admission for eligibility for pneumococcal ~~polysaccharide~~ vaccination or revaccination ~~(PPV)~~ and vaccinate residents when

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indicated within 60 days ~~after the effective date of this act~~ in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. ~~Residents admitted after the effective date of this act shall be assessed within 5 working days of admission and, when indicated, vaccinated within 60 days in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs.~~ Immunization shall not be provided to any resident who provides documentation that he or she has been immunized as required by this paragraph. This paragraph does not prohibit a resident from receiving the immunization from his or her personal physician if he or she so chooses. A resident who chooses to receive the immunization from his or her personal physician shall provide proof of immunization to the facility. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

Section 3. This act shall take effect July 1, 2014.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to infectious disease control; creating a study group to evaluate activities related to antibiotic-resistant bacteria; specifying appointments; providing duties and responsibilities of

164560

the study group; providing for a report and recommendations to be submitted to the Governor, President of the Senate, and Speaker of the House of Representatives; amending s. 400.141, F.S.; revising the type of pneumococcal vaccine given to nursing home residents; deleting obsolete language; providing an effective date.

By Senator Bean

4-01194-14 2014992__

A bill to be entitled

An act relating to infectious disease control; amending s. 381.0011, F.S.; providing duties of the Department of Health relating to the dissemination of information regarding treatment-resistant bacterial infections; providing for the establishment of a research panel and an interagency task force; requiring the department to adopt and enforce minimum standards for infection control practices in certain licensed facilities; providing an effective date.

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

Section 1. Section 381.0011, Florida Statutes, is amended to read:

381.0011 Duties and powers of the Department of Health.—It is the duty of the Department of Health to:

(1) Assess the public health status and needs of the state.

(2) Administer and enforce laws and rules relating to sanitation, control of infectious ~~communicable~~ diseases, illnesses and hazards to health among humans and from animals to humans, and the general health of the people of the state.

(3) Coordinate with federal, state, and local officials for the prevention and suppression of infectious ~~communicable~~ and other diseases, illnesses, injuries, and hazards to human health.

(4) Provide for a thorough investigation and study of the incidence, causes, modes of propagation and transmission, and means of prevention, control, and cure of diseases, illnesses,

4-01194-14 2014992__

and hazards to human health.

(5) Provide for the dissemination of information to the public relating ~~relative~~ to the prevention, control, and cure of diseases, illnesses, and hazards to human health, including information reported by licensed health care practitioners under subsection (6).

(6) Establish an Internet website for health care practitioners licensed under chapter 458, chapter 459, or chapter 464 to report the presence of confirmed treatment-resistant bacterial infections. The website shall require the practitioner to enter his or her license number, the location of the confirmed treatment-resistant bacterial infection, and the type of bacterial infection. The department shall adopt rules establishing a method to ensure that only one report per confirmed case is displayed on the publicly accessible part of the website. The department shall adopt rules requiring that the identity of the practitioner not be displayed on the publicly accessible part of the website and that the report not disclose protected health information but only document the presence, type, and location of a confirmed treatment-resistant bacterial infection.

(7) ~~(6)~~ Act as registrar of vital statistics.

(8) ~~(7)~~ Manage and coordinate emergency preparedness and disaster response functions to: investigate and control the spread of disease; coordinate the availability and staffing of special needs shelters; support patient evacuation; ensure the safety of food and drugs; provide critical incident stress debriefing; and provide surveillance and control of radiological, chemical, biological, and other environmental

hazards.

(9) Establish a research panel composed of experts in the field of treatment-resistant bacterial infections, which shall make recommendations to state agencies regarding biomedical research programs designed to improve treatment outcomes and develop protocols to control the incidence of treatment-resistant bacterial infections.

(10) Establish and lead an interagency task force that includes representatives from health care providers, interested trade associations, and other state agencies to:

(a) Identify emergency response protocols for facilities licensed under part II of chapter 408 when an outbreak of a treatment-resistant bacterial infection occurs in such a facility.

(b) Establish a volunteer statewide emergency response team to investigate, document, and report the presence and outbreak of a treatment-resistant bacterial infection to the department and the Centers for Disease Control and Prevention.

Section 2. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Infectious Disease Control

Bill Number 992 *(if applicable)*

Name Martha DeCastro

Amendment Barcode 164560 *(if applicable)*

Job Title Vice President for Nursing

Address 306 E College Avenue
Street

Phone (850) 222 9800

Tallahassee FL 32301
City *State* *Zip*

E-mail martha@fha.org

Speaking: ☑ For Amendment ☐ Against ☐ Information

Representing Florida Hospital Assoc

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic _____ Bill Number SB 948
(if applicable)

Name Monica Alcantara Amendment Barcode _____
(if applicable)

Job Title Infectious Diseases

Address 4202 E. Fowler Ave Phone 8139744837
Street

Tampa FL 33620 E-mail mmarti30@health.usf.edu
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing USF Health

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

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1470
INTRODUCER:	Health Policy Committee and Senator Thompson
SUBJECT:	HIV Testing
DATE:	April 1, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.			JU	
3.			CA	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Technical Changes

I. Summary:

CS/SB 1470 defines "health care setting" and "nonhealth care setting" and distinguishes the two locations for the purposes of Human Immunodeficiency Virus (HIV) testing. In a health care setting, the patient will be notified of the planned test and be offered the opportunity to refuse the test, or opt out, instead of affirmatively providing informed consent. The health care provider must explain the confidentiality protections of the patient's test results. In a nonhealth care setting, the bill requires the provider to obtain the patient's informed consent after an explanation of the confidentiality protections of the test results.

In either setting, the bill requires the patient to be informed that positive HIV test results will be reported to the county health department (CHD) with sufficient information to identify the patient.

The bill requires all HIV testing programs in a health care setting to meet the notification criteria. All nonhealth care setting HIV testing programs must meet the informed consent criteria.

The bill updates the definition of a "preliminary HIV test" to reflect current advances in HIV testing.

II. Present Situation:

Human Immunodeficiency Virus

Human immunodeficiency virus is an immune system virus that can lead to the fatal acquired immunodeficiency syndrome (AIDS). HIV affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. There is no cure for HIV, yet with proper medical care, HIV can be controlled.[1]

Human immunodeficiency virus is typically spread by having unprotected sex with someone who has HIV, sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV. As of 2010, about 1.1 million people in the United States were living with HIV and approximately 50,000 people get infected with HIV each year.[2] In Florida, the estimated number of adults and children with an AIDS diagnosis was 117,612 through December 2008, making Florida the third highest state in cumulative reported AIDS cases.[3]

HIV Testing

Of the 1.1 million Americans living with AIDS, it is also estimated that one fifth of those are unaware of their infection.[4] The Centers for Disease Control and Prevention (CDC) in 2006, revised its recommendations for HIV testing after a comprehensive review of literature, a consensus of medical opinions, input of community organizations, and the opinion of persons living with HIV.[5] The revised guidelines seek to achieve four objectives:[6]

- Increase HIV screening of patients;
- Foster earlier HIV detection;
- Link infected persons to counseling and treatment; and,
- Further reduce perinatal HIV transmission.

In 2006, the CDC's revised guidelines included additional recommendations to achieve these objectives. The updated recommendations include the following:[7]

- Opt-out HIV screening[8] in all health-care settings;[9]

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[1] Centers for Disease Control and Prevention, *About HIV/AIDS*, http://www.cdc.gov/hiv/basics/whatishiv.html (last visited Mar. 26, 2014).
[2] Centers for Disease Control and Prevention, *Basic Statistics*, http://www.cdc.gov/hiv/basics/statistics.html (last visited Mar. 26, 2014).
[3] Centers for Disease Control and Prevention, *Florida 2010 Profile*, http://www.cdc.gov/nchhstp/stateprofiles/pdf/Florida_profile.pdf (last visited Mar. 26, 2014).
[4] Id.
[5] Centers for Disease Control and Prevention, *Revised CDC Recommendations: HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Annotated Guide* (September 2006), http://www.cdc.gov/hiv/testing/HIVStandardCare/resources/brochures/MMWR-Annotated%20508C_Full.pdf (last visited Mar. 26, 2014).
[6] Id.
[7] Id.
[8] Opt-out screening means the patient must be notified that the screening will be done; the patient may decline the test.
[9] Centers for Disease Control and Prevention, *Assessment of 2010 CDC-funded Health Department HIV Testing Spending and Outcomes (February 2013) http://www.cdc.gov/hiv/pdf/evaluation_HIVTesting_BudgetAllocation.pdf* (last visited Mar. 28, 20140). The CDC refers to health care settings as a place where both medical diagnostic and treatment services are

- Tests for all high risk patients at least annually;
- No requirement for separate written consent for testing;
- No prevention counseling required in conjunction with HIV screening; and,
- Inclusion in all routine prenatal screening, with repeat screening in the third trimester for high risk women.

The most common type of HIV test checks for HIV antibodies in the body. Blood or oral fluid can be used to obtain results. Follow up diagnostic testing is performed if the first test is positive to confirm the result. An RNA test can detect the virus directly and identifies HIV at about 10 days after infection, before antibodies develop.[10]

Florida HIV Testing

Currently, in Florida, every person who is tested for HIV must first give their informed consent before a test is administered, except as specified in s. 381.004(2)(h), F.S. Exceptions to informed consent include the testing of inmates from the state prison system prior to release, testing defendants in sexual battery crimes at the request of the victims; and when mandated by court order.

Informed consent for HIV testing is defined under the Florida Administrative Code and requires:[11]

- An explanation that the information identifying the test subject and the results of the test are confidential and protected against further disclosure to the extent permitted by law;
- Notice that persons who test positive will be reported to the local CHD;
- Notice that anonymous testing is available and the locations of the anonymous sites;
- Written informed consent only for the following:
  - From the potential donor or donor's legal representative prior to first donation of blood, blood components, organs, skin, semen, or other human tissue or body part;
  - For insurance purposes; and,
  - For contracts purposes in a health maintenance organization, pursuant to s. 641.3007, F.S.

Minors meeting certain requirements, such as being married, pregnant, or able to demonstrate maturity to make an informed judgment, can be tested for HIV, without parental consent if the minor provides informed consent.[12]

The other exception to informed consent for HIV testing in Florida relates to pregnancy. Prior to testing, a health care practitioner must inform a pregnant woman that the HIV test will be conducted and of her right to refuse the test. If declined, the refusal will be noted in the medical record.[13]

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provided. A nonhealth care setting does not provide these services. Examples of nonhealth care settings include community-based organization and outreach venues.

[10] Center for Disease Control and Prevention, *Testing*, http://www.cdc.gov/hiv/basics/testing.html (last visited Mar. 26, 2014).

[11] Rule 64D-2.004, F.A.C.

[12] Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.

[13] Sections 381.004(2)(h)(2) and 384.31, F.S.

The Department of Health (DOH) has developed a comprehensive program for preventing the spread of HIV/AIDS with many testing options available throughout the state in a variety of settings. Over 30,000 people receive AIDS treatment and prevention services from the DOH through the CHD and different programs of the DOH.[14]

A nonhealth care setting that offers HIV testing services must first register with the DOH and comply with other statutory requirements listed in s. 381.004(4), F.S., such as providing opportunities for pre-test and post-test counseling by counselors specifically trained to address the needs of persons who may receive positive test results.

III. Effect of Proposed Changes:

Section 1 amends s. 381.004, F.S., and adds definitions for "health care setting" and "nonhealth care setting."

A health care setting is defined as a setting devoted to both the diagnosis and care of persons, such as:

- County health department clinics;
- Hospital emergency departments;
- Urgent care clinics;
- Substance abuse treatment clinics;
- Primary care settings;
- Community clinics;
- Mobile medical clinics; and
- Correctional health care facilities.

CS/SB 1470 modifies the consent requirements for HIV tests specifically conducted in a health care setting to require the health provider to notify the patient the test is planned and advise the patient of his or her option to decline the planned test. This is changed from requiring informed consent and more closely implements the CDC guidelines for HIV testing. The provider must also inform the patient of his or her right to confidential treatment of identifying information under the law. If the patient opts out of the test, the provider must note the denial in the patient's record.

A nonhealth care setting is defined as a site that conducts HIV testing for the sole purpose of identifying HIV infection. These locations do not provide medical treatment but may include sites such as:

- Community based organizations;
- Outreach settings;
- County health department HIV testing programs; and
- Mobile vans.

[14] Department of Health, *County Health Departments*, http://www.floridahealth.gov/public-health-in-your-life/county-health-departments/index.html (last visited: Mar. 26, 2014).

In a nonhealth care setting, the bill requires the provider to obtain the patient's informed consent for the HIV test after an explanation of the patient's right to confidential treatment of identifying information as provided under law, including test results.

In either setting, the patient must be informed that a positive HIV test will be reported to the local CHD with sufficient information to identify the patient. The patient must also be provided information about the availability of anonymous testing sites. Each CHD will be responsible for maintaining a list of available sites with locations, telephone numbers, and hours of operation.

The bill updates the definition for "preliminary HIV test" with current terminology and testing options.

The bill authorizes hospitals licensed under ch. 395, F.S., to release HIV test results, as is currently permitted, if the hospital notifies the patient of the confidentiality protections included in medical records. The bill conforms this requirement to the notification requirements in the bill related to HIV testing in a health care setting.

The bill makes conforming changes and corrects cross-references.
Section 2 amends s. 456.032, F.S., to correct a cross-reference relating to hepatitis B or HIV carriers.

Section 3 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private entities that provide HIV testing may need to modify their policies and procedures to meet any revised requirements for informed consent or notification, depending on their status as a health care setting or nonhealth care setting.

C. Government Sector Impact:

The DOH will need to revise Rule 64D-2.004, F.A.C., to conform to the changes in this bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.004 and 456.032.

IX. Additional Information:

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

CS by Health Policy on April 1, 2014:.
The CS re-inserts deleted language. The provision adds pregnant women to a list of populations for whom informed consent is not required for HIV testing.

B. Amendments:

None.

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Senate	.	House
Comm: RCS	.	
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The Committee on Health Policy (Joyner) recommended the following:

Senate Amendment (with title amendment)

Delete line 146
and insert:
d. HIV testing of pregnant women pursuant to s. 384.31.

========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 6 - 8
and insert:

246082

nonhealth care setting; amending s. 456.032, F.S.;

By Senator Thompson

12-01300A-14 20141470__

A bill to be entitled

An act relating to HIV testing; amending s. 381.004, F.S.; revising and adding definitions; differentiating between the notification and consent procedures for performing an HIV test in a health care setting and a nonhealth care setting; deleting the exemption from the requirement to obtain informed consent before testing a pregnant woman; amending s. 456.032, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Subsection (1), paragraphs (a), (b), (g), and (h) of subsection (2), and paragraph (d) of subsection (4) of section 381.004, Florida Statutes, are amended, and subsection (1) of that section is reordered, to read:

381.004 HIV testing.—

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

(a) "Health care setting" means a setting devoted to both the diagnosis and care of persons, such as county health department clinics, hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, mobile medical clinics, and correctional health care facilities.

(b) ~~(a)~~ "HIV test" means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.

12-01300A-14 20141470__

(c) ~~(b)~~ "HIV test result" means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. ~~As used in this section,~~ The term ~~"HIV test result"~~ does not include test results reported to a health care provider by a patient.

(d) "Nonhealth care setting" means a site that conducts HIV testing for the sole purpose of identifying HIV infection. Such setting does not provide medical treatment but may include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.

(f) ~~(c)~~ "Significant exposure" means:

1. Exposure to blood or body fluids through needlestick, instruments, or sharps;

2. Exposure of mucous membranes to visible blood or body fluids~~,~~ to which universal precautions apply according to the National Centers for Disease Control and Prevention, including, without limitations, the following body fluids:

a. Blood.

b. Semen.

c. Vaginal secretions.

d. Cerebrospinal ~~Cerebro-spinal~~ fluid (CSF).

e. Synovial fluid.

f. Pleural fluid.

g. Peritoneal fluid.

h. Pericardial fluid.

i. Amniotic fluid.

j. Laboratory specimens that contain HIV (e.g., suspensions

of concentrated virus); or

3. Exposure of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.

(e) ~~(d)~~ "Preliminary HIV test" means an antibody or antibody-antigen screening test, such as the ~~enzyme-linked~~ immunosorbent assays (IA), or a rapid test approved by the federal Food and Drug Administration ~~(ELISAs) or the Single-Use Diagnostic System (SUDS)~~.

(g) ~~(c)~~ "Test subject" or "subject of the test" means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.

(2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—

(a) Before performing an HIV test:

1. In a health care setting, the health care provider shall notify the person to be tested that the test is planned, provide information about the test, and advise the person that he or she has the right to decline the test. The health care provider shall also explain the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law. If a person declines the test, the health care provider shall note that fact in the person's medical record. ~~No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed,~~

~~except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained~~.

2. In a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is being performed. Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law.

The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone

numbers, and hours of operation of the sites.

(b) Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law if ~~when~~ the person:

1. Is not competent, is incapacitated, or is otherwise unable to make an informed judgment; or

2. Has not reached the age of majority, except as provided in s. 384.30.

(g) Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to ~~the requirements of~~ subparagraph (e)2., subparagraph (e)9., or paragraph (f) if~~; provided~~ the hospital has notified the patient of the limited confidentiality protections afforded HIV test results contained in hospital medical records ~~obtained written informed consent for the HIV test in accordance with provisions of this section~~.

(h) Notwithstanding ~~the provisions of~~ paragraph (a), informed consent is not required:

1. When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:

a. HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.

b. HIV testing of inmates pursuant to s. 945.355 before ~~prior to their~~ release from prison by reason of parole, accumulation of gain-time credits, or expiration of sentence.

c. Testing for HIV by a medical examiner in accordance with s. 406.11.

~~d. HIV testing of pregnant women pursuant to s. 384.31.~~

2. Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.

3. For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies if ~~when~~ the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results in accordance with paragraph (c) is required.

4. For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, providing notification ~~obtaining informed consent~~ would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results in accordance with paragraph (c) is required if it would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV infection without notification ~~informed consent~~.

5. If ~~When~~ HIV testing is performed as part of an autopsy for which consent was obtained pursuant to s. 872.04.

6. For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to ~~the provisions of~~ s. 775.0877, s. 951.27, or s.

960.003; however, the results of an ~~any~~ HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.

7. If ~~When~~ an HIV test is mandated by court order.

8. For epidemiological research pursuant to s. 381.0031, for research consistent with institutional review boards created by 45 C.F.R. part 46, or for the performance of an HIV-related test for the purpose of research, if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

9. If ~~When~~ human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.

10. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available which ~~that~~ was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.

a. Before performing ~~Prior to performance of~~ an HIV test on a voluntarily obtained blood sample, the individual from whom

the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel, all information concerning the performance of an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.

b. Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the individual cannot be found or is incapable of providing consent, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an HIV test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel.

c. Costs of an ~~any~~ HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or

the employer of the medical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel.

d. In order to use ~~utilize~~ the provisions of this subparagraph, the medical personnel must ~~either~~ be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months before ~~prior to~~ the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

11. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical

personnel while the medical personnel provides emergency medical treatment to the individual; or notwithstanding s. 384.287, an individual who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.

a. An individual who is capable of providing consent shall be requested to consent to an HIV test before ~~prior to the~~ testing. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel and nonmedical personnel, all information concerning the performance of an HIV test and its result, shall be documented only in the medical personnel's or nonmedical personnel's record unless the individual gives written consent to entering this information in ~~on~~ the individual's medical record.

b. HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical

personnel.

c. Costs of any HIV test performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.

d. In order to use ~~utilize~~ the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months before ~~prior to~~ the significant exposure if such test results are negative.

e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).

f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes

probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

12. For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.

a. HIV testing may be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

b. Costs of an ~~any~~ HIV test performed under this subparagraph may not be charged to the deceased or to the family of the deceased person.

c. For ~~the provisions of~~ this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.

d. A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).

13. For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant if ~~when~~, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant must ~~shall~~ reflect the reason consent of the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.

14. For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.

15. For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.

(4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS; REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM REGISTRATION.—No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

(d) A program in a health care setting shall meet the notification criteria contained in subparagraph (2)(a)1. A program in a nonhealth care setting shall meet all informed consent criteria contained in subparagraph (2)(a)2. ~~The program must meet all the informed consent criteria contained in subsection (2).~~

Section 2. Subsection (2) of section 456.032, Florida

Statutes, is amended to read:

456.032 Hepatitis B or HIV carriers.—

(2) Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s. 381.004(1)~~(c)~~, to blood or body fluids. The employer may test the blood or body fluid to determine if it is infected with the same disease contracted by the employee. The employer may rebut the presumption by the preponderance of the evidence. Except as expressly provided in this subsection, there shall be no presumption that a blood-borne infection is a job-related injury or illness.

Section 3. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic _____ Bill Number 1470 *(if applicable)*

Name Chris Nuland Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 1000 Riverside Ave #115 Phone 904-233-3051

Street

Jacksonville, FL 32204 E-mail nulandlaw@aol.com

City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

Representing ~~Chr~~ Florida Public Health Association

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic HIV Testing

Bill Number 1470 *(if applicable)*

Name Spencer Lieb

Amendment Barcode _____ *(if applicable)*

Job Title HIV/AIDS Research Coordinator

Address 410 Victory Garden Dr. #127 *Street*

Phone 850-408-4512

Tallahassee *City* FL *State* 32301 *Zip*

E-mail slieb@theaidsinstitute.org

Speaking: ☑ For ☐ Against ☐ Information

Representing The AIDS Institute

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/20/11)

HEALTH POLICY
3:00 412-K

THE FLORIDA SENATE

APPEARANCE RECORD

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

WAIVE TIME IN SUPPORT

4-1-2014
Meeting Date

Topic HIV TESTING

Bill Number SB 1470 *(if applicable)*

Name STEPHEN R. WINN

Amendment Barcode _____ *(if applicable)*

Job Title EXECUTIVE DIRECTOR

Address 2007 APALACHEE PARKWAY *Street*

Phone 878-7364

TALLAHASSEE, FL 32301
City *State* *Zip*

E-mail _____

Speaking: ☒ For ☐ Against ☐ Information

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic HIV Testing Bill Number 1470
(if applicable)

Name Michelle Jacquis Amendment Barcode
(if applicable)

Job Title

Address PO Box 10269 Phone 850-251-2288
Street

Tallahassee, FL 32302 E-mail Mjacquis@flmedical.org
City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information *waive in support*

Representing FL Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1212
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Behavior Analysts
DATE:	April 2, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Fav/CS**
2.			RI	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1212 creates ch. 470, F.S., titled "Behavior Analysts," for the purpose of regulating the practice of applied behavior analysis. The bill provides definitions of terms used in the chapter and creates a seven-member Board of Applied Behavior Analysis, which is appointed by the Governor and confirmed by the Senate.

The bill establishes eligibility criteria for persons applying for initial or renewal licensure as a behavior analyst or assistant behavior analyst which require board-certification and background screening for both. The board is authorized to issue a reciprocal license to a person licensed in another state under certain circumstances. The bill contains a lengthy series of exemptions from licensure.

The bill authorizes the board to discipline licensees as provided in ch. 456, F.S. The board is authorized to adopt rules to implement the act, including rules defining standards of practice and required supervision. The department is authorized to adopt rules related to procedures for licensure and relicensure, educational requirements, and continuing education.

II. Present Situation:

Behavior Analysis

Behavior analysis grew out of the scientific study of principles of learning and behavior. It has two main branches: experimental and applied behavior analysis. The experimental analysis of behavior is the basic science which provides the scientific foundation for applied behavior analysis.[1] Florida law defines applied behavior analysis as "the design, implementation, and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvement in human behavior, including, but not limited to, the use of direct observation, measurement, and functional analysis of the relations between environment and behavior."[2] Examples of applied behavior analysis practice include: building the skills and achievements of children in school settings and enhancing the development, abilities, and choices of children and adults with different kinds of emotional and behavioral disabilities.[3]

Certification of Behavior Analysts

The Behavior Analyst Certification Board (BACB or board) is the exclusive entity that certifies behavior analysts. The board is a nonprofit 501(c)(3) corporation established in 1998 based on the behavior analysis certification program developed in Florida. Similar programs were established in California, Texas, Pennsylvania, New York and Oklahoma. All of these programs transferred their certificants and credentialing responsibilities to the board and closed.[4]

As part of its credentialing program, the BACB has developed:[5]

- Eligibility standards.
- Renewal and recertification standards to maintain certification.
- Guidelines for responsible conduct.
- Professional disciplinary standards with appeal procedures.
- A certificant registry.
- A process to approve university course sequences and practica.
- Procedures to approve continuing education providers.
- Certification examinations.

Currently, the BACB offers two certifications: Board Certified Behavior Analyst and Board Certified Assistant Behavior Analyst. The Board Certified Behavior Analyst conducts descriptive and systematic behavioral assessments, including functional analyses, and provides behavior analytic interpretations of the results. The Board Certified Behavior Analyst also designs and supervises behavior analytic interventions. To be eligible for certification as a

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[1] Behavior Analyst Certification Board, *About Behavior Analysis* http://www.bacb.com/index.php?page=2 (last visited Mar. 29, 2014).
[2] Sections 627.6686(2)(a) and 641.31098(2)(a), F.S. The definitions are part of a mandate for health care coverage for individuals with autism spectrum disorder. Applied behavior analysis is one of the required services.
[3] *Supra* note 1.
[4] Behavior Analyst Certification Board, *About the BACB* http://www.bacb.com/index.php?page=1 (last visited Mar. 29, 2014).
[5] *Id.*

behavior analyst, an applicant must have a master's degree in behavior analysis or other natural science, education, human services, engineering, medicine or a field related to behavior analysis approved by the board. In addition, the applicant must have 225 hours of graduate level instruction; 1-year, full time faculty appointment at a college or university teaching behavior analysis; or a doctoral degree conferred 10 years prior to applying for certification and meet certain experience requirements.[6]

The Board Certified Assistant Behavior Analyst conducts descriptive behavioral assessments, interprets their results, and designs behavior analytic interventions under the supervision of a Board Certified Behavior Analyst.[7] To be eligible for certification as a Board Certified Assistant Behavior Analyst, an applicant must have a bachelor's degree and 135 hours of instruction, and meet certain experience requirements.[8]

Currently, there are 1,821 behavior analysts or assistant behavior analysts in Florida who are board-certified by the BACB.[9]

Florida-Certified Behavior Analysts

Florida began training and certifying behavior analysts in 1983, through the Department of Health and Rehabilitative Services. In 2001, the Florida program was discontinued and all credentialing responsibilities were transferred to the BACB.[10] Behavior analysts certified through the Florida program are authorized to use only the designation Florida Certified Behavior Analyst. Recertification as a Florida Certified Behavior Analyst occurs every 3 years and requires 36 hours of continuing education.[11]

Recognition of Behavior Analysis in Florida Law

Although Florida does not license behavior analysts, its laws do recognize them in ways that may provide for some oversight. Specific references are as follows:

- Section 381.75, F.S., requires that transitional living facilities that provide services to patients in the brain and spinal cord injury program must offer behavior analysis services. The law does not specify credentials, but the services will be provided under contract and by a facility that is subject to state licensure.
- Section 393.17, F.S., authorizes the Agency for Persons with Disabilities to establish a certification process for behavior analysts who serve its clients, and requires the agency to recognize the certification "awarded by a nonprofit corporation that adheres to the national standards of boards that determine professional credentials and whose mission is to meet

[6] Behavior Analyst Certification Board, *Standards for Board Certified Behavior Analysts (BCBA)* http://www.bacb.com/index.php?page=158 (last visited Mar. 30, 2014).
[7] Behavior Analyst Certification Board, *About BACB Credentials* http://www.bacb.com/index.php?page=4 (last visited Mar. 29, 2014).
[8] Behavior Analyst Certification Board, *Standards for Board Certified Assistant Behavior Analysts (BCABA)*, http://www.bacb.com/index.php?page=52 (last visited Mar. 31, 2014).
[9] Behavior Analyst Certification Board, *Certificant Registry* http://www.bacb.com/index.php?page=100155&by=state (last visited Mar. 30, 2014).
[10] *See Infra* note 20 at 2.
[11] Behavior Analyst Certification Board, *Florida Behavior Analyst Certification Committee* http://www.bacb.com/index.php?page=100202 (last visited Mar. 29, 2014).

professional credentialing needs identified by behavior analysts, state governments, and consumers of behavior analysis services." This language describes the BACB.[12] The agency has opted not to create a separate certification process.[13]

- Section 393.18, F.S., requires a behavior analyst who provides services as part of a comprehensive transitional education program for persons with developmental disabilities to be certified as provided under s. 393.17, F.S.
- Section 409.906(26), F.S., authorizes the Agency for Health Care Administration to obtain federal approval to provide behavior analysis services to children 5 years old and younger who have a developmental disability, autism spectrum disorder, or Down syndrome through the Medicaid program.
- Sections 627.6686 and 641.31098, F.S., mandate coverage for autism spectrum disorder which includes applied behavior analysis services. The services must be provided by a person who is licensed under ch. 490 or 491, F.S., or certified pursuant to s. 393.17, F.S.
- Section 1002.66, F.S., includes applied behavioral analysis among the specialized instructional services a parent may select for a child with disabilities who is eligible for prekindergarten. As part of the exceptional student education legislation, the 2013 Legislature created a definition of private instructional personnel which includes persons certified under s. 393.17, F.S., or licensed under ch. 490 or 491, F.S., to provide behavior analysis.

Regulation of Health Care Professions

The DOH is responsible for licensing and regulating health care practitioners in order to preserve the health, safety, and welfare of the public.[14] General licensing provisions applicable to health care practitioners are contained in ch. 456, F.S., which also sets out in more detail the policy framework for regulation. Specifically, regulation is to occur when:[15]

- Unregulated practice can harm or endanger the health, safety, and welfare of the public, and the potential for harm outweighs the potentially anticompetitive effect of regulation.
- The public is not adequately protected by other means, including other statutes, federal law, or local ordinances.
- Less restrictive means of regulation are not available.

The Division of Medical Quality Assurance (MQA) within the DOH has responsibility for licensing health care practitioners, and certain facilities and businesses; enforcing health care practitioner standards; and providing licensure and disciplinary information to enable health care consumers to make more informed health care decisions.[16]

Regulation of some professions occurs under the purview of a board or council. A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[17] In general, boards are responsible for approving or denying applications for

[12] *See Supra* note 4.
[13] Rule 65G-4.0011, F.A.C.
[14] Section 20.43(1)(g), F.S.
[15] Section 456.003(2), F.S.
[16] Fla. Dept. of Health, *Resource Manual for the Florida Department of Health*, 252 (FY 2012–2013) (on file with the Senate Health Policy Committee).
[17] Section 456.001(1), F.S.

licensure, establishing continuing education requirements, and disciplining practitioners for violations of the relevant practice act.[18] Currently, The MQA regulates seven types of facilities and 200-plus license types in 43 health care professions through coordination with 22 boards and six councils.[19]

The Sunrise Act

Section 11.62, F.S., "The Sunrise Act," sets forth policy and minimum requirements for legislative review of bills proposing regulation of an unregulated function. In general, the act states that regulation should not occur unless:

- Necessary to protect the public health, safety, or welfare from significant and discernible harm or damage;
- Exercised only to the extent necessary to prevent the harm; and,
- Limited so as not to unnecessarily restrict entry into the practice of the profession or adversely affect public access to the professional services.

The act directs the Legislature to consider the following factors:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and,
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires proponents of legislation proposing new regulation to provide detailed information regarding the need and potential impact of the regulation. The act also requires the agency that will be responsible for its implementation to assess the cost of implementation, the technical sufficiency of the proposal, and whether alternatives to regulation exist.

In determining whether to recommend regulation, the legislative committee reviewing the proposal is directed to assess whether the proposed regulation is:

- Justified based on the statutory criteria and the information provided by both the proponents of regulation and the agency responsible for its implementation;
- The least restrictive and most cost-effective regulatory scheme necessary to protect the public; and,

[18] *See, e.g.* s. 491.004, F.S., creating the Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling and authorizing it to adopt rules necessary to implement and enforce provisions of ch. 491, F.S.
[19] *Supra* note 16 at 167.

- Technically sufficient and consistent with the regulation of other professions under existing law.

Summary of Sunrise Act Questionnaire and Responses

The following summarizes information submitted by the proponent of the legislation in its responses to questions in the Sunrise Questionnaire.[20] The responses summarized relate to the five factors the Sunrise Act directs the Legislature to consider.

Substantial Harm or Endangerment

The proponent states that a majority of persons treated by applied behavior analysis services are highly vulnerable because of their age, the nature of their disability or illness, or the magnitude of the stress experienced by the caretaker. This makes them susceptible to fraudulent, ineffective practices, or unethical interventions. Because there is not a regulatory system currently in place, the proponent indicates that quantifying the need for regulation is difficult. The proponent uses complaints filed with the BACB as a proxy for need, but believes the number underestimates the problem. In the past 13 years, 26 events of unethical or improper practice have been investigated by the certifying agency in Florida. These violations involved negligence, incompetence, malpractice, or misconduct.[21]

Specialized Skill or Training, and Measurability

The proponent states that board certification defines and measures the requisite knowledge, skills, and abilities. These fall into 10 general content areas which are tested by examination in multiple-choice format with specific questions in each of the content areas. To be eligible for examination, a person must have at least a master's degree in behavior analysis or other natural science, education, human services, medicine, or a field related to behavior analysis. Currently, nine universities in Florida offer programs that would qualify a person to sit for the certification exam.[22]

Unreasonable Effect on Job Creation or Job Retention

The proponent indicates that the requirements for licensure under the proposed legislation align with current credentialing requirements for certification as a behavior analyst. Thus, the legislation does not create a more onerous standard. Currently, this credentialing function is handled by the BACB.[23]

Other persons who may implement behavioral interventions and provide counseling services similar to that of behavioral analysts include schoolteachers, school psychologists, parents, physicians, school faculty, priests, and ministers. These persons are not required to obtain

[20] The Sunrise Questionnaire is a questionnaire developed by Legislative staff to solicit the responses required by the proponent of new regulation pursuant to s. 11.62(4), F.S. A copy of the questionnaire is on file with the Senate Health Policy Committee. The legislation has been proposed by the Florida Association for Behavioral Analysis.
[21] *Id*. at 4 – 7.
[22] *Id.*at 19 – 23.
[23] *Id.* at 25.

certification under the bill.[24] In addition, behavior analysis is an element of the practice of psychology, thus it may be provided by a psychologist.[25]

Can the Public Be Effectively Protected by Other Means?

The proponent indicates that the certification entity receives and responds to complaints it receives about board certified behavioral analysts and those who are fraudulently claiming to be board certified. Over the past 13 years, the certifying entity has investigated 26 claims of unethical or improper practice in Florida. The proponent indicates that the requirements for filing a complaint with the certifying entity, however, are time consuming, requiring consumers to produce written records of correspondence to the behavior analyst, correspondence to fiscal agencies or funding sources, and correspondence with state regulatory agencies (which is currently unavailable in Florida).[26]

Favorable Cost-effectiveness and Economic Impact

The proponent does not anticipate that licensure will result in any changes to the current costs of services for consumers because the number of persons seeking certification as a behavioral analyst is growing.[27]

Statutory Creation of Advisory Bodies, Commissions, or Boards

The statutory creation of any collegial body to serve as an adjunct to an executive agency is subject to certain provisions in s. 20.052, F.S. Such a body may only be created when it is found to be necessary and beneficial to the furtherance of a public purpose, and it must be terminated by the Legislature when it no longer fulfills such a purpose. The Legislature and the public must be kept informed of the numbers, purposes, memberships, activities, and expenses of any collegial or advisory bodies.

A board of trustees is defined as "a board created by specific statutory enactment and appointed to function adjunctively to a department, the Governor, or the Executive Office of the Governor to administer public property or a public program."[28] Private citizen members of a board of trustees may only be appointed by the Governor, must be confirmed by the Senate, and are subject to the dual-office-holding prohibition of Art. II, s. 5(a) of the State Constitution.

Members of a board of trustees serve for 4-year staggered terms, unless expressly provided otherwise in the State Constitution, and are ineligible for any compensation other than travel expenses. Unless an exemption is specified by law, all meetings are public, and records of minutes and votes must be maintained.

[24] *Id.* at 18.
[25] Section 490.003(4), F.S.
[26] *Supra* note 20 at 4 – 5.
[27] *Id.* at 23.
[28] Section 20.03(12), F.S.

III. Effect of Proposed Changes:

CS/SB 1212 creates ch. 470, F.S., titled "Behavior Analysts," for the purpose of regulating the practice of applied behavior analysis.

The bill creates the following definitions:

- "Applied behavior analysis" means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior and includes functional assessment and analysis." The definition expressly excludes certain acts that are within the definition of "practice of psychology" in ch. 490, F.S. The definition is consistent with, but not identical to, the current definition in chs. 627 and 641, F.S., relating to health care coverage for persons with autism spectrum disorder.
- "Board" means the Board of Applied Behavior Analysis, as created by the bill, unless the term appears in the context of board certification.
- "Board-certified behavior analyst" and "Board-certified assistant behavior analyst" are practitioners certified by the BACB or its successor.
- "Department" is the Department of Health.
- "Licensed behavior analyst" and "licensed assistant behavior analyst" are practitioners licensed by the board created by the bill.

The bill creates the Board of Applied Behavior Analysis, which is a seven-member board appointed by the Governor and confirmed by the Senate. Three members must be board-certified behavior analysts, at least two of whom are recommended by the Florida Association for Behavior Analysis. One member must be a board-certified assistant behavior analyst; one member a health care practitioner whose practice primarily includes treatment of behavior disorders; and two member-laypersons. The bill provides for staggered 4-year terms and requires that subsequent appointees be licensed under the act. A person may not serve more than two consecutive terms.

The bill directs the board to adopt rules to implement the act, which must include rules related to:

- Standards of practice;
- Supervision, including the number of persons that a licensed behavior analyst may supervise; and,
- Fees, not to exceed $100 for an application and $300 for licensure. Fees must be based on the actual cost to regulate.

In the event that the BACB discontinues certification, the board is directed to approve a successor entity that is accredited by the National Commission for Certifying Agencies or the American National Standards Institute.

The bill authorizes the DOH to adopt rules to implement its duties under the act, including, rules related to:

- Initial and renewal licensure application processes and fees;
- Educational qualifications for licensure; and,
- Continuing education requirements for renewal, not to exceed 30 hours.

The bill requires a person applying for initial or renewal licensure as a behavior analyst to provide evidence that he or she:

- Is board-certified;
- Has paid the licensure or renewal licensure fee; and,
- Has passed a criminal background check.

The bill requires a person applying for initial or renewal licensure as an assistant behavior analyst to provide evidence that he or she:

- Is board-certified;
- Is supervised by a licensed behavior analyst;
- Has paid the licensure or renewal licensure fee; and,
- Has passed a criminal background check.

The bill authorizes the board to issue a reciprocal license to a person licensed in another state if the person:

- Provides proof of licensure and board certification;
- Passes a background check; and,
- Pays the licensure fee.

The bill authorizes the board to discipline licensees as provided in ch. 456, F.S.

The bill prohibits the practice of applied behavior analysis or the use of the titles without first obtaining a license under ch. 470, F.S. Unlicensed practice is a third degree felony and unauthorized use of the title is a second degree misdemeanor. Both violations are punishable as provided in ch. 775, F.S. A third degree felony is punishable by a fine of up to $5,000 or up to 5 years in prison. A second degree misdemeanor is punishable by a fine of up to $500 or up to 60 days in prison.

The bill contains a lengthy series of exemptions from licensure, including:

- Psychologists licensed under ch. 490, F.S.;
- A certified teacher, for behavior analysis services delivered in the course of employment as a teacher that are within the scope of the teacher's education, training, and experience, provided the teacher does not hold him or herself out as a behavior analyst, and a teaching assistant who is supervised by a qualified certified teacher;
- Applied behavior analysts who work with animals;
- A person who teaches behavior analysis or conducts related research not involving direct patient care;
- A college graduate or postdoctoral fellow, working under the direct supervision of a licensed behavior analyst or instructor in an accredited program, whose activities are part of a defined behavior analysis program of study or practicum approved by the BACB, and subject to specified title restrictions;
- A person pursuing training experience required for board certification if supervised by a licensee who has been approved by the BACB to supervise;
- A board-certified behavior analyst or behavior analyst licensed in another state who provides services to a resident in this state for less than 12 days per year;

- A family member of a patient who implements procedures provided the family member does not hold him or herself out as a behavior analyst;
- A behavior analyst who provides services to an organization and not to individuals;
- A physician licensed under ch. 458, 459, or 491, F.S.;
- An occupational therapist licensed under ch. 468, F.S., provided he or she does not hold him or herself out as a behavior analyst;
- A clinical social worker, marriage and family therapist, or mental health counselor licensed under ch. 491, F.S.;
- An employee of a nonprofit organization that provides behavior analysis services to children at no charge, provided the person does not hold him or herself out as a behavior analyst;
- A certified school psychologist who performs behavior analysis as an employee of a public or private school; and,
- A member of the clergy acting within the scope of his or her religious duties.

Conforming provisions of the bill include amendments to:

- Section 20.43, F.S., which sets forth the organizational structure of the DOH, to add the Board of Applied Behavior Analysis;
- Section 456.0135, F.S., related to the general background screening procedures for certain health care practitioners, to add a reference to chapter 470; and,
- The definition of "health care practitioner" in ch. 456, F.S., to add practitioners licensed under ch. 470, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1212 will have a negative impact on persons who are providing behavior analysis services who do not meet the qualifications for licensure. Persons currently certified by the BACB will need to obtain a state license and pay the licensure fee to practice behavior analysis.

C. Government Sector Impact:

Revenue[29]
The DOH estimates it will receive 4,000 applications,[30] which will be subject to an application fee of $100; a licensure fee of $300; and an unlicensed activity fee of $5,[31] for a total of $1,620,000 in fee. Collections are subject to the 8 percent general revenue surcharge, which results in estimated revenue to the DOH of $1,490,400.

Expenses[32]
The DOH estimates it will need 4 FTE positions and 1 OPS position to implement the provisions of the bill. OPS expenses were computed at the base of the position plus 1.45 percent for Medicare tax. Salary was computed at base of the position plus 35 percent for benefits.

The OPS position and 1.5 FTE of the 4 total FTE positions will manage the licensing requirements. The requested expenses are 1.5 FTE Regulatory Specialist II, no travel ($77,326) and 1 OPS Regulatory Specialist II, no travel ($38,483) for a total cost of $115,809.

The DOH estimates it will receive 61 complaints filed against certified behavior analysts and assistant behavior analysts and 25 of those complaints will be deemed legally sufficient for investigation and prosecution. The DOH requests expenses for 2 FTE: 1 Investigation Specialist II, medium travel, and 1 Senior Attorney, no travel, for a total of $144,219.

The DOH estimates it will receive approximately 2,400 additional telephone calls in the Communication Center. It requests .5 Regulatory Specialist II, no travel, with total expenses of $29,238.

The DOH anticipates holding four, 1.5 day meetings per year with seven board members and two staff. Total estimated meeting costs are $34,641.

[29] Fla. Dept. of Health, *Senate Bill 1212 Fiscal Analysis* (Feb. 25, 2014) (on file with the Senate Committee on Health Policy).
[30] The proponent of the legislation estimates a considerably lower number of 1,700 initial applicants, then 125 – 150 applications annually thereafter, based on an average graduation rate of 10 – 15 students from each of the nine schools in Florida that have a behavior analysis program. (*See Supra* note 21 at 24–25.)
[31] Section 456.065(3), F.S.
[32] *See Supra* note 29.

The DOH currently contracts for processing of initial and renewal applications and related fees. The cost of the contracted service is based on a $7.69 per application for the estimated 4,000 applications for a total cost of $30,760.

The DOH will incur non-recurring costs for rulemaking, which current budget authority is adequate to absorb.

Consistent with adding any new profession, the DOH will update the Customer Oriented Medical Practitioner Administration System (COMPAS) to accommodate the new Certified Behavior Analyst and Assistant Behavior Analyst license, which current resources are adequate to absorb.

The DOH will incur an increase in workload associated with the development and maintenance of a new website, online renewals, online applications, and related functions, which current resources are adequate to absorb.

Combined the total estimated costs to implement the bill are: $354,667:

- Salary - $189,237.
- OPS – $31,172.
- Expense - $78,972/Recurring + $22,638/Non-Recurring.
- Contracted Services - $30,760.
- Human Resources - $1,888.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Legislature may wish to consider whether to amend the existing statutes that mandate the provision of behavior analysis services to cross-reference and require compliance with ch. 470, F.S., and the licensing standards created by this bill.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 20.43, 456.001, and 456.0135.

This bill creates the following sections of the Florida Statutes: 470.40, 470.41, 470.415, 470.42, 470.43, 470.44, 470.45, 470.46, and 470.47.

IX. Additional Information:

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

CS by Health Policy on April 1, 2014:
The Committee Substitute:

- Rewrites the bill in a format that conforms it to other practice acts and eliminates provisions that conflict with or duplicate provisions in ch. 456, F.S. Specifically, the CS:
  - Changes the term of a member of the Board of Applied Behavior Analysis to 4 years, consistent with the requirements of s. 20.052, F.S.
  - Revises the rules the board must adopt to include standards of practice and supervision requirements, only.
  - Authorizes the DOH to adopt rules related to licensure and renewal licensure procedures and fees; educational qualifications for licensure; and continuing education.
  - Deletes language that specified certain administrative responsibilities of the board, including: adopting a code of ethics; maintaining minutes and a registry and directory of licensees; and adopting a seal.
  - Substitutes the DOH, in lieu of the board, as the entity that receives and processes applications for licensure and conforms the terms to standard language used elsewhere.
  - Removes language expressly limiting the board's disciplinary authority.
  - Removes language that requires licensees and employers of licensees to report certain information about criminal acts of a licensee or actions against a licensees certification.
- Deletes the definition of "supervised experience," which is not used elsewhere in the bill.
- Removes exemptions for an unlicensed person working under the extended authority of a licensed behavior analyst; and Florida-certified behavior analysts.
- Adds an exemption for occupational therapists licensed under ch. 491, F.S.
- Changes the effective date to January 1, 2015.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Chapter 470, Florida Statutes, is created and entitled "Behavior Analysts."

Section 2. Section 470.40, Florida Statutes, is created to read:

470.40 Purpose.—The practice of applied behavior analysis in this state affects the public health, safety, and welfare of its residents, and this act is intended to protect the public

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from any harmful conduct of unqualified, unprofessional, or unethical applied behavior analysts.

Section 3. Section 470.41, Florida Statutes, is created to read:

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

(1) "Applied behavior analysis" means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior and includes functional assessment and analysis. The term does not include psychological testing, the diagnosis of a mental or physical disorder, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, or long-term counseling.

(2) "Board" means the Board of Applied Behavior Analysis established in s. 470.415, except when the term is used in the context of board certification.

(3) "Board-certified behavior analyst" means a practitioner who is certified as a Board Certified Behavior Analyst, or is recognized as a "Florida-certified behavior analyst," by the national Behavior Analyst Certification Board (BACB), or its successor pursuant to s. 470.42.

(4) "Board-certified assistant behavior analyst" means a practitioner who is certified by the national Behavior Analyst Certification Board, or its successor pursuant to s. 470.42, as a Board Certified Assistant Behavior Analyst.

(5) "Department" means the Department of Health.

(6) "Licensed behavior analyst" means an individual who is licensed by the board and meets the requirements of this chapter.

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(7) "Licensed assistant behavior analyst" means an individual who:

(a) Is licensed by the board as an assistant behavior analyst and meets the requirements of this chapter; and

(b) Works under the supervision of a licensed behavior analyst.

(8) "Supervised experience" means an individual has completed the training necessary to satisfy the eligibility requirements for BACB certification.

Section 4. Section 470.415, Florida Statutes, is created to read:

470.415 Board of Applied Behavior Analysis.—

(1) The Board of Applied Behavior Analysis is created within the department. The board consists of seven members who must be appointed by the Governor and confirmed by the Senate.

(2) The initial board members, who are not required to be licensed as a condition of appointment, shall be appointed as follows:

(a) Three board-certified behavior analysts, which may include board-certified behavior analysts who are at the doctoral level, two of whom shall be selected from a list of six nominations submitted by the Florida Association for Behavior Analysis. One shall be appointed to a 1-year term, and two shall be appointed to 3-year terms;

(b) One board-certified assistant behavior analyst, who shall be appointed to a 1-year term;

(c) One health care practitioner licensed in this state, who shall be appointed to a 2-year term. The majority of the appointed health care practitioner's practice must be related to

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the treatment of behavior disorders, including, but not limited to, autism spectrum disorders; and

(d) Two laypersons, who may include a parent or guardian of an individual who is a recipient of applied behavior analysis services, one of whom shall serve a 1-year term, and one of whom shall serve a 2-year term.

(3) As the terms of the initial members expire, the Governor shall appoint successors for 4-year terms. Each successor, except for the laypersons, must be licensed. A member may not serve more than two consecutive terms.

Section 5. Section 470.42, Florida Statutes, is created to read:

470.42 Authority of the board; board duties; authority of the department.—

(1) The board may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Standards of practice for licensed behavior analysts and licensed assistant behavior analysts.

(b) Supervision of licensed assistant behavior analysts or students in training to be licensed behavior analysts, including the number of persons that a licensed behavior analyst or licensed assistant behavior analyst may supervise at one time.

(2) If the Behavior Analyst Certification Board stops certifying practitioners of applied behavior analysis in this state, the board shall approve a successor certification board that is accredited by the National Commission for Certifying Agencies or the American National Standards Institute to certify

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applied behavior analysts.

(3) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Licensure and licensure renewal applications and processes, including licensure fees.

(b) Educational qualifications for licensure.

(c) Continuing education requirements for biennial renewal of licensure not to exceed 30 hours biennially as a condition for renewal of a license.

Section 6. Section 470.43, Florida Statutes, is created to read:

470.43 Licensure and renewal.—

(1) A person applying for an initial or renewal license as a licensed behavior analyst or licensed assistant behavior analyst shall apply to the department on such form and in such manner as the department prescribes. The person shall furnish evidence to the department that he or she:

(a) Is a board-certified behavior analyst;

(b) Has paid the licensure fee or the biennial renewal fee; and

(c) Has passed a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135.

(2) A person applying for an initial or renewal license as an assistant behavior analyst shall apply to the department upon such form and in such manner as the department prescribes and shall furnish evidence to the department that such person:

(a) Is a board-certified assistant behavior analyst;

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(b) Is supervised by a licensed behavior analyst in a manner consistent with BACB requirements and this chapter;

(c) Has paid the licensure fee or the biennial renewal fee; and

(d) Has passed a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135.

(3) The board may issue a license to a person who holds an active license as a behavior analyst or assistant behavior analyst in another state if the person:

(a) Submits proof of licensure and board certification;

(b) Passes a criminal background check after submitting fingerprints and a fee pursuant to s. 456.0135; and

(c) Pays the licensure fee.

Section 7. Section 470.44, Florida Statutes, is created to read:

470.44 Fees.—

(1) The board shall establish by rule a fee not to exceed $100 for an application and a fee not to exceed $300 for an initial license or license renewal.

(2) All moneys collected by the department under this chapter shall be deposited as provided under s. 456.025.

Section 8. Section 470.45, Florida Statutes, is created to read:

470.45 Disciplinary grounds and actions.—The board may enter an order imposing any of the penalties provided under s. 456.072(2) against a licensee who violates any provision of s. 456.072(1).

Section 9. Section 470.46, Florida Statutes, is created to read:

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470.46 Violations and penalties.—

(1) Unless licensed or authorized under this chapter, a person who engages in the practice of applied behavior analysis, assists in the practice of applied behavior analysis, renders services designated as applied behavior analysis, or represents himself or herself as a practitioner of applied behavior analysis in this state commits a felony of the third degree, punishable as provided under s. 775.082, s. 775.083, or s. 775.084.

(2) Unless licensed or authorized under this chapter, a person who uses the title "licensed behavior analyst," "licensed assistant behavior analyst," or any other title that is substantially similar commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 10. Section 470.47, Florida Statutes, is created to read:

470.47 Exceptions to applicability.—This chapter does not prohibit or restrict the practice of the following:

(1) An individual licensed under chapter 490 to practice psychology.

(2) A certified teacher authorized to practice in this state who is not a behavior analyst if he or she does not represent himself or herself as a behavior analyst. The services provided by a certified teacher must be within his or her authorized scope of practice and within the scope of his or her education, training, and experience and must be provided in the course of his or her employment in a program approved by the Department of Education. Teaching assistants, other than those engaged in pupil personnel services, and student support

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professionals are exempt from the requirements of this chapter if they provide applied behavior analysis services under the supervision of a certified teacher who meets the requirements of this paragraph.

(3) A behavior analyst who practices with nonhuman clients, including, but not limited to, applied animal behaviorists and animal trainers.

(4) An individual who teaches applied behavior analysis or who conducts behavior analytic research if such teaching or research does not involve the delivery of applied behavior analysis.

(5) A matriculated college or university student or postdoctoral fellow whose activities are part of a defined behavior analysis program of study, practicum, or intensive practicum if his or her practice under this subsection is directly supervised by a licensed behavior analyst or an instructor of an accredited course sequence approved by the Behavior Analyst Certification Board (BACB). A student or intern may not represent himself or herself as a professional behavior analyst but may use a title indicating his or her trainee status, such as "behavior analyst student," "behavior analyst intern," or "behavior analyst trainee."

(6) An unlicensed individual pursuing supervised experiential training to meet eligibility requirements for BACB certification if such training is supervised by an individual who is licensed to practice applied behavior analysis and who meets BACB supervisor requirements and if the supervised experiential training is conducted in accordance with other BACB standards and requirements.

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(7) A board-certified behavior analyst, a doctoral level board-certified behavior analyst, or an individual licensed to practice applied behavior analysis in another state who resides in another state and provides applied behavior analysis in this state or to a resident of this state for less than 12 days per year.

(8) A family member of a recipient of applied behavior analysis services who implements certain procedures with the recipient. Such a family member may not represent himself or herself as a professional behavior analyst.

(9) A behavior analyst who provides general behavior analysis services to organizations if the services are for the benefit of the organizations and do not involve direct services to individuals.

(10) A physician licensed pursuant to chapter 458 or chapter 459.

(11) An occupational therapist licensed pursuant to chapter 468 if he or she does not represent himself or herself as a behavior analyst.

(12) An individual licensed pursuant to chapter 491 as a clinical social worker, marriage and family therapist, or mental health counselor.

(13) A salaried employee of a private, nonprofit organization providing behavior analysis services to children, youth, and families if the services are provided for no charge, the employee is performing duties for which he or she was trained and hired, and the employee does not represent himself or herself as a professional behavior analyst.

(14) A school psychologist certified in school psychology

by the Department of Education who performs behavior analysis services as an employee of a public or private educational institution. Such exemption does not authorize unlicensed practice that is not performed directly as an employee of an educational institution.

(15) A rabbi, priest, minister, or member of the clergy of a religious denomination or sect if engaging in activities that are within the scope of the performance of his or her regular or specialized ministerial duties and for which no separate fee is charged, or if such activities are performed, with or without a fee, for or under the auspices or sponsorship, individually or in conjunction with others, of an established and legally cognizable church, denomination, or sect; and if the person rendering service remains accountable to the established authority thereof.

Section 11. Paragraph (g) of subsection (3) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

(3) The following divisions of the Department of Health are established:

(g) Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

1. The Board of Acupuncture, created under chapter 457.

2. The Board of Medicine, created under chapter 458.

3. The Board of Osteopathic Medicine, created under chapter 459.

4. The Board of Chiropractic Medicine, created under

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chapter 460.

5. The Board of Podiatric Medicine, created under chapter 461.

6. Naturopathy, as provided under chapter 462.

7. The Board of Optometry, created under chapter 463.

8. The Board of Nursing, created under part I of chapter 464.

9. Nursing assistants, as provided under part II of chapter 464.

10. The Board of Pharmacy, created under chapter 465.

11. The Board of Dentistry, created under chapter 466.

12. Midwifery, as provided under chapter 467.

13. The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.

14. The Board of Nursing Home Administrators, created under part II of chapter 468.

15. The Board of Occupational Therapy, created under part III of chapter 468.

16. Respiratory therapy, as provided under part V of chapter 468.

17. Dietetics and nutrition practice, as provided under part X of chapter 468.

18. The Board of Athletic Training, created under part XIII of chapter 468.

19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.

20. The Board of Applied Behavior Analysis, created under chapter 470.

21.~~20.~~ Electrolysis, as provided under chapter 478.

331530

22.~~21.~~ The Board of Massage Therapy, created under chapter 480.

23.~~22.~~ The Board of Clinical Laboratory Personnel, created under part III of chapter 483.

24.~~23.~~ Medical physicists, as provided under part IV of chapter 483.

25.~~24.~~ The Board of Opticianry, created under part I of chapter 484.

26.~~25.~~ The Board of Hearing Aid Specialists, created under part II of chapter 484.

27.~~26.~~ The Board of Physical Therapy Practice, created under chapter 486.

28.~~27.~~ The Board of Psychology, created under chapter 490.

29.~~28.~~ School psychologists, as provided under chapter 490.

30.~~29.~~ The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

31.~~30.~~ Emergency medical technicians and paramedics, as provided under part III of chapter 401.

Section 12. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 470; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

331530

Section 13. Section 456.0135, Florida Statutes, is amended to read:

456.0135 General background screening provisions.—

(1) An application for initial licensure received on or after January 1, 2013, under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, ~~or~~ s. 465.022, or chapter 470 shall include fingerprints pursuant to procedures established by the department through a vendor approved by the Department of Law Enforcement and fees imposed for the initial screening and retention of fingerprints. Fingerprints must be submitted electronically to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing. Each board, or the department if there is no board, shall screen the results to determine if an applicant meets licensure requirements. For any subsequent renewal of the applicant's license that requires a national criminal history check, the department shall request the Department of Law Enforcement to forward the retained fingerprints of the applicant to the Federal Bureau of Investigation.

(2) All fingerprints submitted to the Department of Law Enforcement as required under subsection (1) shall be retained by the Department of Law Enforcement as provided under s. 943.05(2)(g) and (h) and (3). The department shall notify the Department of Law Enforcement regarding any person whose fingerprints have been retained but who is no longer licensed.

(3) The costs of fingerprint processing, including the cost for retaining fingerprints, shall be borne by the applicant subject to the background screening.

331530

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

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to behavior analysts; creating ch. 470, F.S.; entitling the chapter; creating s. 470.40, F.S.; providing a purpose; creating s. 470.41, F.S.; defining terms; creating s. 470.415, F.S.; creating the Board of Applied Behavior Analysis; creating s. 470.42, F.S.; specifying the authority and duties of the board; creating s. 470.43, F.S.; providing requirements for licensure and renewal; creating s. 470.44, F.S.; establishing maximum fees for applications, initial licenses, and license renewals; providing for the deposit of funds; creating s. 470.45, F.S.; providing grounds for disciplinary action by the board; creating s. 470.46, F.S.; providing penalties for practicing applied behavior analysis without a license or wrongfully identifying oneself as a licensed behavior analyst; creating s. 470.47, F.S.; providing exceptions to applicability of the chapter; amending s. 20.43, F.S.; making the Division of Medical Quality Assurance within the Department of Health responsible for the board; amending s. 456.001, F.S.; including licensed behavior analysts and licensed assistant behavior analysts in

331530

the definition of "health care practitioner"; amending s. 456.0135, F.S.; requiring an applicant for licensure under ch. 470, F.S., to submit to certain fingerprinting requirements; providing an effective date.

577454

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
	.	
	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (331530)

Delete lines 47 - 49.

By Senator Bean

4-00250A-14 20141212__

A bill to be entitled

An act relating to behavior analysts; creating ch. 470, F.S.; entitling the chapter; creating s. 470.40, F.S.; providing a purpose; creating s. 470.41, F.S.; defining terms; creating s. 470.415, F.S.; creating the Board of Applied Behavior Analysis; creating s. 470.42, F.S.; specifying the authority and duties of the board; creating s. 470.43, F.S.; providing requirements for licensure and renewal; creating s. 470.44, F.S.; establishing maximum fees for applications, initial licenses, and license renewals; creating s. 470.45, F.S.; providing grounds for disciplinary action by the board; providing for reinstatement of a license; creating s. 470.46, F.S.; requiring a licensee or his or her employer to report to the board certain felony convictions on the part of a licensee or suspicions that a licensee has committed fraud or deceit; creating s. 470.47, F.S.; providing penalties for practicing applied behavior analysis without a license or wrongfully identifying oneself as a licensed behavior analyst; creating s. 470.48, F.S.; providing exceptions to the chapter; amending s. 456.001, F.S.; including licensed behavior analysts and licensed assistant behavior analysts in the definition of "health care practitioner"; providing an effective date.

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

4-00250A-14 20141212__

Section 1. Chapter 470, Florida Statutes, is created and entitled "Behavior Analysts."

Section 2. Section 470.40, Florida Statutes, is created to read:

470.40 Purpose.—The practice of applied behavior analysis in this state affects the public health, safety, and welfare of its residents, and this act is intended to protect the public from any harmful conduct of unqualified, unprofessional, or unethical applied behavior analysts.

Section 3. Section 470.41, Florida Statutes, is created to read:

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

(1) "Applied behavior analysis" means the design, implementation, and evaluation of instructional and environmental modifications to produce socially significant improvements in human behavior and includes functional assessment and analysis. The term does not include psychological testing, the diagnosis of a mental or physical disorder, neuropsychology, psychotherapy, cognitive therapy, sex therapy, psychoanalysis, hypnotherapy, or long-term counseling.

(2) "Board" means the Board of Applied Behavior Analysis established in s. 470.415, except when the term is used in the context of board certification.

(3) "Board-certified behavior analyst" means a practitioner who is certified by the national Behavior Analyst Certification Board (BACB), or its successor pursuant to s. 470.42, as a Board Certified Behavior Analyst.

(4) "Board-certified assistant behavior analyst" means a practitioner who is certified by the national Behavior Analyst

Certification Board, or its successor pursuant to s. 470.42, as a Board Certified Assistant Behavior Analyst.

(5) "Department" means the Department of Health.

(6) "Licensed behavior analyst" means an individual who is licensed by the board and meets the requirements of this chapter.

(7) "Licensed assistant behavior analyst" means an individual who:

(a) Is licensed by the board as an assistant behavior analyst and meets the requirements of this chapter; and

(b) Works under the supervision of a licensed behavior analyst.

(8) "Supervised experience" means an individual has completed the training necessary to satisfy the eligibility requirements for BACB certification.

Section 4. Section 470.415, Florida Statutes, is created to read:

470.415 Board of Applied Behavior Analysis.—

(1) The Board of Applied Behavior Analysis is created within the department. The board consists of seven members who must be appointed by the Governor and confirmed by the Senate.

(2) The initial board members, who are not required to be licensed as a condition of appointment, shall be appointed as follows:

(a) Three board-certified behavior analysts, which may include board-certified behavior analysts who are at the doctoral level, two of whom shall be selected from a list of six nominations submitted by the Florida Association for Behavior Analysis. One shall be appointed to a 1-year term, and two shall

be appointed to 3-year terms;

(b) One board-certified assistant behavior analyst, who shall be appointed to a 1-year term;

(c) One health care provider licensed in this state, who shall be appointed to a 2-year term. The majority of the appointed health care provider's practice must be related to the treatment of behavior disorders, including, but not limited to, autism spectrum disorders; and

(d) Two laypersons, who may include a parent or guardian of an individual who is a recipient of applied behavior analysis services, one of whom shall serve a 1-year term, and one of whom shall serve a 2-year term.

(3) As the terms of the initial members expire, the Governor shall appoint successors for 3-year terms. Each successor, except for the laypersons, must be licensed. A member may not serve more than two consecutive terms.

(4) All provisions of chapter 456 relating to the board apply.

Section 5. Section 470.42, Florida Statutes, is created to read:

470.42 Authority of the board; duties.—

(1) The board may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules must include, but are not limited to, rules relating to all of the following:

(a) Standards of practice.

(b) Licensure, including the suspension and revocation of a license and the refusal to issue or renew a license.

(c) Limitations of activities.

(d) Supervision.

(e) Educational qualifications and continuing education requirements.

(f) The number of persons that a licensed behavior analyst or licensed assistant behavior analyst may supervise at one time.

(g) The competency of a person to receive or renew his or her license.

(h) The physical and mental examination of licensed behavior analysts and licensed assistant behavior analysts who may be impaired by reason of a mental, physical, or other condition that impedes their ability to practice competently.

(2) The board shall perform all of the following:

(a) Adopt a code of ethical standards and standards of practice for licensed behavior analysts and licensed assistant behavior analysts.

(b) Keep a minute book containing a record of all meetings of the board.

(c) Maintain a registry of all persons licensed under this chapter. This registry must show the name of every licensee in this state, his or her current business and residence address and telephone number, and his or her licensure date and license number. A licensee shall notify the board of a change of name, address, or telephone number within 30 days after the change.

(d) Update its records annually.

(e) Publish annually and make available a current directory of all licensed behavior analysts and licensed assistant behavior analysts in this state.

(f) Adopt a seal and affix it to every license granted by

the board.

(g) Maintain its official headquarters in Tallahassee.

(3) If the Behavior Analyst Certification Board stops certifying practitioners of applied behavior analysis in this state, the board shall approve a successor certification board that is accredited by the National Commission for Certifying Agencies or the American National Standards Institute to certify applied behavior analysts.

Section 6. Section 470.43, Florida Statutes, is created to read:

470.43 Licensure and renewal.—

(1) A person applying for an initial or renewal license as a licensed behavior analyst or licensed assistant behavior analyst shall apply to the board on such form and in such manner as the board prescribes. The person shall furnish evidence to the board that he or she:

(a) Is a board-certified behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards as required by rule;

(c) Complies with all applicable rules adopted by the board;

(d) Has paid the licensure fee or the biennial renewal fee; and

(e) Has passed a criminal background check, as determined by the board.

(2) A person applying for an initial or renewal license as an assistant behavior analyst shall apply to the board upon such form and in such manner as the board prescribes and shall furnish evidence to the board that such person:

(a) Is a board-certified assistant behavior analyst;

(b) Conducts his or her professional activities in accordance with accepted standards, as required by rule;

(c) Complies with all applicable rules promulgated by the board;

(d) Is supervised by a licensed behavior analyst in a manner consistent with BACB requirements and this chapter;

(e) Has paid the licensure fee or the biennial renewal fee; and

(f) Has passed a criminal background check, as determined by the board.

(3) The board may issue a license to a person who holds an active license as a behavior analyst or assistant behavior analyst in another state that imposes comparable licensure requirements to those imposed by this state and that offers reciprocity to individuals licensed under this chapter. Applicants for reciprocity must:

(a) Submit proof of licensure and board certification;

(b) Pass a criminal background check, as determined by the board; and

(c) Pay the licensure fee.

Section 7. Section 470.44, Florida Statutes, is created to read:

470.44 Fees.—

(1) The board shall establish by rule a fee not to exceed $100 for an application and a fee not to exceed $300 for an initial license or license renewal.

(2) In establishing fees pursuant to subsection (1), the board shall consider the actual costs incurred in carrying out

its duties under this chapter.

(3) All moneys collected by the department under this chapter shall be deposited as provided under s. 456.025.

Section 8. Section 470.45, Florida Statutes, is created to read:

470.45 Disciplinary grounds and actions; reinstatement.—

(1) The board may enter an order imposing any of the penalties provided under s. 456.072(2) against a licensee who violates any provision of s. 456.072(1), except that the board may not do any of the following:

(a) Place a licensee on probation for more than 5 years.

(b) Impose a fine that exceeds $2,500.

(c) Suspend a license for more than 5 years.

(d) Limit or restrict a license for an indefinite period.

(2) The board may reinstate a license that has been suspended or revoked if, after a hearing conducted pursuant to s. 120.54, the board determines that the applicant is able to practice his or her profession with reasonable competency and in accordance with the code of ethics and standards of practice established by rule under s. 470.42. As a condition of reinstatement, the board may impose reasonable restrictions on the licensee's license to practice.

Section 9. Section 470.46, Florida Statutes, is created to read:

470.46 Duty to report felony or suspicion of fraud or deceit.—A licensee or employer of a licensee having actual or direct knowledge of facts shall report to the board a behavior analyst or assistant behavior analyst who:

(1) Has been charged or convicted of a felony that involved

any act that bears directly on his or her qualifications or ability to practice applied behavior analysis or any act that bears directly on the public health, safety, or welfare;

(2) Is suspected of fraud or deceit in procuring or attempting to procure a license to practice applied behavior analysis or of negligently performing actions that justify action against the license of the behavior analyst or assistant behavior analyst;

(3) Has had a board certification or a license to practice as a behavior analyst or assistant behavior analyst denied, limited, suspended, placed on probation, or revoked in another jurisdiction on grounds sufficient to cause a license or certificate to be denied, limited, suspended, placed on probation, or revoked in this state; or

(4) Is practicing applied behavior analysis without a license issued by the board unless specifically exempted in this chapter.

Section 10. Section 470.47, Florida Statutes, is created to read:

470.47 Violations and penalties.—

(1) Unless licensed or authorized under this chapter, a person who engages in the practice of applied behavior analysis, assists in the practice of applied behavior analysis, renders services designated as applied behavior analysis, or represents himself or herself as a practitioner of applied behavior analysis in this state commits a felony of the third degree, punishable as provided under s. 775.082, s. 775.083, or s. 775.084.

(2) Unless licensed or authorized under this chapter, a

person who uses the title "licensed behavior analyst," "licensed assistant behavior analyst," or any other title that is substantially similar commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 11. Section 470.48, Florida Statutes, is created to read:

470.48 Exceptions to applicability.—This chapter does not prohibit or restrict the practice of the following:

(1) An individual licensed under chapter 490 to practice psychology if the applied behavior analysis services he or she provides are within the scope of chapter 490 and his or her education, training, and experience.

(2) A certified teacher authorized to practice in this state who is not a behavior analyst if he or she does not represent himself or herself as a behavior analyst. The services provided by a certified teacher must be within his or her authorized scope of practice and within the scope of his or her education, training, and experience and must be provided in the course of his or her employment in a program approved by the Department of Education. Teaching assistants, other than those engaged in pupil personnel services, and student support professionals are exempt from the requirements of this chapter if they provide behavior analysis services under the supervision of a certified teacher who meets the requirements of this paragraph.

(3) A behavior analyst who practices with nonhuman clients, including, but not limited to, applied animal behaviorists and animal trainers.

(4) An unlicensed individual who provides applied behavior

analysis services under the extended authority and direction of a licensed behavior analyst or licensed assistant behavior analyst.

(5) An individual who teaches applied behavior analysis or who conducts behavior analytic research if such teaching or research does not involve the delivery of direct behavior analysis interventions to individuals.

(6) A matriculated college or university student or postdoctoral fellow whose activities are part of a defined behavior analysis program of study, practicum, or intensive practicum if his or her practice under this subsection is directly supervised by a licensed behavior analyst or an instructor of an accredited course sequence approved by the Behavior Analyst Certification Board (BACB). A student or intern may not represent himself or herself as a professional behavior analyst but may use a title indicating his or her trainee status, such as "behavior analyst student," "behavior analyst intern," or "behavior analyst trainee."

(7) An unlicensed individual pursuing supervised experiential training to meet eligibility requirements for BACB certification if such training is supervised by an individual who is licensed to practice applied behavior analysis and who meets BACB supervisor requirements and if the supervised experience is conducted in accordance with other BACB standards and requirements.

(8) A board-certified behavior analyst, a doctoral level board-certified behavior analyst, or an individual licensed to practice applied behavior analysis in another state who resides in another state and provides applied behavior analysis in this

state or to a resident of this state for less than 12 days per year.

(9) A Florida-certified behavior analyst who is in good standing with the Behavior Analyst Certification Board and who is not a board-certified behavior analyst.

(10) A family member of a recipient of applied behavior analysis services who implements certain procedures with the recipient under the extended authority and direction of a licensed behavior analyst or licensed assistant behavior analyst. Such a family member may not represent himself or herself as a professional behavior analyst.

(11) A behavior analyst who provides general behavior analysis services to organizations if the services are for the benefit of the organizations and do not involve direct services to individuals.

(12) A physician licensed pursuant to chapter 458 or chapter 459 if he or she does not represent himself or herself as a professional behavior analyst.

(13) An individual licensed pursuant to chapter 491 as a clinical social worker, marriage and family therapist, or mental health counselor if he or she does not represent himself or herself as a professional behavior analyst.

(14) A salaried employee of a private, nonprofit organization providing behavior analysis services to children, youth, and families if the services are provided for no charge, the employee is performing duties for which he or she was trained and hired, and the employee does not represent himself or herself as a professional behavior analyst.

(15) A school psychologist certified in school psychology

by the Department of Education who performs behavior analysis services as an employee of a public or private educational institution. Such exemption does not authorize unlicensed practice that is not performed directly as an employee of an educational institution.

(16) A rabbi, priest, minister, or member of the clergy of a religious denomination or sect if engaging in activities that are within the scope of the performance of his or her regular or specialized ministerial duties and for which no separate fee is charged, or if such activities are performed, with or without a fee, for or under the auspices or sponsorship, individually or in conjunction with others, of an established and legally cognizable church, denomination, or sect; and if the person rendering service remains accountable to the established authority thereof.

Section 12. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 470; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 13. This act shall take effect October 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Behavior Analysts

Bill Number SB 1212 *(if applicable)*

Name Larry Gonzalez

Amendment Barcode 331530 *(if applicable)*

Job Title General Counsel, FOTA*

Address 223 S. Gadsden St.
Street

Phone 850-570-6307

Tallahassee FL 32301
City *State* *Zip*

E-mail lawgonz@earthlink.net

Speaking: ☑ For ☐ Against ☐ Information

Representing *Florida Occupational Therapy Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic _____ Bill Number 1212 *(if applicable)*

Name Dr Carolyn Stimel Amendment Barcode _____ *(if applicable)*

Job Title Psychologist

Address 2704 Apalachee Pkwy Phone 850 386 8116
Street

Tallahassee FL 32301 E-mail stimel@aol.com
City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information

Representing FL Psychological Ass.

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

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-14
Meeting Date

Topic Behavior Analysts

Bill Number 1212 *(if applicable)*

Name Adam Roberts

Amendment Barcode _____ *(if applicable)*

Job Title Lobbyist

Address 2924 Quail Ridge Court
Street

Phone 591-9293

Tallahassee FL 32309
City *State* *Zip*

E-mail adam@gmalobby.com

Speaking: ☑ For ☐ Against ☐ Information

Representing The Florida Autism Center

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Behavior Analysts

Bill Number SB 1212 *(if applicable)*

Name Ron Watson

Amendment Barcode _____ *(if applicable)*

Job Title Father

Address 3738 Murdon Way
Street
Tallahassee FL 32309
City *State* *Zip*

Phone (850) 567-1202

E-mail watson.strategies@comcast.net

Speaking: ☒ For ☐ Against ☐ Information

Representing my son

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Behavior Analysts

Bill Number 1212 *(if applicable)*

Name Lynn Yeager

Amendment Barcode _____ *(if applicable)*

Job Title parent

Address 7927 Pine Lake Rd
Street
Jacksonville FL 32256
City *State* *Zip*

Phone 727-947-2066

E-mail lynnyeager7@aol.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Myself

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic BEHAVIOR ANALYSTS

Bill Number SB 1212 *(if applicable)*

Name MARY M. RIORDAN, Ph.D.

Amendment Barcode *(if applicable)*

Job Title BCBA-D

Address 1010 REDBUD *Street*

Phone 850 933 6654

Tallahassee FL 32303 *City* *State* *Zip*

E-mail mmriordan@me.com

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

Representing Association of Professional Behavior Analysts

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

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

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

_____
Meeting Date

Topic Behavior Analyst Licensure

Bill Number 1212 *(if applicable)*

Name Dr. Katherine Falwell

Amendment Barcode _____ *(if applicable)*

Job Title _____

Address 129 Retreat place *Street*

Ponte Vedra Beach, FL 32082 *City* *State* *Zip*

Phone 904-521-6206

E-mail falwell@keystonebehavioral.com

Speaking: ☑ For ☐ Against ☐ Information

Representing Self

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Behavior Analysts

Bill Number 1212 *(if applicable)*

Name Dr. Kim Lucker-Greene

Amendment Barcode *(if applicable)*

Job Title Consultant

Address 8700 Rolling Brook Lane
Street

Phone 904-534-6935

Jacksonville, FL 32256
City / *State* *Zip*

E-mail KdluckergreenecomcastNet

Speaking: ☑ For ☐ Against ☐ Information

Representing ~~Self~~ myself

Appearing at request of Chair: ☐ Yes ☑ ~~No~~

Lobbyist registered with Legislature: ☐ Yes ☑ ~~No~~

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

4/1/14
Meeting Date

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

Topic Behavior Analysis

Bill Number 1212 *(if applicable)*

Name AMANDA BROADFOOT

Amendment Barcode _____ *(if applicable)*

Job Title Parent

Address 1861 Eastern Forest Dr. *Street*
Tallahassee, FL 32317 *City State Zip*

Phone 850 570 7147

E-mail mandi@goodsamaritantallahassee.org

Speaking: ☑ For ☐ Against ☐ Information

Representing Myself

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic _____ Bill Number 1202 *(if applicable)*

Name BRIAN PITTS Amendment Barcode _____ *(if applicable)*

Job Title TRUSTEE

Address 1119 NEWTON AVNUE SOUTH Phone 727-897-9291
Street

SAINT PETERSBURG FLORIDA 33705 E-mail JUSTICE2JESUS@YAHOO.COM
City *State* *Zip*

Speaking: ☐ For ☑ Against ☑ Information

Representing JUSTICE-2-JESUS

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

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

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

S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/CS/SB 316
INTRODUCER:	Health Policy Committee; Children, Families, and Elder Affairs Committee; and Senator Bean
SUBJECT:	Certification of Assisted Living Facility Administrators
DATE:	April 2, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Crosier	Hendon	CF	**Fav/CS**
2.	Looke	Stovall	HP	**Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 316 provides an option for administrators of Assisted Living Facilities (ALFs) to meet the minimum training and education requirements and pass a competency examination established by the Department of Elder Affairs (DOEA) or become certified by a third party credentialing entity selected by the department. The bill requires the DOEA to approve one or more third party credentialing entities and establishes standards for a credentialing entity.

II. Present Situation:

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.[1] An ALF does not include an adult family-care home or a non-transient public lodging establishment. A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[2] Activities of daily living include: ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[3]

[1] Section 429.02(5), F.S.
[2] Section 429.02(16), F.S.
[3] Section 429.02(1), F.S.

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[4] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[5] If 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.[6]

Department of Elder Affairs Rules

In addition to ch. 429, F.S., ALFs are subject to regulation pursuant to Rule 58A-5 of the Florida Administrative Code. These rules are adopted by the DOEA in consultation with the Agency for Health Care Administration (AHCA), the Department of Children and Families, and the Department of Health.[7] In June 2012, the DOEA initiated negotiated rulemaking to revise many of its rules regarding ALFs. A committee that consisted of agency staff, consumer advocates, and industry representatives voted on numerous changes to Rule 58A-5, Florida Administrative Code. The DOEA held five public hearings around the state and on February 20, 2014, submitted the proposed rules to the President of the Senate, the Speaker of the House of Representatives, and the appropriate committees of substance for review and comment prior to the adoption thereof.[8]

ALF Administrators

Administrators and other ALF staff must meet minimum training and education requirements established by rule of the DOEA.[9,10] This training and education is intended to assist facility employees in responding appropriately to the needs of residents, maintaining resident care and facility standards, and meeting licensure requirements.[11]

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 must successfully complete the core training requirements within 3 months from the date of becoming a facility administrator or manager. The minimum passing score for the competency test is 75 percent.

Administrators must also participate in 12 hours of continuing education on topics related to assisted living every 2 years. A newly-hired administrator who has successfully completed the ALF core training and continuing education requirements is not required to retake the core training. An administrator who has successfully completed the core training, but has not

[4] For specific minimum standards see Rule 58A-5.0182, F.A.C.
[5] Section 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[6] Section 429.28, F.S.
[7] Section 429.41(1), F.S.
[8] Letter from Secretary Charles T. Corley, DOEA to The Honorable Don Gaetz, President, Florida Senate, (Feb. 20, 2014) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[9] Rule 58A-5.0191, F.A.C.
[10] Many of the training requirements in rule may be subject to change due to the negotiated rulemaking process undertaken by DOEA.
[11] Section 429.52(1), F.S.

maintained the continuing education requirements must retake the ALF core training and the competency test.[12]

Currently, the DOEA approves registration of core trainers based on the qualifications established in s. 429.52, F.S., and is authorized to adopt rules to define additional qualification criteria for becoming a core trainer and maintaining that status.

III. Effect of Proposed Changes:

Section 1 amends s. 429.52, F.S., to provide that effective July 1, 2014, ALF administrators must either meet the minimum training and education requirements and pass a competency examination that are established by a third party credentialing entity pursuant to s. 429.55, F.S., or by the DOEA by rule. However, a licensed nursing home administrator is exempt from this requirement.

A facility administrator hired on or after July 1, 2014, who fails to complete the DOEA option, within a reasonable time after being employed as an administrator or earn and maintain certification is subject to an administrative fine under s. 429.19, F.S.

Maintaining certification under s. 429.55, F.S., exempts the administrator from additional training as prescribed by the DOEA.

Section 2 creates s. 429.55, F.S., to establish the ALF administrator certification option in law. This section provides a definition of third-party credentialing entity as an organization that develops and administers certification programs according to standards established by the National Commission for Certifying Agencies. The DOEA is required to approve one or more third-party credentialing entities to develop and administer a professional credentialing program for ALF administrators within 90 days after receiving documentation that demonstrates the third-party credentialing entity's compliance with certain minimum standards including:

- Establishment of ALF administrator core competencies,[13] certification standards, testing instruments, and recertification standards;
- A demonstrated ability to administer a professional code of ethics, disciplinary process, biennial continuing education and certification renewal requirements, and an education provider program;
- Establishment of a process to administer the certification application, award, and maintenance processes according to national psychometric standards;
- Establishment of, and ability to maintain a publicly accessible Internet-based database that contains information on each person who applies for and is awarded certification, such as the person's first and last name, certification status, and ethical or disciplinary history; and
- Establishment of credentialing standards that meet or exceed DOEA standards for training and education programs.

A grandfather clause allows certain people who are employed as ALF administrators as of July 1, 2014, and are in compliance with the requirements in s. 429.52, F.S., including continuing

[12] Rule 59A-5.0191, F.A.C.
[13] These core competency standards must be established according to nationally recognized psychometric standards.

education requirements in place before July 1, 2014, and persons who have completed the required training as an administrator, including the competency test and continuing education requirements as of July 1, 2014, to be enrolled in a third-party credentialing entity certification program at no cost. Such ALF administrators must be allowed to enroll in the certification program offered by a third-party credentialing entity for up to 12 months immediately after the credentialing entity is approved by the department.

The bill enumerates requirements for approval as a certification program. Any approved certification program must be established according to nationally recognized psychometric standards; be directly related to the core competencies; establish minimum standards including formal education, training, on-the-job work experience, supervision, testing, and continuing education; administer a professional code of ethics and disciplinary process; administer and maintain an internet database with information for each person who is certified or applies for certification; and approve training entities that provide precertification training to applicants and continuing education to certified ALF determination.

A person who is adversely affected by a decision of a credentialing entity under this section, as to denial of initial certification or continued certification, is authorized to appeal the decision to the DOEA for a final administration.

The bill also requires a credentialing entity to establish a fee for application, examination, certification, and biennial certification renewal. The initial fee may not exceed $200 and renewal fees may not exceed $100.

Section 3 provides for an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/CS/SB 316 allows ALF administrators the option to be certified by a third party credentialing entity and specifies an initial fee of up to $200 and renewal fees of up to $100. The bill provides for existing ALF administrators who have completed the competency test as of the effective date of the bill to enroll in the certification program at no cost if they enroll within 12 months after DOEA approves a credentialing entity.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill states that ALF administrators who fail to be certified or to meet the DOEA training and educational requirements by July 1, 2014, are subject to an administrative fine pursuant to s. 429.19, F.S. Fines in this section are separated into four classes based on the severity of the violation. The newly-created violation of an ALF administrator who do not meet certification or training and educational requirements does not direct the AHCA as to which class of violation to cite.

VII. Related Issues:

Section 2 of the bill directs the third-party credentialing entity to administer a professional code of ethics and a disciplinary process that applies to all certified persons. No guidance or criteria is provided regarding the code of ethics or the disciplinary process. The decisions left to the third party entity by this language may be an unconstitutional delegation of authority.

VIII. Statutes Affected:

This bill substantially amends section 429.52 of the Florida Statutes.
This bill creates section 429.55 of the Florida Statutes.

IX. Additional Information:

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

CS/CS by Health Policy on April 1, 2014:
The Committee Substitute:

- Requires third party credentialing entities to establish credentialing standards that meet or exceed the DOEA standards for training and education programs;
- Requires third party credentialing entities to establish fees that cannot exceed $200 for an initial certification and $100 for a renewal.
- Clarifies that persons employed as ALF administrators as of July 1, 2014, may be certified at no cost; and,
- Changes “biannual continuing education” to “biennial continuing education” in order to remain in line with current administrator continuing education practices.

CS by Children, Families, and Elder Affairs on March 25, 2014:
The Committee Substitute:

- Establishes an effective date of July 1, 2014, that administrators have the option to meet the minimum training and education requirements established by the department or the certification provided by a third-party credentialing entity approved by the department pursuant to s. 429.55, F.S.
- Directs the third-party credential entity approved by the department to develop a competency test and a minimum required score to indicate successful completion of the training and educational requirements. The competency test and minimum required score is in addition to the test and score established by the department.
- A facility administrator hired on or after July 1, 2014, must complete the training and education requirements of the department or earn and maintain certification from the third-party credentialing entity. Failure to comply with this requirement subjects the violator to an administrative fine.
- Provides that a third-party credentialing entity is an organization that develops and administers certification programs according to standards established by the National Commission for Certifying Agencies.
- Provides a grandfather clause that allows persons employed as an ALF administrator and are in compliance with the training and education requirements in place before July 1, 2014, or who has completed the required training, competency test and continuing education requirements as of July 1, 2014, to enroll in the third-party credentialing entity's certification program at no cost to the person or the department in the 12 months immediately after the entity is approved by the department.
- Creates the right of appeal to the department for final determination by an individual adversely affected by the third-party credentialing entity.

B. Amendments:

None.

794588

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
04/01/2014	.	
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	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete lines 224 - 278

and insert:

(g) Establish certification standards for third-party credentialing entities which meet or exceed the department standards for training and education programs for assisted living facility administrators.

(4) ASSISTED LIVING FACILITY ADMINISTRATOR CERTIFICATION.—Effective July 1, 2014, an assisted living facility administrator may be certified by a third-party credentialing

entity that is approved by the department under this section. An assisted living facility administrator who fails to be certified under this section or fails to meet training and educational requirements of s. 429.52 violates this section and is subject to an administrative fine as provided under s. 429.19. This subsection does not apply to an administrator licensed under part II of chapter 468.

(5) GRANDFATHER CLAUSE.—A third-party credentialing entity shall allow the following persons to enroll in its certification program, at no cost to the department or the person, in the 12 months immediately after the department approves the third-party credentialing entity as provided in subsection (3):

(a) A person who is employed as of July 1, 2014, as an assisted living facility administrator and is in compliance with the requirements under s. 429.52.

(b) A person who has completed before July 1, 2014, the required training as an administrator, including the competency test and continuing education requirements under s. 429.52.

(6) CORE COMPETENCIES.—A third-party credentialing entity that is approved by the department shall establish the core competencies for assisted living facility administrators according to the standards established by the National Commission for Certifying Agencies.

(7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification program of a third-party credentialing entity that is approved by the department must:

(a) Be established according to the standards set forth by the National Commission for Certifying Agencies.

(b) Be directly related to the core competencies.

794588

(c) Establish minimum requirements in each of the following categories:

1. Formal education.

2. Training.

3. On-the-job work experience.

4. Supervision.

5. Testing.

6. Biennial continuing education.

(d) Administer a professional code of ethics and disciplinary process that applies to all certified persons.

(e) Administer and maintain a publicly accessible Internet-based database that contains information on each person who applies for certification or is certified.

(f) Approve qualified training entities that provide precertification training to applicants and continuing education to certified assisted living facility administrators.

(8) APPEAL.—An individual who is adversely affected by the decision of a department-approved, third-party credentialing entity with regard to the denial of initial certification or an adverse action on continued certification may appeal such decision to the department for a final determination.

(9) FEES.—A third-party credentialing entity shall establish a fee for application, examination, certification, and biennial certification renewal. The fee for application, examination, and certification may not exceed $200. The fee for biennial certification renewal may not exceed $100.

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

And the title is amended as follows:

794588

Delete line 49

and insert:

certain circumstances; requiring a third-party credentialing entity to establish fees; providing an effective date.

211298

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/01/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (794588)

Delete lines 5 - 6
and insert:
(g) Establishment of credentialing standards that meet or exceed the department

106366

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/01/2014	.	
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	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment to Amendment (794588)

Delete lines 33 - 34
and insert:
according to nationally recognized professional psychometric standards.

Delete lines 38 - 39
and insert:
(a) Be established according to nationally recognized professional psychometric standards.

937330

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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	.	
	.	

The Committee on Health Policy (Bean) recommended the following:

Senate Substitute for Amendment (794588) (with title amendment)

Delete lines 224 - 278

and insert:

(g) Establishment of credentialing standards that meet or exceed the department standards for training and education programs for assisted living facility administrators.

(4) ASSISTED LIVING FACILITY ADMINISTRATOR CERTIFICATION.—Effective July 1, 2014, an assisted living facility administrator may be certified by a third-party credentialing

937330

entity that is approved by the department under this section. An assisted living facility administrator who fails to be certified under this section or fails to meet training and educational requirements of s. 429.52 violates this section and is subject to an administrative fine as provided under s. 429.19. This subsection does not apply to an administrator licensed under part II of chapter 468.

(5) GRANDFATHER CLAUSE.—A third-party credentialing entity shall allow the following persons to enroll in its certification program, at no cost to the department or the person, in the 12 months immediately after the department approves the third-party credentialing entity as provided in subsection (3):

(a) A person who is employed as of July 1, 2014, as an assisted living facility administrator and is in compliance with the requirements under s. 429.52.

(b) A person who has completed before July 1, 2014, the required training as an administrator, including the competency test and continuing education requirements under s. 429.52.

(6) CORE COMPETENCIES.—A third-party credentialing entity that is approved by the department shall establish the core competencies for assisted living facility administrators according to nationally recognized professional psychometric standards.

(7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification program of a third-party credentialing entity that is approved by the department must:

(a) Be established according to nationally recognized professional psychometric standards.

(b) Be directly related to the core competencies.

937330

(c) Establish minimum requirements in each of the following categories:

1. Formal education.

2. Training.

3. On-the-job work experience.

4. Supervision.

5. Testing.

6. Biennial continuing education.

(d) Administer a professional code of ethics and disciplinary process that applies to all certified persons.

(e) Administer and maintain a publicly accessible Internet-based database that contains information on each person who applies for certification or is certified.

(f) Approve qualified training entities that provide precertification training to applicants and continuing education to certified assisted living facility administrators.

(8) APPEAL.—An individual who is adversely affected by the decision of a department-approved, third-party credentialing entity with regard to the denial of initial certification or an adverse action on continued certification may appeal such decision to the department for a final determination.

(9) FEES.—A third-party credentialing entity shall establish a fee for application, examination, certification, and biennial certification renewal. The fee for application, examination, and certification may not exceed $200. The fee for biennial certification renewal may not exceed $100.

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

And the title is amended as follows:

937330

Delete lines 43 - 49

and insert:

nationally recognized professional psychometric standards; requiring a certification program of a third-party credentialing entity to meet certain requirements; authorizing an individual adversely affected by the decision of a third-part credentialing entity to appeal the decision under certain circumstances; requiring a third-party credentialing entity to establish fees; providing an effective date.

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

586-03141-14 2014316c1

A bill to be entitled

An act relating to certification of assisted living facility administrators; amending s. 429.52, F.S.; requiring assisted living facility administrators to meet the training and education requirements established by a third-party credentialing entity or by the Department of Elderly Affairs; requiring the department to establish a competency test; requiring a third-party credentialing entity to develop a competency test and a minimum required score to indicate successful completion of the training and educational requirements; revising requirements for facility administrators who are hired on or after a specified date; authorizing the department to require additional training and education of any personal care staff in the facility, except for certain assisted living facility administrators; requiring training to be conducted by an entity recognized by a third-party credentialing entity under s. 429.55, F.S.; authorizing the department to adopt rules to establish staff training requirements; creating s. 429.55, F.S.; providing legislative intent; defining terms; authorizing the department to approve third-party credentialing entities for the purpose of developing and administering a professional credentialing program for assisted living facility administrators; requiring the department to approve a third-party credentialing entity that documents compliance with certain minimum standards; authorizing an administrator to be

586-03141-14 2014316c1

certified by a third-party credentialing entity; providing that an administrator who fails to be certified under s. 429.55, F.S., or fails to complete training and educational requirements under s. 429.55 is subject to an administrative fine; providing an exemption for an administrator licensed under part II of ch. 468, F.S.; requiring a third-party credentialing entity to allow certain persons to enroll in its certification program for a specified time after the department approves the third-party credentialing entity; requiring an approved third-party credentialing entity to establish the core competencies for administrators according to the standards set forth by the National Commission for Certifying Agencies; requiring a certification program of a third-party credentialing entity to meet certain requirements; authorizing an individual adversely affected by the decision of a third-party credentialing entity to appeal the decision under certain circumstances; providing an effective date.

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

Section 1. Section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational programs; core educational requirement.—

(1) Effective July 1, 2014, administrators shall meet the minimum training and education requirements established by a

third-party credentialing entity pursuant to s. 429.55 or by the Department of Elderly Affairs by rule. ~~and~~ Other assisted living facility staff shall ~~must~~ meet minimum training and education requirements established by the department ~~of Elderly Affairs~~ by rule. This training and education is intended to assist facilities to appropriately respond to the needs of residents, to maintain resident care and facility standards, and to meet licensure requirements.

(2) The department shall establish a competency test and a minimum required score to indicate successful completion of the training and educational requirements. The department shall develop the competency test ~~must be developed by the department~~ in conjunction with the agency and providers. A third-party credentialing entity approved under s. 429.55 must also develop a competency test and a minimum required score to indicate successful completion of the training and educational requirements. The required training and education must cover at least the following topics:

(a) State law and rules relating to assisted living facilities.

(b) Resident rights and identifying and reporting abuse, neglect, and exploitation.

(c) Special needs of elderly persons, persons with mental illness, and persons with developmental disabilities and how to meet those needs.

(d) Nutrition and food service, including acceptable sanitation practices for preparing, storing, and serving food.

(e) Medication management, recordkeeping, and proper techniques for assisting residents with self-administered

medication.

(f) Firesafety requirements, including fire evacuation drill procedures and other emergency procedures.

(g) Care of persons who have ~~with~~ Alzheimer's disease and related disorders.

(3) ~~Effective January 1, 2004,~~ A ~~new~~ facility administrator hired on or after July 1, 2014, must:

(a) Complete the required training and education, including the competency test, within a reasonable time after being employed as an administrator, as determined by the department; or

(b) Earn and maintain certification as an assisted living facility administrator from a third-party credentialing entity that is approved by the department as provided in s. 429.55.

Failure of a facility administrator to comply with paragraph (a) or paragraph (b) ~~do so~~ is a violation of this part and subjects the violator to an administrative fine as prescribed in s. 429.19. Administrators licensed in accordance with part II of chapter 468 are exempt from this requirement. ~~Other licensed professionals may be exempted, as determined by the department by rule.~~

(4) Administrators shall ~~are required to~~ participate in continuing education for a minimum of 12 contact hours every 2 years.

(5) Staff involved with the management of medications and assisting with the self-administration of medications under s. 429.256 must complete a minimum of 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.

(6) Other facility staff shall participate in training relevant to their job duties as specified by rule of the department.

(7) If the department ~~or the agency~~ determines that there is a need for ~~are problems in a facility that could be reduced through~~ specific staff training or education beyond that already required under this section, the department ~~or the agency~~ may require~~,~~ and provide, or cause to be provided, the training or education of ~~any~~ personal care staff in the facility. However, this subsection does not apply to an assisted living facility administrator certified under s. 429.55.

(8) The department shall adopt rules related to these training requirements, the competency test, necessary procedures, and competency test fees and shall adopt or contract with another entity to develop a curriculum, which shall be used as the minimum core training requirements. The department shall consult with representatives of stakeholder associations and agencies in the development of the curriculum.

(9) The training required by this section must ~~shall~~ be conducted by a person who is ~~persons~~ registered with the department as having the requisite experience and credentials to conduct the training or by a training entity recognized by a third-party credentialing entity under s. 429.55(7)(f). A person seeking to register as a trainer must provide the department with proof of completion of the minimum core training education requirements, successful passage of the competency test established under this section, and proof of compliance with the

continuing education requirement in subsection (4).

(10) A person seeking to register as a trainer must also:

(a) Provide proof of completion of a 4-year degree from an accredited college or university and must have worked in a management position in an assisted living facility for 3 years after being core certified;

(b) Have worked in a management position in an assisted living facility for 5 years after being core certified and have 1 year of teaching experience as an educator or staff trainer for persons who work in assisted living facilities or other long-term care settings;

(c) Have been previously employed as a core trainer for the department; or

(d) Meet other qualification criteria as defined in rule, which the department may ~~is authorized to~~ adopt.

(11) The department may ~~shall~~ adopt rules to establish staff training ~~trainer registration~~ requirements.

Section 2. Section 429.55, Florida Statutes, is created to read:

429.55 Assisted living facility administrator; certification.—

(1) LEGISLATIVE INTENT.—It is the intent of the Legislature that each assisted living facility administrator have the option to earn and maintain professional certification from a third-party credentialing entity that is approved by the Department of Elderly Affairs. The Legislature further intends that certification ensure that an administrator has the competencies necessary to appropriately respond to the needs of residents, to maintain resident care and facility standards, and to meet

licensure requirements for a facility. The Legislature recognizes professional certification by a professional credentialing organization as an equivalent alternative to a state-run licensure program and, therefore, intends that certification pursuant to this section is sufficient as an acceptable alternative to the training and educational requirements of s. 429.52.

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

(a) "Assisted living facility administrator certification" means a professional credential awarded by a department-approved third-party credentialing entity to a person who meets core competency requirements in assisted living facility practice areas.

(b) "Core competency" means the minimum knowledge and skills necessary to carry out work responsibilities.

(c) "Department" means the Department of Elderly Affairs.

(d) "Third-party credentialing entity" means an organization that develops and administers certification programs according to the standards established by the National Commission for Certifying Agencies.

(3) THIRD-PARTY CREDENTIALING ENTITIES.—The department shall approve one or more third-party credentialing entities for the purpose of developing and administering a professional credentialing program for administrators. Within 90 days after receiving documentation from a third-party credentialing entity, the department shall approve a third-party credentialing entity that demonstrates compliance with the following minimum standards:

(a) Establishment of assisted living facility administrator

core competencies, certification standards, testing instruments, and recertification standards according to national psychometric standards.

(b) Establishment of a process to administer the certification application, award, and maintenance processes according to national psychometric standards.

(c) Demonstrated ability to administer a professional code of ethics and disciplinary process that applies to all certified persons.

(d) Establishment of, and ability to maintain a publicly accessible Internet-based database that contains information on each person who applies for and is awarded certification, such as the person's first and last name, certification status, and ethical or disciplinary history.

(e) Demonstrated ability to administer biannual continuing education and certification renewal requirements.

(f) Demonstrated ability to administer an education provider program to approve qualified training entities and to provide precertification training to applicants and continuing education opportunities to certified professionals.

(4) ASSISTED LIVING FACILITY ADMINISTRATOR CERTIFICATION.—Effective July 1, 2014, an assisted living facility administrator may be certified by a third-party credentialing entity that is approved by the department under this section. An assisted living facility administrator who fails to be certified under this section or fails to meet training and educational requirements of s. 429.52 violates this section and is subject to an administrative fine as provided under s. 429.19. This subsection does not apply to an administrator licensed under

part II of chapter 468.

(5) GRANDFATHER CLAUSE.—A third-party credentialing entity shall allow the following persons to enroll in its certification program, at no cost to the department or the person, in the 12 months immediately after the department approves the third-party credentialing entity as provided in subsection (3):

(a) A person who is employed as an assisted living facility administrator and is in compliance with the requirements in s. 429.52, including continuing education requirements in place before July 1, 2014.

(b) A person who has completed before July 1, 2014, the required training as an administrator, including the competency test and continuing education requirements established in s. 429.52.

(6) CORE COMPETENCIES.—A third-party credentialing entity that is approved by the department shall establish the core competencies for assisted living facility administrators according to the standards established by the National Commission for Certifying Agencies.

(7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification program of a third-party credentialing entity that is approved by the department must:

(a) Be established according to the standards set forth by the National Commission for Certifying Agencies.

(b) Be directly related to the core competencies.

(c) Establish minimum requirements in each of the following categories:

1. Formal education.

2. Training.

3. On-the-job work experience.

4. Supervision.

5. Testing.

6. Biannual continuing education.

(d) Administer a professional code of ethics and disciplinary process that applies to all certified persons.

(e) Administer and maintain a publicly accessible Internet-based database that contains information on each person who applies for certification or is certified.

(f) Approve qualified training entities that provide precertification training to applicants and continuing education to certified assisted living facility administrators.

(8) APPEAL.—An individual who is adversely affected by the decision of a department-approved, third-party credentialing entity with regard to the denial of initial certification or an adverse action on continued certification may appeal such decision to the department for a final determination.

Section 3. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/2014
Meeting Date

Topic Assisted Living Facilities

Bill Number CS/SB 316 *(if applicable)*

Name Richard Polangin

Amendment Barcode *(if applicable)*

Job Title Director of Government Affairs

Address 1300 N Duval St

Phone 850 224-4206

Street

Tallahassee FL 32303

E-mail richardpolangin@hotmail.com

City *State* *Zip*

Speaking: ☒ For ☐ Against ☐ Information

Representing Florida Alliance for Retired Americans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Certification

Bill Number SB 316 *(if applicable)*

Name Gail Natillo

Amendment Barcode _____ *(if applicable)*

Job Title Executive Director

Address 9445 Buck Haven Tr.
Street
Tallahassee, FL 32312
City *State* *Zip*

Phone 850-496-2562

E-mail gnatillo@flalfa.org

Speaking: ☐ For ☒ Against ☐ Information

Representing FL ALFA

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/11/14
Meeting Date

Topic SB 316 Bill Number 316 *(if applicable)*

Name Leslie Dughi Amendment Barcode *(if applicable)*

Job Title

Address *Street* Phone

City *State* *Zip* E-mail dughi1@gtlaw.com

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

Representing Florida Assisted Living Assoc.

Appearing at request of Chair: [ ] Yes [X] No Lobbyist registered with Legislature: [X] Yes [ ] No

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

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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/1/14
Meeting Date

Topic Certification

Bill Number CS/SB 316 *(if applicable)*

Name Neal McGarry

Amendment Barcode *(if applicable)*

Job Title Executive Director

Address 1715 South Gadsden St
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-222-6314

E-mail nawcgarry@flcertificationboard.org

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

Representing Florida Certification Board

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

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

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

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S-001 (10/20/11)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1428
INTRODUCER:	Senator Joyner
SUBJECT:	Reducing Racial and Ethnic Health Disparities
DATE:	March 27, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1428 requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to conduct a study of obstacles to achieving an adequate health care provider network for Medicaid recipients and to consult with the Agency for Health Care Administration (AHCA) and the Department of Health (DOH) to develop strategies to reduce racial and ethnic disparities in the state. The report is due to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2016.

The bill creates an undesignated section of law that expires on June 30, 2016.

II. Present Situation:

Medicaid

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. The program is administered by the AHCA and financed with federal and state funds. Over 3.4 million Floridians are currently enrolled in Medicaid and the program's estimated expenditures for Fiscal Year 2013-14 are approximately $22 billion.[1] The statutory authority for the Medicaid program is contained in ch. 409, F.S.

The AHCA has more than 114,000 individuals and facilities providing services to Medicaid recipients.[2] In addition, in 2011 the Legislature passed HB 7107[3] creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The SMMC program

[1] Social Services Estimating Conference, *Medicaid Caseload and Expenditures* (Feb. 26, 2014) http://edr.state.fl.us/Content/conferences/medicaid/index.cfm (last visited: Mar. 27, 2014).
[2] Agency for Health Care Administration, *Welcome to Medicaid*, http://ahca.myflorida.com/Medicaid/index.shtml#about (last visited Mar. 27, 2014).
[3] *See* ch. 2011-134, L.O.F.

requires the AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits for the delivery of primary and acute care, under the Managed Medical Assistance component (MMA).[4] Medicaid recipients who are enrolled in the MMA program will receive all of their services through fully integrated managed care plans and the provider networks contracted under those plans.

The AHCA released an ITN to competitively procure managed care plans on a statewide basis in December 2012. In February 2014, the AHCA contracted with 14 general, non-specialty plans and 5 specialty plans that focus on specific conditions or populations, such as HIV/AIDS or foster children.[5]

The AHCA has released an implementation schedule by region with the first roll-out scheduled for May 1, 2014, and the final group for August 1, 2014.[6] The enabling legislation required the statewide roll-out to be completed by October 2014.

Under SMMC, managed care plans must develop and maintain networks that meet the needs of their enrollees.[7] Plans are also required to include any providers deemed "essential" by the AHCA.[8] Examples of "essential providers" include federally qualified health centers, statutory teaching hospitals, trauma centers, faculty plans of Florida medical schools, regional perinatal intensive care, specialty children's hospitals and accredited and integrated systems serving medically complex children.[9]

The contract between the AHCA and the managed care plans provides additional specifications for the delivery of services to Medicaid enrollees by benefit and provider type.[10] Maximum travel times for access to individual provider types and provider to enrollee ratios are incorporated into the contract. Network adequacy reports by the managed care plans are submitted to the AHCA on a quarterly basis. The managed care plans are also required to inform the AHCA within 7 business days of any significant changes to its regional provider network.[11]

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[4] Health and Human Services Committee, Fla. House of Representatives, *PCS HHSC 11-01 Staff Analysis*, p.25, (Mar. 25, 2011).
[5] Agency for Health Care Administration, *Florida Medicaid - What Plans are Available in My Region?* http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#MMA (last visited Mar. 27, 2014).
[6] Agency for Health Care Administration, *Implementation Plan - Managed Medical Assistance Program*, p.5, http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/FL_1115_MMA_IP_10-30-2013_Final.pdf (last visited Nov. 21, 2013).
[7] *See* s. 409.975(1), F.S.
[8] Under s. 409.975(1)(a), F.S., an "essential provider" is further defined as a provider that offers services that is not available from any other provider within a reasonable access standard, or if they provided a substantial amount of services to Medicaid enrollees in the past 3 years and the combined capacity of other Medicaid providers in the region is insufficient to meet the need.
[9] *See* s. 409.975(1)(a) and (b), F.S.
[10] Agency for Health Care Administration, *MMA Program Model Agreement - Attachment II, Exhibit II-A*, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Exhibit_II-A_MMA_Model_2014-01-31.pdf (last visited: Mar. 28, 2014).
[11] Agency for Health Care Administration, *Supra* note 10, at 88. A "significant change" is defined in the contract as any change that would cause more than 5 percent of enrollees in the region to change the location where services are rendered; or for MMA plans, a decrease in the total number of primary care physicians by more than 5 percent.

By contract, the MMA plans must make all enrollee materials, including the provider directory, available online without requiring the enrollee to first log-in.[12] The model contract delineates the required searchable elements which include provider name, provider type, distance from enrollee's address, zip code, and whether the provider is accepting new patients.[13]

Failure to maintain adequate networks or to attain performance goals may result in liquidated damages or performance measure sanctions against the MMA.[14] For example, liquidated damages may be assessed for non-compliance with screening rates or preventive dental service goals.[15] An MMA that misses a performance standard may also receive a sanction of up to $10,000 for each missed performance measure group that scores a 3 out of a possible 6.[16]

Florida's Demographics

Florida has a large and diverse population of over 18.8 million residents.[17] Based on the 2010 Census data, Florida's population racial breakdown includes the following:[18]

Race	Population	Percentage
White	14,109,162	75%
Black or African American	2,999,862	16%
American Indian and Alaska Native	71,458	0.4%
Asian	454,821	2.4%
Native Hawaiian or Pacific Islander	12,286	0.1%
Total Population:		**18,801,310**

Florida's ethnic make-up is 22.5 percent Hispanic or Latino and 77.5 percent non-Hispanic or Latino.[19] The vast majority of Florida's Hispanic and Latino population, 1,533,100 individuals, identify as "Other Hispanic or Latino" which is comprised of those whose origins are from the Dominican Republic, Spain and Spanish-speaking Central or South-American countries.[20] The second largest Hispanic and Latino group, 1,213,438 individuals, identify their origins as Cuban.[21]

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[12] Agency for Health Care Administration, *MMA Model Contract - Attachment II: Core Contract Provisions* http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Core_Model_2014-01-31.pdf , p. 74, (last visited Mar. 28, 2014).
[13] Id.
[14] Agency for Health Care Administration, *Supra* note 10 at 101-105.
[15] Id. at 101.
[16] Id. at 98.
[17] Florida Legislature, Office of Economic and Demographic Research, *2010 Census Summary*, http://edr.state.fl.us/Content/population-demographics/2010-census/data/2010SF1_PROFILE_Florida.pdf (last visited: Mar. 28, 2014).
[18] U.S. Census Bureau, *2010 Census Demographic Profile Summary File*; As Prepared by the Florida Legislative Office of Economic and Demographic Research, http://edr.state.fl.us/Content/population-demographics/2010-census/data/2010DP_Florida.pdf (last visited Mar. 28, 2014).
[19] Id.
[20] Id.
[21] Id.

Current Programs to Reduce Racial and Ethnic Disparities

Florida has several initiatives to address racial and ethnic disparities in health care. The Office of Minority Health (office) was created by the Legislature in 2004 within the DOH.[22] This office coordinates the *Reducing Racial and Ethnic Disparities: Closing the Gap Grant Program*.[23] Projects funded under the *Closing the Gap* grant program support public and private entities by:[24]

- Fostering partnerships between local governments, community groups, and private sector health care organizations;
- Helping communities address their most pressing health needs through targeted health screenings, education and awareness programs; and
- Helping communities better understand the nature of ethnic and racial groups.

The *Closing the Gap* program has identified 7 priority areas for funding:[25]

- Cancer;
- Cardiovascular disease;
- Diabetes;
- Adult and child immunizations;
- HIV/AIDS;
- Maternal and Infant Mortality; and
- Oral Healthcare.

An American Indian Health Advisory Committee (committee) was created in the DOH in 2010 to provide guidance on issues impacting American Indians that reside in Florida.[26] The committee includes 15 representatives from Tribes and other stakeholders, including an office representative.

Minority Health Liaisons are links between the DOH and the county health departments. A representative from each county health department comprises the Minority Health Liaisons Workgroup. The office and the liaisons work collaboratively to address health issues, with a focus on minority health.[27] The partnership between the office and the liaisons are intended to accomplish several objectives, including:[28]

- Sharing information on minority health, especially health disparities due to race, class, gender, culture, education, sexual orientation, religion, immigration status, and age;
- Coordinating events to improve minority health;
- Developing statewide initiatives;

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[22] *See* s. 20.43(9), F.S.
[23] *See* s. 381.7351, F.S.
[24] Florida Department of Health, *Closing the Gap*, http://www.floridahealth.gov/healthy-people-and-families/minority-health/closing-the-gap.html (last visited Mar. 27, 2014).
[25] Id.
[26] Department of Health, *American Indian Health Advisory Committee*, http://www.floridahealth.gov/healthy-people-and-families/minority-health/aihac.html (last visited: Mar. 27, 2014).
[27] Department of Health, *Minority Health Liaisons, http://www.floridahealth.gov/healthy-people-and-families/minority-health/minority-health-liaisons.html* (last visited Mar. 27, 2014).
[28] *Id*.

- Promoting state and local activities and events to raise awareness of programs and services available to minorities and underserved populations;
- Maintaining an office presence at the state and local levels; and,
- Helping the DOH meet its mission by achieving its primary responsibility in eliminating health disparities.

The office also observes several recognition months that focus on or recognize minority populations. The office utilizes these opportunities to educate and bring awareness of important health issues. Examples of recognitions by the office include:

- American Indian Heritage Month (November);
- Asian American and Pacific Islander Month (May);
- Black History Month (February);
- Minority Health Month (April);
- Hispanic and Latino Heritage Month (September 15 to October 15); and,
- Take a Loved One to the Doctor Month (September).

In 2005, the agency contracted for a study on racial and ethnic disparities in health status and access to health care in the Medicaid program. In that study, disparities in access to health care were identified between black children and white children for unmet medical needs and black adults reported more unmet needs for mental health services than other ethnic groups.[29]

III. Effect of Proposed Changes:

SB 1428 directs the OPPAGA to conduct a study of obstacles to achieving an adequate health care provider network for Medicaid recipients and to consult with the AHCA and the DOH on strategies to reduce racial and ethnic disparities in the state.

The office must submit its findings and recommendations to the Governor, President of the Senate, and Speaker of the House of the Representatives by January 1, 2016.

The undesignated section of law created under SB 1428 expires June 30, 2016.

The effective date of the bill is July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[29] Louis de la Parte Florida Mental Health Institute, *Policy Brief #31 - Racial and Ethnic Disparities in Medicaid Eligibility Change and Unmet Health Needs*, http://www.fdhc.state.fl.us/medicaid/quality_management/mrp/contracts/m0505/disparity.pdf (last visited: March 27, 2014).

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Both the Office of Legislative Services and the department report no fiscal impact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates an undesignated section of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Joyner

19-01518-14 20141428__

A bill to be entitled

An act relating to reducing racial and ethnic health disparities; requiring the Office of Program Policy Analysis and Government Accountability to conduct a study and provide recommendations relating to Medicaid provider networks; requiring a report to the Governor and Legislature; providing for expiration; providing an effective date.

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

Section 1. The Office of Program Policy Analysis and Government Accountability shall conduct a study of obstacles to achieving an adequate health care provider network for Medicaid recipients. The office shall consult with the Agency for Health Care Administration and the Department of Health to develop and recommend strategies to reduce racial and ethnic health disparities in this state. The office shall submit its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2016. This section expires June 30, 2016.

Section 2. This act shall take effect July 1, 2014.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR ARTHENIA L. JOYNER
19th District

COMMITTEES:
Appropriations Subcommittee on Criminal and Civil Justice, *Vice Chair*
Appropriations
Appropriations Subcommittee on General Government
Ethics and Elections
Health Policy
Judiciary
Transportation

SELECT COMMITTEE:
Select Committee on Indian River Lagoon and Lake Okeechobee Basin

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

March 5, 2014

Senator Aaron Bean, Chair
Senate Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bean:

This is to request that Senate Bill 1428, Reducing Racial and Ethnic Health Disparities, be placed on the agenda for the Committee on Health Policy. Your consideration of this request is greatly appreciated.

Sincerely,

Arthenia L. Joyner
State Senator, District 19

REPLY TO:
☐ 508 W. Dr. Martin Luther King, Jr. Blvd., Suite C, Tampa, Florida 33603-3415 (813) 233-4277
☐ 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5019 FAX: (813) 233-4280

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

DON GAETZ
President of the Senate

GARRETT RICHTER
President Pro Tempore

ENTERED

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-1-2014
Meeting Date

Topic Reducing Health Disparities

Bill Number SB 1428 *(if applicable)*

Name Jabari Paul

Amendment Barcode _____ *(if applicable)*

Job Title State Health Coordinator

Address 540 Beverly Ct
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850.509.2535

E-mail jpaul@picoflorida.org

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

Representing PICO Florida

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

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

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S-001 (10/20/11)

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy **Judge:**

Started: 4/1/2014 3:04:09 PM
Ends: 4/1/2014 6:01:00 PM Length: 02:56:52

3:04:11 PM Meeting Called to Order
3:05:12 PM Roll Call
3:05:19 PM (Tab 3) SB 1230 Physician Assistants
3:05:50 PM Sen. Hays explains the bill
3:06:22 PM Brandes AM Barcode 730402 is explained
3:07:51 PM Barcode 582422 is explained by Sen. Grimsley
3:08:55 PM Grimsley AM is adopted
3:09:03 PM Chair Bean asks for debate/objections
3:09:19 PM Barcode 730402 is adopted
3:09:37 PM Testimony by Nicole Strothman, Ideal Image, waives in support
3:09:51 PM Chris Nuland, FL Society of Plastic Surgeons, waives against AM to AM
3:10:08 PM Monika Alesnuk, USF Health, waives in support
3:10:20 PM Testimony by Corinne Mixon, FL Academy of Physician Assistants
3:11:22 PM Testimony by Chris Nuland, FL Society of Plastic Surgeons
3:12:15 PM Sen. Sobel comments in debate
3:13:45 PM Sen. Hays moves to make traveling amendment
3:14:06 PM Roll Call on SB 1230
3:14:20 PM Bill reported favorably
3:14:37 PM (Tab 10) SB 1470- HIV Testing
3:14:49 PM Sen. Thompson explains the bill
3:15:30 PM Sen. Joyner explains AM Barcode 246082
3:16:05 PM AM is adopted
3:16:24 PM Chris Nuland, FL Public Health Assoc. waives in support
3:16:38 PM Testimony by Spencer Lieb, The AIDS Institute
3:18:01 PM Michelle Jacquis, FL Medical Assoc. waives in support
3:18:13 PM Stephen Winn, FL Osteopathic Medical Assoc. waives in support
3:18:25 PM Sen Garcia comments in debate
3:20:03 PM Sen. Joyner moves to consider SB 1470 as a committee substitute
3:20:18 PM Sen. Thompson closes on bill
3:20:50 PM Roll Call on SB 1470
3:21:08 PM Bill reported favorably
3:21:12 PM (Tab 8) SB 1160- Onsite Sewage Treatment
3:21:30 PM Ms. Miller explains the bill
3:22:41 PM Darla Huntley, FOWA waives in support
3:23:08 PM Roxanne Groover, FL Onsite Wastewater Assoc. waives in support
3:23:31 PM Testimony by Jeff Mann, FOWA
3:24:56 PM Chris Doolin, Small County Coalition, waives in support
3:25:13 PM Ms. Miller waives close
3:25:15 PM Roll call on CS 1160
3:25:31 PM Bill recorded favorably
3:25:41 PM (Tab 2) SB 1388- Registered Interns in Clinical Social Work
3:25:58 PM Marsha explains the bill
3:26:33 PM Testimony by Larry Barlow, FL Assoc. for Marriage and Family Therapy
3:27:40 PM Jim Akin, National Assn. of Social Workers, waives in support
3:27:54 PM Corinne Mixon, FL Mental Health Counselors waives in support
3:28:06 PM Sen. Sobel comments in debate
3:28:25 PM Marsha waives close
3:28:35 PM Roll Call on SB 1388
3:28:54 PM Bill recorded favorably
3:29:09 PM (Tab 4) SPB 7124- Program of All-Inclusive care for the Elderly
3:30:02 PM Ms. Lloyd explains the bill
3:32:24 PM Sen. Galvano asks a question

3:32:34 PM Ms. Lloyd responds
3:32:41 PM Sen. Garcia asks a question
3:33:04 PM Ms. Lloyd responds
3:33:56 PM Sen. Garcia asks a follow-up question
3:34:02 PM Ms. Lloyd responds
3:34:38 PM Sen. Grimsley asks a question
3:34:55 PM Ms. Lloyd responds
3:35:00 PM Sen. Grimsley asks follow-up question
3:35:09 PM Ms. Lloyd responds
3:35:29 PM Sen. Sobel asks question
3:35:45 PM Ms. Lloyd responds
3:36:17 PM Sen. Sobel asks follow-up question
3:36:21 PM Ms. Lloyd responds
3:36:37 PM Question by Sen. Joyner
3:37:34 PM Ms. Lloyd responds
3:37:53 PM Follow-up question by Sen. Joyner
3:38:35 PM Ms. Lloyd responds
3:39:37 PM Sen. Grimsley comments
3:40:10 PM Follow-up question by Sen. Joyner
3:40:34 PM Sen. Grimsley comments
3:41:11 PM Follow-up question by Sen. Joyner
3:41:38 PM Sen. Grimsley comments
3:42:33 PM AM 646564 is explained
3:42:48 PM Barcode 646564 is adopted
3:43:05 PM Testimony by Cliff Bauer, FL PACE Centers/Miami Jewish Health Systems
3:44:59 PM Sen. Joyner asks a question
3:45:20 PM Mr. Bauer responds
3:45:39 PM Follow-up question by Sen. Joyner
3:45:44 PM Mr. Bauer responds
3:46:02 PM Sen. Garcia asks a question
3:47:13 PM Sen. Sobel asks a question
3:47:45 PM Chair Bean responds
3:47:50 PM Mr. Bauer responds
3:48:50 PM Sen. Joyner asks a question
3:49:09 PM Mr. Bauer responds
3:50:02 PM Testimony by Stephanie Sessions, Suncoast PACE
3:51:14 PM Sen. Joyner asks a question
3:51:55 PM Ms. Sessions responds
3:52:00 PM Follow-up question by Sen. Joyner
3:52:09 PM Ms. Sessions responds
3:52:57 PM Testimony by Samira Beckwith, President, Hope PACE
3:55:07 PM Sen. Joyner asks a question
3:55:23 PM Testimony by Richard Polanguin, FL Alliance for Retired Americans
3:55:49 PM Sen. Joyner comments in debate
3:57:09 PM Sen. Grimsley comments in debate
3:58:20 PM Sen. Garcia comments
3:58:47 PM Sen. Galvano makes motion to TP the bill
3:59:00 PM Show bill Temporarily Postponed
3:59:26 PM (Tab 13) SB 1428- Reducing Racial and Ethnic Helath Disparities
3:59:41 PM Sen. Joyner explains the bill
3:59:44 PM Jabari Paul, PICO Florida, waives in support
4:00:39 PM Brian Pitts, Justice-2-Jesus, waives in support
4:00:56 PM Sen. Joyner waives close
4:00:59 PM Roll call on SB 1428
4:01:19 PM Bill reported favorably
4:01:53 PM (Tab 5) SB 1700- Public Records
4:02:03 PM Sen. Bean explains the bill
4:02:58 PM Jodi James, FL Cannabis Action Network, waives in support
4:03:24 PM Sen. Bean waives close
4:03:27 PM Roll call on SB 1700
4:03:43 PM Bill recorded favorably
4:03:48 PM (Tab 6) CS/SB 836- Medical Gas

4:04:03 PM Sen. Bean explains the bill
4:05:08 PM Sen Bean explains Barcode 181392
4:05:31 PM Sen Bean explains AM to AM 771184
4:05:56 PM Chair Sobel asks for questions/testimony/debate
4:06:04 PM Show amendment adopted
4:06:19 PM Sen. Galvano asks a question
4:06:41 PM Mark Delegal, Compressed Gas Assn, responds
4:07:21 PM Sen. Joyner asks a question
4:07:59 PM Sen. Bean waives close
4:08:03 PM Sen. Joyner moves bill as committee substitute
4:08:11 PM Roll Call on SB 836
4:08:26 PM Show bill passing
4:08:36 PM (Tab 9) SB 992- Infectious Disease Control
4:08:51 PM Sen. Bean explains barcode 164560
4:10:04 PM Sen. Sobel asks a question
4:10:21 PM Sen. Bean responds
4:10:35 PM Karen responds
4:11:07 PM Martha Decastro, FL Hospital Assoc. waives in support
4:11:24 PM Show AM adopted
4:11:29 PM Monica Alesnuk, USF Health, waives in support
4:11:52 PM Chair Sobel asks for debate
4:11:57 PM Sen. Bean waives close
4:12:00 PM Sen. Grimsley moves bill as committee substitute
4:12:07 PM Roll call on CS 992
4:12:25 PM Show bill passing
4:12:33 PM (Tab 11) SB 1212- Behavior analysts
4:13:05 PM (Tab 12) CS/SB316- Certification of Assisted Living Facility Administrators
4:13:26 PM Sen. Bean explains the bill
4:14:12 PM Barcode 937330 is explained by Sen. Bean
4:15:21 PM Chair Sobel asks for questions
4:15:34 PM Substitute AM is adopted
4:16:15 PM Sen. Joyner asks a question
4:16:56 PM Sen. Bean responds
4:18:07 PM Follow-up question by Sen. Joyner
4:19:39 PM Chair Sobel comments
4:20:52 PM Sen. Joyner comments
4:21:26 PM Sen. Bean responds
4:22:32 PM Sen. Garcia comments
4:22:55 PM Testimony by Neal McGarry, FL Certification Board
4:25:04 PM question by Sen. Joyner
4:25:23 PM Mr. McGarry responds
4:25:44 PM Follow-up question by Sen. Joyner
4:25:53 PM Mr. McGarry responds
4:27:27 PM Sen. Sobel recognizes Lori Book
4:29:14 PM Testimony by Richard Pelargin, FL Alliance for Retired Americans
4:29:35 PM Testimony by Gail Matillo, FL ALFA waives in opposition
4:29:59 PM Testimony by Brian Pitts, Justice-2-Jesus
4:33:28 PM Sen. Joyner comments in debate
4:37:04 PM Sen. Bean closes on bill
4:38:37 PM Sen. Garcia moves bill as committee substitute
4:38:43 PM Roll call on CS 316
4:39:02 PM show bill passin g
4:39:16 PM (Tab 1) CS/SB 1106- Building Construction
4:39:37 PM Sen. Simpson's aid explains bill
4:40:01 PM Sen. Joyner asks a question
4:40:33 PM Sen. Simpson's aide responds
4:41:31 PM Follow-up question by Sen. Joyner
4:41:43 PM Sen. Simpson's aide responds
4:42:10 PM Testimony by J.B. Clark, FL Assoc. of Apprenticeship Administrators
4:43:53 PM Sen. Joyner asks a question
4:44:12 PM Mr. Clark responds
4:44:52 PM Question by Sen. Sobel

4:45:12 PM Mr. Clark responds
4:45:35 PM Testimony by Kari Herbrank, Florida Home Busilders Assoc.
4:47:35 PM Question by Sen. Joyner
4:48:32 PM Ms. Herbrank responds
4:49:41 PM Testimony by John Parker, President of Florida Building Trades
4:52:13 PM Gerald Sommers, waives in opposition
4:52:25 PM Testimony by Brian Pitts, Justice-2-Jesus
4:54:27 PM Sen. Garcia comments
4:55:10 PM Larry Kidd, waives in opposition
4:55:23 PM Randall King, Business Manager, waives in opposition
4:55:42 PM Bruce Kershiner, United Pool and Spa Assoc. waives in support
4:55:56 PM Testimony by casey Cook, FL League of Cities
4:56:37 PM Question by Sen. Sobel
4:56:44 PM Mr. Cook responds
4:57:29 PM Follow-up question by Sen. Sobel
4:57:36 PM Mr. Cook responds
4:58:28 PM Sen. Joyner comments in debate
5:02:43 PM Rachel closes on bill
5:03:02 PM Roll call on CS 1106
5:03:21 PM Bill recorded favorably
5:03:29 PM (Tab 11) SB 1212- Behavior analysts
5:04:08 PM Barcode 331530 is explained by Sen. Bean
5:04:56 PM Barcode 577454 AM to AM is explained
5:05:18 PM show amendment adopted
5:05:36 PM Question by Sen. Joyner
5:05:42 PM Sen. Bean responds
5:06:05 PM Larry Gonzalez, FL Occupational Therapy Assoc. waives in support
5:06:21 PM Adam Roberts, The Florida Autism Center, waives in support
5:06:24 PM Ron Watson waives in support
5:06:29 PM Testimony by Dr. Carolyn Stimel Fl Psychological Assn.
5:09:24 PM Question by Sen. Joyner
5:10:45 PM Dr. Stimel responds
5:10:48 PM Follow-up question by Sen. Joyner
5:10:56 PM Dr. Stimel responds
5:12:13 PM Question by Sen. Sobel
5:12:27 PM Dr. Stimel responds
5:12:42 PM Follow-up question by Sen. Sobel
5:12:58 PM Dr. Stimel responds
5:14:20 PM Question by Sen. Joyner
5:14:46 PM Dr. Stimel responds
5:14:57 PM Testimony by Lynn Yeager
5:17:54 PM Testimony by Mary Riordan, Ph.D. Assoc of Professional Behavior Analysts
5:20:19 PM Question by Sen. Sobel
5:20:25 PM Dr. Riordan responds
5:21:56 PM Question by Sen. Joyner
5:22:09 PM Dr. Riordan responds
5:27:26 PM Testimony by Dr. Kim Lucker-Greens
5:30:10 PM Question by Sen. Joyner
5:31:02 PM Dr. Kim Lucker-Greens responds
5:31:39 PM Testimony by Amanda Broadfoot
5:35:22 PM Testimony by Brian Pitts, Justice-2-Jesus
5:40:36 PM Sen. Bean closes on the bill
5:41:20 PM Sen. Galvano moves as a CS
5:41:32 PM Roll Call on CS 1212
5:41:54 PM Chair Bean delivers opening comments
5:42:07 PM (Tab 7) SB 918- Termination of Pregnancies
5:43:17 PM Sen. Flores explains strike-all barcode 791524
5:43:36 PM Sen. Joyner asks question ab strike-all
5:44:05 PM Sen. Flores replies
5:44:26 PM Sen. Beane asks for debate
5:44:35 PM No objection - AM adopted
5:44:51 PM Sen. Galvano makes motion to limit debate to 10 minutes.

5:45:02 PM Question by Sen. Joyner
5:45:33 PM Motion to vote at time certain 5:59.
5:46:38 PM Bill Bunkley waives in supp
5:46:38 PM Question by Sen. Joyner
5:46:53 PM Richard Polangin, League of Women Voters of Florida, waives in opposition
5:46:59 PM Testimony by Barbara DeVane, FL NOW
5:47:27 PM Testimony by Ingrid Delgado -FL Conf of Catholic Bishops
5:48:53 PM Matthew Van Name, SEIU, waives in opposition
5:49:06 PM Stephanie Kunkel, Business and Professional Women Inc, Waives in opp
5:49:14 PM Mone Holder, Florida New Majority, waive in opposition
5:49:22 PM Mallory Garner-Wells, Equality Florida, waives in opposition
5:49:30 PM Beth Swickard, Florida Alliance of Planned Parenthood Affiliates, waives in opposition
5:49:37 PM Pamela Burch Fort, ACLU of Florida, waives in opposition
5:49:44 PM Benjamin Dowd-Arrow, Unite women, waives in opposition
5:49:56 PM Sara Johnson, Florida Family Action, waives in support
5:50:10 PM Question by Sen. Joyner
5:51:21 PM Sen. Flores responds
5:51:39 PM Sen. Joyner asks question
5:51:59 PM Sen. Flores responds
5:52:26 PM Sen. Bean asks for questions
5:52:31 PM Sen. Joyner continues
5:52:37 PM Sen. Flores responds
5:52:53 PM Sen. Joyner for followup
5:53:06 PM Sen. Flores responds
5:53:17 PM Additional questions
5:53:29 PM Debate by Sen. Sobel
5:55:30 PM Debate by Sen. Sobel
5:55:40 PM Sen. Joyner
5:57:39 PM Sen. Beane
5:57:54 PM Sen. Flores closes on SB 918
5:59:50 PM Sen. Galvano moves for CS
5:59:58 PM Roll Call on CS 918
6:00:06 PM Favorable as CS
6:00:13 PM Sen. Garcia moves to vote affirmative on SB 1428 and SB 1212
6:00:28 PM Sen. Brandes moves to vote affirmative on SB 1230, SB 1470, SB 1160, SB 1388
6:00:42 PM Motion to adjourn