

**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	<b>CS/SB 1106</b> 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	<b>SB 1388</b> 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	<b>SB 1230</b> 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

**COMMITTEE MEETING EXPANDED AGENDA**

Health Policy

Tuesday, April 1, 2014, 3:00 —6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
Consideration of proposed committee bill:			
4	<b>SPB 7124</b>	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	<b>SB 1700</b> 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	<b>CS/SB 836</b> 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	<b>SB 918</b> 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

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Health Policy

Tuesday, April 1, 2014, 3:00 —6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	<b>CS/SB 1160</b> 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	<b>SB 992</b> 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	<b>SB 1470</b> 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	<b>SB 1212</b> 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

**COMMITTEE MEETING EXPANDED AGENDA**

Health Policy

Tuesday, April 1, 2014, 3:00 —6:00 p.m.

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TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
12	<b>CS/SB 316</b> 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	<b>SB 1428</b> 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

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Other Related Meeting Documents

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**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.)

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

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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.	<u>White</u>	<u>Yeatman</u>	<u>CA</u>	<b>Fav/CS</b>
2.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<b>Favorable</b>
3.	_____	_____	<u>RI</u>	_____
4.	_____	_____	<u>AP</u>	_____

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**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.<sup>1</sup>

### 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.<sup>2</sup>
- 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.<sup>3</sup>

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.<sup>4</sup>

### Pool Construction and Operation in Florida

The DOH estimates that there are approximately 37,000 public pools in Florida.<sup>5</sup> 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

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<sup>1</sup> Sections 553.74, 553.76 and 553.77, F.S.

<sup>2</sup> Relating to publication of notices and the physical posting of notices, respectively.

<sup>3</sup> See ss. 162.12(1)(b)-(d), F.S.

<sup>4</sup> See s.162.12(2), F.S.

<sup>5</sup> 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.<sup>6</sup>

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.<sup>7</sup>

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.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> The operating permit must be renewed annually and posted in a conspicuous place.<sup>11</sup>

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<sup>6</sup> Section 514.011(2), F.S.

<sup>7</sup> Section 514.011(4), F.S.

<sup>8</sup> Chapter 2012-184, Laws of Fla.

<sup>9</sup> Section 514.031(1), F.S.

<sup>10</sup> *Id.*

<sup>11</sup> 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:<sup>12</sup>

- 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.<sup>13</sup>

“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.<sup>14</sup>

## **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.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup> 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.<sup>18</sup>

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<sup>12</sup> Section 553.37(1), F.S.

<sup>13</sup> Section 553.36(13), F.S.

<sup>14</sup> Section 553.36(15), F.S.

<sup>15</sup> Section 553.72(3), F.S.

<sup>16</sup> The minimum amount collected on any permit issued is \$2. Section 553.721, F.S.

<sup>17</sup> DBPR, *Legislative Analysis of HB 593* (Feb. 20, 2014).

<sup>18</sup> 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.<sup>19</sup> 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.<sup>20</sup>

### **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.<sup>21</sup> 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.<sup>22</sup>

### **Building Energy-Efficiency Rating System**

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

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<sup>19</sup> Future Builders of America, <http://www.futurebuildersofamerica.org> (Last visited Mar. 26, 2014).

<sup>20</sup> *Id.*

<sup>21</sup> Section 553.841(2), F.S.

<sup>22</sup> Section 553.841(3), F.S.

<sup>23</sup> Chapter 93-249, s.12, Laws of Fla.

energy-efficiency rating systems in the market.<sup>24</sup> 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.”<sup>25</sup> 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.<sup>26</sup>

### **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.

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<sup>24</sup> Section 553.991, F.S.

<sup>25</sup> Section 553.993(3), F.S.

<sup>26</sup> 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.<sup>27</sup>

### **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;

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<sup>27</sup> 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.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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By the Committee on Community Affairs; and Senator Simpson

578-02837-14

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1 A bill to be entitled  
 2 An act relating to building construction; amending s.  
 3 162.12, F.S.; providing an additional method for local  
 4 governments to provide notices to alleged code  
 5 enforcement violators; amending s. 514.03, F.S.;  
 6 requiring application for an operating permit before  
 7 filing an application for a building permit for a  
 8 public swimming pool; amending s. 514.031, F.S.;  
 9 providing additional requirements for obtaining a  
 10 public swimming pool operating permit; amending s.  
 11 553.37, F.S.; specifying inspection criteria for  
 12 construction or modification of manufactured buildings  
 13 or modules; amending s. 553.721, F.S.; revising the  
 14 allocation of funds from the building permit  
 15 surcharge; amending s. 553.775, F.S.; authorizing  
 16 building officials, local enforcement agencies, and  
 17 the Florida Building Commission to interpret the  
 18 Florida Accessibility Code for Building Construction;  
 19 specifying procedures for such interpretations;  
 20 deleting provisions relating to declaratory statements  
 21 and interpretations of the Florida Accessibility Code  
 22 for Building Construction, to conform; amending s.  
 23 553.79, F.S.; prohibiting a local enforcing agency  
 24 from issuing a building permit for a public swimming  
 25 pool without proof of application for an operating  
 26 permit; requiring issuance of an operating permit  
 27 before a certificate of completion or occupancy is  
 28 issued; amending s. 553.841, F.S.; revising education  
 29 and training requirements of the Florida Building Code

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

578-02837-14

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30 Compliance and Mitigation Program; creating s.  
 31 553.883, F.S.; authorizing use of smoke alarms powered  
 32 by 10-year nonremovable, nonreplaceable batteries in  
 33 certain circumstances; requiring use of such alarms by  
 34 a certain date; amending s. 553.993, F.S.; revising  
 35 the definition of the term "building energy-efficiency  
 36 rating system" to require consistency with certain  
 37 national standards for new construction and existing  
 38 construction; providing for oversight; amending s.  
 39 633.202, F.S.; exempting certain tents from the  
 40 Florida Fire Prevention Code; providing an effective  
 41 date.

42  
 43 Be It Enacted by the Legislature of the State of Florida:

44  
 45 Section 1. Section 162.12, Florida Statutes, is amended to  
 46 read:

47 162.12 Notices.—

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

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

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

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

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

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

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

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

80 2. Proof of publication shall be made as provided in ss.  
 81 50.041 and 50.051.

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

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

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

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

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

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

105 514.03 Approval necessary to construct, develop, or modify  
 106 public swimming pools or public bathing places.—

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

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

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117 Section 3. Paragraph (a) of subsection (1) of section  
 118 514.031, Florida Statutes, is amended to read:  
 119 514.031 Permit necessary to operate public swimming pool.—  
 120 (1) It is unlawful for any person or public body to operate  
 121 or continue to operate any public swimming pool without a valid  
 122 permit from the department, such permit to be obtained in the  
 123 following manner:  
 124 (a) Any person or public body desiring to operate any  
 125 public swimming pool shall file an application for an operating  
 126 a permit with the department, on application forms provided by  
 127 the department, and shall accompany such application with:  
 128 1. A description of the structure, its appurtenances, and  
 129 its operation.  
 130 2.1- A description of the source or sources of water  
 131 supply, and the amount and quality of water available and  
 132 intended to be used.  
 133 3.2- The method and manner of water purification,  
 134 treatment, disinfection, and heating.  
 135 4.3- The safety equipment and standards to be used.  
 136 5. A copy of the final inspection from the local  
 137 enforcement agency as defined in chapter 553.  
 138 6.4- Any other pertinent information deemed necessary by  
 139 the department.  
 140 Section 4. Paragraph (c) of subsection (1) of section  
 141 553.37, Florida Statutes, is amended to read:  
 142 553.37 Rules; inspections; and insignia.—  
 143 (1) The Florida Building Commission shall adopt within the  
 144 Florida Building Code requirements for construction or  
 145 modification of manufactured buildings and building modules, to

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146 address:  
 147 (c) ~~Minimum~~ Inspection criteria, which shall require the  
 148 approved inspection agency to:  
 149 1. Observe the first building built, or with regard to  
 150 components, observe the first unit assembled, after  
 151 certification from the manufacturer, from start to finish,  
 152 inspecting all subsystems: electrical, plumbing, structural,  
 153 mechanical, or thermal.  
 154 2. Continue observation of the manufacturing process until  
 155 the approved inspection agency determines that the  
 156 manufacturer's quality control program, in conjunction with the  
 157 application of the plans approved by the approved inspection  
 158 agency, will result in a building and components that meet or  
 159 exceed the applicable Florida Building Code requirements.  
 160 3. Inspect each module produced during at least one point  
 161 of the manufacturing process and inspect at least 75 percent of  
 162 the subsystems of each module: electrical, plumbing, structural,  
 163 mechanical, or thermal.  
 164 4. With respect to components, inspect at least 75 percent  
 165 of the manufactured building components and at least 20 percent  
 166 of the storage sheds that are not designed for human habitation  
 167 and that have a floor area of 720 square feet or less.  
 168 Section 5. Section 553.721, Florida Statutes, is amended to  
 169 read:  
 170 553.721 Surcharge.—In order for the Department of Business  
 171 and Professional Regulation to administer and carry out the  
 172 purposes of this part and related activities, there is created a  
 173 surcharge, to be assessed at the rate of 1.5 percent of the  
 174 permit fees associated with enforcement of the Florida Building

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

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204 remittance of surcharges pursuant to chapter 120.  
 205 Section 6. Section 553.775, Florida Statutes, is amended to  
 206 read:  
 207 553.775 Interpretations.—  
 208 (1) It is the intent of the Legislature that the Florida  
 209 Building Code and the Florida Accessibility Code for Building  
 210 Construction be interpreted by building officials, local  
 211 enforcement agencies, and the commission in a manner that  
 212 protects the public safety, health, and welfare at the most  
 213 reasonable cost to the consumer by ensuring uniform  
 214 interpretations throughout the state and by providing processes  
 215 for resolving disputes regarding interpretations of the Florida  
 216 Building Code and the Florida Accessibility Code for Building  
 217 Construction which are just and expeditious.  
 218 (2) Local enforcement agencies, local building officials,  
 219 state agencies, and the commission shall interpret provisions of  
 220 the Florida Building Code and the Florida Accessibility Code for  
 221 Building Construction in a manner that is consistent with  
 222 declaratory statements and interpretations entered by the  
 223 commission, except that conflicts between the Florida Fire  
 224 Prevention Code and the Florida Building Code shall be resolved  
 225 in accordance with s. 553.73(11)(c) and (d).  
 226 (3) The following procedures may be invoked regarding  
 227 interpretations of the Florida Building Code or the Florida  
 228 Accessibility Code for Building Construction:  
 229 (a) Upon written application by any substantially affected  
 230 person or state agency or by a local enforcement agency, the  
 231 commission shall issue declaratory statements pursuant to s.  
 232 120.565 relating to the enforcement or administration by local

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

235 (b) When requested in writing by any substantially affected  
 236 person or state agency or by a local enforcement agency, the  
 237 commission shall issue a declaratory statement pursuant to s.  
 238 120.565 relating to this part and ss. 515.25, 515.27, 515.29,  
 239 and 515.37. Actions of the commission are subject to judicial  
 240 review under s. 120.68.

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

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

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

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

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

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

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

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

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

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

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291 interpretation.

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

301 3. The petitioner shall submit the petition to the local  
 302 building official, who shall place the date of receipt on the  
 303 petition. The local building official shall respond to the  
 304 petition in accordance with the form and shall return the  
 305 petition along with his or her response to the petitioner within  
 306 5 days after receipt, exclusive of Saturdays, Sundays, and legal  
 307 holidays. The petitioner may file the petition with the  
 308 commission at any time after the local building official  
 309 provides a response. If no response is provided by the local  
 310 building official, the petitioner may file the petition with the  
 311 commission 10 days after submission of the petition to the local  
 312 building official and shall note that the local building  
 313 official did not respond.

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

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320 by posting comments.

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

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

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

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

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

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

368  
 369 This paragraph provides the exclusive remedy for addressing  
 370 requests to review local interpretations of the Florida Building  
 371 Code or the Florida Accessibility Code for Building Construction  
 372 and appeals from review proceedings.

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

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

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

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

394 (g) The commission may designate a commission member who  
 395 has demonstrated expertise in interpreting building plans to  
 396 attend each meeting of the advisory council created in s.  
 397 553.512. The commission member may vary from meeting to meeting,  
 398 shall serve on the council in a nonvoting capacity, and shall  
 399 receive per diem and expenses as provided in s. 553.74(3).

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

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407 rulemaking. It is the intent of the Legislature that the  
 408 commission create a process to refer questions to a small,  
 409 rotating group of individuals licensed under part XII of chapter  
 410 468, to which a party may pose questions regarding the  
 411 interpretation of code provisions. It is the intent of the  
 412 Legislature that the process provide for the expeditious  
 413 resolution of the issues presented and publication of the  
 414 resulting interpretation on the Building Code Information  
 415 System. Such interpretations shall be advisory only and  
 416 nonbinding on the parties and the commission.

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

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

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436 ~~the procedures specified in this section. This subsection has no~~  
 437 ~~effect upon the commission's authority to waive the Florida~~  
 438 ~~Accessibility Code for Building Construction as provided by s.~~  
 439 ~~553.512.~~

440 Section 7. Present subsections (11) through (18) of section  
 441 553.79, Florida Statutes, are redesignated as subsections (12)  
 442 through (19), respectively, and a new subsection (11) is added  
 443 to that section, to read:

444 553.79 Permits; applications; issuance; inspections.—

445 (11) The local enforcing agency may not issue a building  
 446 permit to construct, develop, or modify a public swimming pool  
 447 without proof of application for an operating permit under s.  
 448 514.031. A certificate of completion or occupancy may not be  
 449 issued until such operating permit is issued.

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

452 553.841 Building code compliance and mitigation program.—  
 453 (1) The Legislature finds that knowledge and understanding  
 454 by persons licensed or employed in the design and construction  
 455 industries of the importance and need for complying with the  
 456 Florida Building Code and related laws is vital to the public  
 457 health, safety, and welfare of this state, especially for  
 458 protecting consumers and mitigating damage caused by hurricanes  
 459 to residents and visitors to the state. The Legislature further  
 460 finds that the Florida Building Code can be effective only if  
 461 all participants in the design and construction industries  
 462 maintain a thorough knowledge of the code, code compliance and  
 463 enforcement, duties related to consumers, and changes that  
 464 additions thereto which improve construction standards, project

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465 completion, and compliance of design and construction to protect  
466 against consumer harm, storm damage, and other damage.

467 Consequently, the Legislature finds that there is a need for a  
468 program to provide ongoing education and outreach activities  
469 concerning compliance with the Florida Building Code, the  
470 Florida Fire Prevention Code, construction plan and permitting  
471 requirements, construction liens, and hurricane mitigation.

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

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

488 553.883 Smoke alarms in one-family and two-family dwellings  
489 and townhomes.—One-family and two-family dwellings and townhomes  
490 undergoing a repair, or a level 1 alteration as defined in the  
491 Florida Building Code, Existing Building, may use smoke alarms  
492 powered by 10-year nonremovable, nonreplaceable batteries in  
493 lieu of retrofitting such dwelling with smoke alarms powered by

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

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

501 553.993 Definitions.—For purposes of this part:

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

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523 ~~Florida Solar Energy Center.~~

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

526 633.202 Florida Fire Prevention Code.—

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

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

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

546 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.

A handwritten signature in black ink, appearing to read "Wilton Simpson".

Wilton Simpson  
Senator, 18<sup>th</sup> 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

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**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)



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

*City*

*State*

*Zip*

E-mail ccook@flcities.com

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.*

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THE FLORIDA SENATE  
**APPEARANCE RECORD**



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4-1-14

Meeting Date

Topic Building Const.

Bill Number SB 1104  
*(if applicable)*

Name Bruce Kershner

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title \_\_\_\_\_

Address 231 West Bay Avenue

Phone 407-830-1882

Street

Longwood  
City

FL  
State

32750  
Zip

E-mail BKershner@att.net

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



4/1/14

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Meeting Date

Topic BUILDING CONSTRUCTION

Bill Number CS FOR SB 1106 (if applicable)

Name RANDALL KING

Amendment Barcode (if applicable)

Job Title BUSINESS MANAGER E.B.E.W. LLC

Address 5621 HARNEY RD

Phone 813-621-6451

Street

TAMPA

FL.

33610

City

State

Zip

E-mail RANDALLKING@EBEWLLC.ORG

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

Representing \_\_\_\_\_

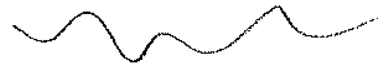
Appearing at request of Chair: [ ] Yes [X] No

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

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THE FLORIDA SENATE  
**APPEARANCE RECORD**



4-1-14

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

Meeting Date

Topic Building Construction

Bill Number CS <sup>For</sup> SB 1106  
*(if applicable)*

Name Larry Kidd

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Construction Worker

Address 820 Virginia Dr

Phone 407-896-7271

Street

City

Orlando FL 32803

State

Zip

E-mail LKidd01@aol.com

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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4-1-14

Meeting Date

Topic ~~Building Trades~~ 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*

Phone 850-224-4440

TALLAHASSEE, FL 32301  
*City State Zip*

E-mail FLORIDABUILDINGTRADES@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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THE FLORIDA SENATE

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8-1-14

Meeting Date

Topic BUILDINGS CODES/CONSTRUCTION

Bill Number SB 1106 (if applicable)

Name KARI HEBRANK

Amendment Barcode (if applicable)

Job Title

Address 113 EAST COLLEGE, #200

Phone 850-566-7824

TALLAHASSEE FL 32301

E-mail khebrank@wilsonmgmt.com

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

Representing FLORIDA HOME BUILDERS ASSOCIATION

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

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

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

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THE FLORIDA SENATE  
**APPEARANCE RECORD**

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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 2071 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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**THE FLORIDA SENATE**  
**APPEARANCE RECORD**

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Meeting Date \_\_\_\_\_

Topic \_\_\_\_\_

Bill Number SB 1106  
(if applicable)

Name GERARD Sommers

Amendment Barcode \_\_\_\_\_  
(if applicable)

Job Title \_\_\_\_\_

Address 8164 English Elm Ct  
Street  
Spring Hill FL 34606  
City State Zip

Phone 585-613-5571

E-mail GERARD@SOMMERSPAD.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.*

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**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.)

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

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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.	<u>Sanford</u>	<u>Hendon</u>	<u>CF</u>	<b>Favorable</b>
2.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<b>Favorable</b>
3.	_____	_____	<u>AP</u>	_____

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**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.<sup>1</sup>

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.<sup>2</sup>

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.<sup>3</sup>

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.

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<sup>1</sup> Section 491.003(7), F.S.

<sup>2</sup> Section 491.003(8), F.S.

<sup>3</sup> 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.<sup>4</sup>

### **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.<sup>5</sup> During the time that the person is completing the experience requirement, he or she must register as an intern.<sup>6</sup>

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.<sup>7</sup>

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.<sup>8</sup>

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.<sup>9</sup>

### **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

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<sup>4</sup> Section 491.005(1)(d), (3)(d), and (4)(d), F.S.

<sup>5</sup> Section 491.005, F.S.

<sup>6</sup> Section 491.0045, F.S.

<sup>7</sup> *Id.*

<sup>8</sup> Department of Health, *Senate Bill 1388 Fiscal Analysis* (Mar. 4, 2014) (on file with the Senate Committee on Children, Families, and Elder Affairs).

<sup>9</sup> *Id.*

and may not be renewed or reissued.<sup>10</sup> 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.<sup>11</sup>

### 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.

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<sup>10</sup> Section 491.0046, F.S.

<sup>11</sup> 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

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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

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

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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~~ 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.

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

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

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

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

82 (6) An intern registration issued on or before March 31,  
83 2015, expires March 31, 2020, and may not be renewed or  
84 reissued. An intern registration issued after March 31, 2015,  
85 expires 60 months after the date it is issued. A subsequent  
86 intern registration may not be issued unless the candidate has  
87 passed the theory and practice examination described in s.

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88 491.005(1)(d), (3)(d), and (4)(d).

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

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

95 491.005 Licensure by examination.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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175 health counseling.

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

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

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

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

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

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

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

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

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

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

240  
241 The required master's degree must have been received in an  
242 institution of higher education which at the time the applicant  
243 graduated was: fully accredited by a regional accrediting body  
244 recognized by the Commission on Recognition of Postsecondary  
245 Accreditation; publicly recognized as a member in good standing  
246 with the Association of Universities and Colleges of Canada; or  
247 an institution of higher education located outside the United  
248 States and Canada, which at the time the applicant was enrolled  
249 and at the time the applicant graduated maintained a standard of  
250 training substantially equivalent to the standards of training  
251 of those institutions in the United States which are accredited  
252 by a regional accrediting body recognized by the Commission on  
253 Recognition of Postsecondary Accreditation. Such foreign  
254 education and training must have been received in an institution  
255 or program of higher education officially recognized by the  
256 government of the country in which it is located as an  
257 institution or program to train students to practice as  
258 professional marriage and family therapists or psychotherapists.  
259 The burden of establishing that the requirements of this  
260 provision have been met shall be upon the applicant, and the  
261 board shall require documentation, such as, but not limited to,

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

271 (c) Has had at least ~~not less than~~ 2 years of clinical  
272 experience during which 50 percent of the applicant's clients  
273 were receiving marriage and family therapy services, which must  
274 be at the post-master's level under the supervision of a  
275 licensed marriage and family therapist who has ~~with~~ at least 5  
276 years of experience, or the equivalent, and who is a qualified  
277 supervisor as determined by the board. An individual who intends  
278 to practice in Florida to satisfy the clinical experience  
279 requirements must register pursuant to s. 491.0045 before ~~prior~~  
280 ~~to~~ commencing practice. If a graduate has a master's degree with  
281 a major emphasis in marriage and family therapy or a closely  
282 related field which ~~that~~ did not include all the coursework  
283 required under sub-subparagraphs (b)1.a.-c., credit for the  
284 post-master's level clinical experience may ~~shall~~ not commence  
285 until the applicant has completed a minimum of 10 of the courses  
286 required under sub-subparagraphs (b)1.a.-c., as determined by  
287 the board, and at least 6 semester hours or 9 quarter hours of  
288 the course credits must have been completed in the area of  
289 marriage and family systems, theories, or techniques. Within the  
290 3 years of required experience, the applicant shall provide

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

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

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

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

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

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

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

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

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

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

359 ~~(5)(6) RULES.~~—The board may adopt rules necessary to  
360 implement any education or experience requirement in ~~of~~ this  
361 section for licensure as a clinical social worker, marriage and  
362 family therapist, or mental health counselor.

363 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

Mental Health Counselors  
~~Proprietary Assistants~~

Bill Number

~~1253~~ 1388

(if applicable)

Name

Corinne Mixon

Amendment Barcode

(if applicable)

Job Title

Lobbyist

Address

119 E. Park Avenue

Phone

850-202-2591

Street

Tallahassee

FL

32301

E-mail

corinne@mixonand  
associates.com

City

State

Zip

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 AKIN

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title EXECUTIVE DIRECTOR

Address 1931 ORCHARD DRIVE

Phone 850-224-2400

Street

TALLAHASSEE, FL 32306

City

State

Zip

E-mail JIM@NASWFL.ORG

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

City

State

Zip

E-mail lbarlow110@msn.com

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.)

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

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BILL: SB 1230

INTRODUCER: Senator Hays

SUBJECT: Physician Assistants

DATE: April 1, 2014

REVISED: 04/02/14

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

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**Please see Section IX. for Additional Information:**

AMENDMENTS - Significant amendments were recommended

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**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.<sup>1</sup>

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.<sup>2</sup> 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.<sup>3</sup> In

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<sup>1</sup> 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.).

<sup>2</sup> Sections 458.347(4) and 459.022(4), F.S.

<sup>3</sup> 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:<sup>4</sup>

- 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.<sup>5</sup>

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<sup>6</sup> and indirect<sup>7</sup> 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.<sup>8</sup>

Rules of both boards prohibit the delegation of prescribing, dispensing, or compounding of medicinal drugs, or final diagnosis, except as authorized by statute.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup>

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

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<sup>4</sup> Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.

<sup>5</sup> Sections 458.347(3) and 459.022(3), F.S.

<sup>6</sup> "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.)

<sup>7</sup> "Indirect supervision" requires the physician to be within reasonable physical proximity. (Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.)

<sup>8</sup> Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

<sup>9</sup> *Id.*

<sup>10</sup> 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.

<sup>11</sup> *See supra* note 8.

<sup>12</sup> 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;<sup>13</sup> nine states allow supervision of up to two physician assistants;<sup>14</sup> six states allow supervision of up to three physician assistants;<sup>15</sup> and 16 states (plus the District of Columbia) allow supervision of up to four physician assistants.<sup>16</sup> The six remaining states have ratios up to 1 to 7.<sup>17</sup>

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.<sup>18</sup> The 2013 Physician Workforce Annual Report<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup>

### 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

<sup>13</sup> Alabama, Arkansas, Maine, Montana, New Mexico, North Carolina, North Dakota, Rhode Island, Tennessee, and Vermont.

<sup>14</sup> Hawaii, Indiana, Kansas, Kentucky, Louisiana, Ohio, Mississippi, Oklahoma, and Wisconsin.

<sup>15</sup> Idaho, Missouri, Nevada, South Carolina, West Virginia, and Wyoming.

<sup>16</sup> Arizona, California, Colorado, Delaware, Florida, Georgia, Maryland, Michigan, Nebraska, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, South Dakota, and Utah.

<sup>17</sup> 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).

<sup>18</sup> 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.

<sup>19</sup> 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.

<sup>20</sup> 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).

<sup>21</sup> 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.<sup>22</sup> An applicant who lies on an application is subject to disciplinary action, thus the DOH has recourse.<sup>23</sup> 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.<sup>24</sup>

#### **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.

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<sup>22</sup> Conversation with Allison M. Dudley, J.D., Executive Director, Fla. Board of Medicine, Fla. Dept. of Health (Mar. 26, 2014).

<sup>23</sup> Sections 458.331(1)(a) and 459.015(1)(a), F.S.

<sup>24</sup> *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.”<sup>25</sup> 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.<sup>26</sup>

**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.

<sup>25</sup> Section 499.002(2), F.S.

<sup>26</sup> 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)



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

22 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

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

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

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



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

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

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

52 5. The prescription may ~~must~~ be written or electronic, but  
53 must be in a form that complies with ss. 456.0392(1) and  
54 456.42(1), chapter 499 and must contain, in addition to the  
55 supervisory physician's name, address, and telephone number, the  
56 physician assistant's prescriber number. Unless it is a drug or  
57 drug sample dispensed by the physician assistant, the  
58 prescription must be filled in a pharmacy permitted under  
59 chapter 465 and must be dispensed in that pharmacy by a  
60 pharmacist licensed under chapter 465. The appearance of the  
61 prescriber number creates a presumption that the physician  
62 assistant is authorized to prescribe the medicinal drug and the  
63 prescription is valid.

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

66 (7) PHYSICIAN ASSISTANT LICENSURE.—

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



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

71 1. Is at least 18 years of age.

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

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

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

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

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

91 ~~d. Two letters of recommendation.~~

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

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



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

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

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

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

105 (e) Upon employment as a physician assistant, a licensed  
106 physician assistant must notify the department in writing within  
107 30 days after such employment and provide ~~or after any~~  
108 ~~subsequent changes in the supervising physician. The~~  
109 ~~notification must include~~ the full name, Florida medical license  
110 number, specialty, and address of a designated ~~the~~ supervising  
111 physician. Any subsequent change in the designated supervising  
112 physician shall be reported by the physician assistant to the  
113 department within 30 days after the change. The assignment of a  
114 designated supervising physician does not preclude a physician  
115 assistant from practicing under multiple supervising physicians.

116 Section 2. Subsection (3), paragraph (e) of subsection (4),  
117 and paragraphs (a), (b), and (d) of subsection (7) of section  
118 459.022, Florida Statutes, are amended to read:

119 459.022 Physician assistants.—

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



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

133 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

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

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

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

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



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

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

163 5. The prescription may ~~must~~ be written or electronic, but  
164 must be in a form that complies with ss. 456.0392(1) and  
165 456.42(1) chapter 499 and must contain, in addition to the  
166 supervisory physician's name, address, and telephone number, the  
167 physician assistant's prescriber number. Unless it is a drug or  
168 drug sample dispensed by the physician assistant, the  
169 prescription must be filled in a pharmacy permitted under  
170 chapter 465, and must be dispensed in that pharmacy by a  
171 pharmacist licensed under chapter 465. The appearance of the  
172 prescriber number creates a presumption that the physician  
173 assistant is authorized to prescribe the medicinal drug and the  
174 prescription is valid.

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

177 (7) PHYSICIAN ASSISTANT LICENSURE.—

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

182 1. Is at least 18 years of age.

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



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

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

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

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

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

202 ~~d. Two letters of recommendation.~~

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

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

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

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



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

216 (d) Upon employment as a physician assistant, a licensed  
217 physician assistant must notify the department in writing within  
218 30 days after such employment and provide ~~or after any~~  
219 ~~subsequent changes in the supervising physician. The~~  
220 ~~notification must include~~ the full name, Florida medical license  
221 number, specialty, and address of a designated ~~the~~ supervising  
222 physician. Any subsequent change in the designated supervising  
223 physician shall be reported by the physician assistant to the  
224 department within 30 days after the change. The assignment of a  
225 designated supervising physician does not preclude a physician  
226 assistant from practicing under multiple supervising physicians.

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

228  
229 ===== T I T L E A M E N D M E N T =====

230 And the title is amended as follows:

231 Delete everything before the enacting clause  
232 and insert:

233 A bill to be entitled  
234 An act relating to physician assistants; amending ss.  
235 458.347 and 459.022, F.S.; increasing the number of  
236 licensed physician assistants that a physician may  
237 supervise at any one time; providing an exception;  
238 revising circumstances under which a physician  
239 assistant is authorized to prescribe or dispense  
240 medication; specifying that a prescription may be in  
241 written or electronic form and must meet certain  
242 requirements; revising application requirements for





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243 licensure as a physician assistant and license  
244 renewal; revising the notification requirements for a  
245 physician assistant to the Department of Health upon  
246 employment as a physician assistant; providing an  
247 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:

1           **Senate Amendment to Amendment (730402) (with title**  
2 **amendment)**

3  
4           Between lines 115 and 116  
5 insert:

6           Section 2. Paragraph (c) of subsection (4) of section  
7 458.348, Florida Statutes, is amended to read:

8           458.348 Formal supervisory relationships, standing orders,  
9 and established protocols; notice; standards.—

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



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

20 (c) A physician who supervises an advanced registered nurse  
21 practitioner or physician assistant at a medical office other  
22 than the physician's primary practice location, where the  
23 advanced registered nurse practitioner or physician assistant is  
24 not under the onsite supervision of a supervising physician and  
25 the services offered at the office are primarily dermatologic or  
26 skin care services, which include aesthetic skin care services  
27 other than plastic surgery, must comply with the standards  
28 listed in subparagraphs 1.-4. Notwithstanding s.  
29 458.347(4)(e)6., a physician supervising a physician assistant  
30 pursuant to this paragraph may not be required to review and  
31 cosign charts or medical records prepared by such physician  
32 assistant.

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

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



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40           3. All such offices that are not the physician's primary  
41 place of practice must be within 25 miles of the physician's  
42 primary place of practice or in a county that is contiguous to  
43 the county of the physician's primary place of practice.  
44 However, the distance between any of the offices may not exceed  
45 75 miles.

46           4. The physician may supervise only one office other than  
47 the physician's primary place of practice except that until July  
48 1, 2011, the physician may supervise up to two medical offices  
49 other than the physician's primary place of practice if the  
50 addresses of the offices are submitted to the board before July  
51 1, 2006. Effective July 1, 2011, the physician may supervise  
52 only one office other than the physician's primary place of  
53 practice, regardless of when the addresses of the offices were  
54 submitted to the board.

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

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

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

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

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



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

77  
78 ===== T I T L E A M E N D M E N T =====

79 And the title is amended as follows:

80 Delete lines 234 - 235

81 and insert:

82 An act relating to physician assistants; amending s.  
83 458.347, F.S.; increasing the number of licensed  
84 physician assistants that a physician may supervise at  
85 any one time; providing an exception; revising  
86 circumstances under which a physician assistant is  
87 authorized to prescribe or dispense medication;  
88 specifying that a prescription may be in written or  
89 electronic form and must meet certain requirements;  
90 revising application requirements for licensure as a  
91 physician assistant and license renewal; revising the  
92 notification requirements for a physician assistant to  
93 the Department of Health upon employment as a  
94 physician assistant; amending s. 458.348, F.S.;  
95 providing exceptions to the requirements for  
96 supervising physician assistants at offices providing  
97 certain skin care services under certain



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98           circumstances; defining the term "nonablative  
99           aesthetic services"; requiring a supervising physician  
100          to submit to the Board of Medicine certain  
101          documentation regarding the physician assistant;  
102          limiting the number of offices that such physician may  
103          supervise in addition to his or her primary practice  
104          location; amending s. 459.022, F.S.; increasing the  
105          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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11 must be qualified in the medical areas in which the physician  
12 assistant is to perform and shall be individually or  
13 collectively responsible and liable for the performance and the  
14 acts and omissions of the physician assistant. A physician may  
15 not supervise more than five ~~four~~ currently licensed physician  
16 assistants at any one time. A physician supervising a physician  
17 assistant pursuant to this section may not be required to review  
18 and cosign charts or medical records prepared by such physician  
19 assistant. Notwithstanding this subsection, a physician may only  
20 supervise up to four physician assistants in an office regulated  
21 under s. 458.348(4)(c) or s. 459.025(3)(c).

22 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

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

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

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





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

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

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

52 5. The prescription may ~~must~~ be written or electronic, but  
53 must be in a form that complies with ss. 456.0392(1) and  
54 456.42(1), chapter 499 and must contain, in addition to the  
55 supervisory physician's name, address, and telephone number, the  
56 physician assistant's prescriber number. Unless it is a drug or  
57 drug sample dispensed by the physician assistant, the  
58 prescription must be filled in a pharmacy permitted under  
59 chapter 465 and must be dispensed in that pharmacy by a  
60 pharmacist licensed under chapter 465. The appearance of the  
61 prescriber number creates a presumption that the physician  
62 assistant is authorized to prescribe the medicinal drug and the  
63 prescription is valid.

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

66 (7) PHYSICIAN ASSISTANT LICENSURE.—

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



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

71 1. Is at least 18 years of age.

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

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

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

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

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

91 ~~d. Two letters of recommendation.~~

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

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



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

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

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

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

105 (e) Upon employment as a physician assistant, a licensed  
106 physician assistant must notify the department in writing within  
107 30 days after such employment and provide ~~or after any~~  
108 ~~subsequent changes in the supervising physician. The~~  
109 ~~notification must include~~ the full name, Florida medical license  
110 number, specialty, and address of a designated ~~the~~ supervising  
111 physician. Any subsequent change in the designated supervising  
112 physician shall be reported by the physician assistant to the  
113 department within 30 days after the change. The assignment of a  
114 designated supervising physician does not preclude a physician  
115 assistant from practicing under multiple supervising physicians.

116 Section 2. Paragraph (c) of subsection (4) of section  
117 458.348, Florida Statutes, is amended to read:

118 458.348 Formal supervisory relationships, standing orders,  
119 and established protocols; notice; standards.—

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



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

130 (c) A physician who supervises an advanced registered nurse  
131 practitioner or physician assistant at a medical office other  
132 than the physician's primary practice location, where the  
133 advanced registered nurse practitioner or physician assistant is  
134 not under the onsite supervision of a supervising physician and  
135 the services offered at the office are primarily dermatologic or  
136 skin care services, which include aesthetic skin care services  
137 other than plastic surgery, must comply with the standards  
138 listed in subparagraphs 1.-4. Notwithstanding s.  
139 458.347(4)(e)6., a physician supervising a physician assistant  
140 pursuant to this paragraph may not be required to review and  
141 cosign charts or medical records prepared by such physician  
142 assistant.

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

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

150 3. All such offices that are not the physician's primary  
151 place of practice must be within 25 miles of the physician's  
152 primary place of practice or in a county that is contiguous to  
153 the county of the physician's primary place of practice.  
154 However, the distance between any of the offices may not exceed  
155 75 miles.



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156           4. The physician may supervise only one office other than  
157 the physician's primary place of practice except that until July  
158 1, 2011, the physician may supervise up to two medical offices  
159 other than the physician's primary place of practice if the  
160 addresses of the offices are submitted to the board before July  
161 1, 2006. Effective July 1, 2011, the physician may supervise  
162 only one office other than the physician's primary place of  
163 practice, regardless of when the addresses of the offices were  
164 submitted to the board.

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

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

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

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

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



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

187 Section 3. Subsection (3), paragraph (e) of subsection (4),  
188 and paragraphs (a), (b), and (d) of subsection (7) of section  
189 459.022, Florida Statutes, are amended to read:

190 459.022 Physician assistants.—

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

204 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

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

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



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

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

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

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

234 5. The prescription may ~~must~~ be written or electronic, but  
235 must be in a form that complies with ss. 456.0392(1) and  
236 456.42(1) ~~chapter 499~~ and must contain, in addition to the  
237 supervisory physician's name, address, and telephone number, the  
238 physician assistant's prescriber number. Unless it is a drug or  
239 drug sample dispensed by the physician assistant, the  
240 prescription must be filled in a pharmacy permitted under  
241 chapter 465, and must be dispensed in that pharmacy by a  
242 pharmacist licensed under chapter 465. The appearance of the



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

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

248 (7) PHYSICIAN ASSISTANT LICENSURE.—

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

253 1. Is at least 18 years of age.

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

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

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

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

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





630784

272 of licensure or certification in any state.

273 ~~d. Two letters of recommendation.~~

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

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

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

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

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

287 (d) Upon employment as a physician assistant, a licensed  
288 physician assistant must notify the department in writing within  
289 30 days after such employment and provide ~~or after any~~  
290 ~~subsequent changes in the supervising physician. The~~  
291 ~~notification must include~~ the full name, Florida medical license  
292 number, specialty, and address of a designated ~~the~~ supervising  
293 physician. Any subsequent change in the designated supervising  
294 physician shall be reported by the physician assistant to the  
295 department within 30 days after the change. The assignment of a  
296 designated supervising physician does not preclude a physician  
297 assistant from practicing under multiple supervising physicians.

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

299  
300 ===== T I T L E A M E N D M E N T =====



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301 And the title is amended as follows:

302 Delete everything before the enacting clause  
303 and insert:

304 A bill to be entitled

305 An act relating to physician assistants; amending s.  
306 458.347, F.S.; increasing the number of licensed  
307 physician assistants that a physician may supervise at  
308 any one time; providing an exception; revising  
309 circumstances under which a physician assistant is  
310 authorized to prescribe or dispense medication;  
311 specifying that a prescription may be in written or  
312 electronic form and must meet certain requirements;  
313 revising application requirements for licensure as a  
314 physician assistant and license renewal; revising the  
315 notification requirements for a physician assistant to  
316 the Department of Health upon employment as a  
317 physician assistant; amending s. 458.348, F.S.;  
318 providing exceptions to the requirements for  
319 supervising physician assistants at offices providing  
320 certain skin care services under certain  
321 circumstances; defining the term "nonablative  
322 aesthetic services"; requiring a supervising physician  
323 to submit to the Board of Medicine certain  
324 documentation regarding the physician assistant;  
325 limiting the number of offices that such physician may  
326 supervise in addition to his or her primary practice  
327 location; amending s. 459.022, F.S.; increasing the  
328 number of licensed physician assistants that a  
329 physician may supervise at any one time; providing an



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330           exception; revising circumstances under which a  
331           physician assistant is authorized to prescribe or  
332           dispense medication; specifying that a prescription  
333           may be in written or electronic form and must meet  
334           certain requirements; revising application  
335           requirements for licensure as a physician assistant  
336           and license renewal; revising the notification  
337           requirements for a physician assistant to the  
338           Department of Health upon employment as a physician  
339           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



582424

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

19 (c) A physician who supervises an advanced registered nurse  
20 practitioner or physician assistant at a medical office other  
21 than the physician's primary practice location, where the  
22 advanced registered nurse practitioner or physician assistant is  
23 not under the onsite supervision of a supervising physician and  
24 the services offered at the office are primarily dermatologic or  
25 skin care services, which include aesthetic skin care services  
26 other than plastic surgery, must comply with the standards  
27 listed in subparagraphs 1.-4. Notwithstanding s.  
28 458.347(4)(e)6., a physician supervising a physician assistant  
29 pursuant to this paragraph may not be required to review and  
30 cosign charts or medical records prepared by such physician  
31 assistant.

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

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

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



582424

40 place of practice must be within 25 miles of the physician's  
41 primary place of practice or in a county that is contiguous to  
42 the county of the physician's primary place of practice.  
43 However, the distance between any of the offices may not exceed  
44 75 miles.

45 4. The physician may supervise only one office other than  
46 the physician's primary place of practice except that until July  
47 1, 2011, the physician may supervise up to two medical offices  
48 other than the physician's primary place of practice if the  
49 addresses of the offices are submitted to the board before July  
50 1, 2006. Effective July 1, 2011, the physician may supervise  
51 only one office other than the physician's primary place of  
52 practice, regardless of when the addresses of the offices were  
53 submitted to the board.

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

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

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

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

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



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69 provided using intense pulsed light, lasers, radio frequency,  
70 ultrasound, injectables, and fillers. The supervising physician  
71 shall submit to the board documentation evidencing successful  
72 completion of the education and training required by this  
73 paragraph for the physician assistants that he or she is  
74 supervising. A physician may not supervise more than two offices  
75 in addition to the physician's primary practice location.  
76

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

78 And the title is amended as follows:

79 Delete lines 2 - 3

80 and insert:

81 An act relating to physician assistants; amending s.  
82 458.347, F.S.; increasing the number of licensed  
83 physician assistants that a physician may supervise at  
84 any one time; revising circumstances under which a  
85 physician assistant is authorized to prescribe or  
86 dispense medication; revising application requirements  
87 for licensure as a physician assistant and license  
88 renewal; amending s. 458.348, F.S.; providing  
89 exceptions to the requirements for supervising  
90 physician assistants at offices providing certain skin  
91 care services under certain circumstances; defining  
92 the term "nonablative aesthetic services"; requiring a  
93 supervising physician to submit to the Board of  
94 Medicine certain documentation regarding the physician  
95 assistant; limiting the number of offices that such  
96 physician may supervise in addition to his or her  
97 primary practice location; amending s. 459.022, F.S.;



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98

increasing the number of



By Senator Hays

11-01202A-14

20141230\_\_

1 A bill to be entitled  
 2 An act relating to physician assistants; amending ss.  
 3 458.347 and 459.022, F.S.; increasing the number of  
 4 licensed physician assistants that a physician may  
 5 supervise at any one time; revising circumstances  
 6 under which a physician assistant is authorized to  
 7 prescribe or dispense medication; revising application  
 8 requirements for licensure as a physician assistant  
 9 and license renewal; providing an effective date.

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

11 Section 1. Subsection (3), paragraph (e) of subsection (4),  
 12 and paragraphs (a) and (c) of subsection (7) of section 458.347,  
 13 Florida Statutes, are amended to read:  
 14 458.347 Physician assistants.—  
 15 (3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or  
 16 group of physicians supervising a licensed physician assistant  
 17 must be qualified in the medical areas in which the physician  
 18 assistant is to perform and shall be individually or  
 19 collectively responsible and liable for the performance and the  
 20 acts and omissions of the physician assistant. A physician may  
 21 not supervise more than eight ~~four~~ currently licensed physician  
 22 assistants at any one time. A physician supervising a physician  
 23 assistant pursuant to this section may not be required to review  
 24 and cosign charts or medical records prepared by such physician  
 25 assistant.  
 26 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—  
 27 (e) A supervisory physician may delegate to a fully

Page 1 of 7

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

11-01202A-14

20141230\_\_

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

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

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

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

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

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

Page 2 of 7

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

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

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

71 (7) PHYSICIAN ASSISTANT LICENSURE.—

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

76 1. Is at least 18 years of age.

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

87 3. Has completed the application form and remitted an

11-01202A-14 20141230\_\_  
 88 application fee not to exceed \$300 as set by the boards. An  
 89 application for licensure made by a physician assistant must  
 90 include:

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

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

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

96 ~~d. Two letters of recommendation.~~

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

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

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

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

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

110 459.022 Physician assistants.—

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

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

122 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

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

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

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

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

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20141230\_\_

146 prescriptive privileges with each licensure renewal application.

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

152 5. The prescription must be written in a form that complies  
 153 with chapter 499 and must contain, in addition to the  
 154 supervisory physician's name, address, and telephone number, the  
 155 physician assistant's prescriber number. Unless it is a drug or  
 156 drug sample dispensed by the physician assistant, the  
 157 prescription must be filled in a pharmacy permitted under  
 158 chapter 465, and must be dispensed in that pharmacy by a  
 159 pharmacist licensed under chapter 465. The appearance of the  
 160 prescriber number creates a presumption that the physician  
 161 assistant is authorized to prescribe the medicinal drug and the  
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163 6. The physician assistant must note the prescription or  
 164 dispensing of medication in the appropriate medical record.

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 167 assistant must apply to the department. The department shall  
 168 issue a license to any person certified by the council as having  
 169 met the following requirements:

- 170 1. Is at least 18 years of age.
- 171 2. Has satisfactorily passed a proficiency examination by
- 172 an acceptable score established by the National Commission on
- 173 Certification of Physician Assistants. If an applicant does not
- 174 hold a current certificate issued by the National Commission on

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

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

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

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

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

190 ~~d. Two letters of recommendation.~~

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

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

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

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

201 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, Umalilla, 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](http://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

Phone 813-286-8100

Street

Tampa

FL

33609

City

State

Zip

E-mail nicole.strothman@ideal  
image.com

Speaking:  For  Against  Information

Representing Ideal Image

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 1230

Name Chris Nuland

Amendment Barcode BT24AM ND  
(if applicable)  
(if applicable)

Job Title \_\_\_\_\_

Address 1000 Riverside Ave #115

Phone 904-233-3051

Street

Jacksonville, FL 32204

City

State

Zip

E-mail nulandlaw@aol.com

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 33102 E-mail mmarti300@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.**



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

Phone 850-222-2591

Tallahassee FL 32301  
City State Zip

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. <u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<u>Pre-meeting</u>

---

**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,<sup>1</sup> 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,

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<sup>1</sup>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.<sup>2</sup>

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.<sup>3</sup> 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.<sup>4</sup> In 2008, the Legislature reallocated equally 150 unused PACE slots to Miami-Dade, Lee, and Pinellas Counties.<sup>5</sup> In 2009, the Legislature authorized 100 slots for a program in Hillsborough County.<sup>6</sup> The 2010 GAA funded an additional 100 slots in Pinellas County and authorized and funded a new program with 100 slots in Hillsborough County.<sup>7</sup> That same year, the Legislature, by general law, authorized an additional 50 slots in Miami-Dade and 150 slots

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<sup>2</sup> 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](http://ahca.myflorida.com/docs/PACE_Evaluation_2014.pdf) (last visited Mar. 27, 2014).

<sup>3</sup> 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.

<sup>4</sup> Chapter 2006-25, L.O.F.

<sup>5</sup> Chapter 2008-152, L.O.F.

<sup>6</sup> Chapter 2009-55, s. 20, L.O.F.

<sup>7</sup> Chapter 2010-152, L.O.F.

for a program serving Polk, Hardee, Highlands, and Hillsborough Counties.<sup>8</sup> In 2011, the Legislature authorized a program with 150 slots in Palm Beach County,<sup>9</sup> and funded, through the GAA, 50 additional slots in Lee County and 150 slots for a program serving Polk, Hardee, and Highlands Counties.<sup>10</sup> 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.<sup>11</sup> The 2012–2013 GAA funded 100 additional slots in Miami-Dade and 150 additional slots in Lee County.<sup>12</sup>

The Legislature appropriated \$30,402,775 for PACE in the 2013-2014 GAA.<sup>13</sup> 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.<sup>14</sup>

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.

<b>PACE Organizations and Enrollee Counts<sup>15</sup></b>				
<b>PACE Organization Name</b>	<b>Year Began Operating</b>	<b>County</b>	<b>Current Enrollees Mar-2014</b>	<b>Total Slots Funded</b>
Hope Select Care	2010	Charlotte	37	100
Hope Select Care	2010	Collier	17	50
(No Provider Currently) <sup>16</sup>	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
<b>Total Enrollees - Statewide:</b>			865	1,325

<sup>8</sup> Chapter 2010-156, ss. 14 and 15, L.O.F.

<sup>9</sup> Chapter 2011-61, s. 17, L.O.F.

<sup>10</sup> Chapter 2011-69, L.O.F.

<sup>11</sup> Chapter 2012-33, ss.18 and 19, L.O.F.

<sup>12</sup> Chapter 2012-118, L.O.F.

<sup>13</sup> Chapter 2013-40, L.O.F.

<sup>14</sup> 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).

<sup>15</sup> 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.

<sup>16</sup> 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.<sup>17</sup> The report's findings noted a difference in the average age (81.1 years in SMMC versus 75.5 in PACE),<sup>18</sup> prevalence of severe emotional problems (PACE enrollees are more likely to report) and affliction with cognitive impairments such as dementia (higher with SMMC-LTC).<sup>19</sup>

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.<sup>20</sup> 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.<sup>21</sup>

## 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.

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<sup>17</sup> Chapter 2013-40, L.O.F., line 424.

<sup>18</sup> Department of Elder Affairs, *Supra* note 2 at 20.

<sup>19</sup> *Id* at 19.

<sup>20</sup> Chapter 2011-135, s. 24, L.O.F., repeals Section 430.707, F.S., effective Oct. 1, 2013.

<sup>21</sup> 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.<sup>22</sup> 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<sup>23</sup> 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.<sup>24</sup>

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<sup>22</sup> 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).

<sup>23</sup> Chapter 2011-134, L.O.F.

<sup>24</sup> Agency for Health Care Administration, *Medicaid - Long Term Care Home*, [http://ahca.myflorida.com/Medicaid/statewide\\_mc/index.shtml#LTCMC](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.<sup>25</sup> 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:

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<sup>25</sup> 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

12 consultation with the department,

13

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

15 And the title is amended as follows:

16       Delete lines 4 - 6

17 and insert:

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

FOR CONSIDERATION By the Committee on Health Policy

588-03128A-14

20147124\_\_

1 A bill to be entitled  
 2 An act relating to the Program of All-Inclusive Care  
 3 for the Elderly; creating s. 430.84, F.S.; defining  
 4 terms; authorizing the Department of Elderly Affairs,  
 5 in consultation with the Agency for Health Care  
 6 Administration, to contract with specified entities to  
 7 provide benefits pursuant to the Program of All-  
 8 Inclusive Care for the Elderly (PACE); establishing a  
 9 selection process for PACE providers; requiring an  
 10 annual review by the department and the agency and the  
 11 development of legislative recommendations; providing  
 12 requirements for such review and recommendations;  
 13 providing for accountability for PACE providers;  
 14 providing applicability; providing that enrollment in  
 15 PACE is voluntary; establishing PACE plan payments and  
 16 financial responsibility requirements; providing an  
 17 effective date.  
 18  
 19 Be It Enacted by the Legislature of the State of Florida:  
 20  
 21 Section 1. Section 430.84, Florida Statutes, is created to  
 22 read:  
 23 430.84 Program of All-Inclusive Care for the Elderly.—  
 24 (1) DEFINITIONS.—As used in this section, the term:  
 25 (a) "Agency" means the Agency for Health Care  
 26 Administration.  
 27 (b) "Applicant" means an entity that has filed an  
 28 application with the agency for consideration as a Program of  
 29 All-Inclusive Care for the Elderly (PACE) provider.

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

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30 (c) "Department" means the Department of Elderly Affairs.  
 31 (d) "Eligible entity" means a not-for-profit organization  
 32 that is a PACE provider as of May 1, 2014, or an entity licensed  
 33 as a nursing home diversion program provider or a not-for-profit  
 34 hospice provider which meets the requirements for participation  
 35 established by this section and the agency.  
 36 (e) "Enrollee" means an individual receiving services from  
 37 a PACE provider who is eligible under the Medicaid long-term  
 38 managed care program or another health care services program.  
 39 (f) "Provider" means an eligible entity under contract with  
 40 the department to deliver PACE services.  
 41 (2) PROGRAM CREATION.—The department, in consultation with  
 42 the agency, may contract with entities that have submitted an  
 43 application to provide benefits pursuant to PACE as established  
 44 in 42 U.S.C. s. 1395eee in accordance with the requirements of  
 45 this section.  
 46 (3) PROVIDER SELECTION.—Provider eligibility and enrollment  
 47 for PACE shall be conducted through a two-step process developed  
 48 by the agency and the department consistent with the  
 49 requirements of this section for new and existing sites. A PACE  
 50 provider is exempt from the requirements of chapter 641.  
 51 (a) Eligibility confirmation status.—Applications for  
 52 eligibility confirmation status shall be considered on an  
 53 ongoing basis by the agency, in consultation with the  
 54 department. To be considered for funding as a PACE site, an  
 55 eligible entity must receive an eligibility confirmation status  
 56 and be placed on the annual funding priority list by the agency,  
 57 in consultation with the department. For providers in existence  
 58 as of May 1, 2014, the agency shall document the provider's

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

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

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

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

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

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

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

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

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

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

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88 without duplication of services or target populations.

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

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

97 (c) Annual review.—

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

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

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

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



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117 enrollment for each entity; and  
 118 d. The recommended policy changes to the program which  
 119 require statutory modifications.  
 120 2. In developing the recommendations, the agency and  
 121 department shall consider the following factors:  
 122 a. The services being offered or proposed to be offered to  
 123 the frail elderly population by the provider;  
 124 b. The proposed plan of operation for implementation or  
 125 continuation of PACE services;  
 126 c. An outreach plan to potentially eligible enrollees;  
 127 d. The anticipated costs and enrollment projections; and  
 128 e. Any supplemental benefits offered to enrollees.  
 129 (4) ACCOUNTABILITY.—All PACE providers must meet specific  
 130 quality and performance standards established by the department  
 131 for PACE. The department shall monitor each PACE site  
 132 individually and shall mutually develop with each provider  
 133 additional quality and performance standards.  
 134 (5) APPLICABILITY OF LAWS RELATING TO MEDICAID.—Except as  
 135 modified by subsections (3), (6), and (7), ss. 409.967 and  
 136 409.983 apply to the administration of PACE.  
 137 (6) ENROLLMENT.—Enrollment in PACE is voluntary and shall  
 138 be on a first-come, first-served basis until the enrollment cap  
 139 for a provider or region is reached. The agency shall define a  
 140 cap on the number of PACE slots; however, the number of slots  
 141 available statewide may not exceed 3 percent of the total number  
 142 of enrollees in the long-term managed care program.  
 143 (7) PLAN PAYMENTS.—Prepaid payment rates shall be  
 144 negotiated between the PACE provider and the agency as part of  
 145 the application and contract renewal process and shall be

Page 5 of 6

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146 renegotiated each year. Capitation rates and enrollment caps are  
 147 subject to the General Appropriations Act.  
 148 (a) Payment rates must reflect historic utilization and  
 149 spending for covered services projected forward and adjusted to  
 150 reflect the level of care profile for enrollees in each plan.  
 151 (b) The contract between the agency and provider must  
 152 include a lock-in provision that holds the provider financially  
 153 responsible for a designated period of time for any enrollee who  
 154 disenrolls from PACE and subsequently enrolls or transfers to  
 155 nursing home care within the first 6 months after disenrollment.  
 156 (c) Annual capitation rates to providers under PACE may not  
 157 result in an increase to the capitation rate paid under s.  
 158 409.983 to long-term care managed care plans by more than 3  
 159 percent over the prior fiscal year, as certified by the agency's  
 160 chief financial officer.  
 161 Section 2. This act shall take effect July 1, 2014.

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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

Phone 305-762-1386

Miami  
City State Zip

E-mail cbauer

Speaking:  For  Against  Information

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

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*

Phone 727-773-7184

Oldsmar FL 34677  
*City State Zip*

E-mail Stephanie.Sessions@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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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 LAW FLORIDA PACE ASSOCIATION

Address 9470 HEALTHPARK CIRCLE Phone 239.489.9  
Street

FL. MYERS, FL. 33908  
City State Zip

E-mail SAMIRA.BECKWITH@HOPEPACE.ORG

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.

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 All-Inclusive Care for the Elderly

Bill Number SPB 7124  
(if applicable)

Name Richard Polzengin

Amendment Barcode \_\_\_\_\_  
(if applicable)

Job Title Director of Government Affairs

Address 1300 N Duval St

Phone 850 224-4206

Tallahassee FL 32303  
City State Zip

E-mail richardpolzengin@hotmail.com

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.**

**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.)

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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	<b>Favorable</b>
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<sup>1</sup> (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.<sup>2</sup>

**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.<sup>3</sup> The records of the legislative, executive, and judicial branches are specifically included.<sup>4</sup>

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<sup>1</sup> That will be established under s. 456.60, F.S., if SB 1030 passes.

<sup>2</sup> FLA. CONST., art. I, s. 24(c).

<sup>3</sup> FLA. CONST., art. I, s. 24(a).

<sup>4</sup> *Id.*

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

Only the Legislature may create an exemption to public records requirements.<sup>8</sup> Such an exemption must be created by general law and must specifically state the public necessity justifying the exemption.<sup>9</sup> 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<sup>10</sup> and must pass by a two-thirds vote of the members present and voting in each house of the Legislature.<sup>11</sup>

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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

### **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

---

<sup>5</sup> Chapter 119, F.S.

<sup>6</sup> 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)).

<sup>7</sup> Section 119.07(1)(a), F.S.

<sup>8</sup> 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 (*see 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).

<sup>9</sup> FLA. CONST., art. I, s. 24(c).

<sup>10</sup> The bill may, however, contain multiple exemptions that relate to one subject.

<sup>11</sup> FLA. CONST., art. I, s. 24(c).

<sup>12</sup> 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.).

<sup>13</sup> Section 119.15(3), F.S.

<sup>14</sup> 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.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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By Senator Bean

4-02537B-14

20141700\_\_

1 A bill to be entitled  
 2 An act relating to public records; creating s. 456.61,  
 3 F.S.; exempting from public records requirements  
 4 personal identifying information of patients and  
 5 physicians held by the Department of Health in the  
 6 compassionate use registry; exempting information  
 7 related to ordering and dispensing low-THC marijuana;  
 8 authorizing specified persons and entities access to  
 9 the exempt information; requiring that information  
 10 released from the registry remain confidential;  
 11 providing a criminal penalty; providing for future  
 12 legislative review and repeal; providing a statement  
 13 of public necessity; providing a contingent effective  
 14 date.

15  
 16 Be It Enacted by the Legislature of the State of Florida:

17  
 18 Section 1. Section 456.61, Florida Statutes, is created to  
 19 read:

20 456.61 Public records exemption for personal identifying  
 21 information in the compassionate use registry.—

22 (1) A patient's personal identifying information held by  
 23 the department in the compassionate use registry established  
 24 under s. 456.60, including, but not limited to, the patient's  
 25 name, address, telephone number, and government-issued  
 26 identification number, and all information pertaining to the  
 27 physician's order for low-THC marijuana and the dispensing  
 28 thereof are confidential and exempt from s. 119.07(1) and s.  
 29 24(a), Art. I of the State Constitution.

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

4-02537B-14

20141700\_\_

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

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

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

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

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

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

Page 2 of 5

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

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

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

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

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

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

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

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

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

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

92 Section 2. The Legislature finds that it is a public  
93 necessity that identifying information of patients and  
94 physicians held by the Department of Health in the compassionate  
95 use registry established under s. 456.60, Florida Statutes, be  
96 made confidential and exempt from s. 119.07(1), Florida  
97 Statutes, and s. 24(a), Article I of the State Constitution.  
98 Specifically, the Legislature finds that it is a public  
99 necessity to make confidential and exempt from public records  
100 requirements the names, addresses, telephone numbers, and  
101 government-issued identification numbers of patients and  
102 physicians and any other information on or pertaining to a  
103 physician's order for low-THC marijuana written pursuant to s.  
104 456.60, Florida Statutes, which are held in the registry. The  
105 choice made by a physician and his or her patient to use low-THC  
106 marijuana to treat that patient's medical condition or symptoms  
107 is a personal and private matter between those two parties. The  
108 availability of such information to the public could make the  
109 public aware of both the patient's use of low-THC marijuana and  
110 the patient's diseases or other medical conditions for which the  
111 patient is using low-THC marijuana. The knowledge of the  
112 patient's use of low-THC marijuana, the knowledge that the  
113 physician ordered the use of low-THC marijuana, and the  
114 knowledge of the patient's medical condition could be used to  
115 embarrass, humiliate, harass, or discriminate against the  
116 patient and the physician. This information could be used as a

4-02537B-14

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

130 Section 3. This act shall take effect on the same date that  
131 SB 1030, or similar legislation establishing an electronic  
132 system to record a physician's orders for, and a patient's use  
133 of, low-THC marijuana takes effect, if such legislation is  
134 adopted in the same legislative session or an extension thereof  
135 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

321 890 7302 @

Address 1375 Cypress Ave

Phone 321 253 3673

Street

MELBOURNE FL 32935

City

State

Zip

E-mail jamesflorida@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.

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.)

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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.	<u>Niles</u>	<u>Imhof</u>	<u>RI</u>	<b>Fav/CS</b>
2.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<b>Fav/CS</b>

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**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<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> A medical gas retail establishment permit is required for any person who sells medical oxygen to patients only.<sup>4</sup> Permit holders are overseen by the department under the Division of Drugs, Devices and Cosmetics.

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<sup>1</sup> 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.

<sup>2</sup>Florida Department of Business and Professional Regulation, *Compressed Medical Gas Wholesale Distributor*, [www.myfloridalicense.com/department/ddc/CompressedMedicalGasesWholesaleDistributor.html](http://www.myfloridalicense.com/department/ddc/CompressedMedicalGasesWholesaleDistributor.html) (Last visited Mar. 21, 2014).

<sup>3</sup> Florida Department of Business and Professional Regulation, *Compressed Medical Gas Manufacturer*, [www.myfloridalicense.com/department/ddc/CompressedMedicalGasesManufacturer.html](http://www.myfloridalicense.com/department/ddc/CompressedMedicalGasesManufacturer.html) (Last visited Mar. 21, 2014).

<sup>4</sup> 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.<sup>5</sup> Their mission is to promote safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers.<sup>6</sup> 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.<sup>7</sup> The association defines industrial and medical gases as liquefied, nonliquefied, dissolved, or cryogenic gases.<sup>8</sup>

### **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

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<sup>5</sup> Compressed Gas Association, *About Us*, <http://www.cganet.com/about.php> (Last visited April 2, 2014).

<sup>6</sup> Compressed Gas Association, *CGA Mission*, <http://www.cganet.com/mission.php> (last visited April 2, 2014).

<sup>7</sup> *Id.*

<sup>8</sup> *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.<sup>9</sup> 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<sup>10</sup> medical gas and distributing such medical gas within this state. A medical gas manufacturer:

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<sup>9</sup> 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.

<sup>10</sup>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<sup>11</sup> 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.<sup>12</sup>

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

<sup>11</sup> 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.

<sup>12</sup> *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).<sup>13</sup>

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.

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<sup>13</sup> 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, barter, 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.<sup>14</sup>

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.<sup>15</sup>

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

The definition of “adulteration” in the bill does not include transfer or possession by an unauthorized source.<sup>16</sup> Generally under the current law, if an unauthorized person holds, transfers, purchases, or sells a prescription drug, that drug becomes adulterated.<sup>17</sup> 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.<sup>18</sup> The bill may reduce the incentive of providers to verify current prescriptions before making deliveries.<sup>19</sup>

**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:

<sup>14</sup> Department of Business and Professional Regulation, *Senate Bill 836 Legislative Bill Analysis* (Feb. 21, 2014) (on file with the Senate Committee on Health Policy).

<sup>15</sup> *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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12 renumbered as subsections (11) through (31) and subsections (46)  
13 through (54), respectively, and present subsections (11), (43),  
14 and (46) of that section are amended, to read:

15 499.003 Definitions of terms used in this part.—As used in  
16 this part, the term:

17 (32) ~~(11)~~ “~~Compressed~~ Medical gas” means any liquefied or  
18 vaporized gas that is a prescription drug, whether ~~it is~~ alone  
19 or in combination with other gases, and as defined in the  
20 federal act.

21 (43) “Prescription drug” means a prescription, medicinal,  
22 or legend drug, including, but not limited to, finished dosage  
23 forms or active pharmaceutical ingredients subject to, defined  
24 by, or described by s. 503(b) of the federal ~~Food, Drug, and~~  
25 ~~Cosmetic~~ act or s. 465.003(8), s. 499.007(13), ~~or~~ subsection  
26 (32) ~~(11)~~, ~~subsection (46)~~, or subsection (52) ~~(53)~~, except that  
27 an active pharmaceutical ingredient is a prescription drug only  
28 if substantially all finished dosage forms in which it may be  
29 lawfully dispensed or administered in this state are also  
30 prescription drugs.

31 ~~(46) “Prescription medical oxygen” means oxygen USP which~~  
32 ~~is a drug that can only be sold on the order or prescription of~~  
33 ~~a practitioner authorized by law to prescribe. The label of~~  
34 ~~prescription medical oxygen must comply with current labeling~~  
35 ~~requirements for oxygen under the Federal Food, Drug, and~~  
36 ~~Cosmetic Act.~~

37 Section 3. Subsection (1), paragraphs (a), (c), (g), (m),  
38 (n), and (o) of subsection (2), and subsection (5) of section  
39 499.01, Florida Statutes, are amended to read:

40 499.01 Permits.—



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- 41 (1) Prior to operating, a permit is required for each  
42 person and establishment that intends to operate as:
- 43 (a) A prescription drug manufacturer;
  - 44 (b) A prescription drug repackager;
  - 45 (c) A nonresident prescription drug manufacturer;
  - 46 (d) A prescription drug wholesale distributor;
  - 47 (e) An out-of-state prescription drug wholesale  
48 distributor;
  - 49 (f) A retail pharmacy drug wholesale distributor;
  - 50 (g) A restricted prescription drug distributor;
  - 51 (h) A complimentary drug distributor;
  - 52 (i) A freight forwarder;
  - 53 (j) A veterinary prescription drug retail establishment;
  - 54 (k) A veterinary prescription drug wholesale distributor;
  - 55 (l) A limited prescription drug veterinary wholesale  
56 distributor;
  - 57 ~~(m) A medical oxygen retail establishment;~~
  - 58 ~~(n) A compressed medical gas wholesale distributor;~~
  - 59 ~~(o) A compressed medical gas manufacturer;~~
  - 60 (m)~~(p)~~ An over-the-counter drug manufacturer;
  - 61 (n)~~(q)~~ A device manufacturer;
  - 62 (o)~~(r)~~ A cosmetic manufacturer;
  - 63 (p)~~(s)~~ A third party logistics provider; or
  - 64 (q)~~(t)~~ A health care clinic establishment.
- 65 (2) The following permits are established:
- 66 (a) *Prescription drug manufacturer permit.*—A prescription  
67 drug manufacturer permit is required for any person that is a  
68 manufacturer of a prescription drug and that manufactures or  
69 distributes such prescription drugs in this state.



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

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

79           3. A blood establishment, as defined in s. 381.06014,  
80 operating in a manner consistent with the provisions of 21  
81 C.F.R. parts 211 and 600-640, and manufacturing only the  
82 prescription drugs described in s. 499.003(53)(d) ~~s.~~  
83 ~~499.003(54)(d)~~ is not required to be permitted as a prescription  
84 drug manufacturer under this paragraph or to register products  
85 under s. 499.015.

86           (c) *Nonresident prescription drug manufacturer permit.*—A  
87 nonresident prescription drug manufacturer permit is required  
88 for any person that is a manufacturer of prescription drugs,  
89 unless permitted as a third party logistics provider, located  
90 outside of this state or outside the United States and that  
91 engages in the wholesale distribution in this state of such  
92 prescription drugs. Each such manufacturer must be permitted by  
93 the department and comply with all of the provisions required of  
94 a wholesale distributor under this part, except s. 499.01212.

95           1. A person that distributes prescription drugs for which  
96 the person is not the manufacturer must also obtain an out-of-  
97 state prescription drug wholesale distributor permit or third  
98 party logistics provider permit pursuant to this section to



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99 engage in the wholesale distribution of such prescription drugs.  
100 This subparagraph does not apply to a manufacturer as defined in  
101 s. 499.003(30)(e) ~~s. 499.003(31)(e)~~.

102 2. Any such person must comply with the licensing or  
103 permitting requirements of the jurisdiction in which the  
104 establishment is located and the federal act, and any product  
105 wholesaled into this state must comply with this part. If a  
106 person intends to import prescription drugs from a foreign  
107 country into this state, the nonresident prescription drug  
108 manufacturer must provide to the department a list identifying  
109 each prescription drug it intends to import and document  
110 approval by the United States Food and Drug Administration for  
111 such importation.

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

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

115 a. Any person located in this state who engages in the  
116 distribution of a prescription drug, which distribution is not  
117 considered "wholesale distribution" under s. 499.003(53)(a) ~~s.~~  
118 ~~499.003(54)(a)~~.

119 b. Any person located in this state who engages in the  
120 receipt or distribution of a prescription drug in this state for  
121 the purpose of processing its return or its destruction if such  
122 person is not the person initiating the return, the prescription  
123 drug wholesale supplier of the person initiating the return, or  
124 the manufacturer of the drug.

125 c. A blood establishment located in this state which  
126 collects blood and blood components only from volunteer donors  
127 as defined in s. 381.06014 or pursuant to an authorized



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128 practitioner's order for medical treatment or therapy and  
129 engages in the wholesale distribution of a prescription drug not  
130 described in s. 499.003(53)(d) ~~s. 499.003(54)(d)~~ to a health  
131 care entity. A mobile blood unit operated by a blood  
132 establishment permitted under this sub-subparagraph is not  
133 required to be separately permitted. The health care entity  
134 receiving a prescription drug distributed under this sub-  
135 subparagraph must be licensed as a closed pharmacy or provide  
136 health care services at that establishment. The blood  
137 establishment must operate in accordance with s. 381.06014 and  
138 may distribute only:

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

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

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

145 (IV) Prescription drugs that are identified in rules  
146 adopted by the department and that are essential to services  
147 performed or provided by blood establishments and authorized for  
148 distribution by blood establishments under federal law; or

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



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157  
158 as long as all of the health care services provided by the blood  
159 establishment are related to its activities as a registered  
160 blood establishment or the health care services consist of  
161 collecting, processing, storing, or administering human  
162 hematopoietic stem cells or progenitor cells or performing  
163 diagnostic testing of specimens if such specimens are tested  
164 together with specimens undergoing routine donor testing. The  
165 blood establishment may purchase and possess the drugs described  
166 in this sub-subparagraph without a health care clinic  
167 establishment permit.

168         2. Storage, handling, and recordkeeping of these  
169 distributions by a person required to be permitted as a  
170 restricted prescription drug distributor must be in accordance  
171 with the requirements for wholesale distributors under s.  
172 499.0121, but not those set forth in s. 499.01212 if the  
173 distribution occurs pursuant to sub-subparagraph 1.a. or sub-  
174 subparagraph 1.b.

175         3. A person who applies for a permit as a restricted  
176 prescription drug distributor, or for the renewal of such a  
177 permit, must provide to the department the information required  
178 under s. 499.012.

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

185         ~~(m) Medical oxygen retail establishment permit. A medical~~





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186 ~~oxygen retail establishment permit is required for any person~~  
187 ~~that sells medical oxygen to patients only. The sale must be~~  
188 ~~based on an order from a practitioner authorized by law to~~  
189 ~~prescribe. The term does not include a pharmacy licensed under~~  
190 ~~chapter 465.~~

191 ~~1. A medical oxygen retail establishment may not possess,~~  
192 ~~purchase, sell, or trade any prescription drug other than~~  
193 ~~medical oxygen.~~

194 ~~2. A medical oxygen retail establishment may refill medical~~  
195 ~~oxygen for an individual patient based on an order from a~~  
196 ~~practitioner authorized by law to prescribe. A medical oxygen~~  
197 ~~retail establishment that refills medical oxygen must comply~~  
198 ~~with all appropriate state and federal good manufacturing~~  
199 ~~practices.~~

200 ~~3. A medical oxygen retail establishment must comply with~~  
201 ~~all of the wholesale distribution requirements of s. 499.0121.~~

202 ~~4. Prescription medical oxygen sold by a medical oxygen~~  
203 ~~retail establishment pursuant to a practitioner's order may not~~  
204 ~~be returned into the retail establishment's inventory.~~

205 ~~(n) Compressed medical gas wholesale distributor permit. A~~  
206 ~~compressed medical gas wholesale distributor is a wholesale~~  
207 ~~distributor that is limited to the wholesale distribution of~~  
208 ~~compressed medical gases to other than the consumer or patient.~~  
209 ~~The compressed medical gas must be in the original sealed~~  
210 ~~container that was purchased by that wholesale distributor. A~~  
211 ~~compressed medical gas wholesale distributor may not possess or~~  
212 ~~engage in the wholesale distribution of any prescription drug~~  
213 ~~other than compressed medical gases. The department shall adopt~~  
214 ~~rules that govern the wholesale distribution of prescription~~



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215 ~~medical oxygen for emergency use. With respect to the emergency~~  
216 ~~use of prescription medical oxygen, those rules may not be~~  
217 ~~inconsistent with rules and regulations of federal agencies~~  
218 ~~unless the Legislature specifically directs otherwise.~~

219 ~~(e) Compressed medical gas manufacturer permit. A~~  
220 ~~compressed medical gas manufacturer permit is required for any~~  
221 ~~person that engages in the manufacture of compressed medical~~  
222 ~~gases or repackages compressed medical gases from one container~~  
223 ~~to another.~~

224 ~~1. A compressed medical gas manufacturer may not~~  
225 ~~manufacture or possess any prescription drug other than~~  
226 ~~compressed medical gases.~~

227 ~~2. A compressed medical gas manufacturer may engage in~~  
228 ~~wholesale distribution of compressed medical gases manufactured~~  
229 ~~at that establishment and must comply with all the provisions of~~  
230 ~~this part and the rules adopted under this part that apply to a~~  
231 ~~wholesale distributor.~~

232 ~~3. A compressed medical gas manufacturer must comply with~~  
233 ~~all appropriate state and federal good manufacturing practices.~~

234 (5) A prescription drug repackager permit issued under this  
235 part is not required for a restricted prescription drug  
236 distributor permitholder that is a health care entity to  
237 repackage prescription drugs in this state for its own use or  
238 for distribution to hospitals or other health care entities in  
239 the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s.~~  
240 ~~499.003(54)(a)3.~~, if:

241 (a) The prescription drug distributor notifies the  
242 department, in writing, of its intention to engage in  
243 repackaging under this exemption, 30 days before engaging in the



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244 repackaging of prescription drugs at the permitted  
245 establishment;

246 (b) The prescription drug distributor is under common  
247 control with the hospitals or other health care entities to  
248 which the prescription drug distributor is distributing  
249 prescription drugs. As used in this paragraph, "common control"  
250 means the power to direct or cause the direction of the  
251 management and policies of a person or an organization, whether  
252 by ownership of stock, voting rights, contract, or otherwise;

253 (c) The prescription drug distributor repackages the  
254 prescription drugs in accordance with current state and federal  
255 good manufacturing practices; and

256 (d) The prescription drug distributor labels the  
257 prescription drug it repackages in accordance with state and  
258 federal laws and rules.

259  
260 The prescription drug distributor is exempt from the product  
261 registration requirements of s. 499.015 with regard to the  
262 prescription drugs that it repackages and distributes under this  
263 subsection.

264 Section 4. Paragraph (b) of subsection (2) of section  
265 499.0121, Florida Statutes, is amended to read:

266 499.0121 Storage and handling of prescription drugs;  
267 recordkeeping.—The department shall adopt rules to implement  
268 this section as necessary to protect the public health, safety,  
269 and welfare. Such rules shall include, but not be limited to,  
270 requirements for the storage and handling of prescription drugs  
271 and for the establishment and maintenance of prescription drug  
272 distribution records.



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273 (2) SECURITY.—

274 (b) An establishment that is used for wholesale drug  
275 distribution must be equipped with:

276 1. An alarm system to detect entry after hours; however,  
277 the department may exempt by rule establishments that only hold  
278 a permit as prescription drug wholesale distributor-brokers. ~~and~~  
279 ~~establishments that only handle medical oxygen; and~~

280 2. A security system that will provide suitable protection  
281 against theft and diversion. When appropriate, the security  
282 system must provide protection against theft or diversion that  
283 is facilitated or hidden by tampering with computers or  
284 electronic records.

285 Section 5. Subsections (1) and (2) of section 499.01211,  
286 Florida Statutes, are amended to read:

287 499.01211 Drug Wholesale Distributor Advisory Council.—

288 (1) There is created the Drug Wholesale Distributor  
289 Advisory Council within the department. The council shall meet  
290 at least once each calendar quarter. Staff for the council shall  
291 be provided by the department. The council shall consist of 12  
292 ~~11~~ members who shall serve without compensation. The council  
293 shall elect a chairperson and a vice chairperson annually.

294 (2) The Secretary of Business and Professional Regulation  
295 or his or her designee and the Secretary of Health Care  
296 Administration or her or his designee shall be members of the  
297 council. The Secretary of Business and Professional Regulation  
298 shall appoint 10 ~~nine~~ additional members to the council who  
299 shall be appointed to a term of 4 years each, as follows:

300 (a) Three ~~different~~ persons, each of whom is employed by a  
301 different prescription drug wholesale distributor permitted



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302 ~~licensed~~ under this part which operates nationally and is a  
303 primary wholesale distributor, as defined in s. 499.003 ~~s.~~  
304 ~~499.003(47)~~.

305 (b) One person employed by a prescription drug wholesale  
306 distributor permitted ~~licensed~~ under this part which is a  
307 secondary wholesale distributor, as defined in s. 499.003 ~~s.~~  
308 ~~499.003(52)~~.

309 (c) One person employed by a retail pharmacy chain located  
310 in this state.

311 (d) One person who is a member of the Board of Pharmacy and  
312 is a pharmacist licensed under chapter 465.

313 (e) One person who is a physician licensed pursuant to  
314 chapter 458 or chapter 459.

315 (f) One person who is an employee of a hospital licensed  
316 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
317 chapter 465.

318 (g) One person who is an employee of a pharmaceutical  
319 manufacturer.

320 (h) One person who is an employee of a permitted medical  
321 gas manufacturer or medical gas wholesale distributor and who  
322 has been recommended by the Compressed Gas Association.

323 Section 6. Paragraph (e) of subsection (1), paragraph (b)  
324 of subsection (2), and paragraph (b) of subsection (3) of  
325 section 499.041, Florida Statutes, are amended to read:

326 499.041 Schedule of fees for drug, device, and cosmetic  
327 applications and permits, product registrations, and free-sale  
328 certificates.—

329 (1) The department shall assess applicants requiring a  
330 manufacturing permit an annual fee within the ranges established



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331 in this section for the specific type of manufacturer.

332 ~~(c) The fee for a compressed medical gas manufacturer~~  
333 ~~permit may not be less than \$400 or more than \$500 annually.~~

334 (2) The department shall assess an applicant that is  
335 required to have a wholesaling permit an annual fee within the  
336 ranges established in this section for the specific type of  
337 wholesaling.

338 ~~(b) The fee for a compressed medical gas wholesale~~  
339 ~~distributor permit may not be less than \$200 or more than \$300~~  
340 ~~annually.~~

341 (3) The department shall assess an applicant that is  
342 required to have a retail establishment permit an annual fee  
343 within the ranges established in this section for the specific  
344 type of retail establishment.

345 ~~(b) The fee for a medical oxygen retail establishment~~  
346 ~~permit may not be less than \$200 or more than \$300 annually.~~

347 Section 7. Section 499.05, Florida Statutes, is amended to  
348 read:

349 499.05 Rules.—

350 (1) The department shall adopt rules to implement and  
351 enforce this chapter part with respect to:

352 (a) The definition of terms used in this chapter part, and  
353 used in the rules adopted under this chapter part, when the use  
354 of the term is not its usual and ordinary meaning.

355 (b) Labeling requirements for drugs, devices, and  
356 cosmetics.

357 (c) The establishment of fees authorized in this chapter  
358 part.

359 (d) The identification of permits that require an initial



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360 application and onsite inspection or other prerequisites for  
361 permitting which demonstrate that the establishment and person  
362 are in compliance with the requirements of this chapter part.

363 (e) The application processes and forms for product  
364 registration.

365 (f) Procedures for requesting and issuing certificates of  
366 free sale.

367 (g) Inspections and investigations conducted under s.  
368 499.051 or s. 499.93 ~~s. 499.051~~, and the identification of  
369 information claimed to be a trade secret and exempt from the  
370 public records law as provided in s. 499.051(7).

371 (h) The establishment of a range of penalties, as provided  
372 in s. 499.066; requirements for notifying persons of the  
373 potential impact of a violation of this chapter part; and a  
374 process for the uncontested settlement of alleged violations.

375 (i) Additional conditions that qualify as an emergency  
376 medical reason under s. 499.003(53)(b)2. or s. 499.82 ~~s.~~  
377 ~~499.003(54)(b)2.~~

378 (j) Procedures and forms relating to the pedigree paper  
379 requirement of s. 499.01212.

380 (k) The protection of the public health, safety, and  
381 welfare regarding good manufacturing practices that  
382 manufacturers and repackagers must follow to ensure the safety  
383 of the products.

384 (l) Information required from each retail establishment  
385 pursuant to s.499.012(3) or s 499.83(2)(c) ~~s. 499.012(3)~~,  
386 including requirements for prescriptions or orders.

387 (m) The recordkeeping, storage, and handling with respect  
388 to each of the distributions of prescription drugs specified in



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389 s. 499.003(53)(a)-(d) or s. 499.82(14) ~~s. 499.003(54)(a)-(d).~~

390 (n) Alternatives to compliance with s. 499.01212 for a  
391 prescription drug in the inventory of a permitted prescription  
392 drug wholesale distributor as of June 30, 2006, and the return  
393 of a prescription drug purchased prior to July 1, 2006. The  
394 department may specify time limits for such alternatives.

395 (o) Wholesale distributor reporting requirements of s.  
396 499.0121(14).

397 (p) Wholesale distributor credentialing and distribution  
398 requirements of s. 499.0121(15).

399 (2) With respect to products in interstate commerce, those  
400 rules must not be inconsistent with rules and regulations of  
401 federal agencies unless specifically otherwise directed by the  
402 Legislature.

403 (3) The department shall adopt rules regulating  
404 recordkeeping for and the storage, handling, and distribution of  
405 medical devices and over-the-counter drugs to protect the public  
406 from adulterated products.

407 Section 8. Subsections (1) through (4) of section 499.051,  
408 Florida Statutes, are amended to read:

409 499.051 Inspections and investigations.—

410 (1) The agents of the department and of the Department of  
411 Law Enforcement, after they present proper identification, may  
412 inspect, monitor, and investigate any establishment permitted  
413 pursuant to this chapter part during business hours for the  
414 purpose of enforcing this chapter part, chapters 465, 501, and  
415 893, and the rules of the department that protect the public  
416 health, safety, and welfare.

417 (2) In addition to the authority set forth in subsection





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418 (1), the department and any duly designated officer or employee  
419 of the department may enter and inspect any other establishment  
420 for the purpose of determining compliance with this chapter part  
421 and rules adopted under this chapter part regarding any drug,  
422 device, or cosmetic product.

423 (3) Any application for a permit or product registration or  
424 for renewal of such permit or registration made pursuant to this  
425 chapter part and rules adopted under this chapter part  
426 constitutes permission for any entry or inspection of the  
427 premises in order to verify compliance with this chapter part  
428 and rules; to discover, investigate, and determine the existence  
429 of compliance; or to elicit, receive, respond to, and resolve  
430 complaints and violations.

431 (4) Any application for a permit made pursuant to s.  
432 499.012 or s. 499.831 and rules adopted under those sections  
433 ~~that section~~ constitutes permission for agents of the department  
434 and the Department of Law Enforcement, after presenting proper  
435 identification, to inspect, review, and copy any financial  
436 document or record related to the manufacture, repackaging, or  
437 distribution of a drug as is necessary to verify compliance with  
438 this chapter part and the rules adopted by the department to  
439 administer this chapter part, in order to discover, investigate,  
440 and determine the existence of compliance, or to elicit,  
441 receive, respond to, and resolve complaints and violations.

442 Section 9. Subsections (1) through (4) of section 499.066,  
443 Florida Statutes, are amended to read:

444 499.066 Penalties; remedies.—In addition to other penalties  
445 and other enforcement provisions:

446 (1) The department may institute such suits or other legal



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447 proceedings as are required to enforce any provision of this  
448 chapter part. If it appears that a person has violated any  
449 provision of this chapter part for which criminal prosecution is  
450 provided, the department may provide the appropriate state  
451 attorney or other prosecuting agency having jurisdiction with  
452 respect to such prosecution with the relevant information in the  
453 department's possession.

454 (2) If any person engaged in any activity covered by this  
455 chapter part violates any provision of this chapter part, any  
456 rule adopted under this chapter part, or a cease and desist  
457 order as provided by this chapter part, the department may  
458 obtain an injunction in the circuit court of the county in which  
459 the violation occurred or in which the person resides or has its  
460 principal place of business, and may apply in that court for  
461 such temporary and permanent orders as the department considers  
462 necessary to restrain the person from engaging in any such  
463 activities until the person complies with this chapter part, the  
464 rules adopted under this chapter part, and the orders of the  
465 department authorized by this chapter part or to mandate  
466 compliance with this chapter part, the rules adopted under this  
467 chapter part, and any order or permit issued by the department  
468 under this chapter part.

469 (3) The department may impose an administrative fine, not  
470 to exceed \$5,000 per violation per day, for the violation of any  
471 provision of this chapter part or rules adopted under this  
472 chapter part. Each day a violation continues constitutes a  
473 separate violation, and each separate violation is subject to a  
474 separate fine. All amounts collected pursuant to this section  
475 shall be deposited into the Professional Regulation Trust Fund



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476 and are appropriated for the use of the department in  
477 administering this chapter part. In determining the amount of  
478 the fine to be levied for a violation, the department shall  
479 consider:

480 (a) The severity of the violation;

481 (b) Any actions taken by the person to correct the  
482 violation or to remedy complaints; and

483 (c) Any previous violations.

484 (4) The department shall deposit any rewards, fines, or  
485 collections that are due the department and which derive from  
486 joint enforcement activities with other state and federal  
487 agencies which relate to this chapter part, chapter 893, or the  
488 federal act, into the Professional Regulation Trust Fund. The  
489 proceeds of those rewards, fines, and collections are  
490 appropriated for the use of the department in administering this  
491 chapter part.

492 Section 10. Paragraph (a) of subsection (1) and paragraph  
493 (a) of subsection (2) of section 499.0661, Florida Statutes, are  
494 amended to read:

495 499.0661 Cease and desist orders; removal of certain  
496 persons.—

497 (1) CEASE AND DESIST ORDERS.—

498 (a) In addition to any authority otherwise provided in this  
499 chapter, the department may issue and serve a complaint stating  
500 charges upon a any permittee or upon an any affiliated party,  
501 whenever the department has reasonable cause to believe that the  
502 person or individual named therein is engaging in or has engaged  
503 in conduct that is:

504 1. An act that demonstrates a lack of fitness or



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505 trustworthiness to engage in the business authorized under the  
506 permit issued pursuant to this chapter part, is hazardous to the  
507 public health, or constitutes business operations that are a  
508 detriment to the public health;

- 509 2. A violation of a any provision of this chapter part;
- 510 3. A violation of a any rule of the department;
- 511 4. A violation of an any order of the department; or
- 512 5. A breach of a any written agreement with the department.

513 (2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

514 (a) The department may issue and serve a complaint stating  
515 charges upon an any affiliated party and upon the permittee  
516 involved whenever the department has reason to believe that an  
517 affiliated party is engaging in or has engaged in conduct that  
518 constitutes:

519 1. An act that demonstrates a lack of fitness or  
520 trustworthiness to engage in the business authorized under the  
521 permit issued pursuant to this chapter part, is hazardous to the  
522 public health, or constitutes business operations that are a  
523 detriment to the public health;

524 2. A willful violation of this chapter part; however, if  
525 the violation constitutes a misdemeanor, a complaint may not be  
526 served as provided in this section until the affiliated party is  
527 notified in writing of the matter of the violation and has been  
528 afforded a reasonable period of time, as set forth in the  
529 notice, to correct the violation and has failed to do so;

530 3. A violation of a any other law involving fraud or moral  
531 turpitude which constitutes a felony;

532 4. A willful violation of a any rule of the department;

533 5. A willful violation of an any order of the department;



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534 or

535 6. A material misrepresentation of fact, made knowingly and  
536 willfully or made with reckless disregard for the truth of the  
537 matter.

538 Section 11. Section 499.067, Florida Statutes, is amended  
539 to read:

540 499.067 Denial, suspension, or revocation of permit,  
541 certification, or registration.—

542 (1)(a) The department may deny, suspend, or revoke a permit  
543 if it finds that there has been a substantial failure to comply  
544 with this chapter ~~part~~ or chapter 465, chapter 501, or chapter  
545 893, the rules adopted under ~~this part~~ or those chapters, any  
546 final order of the department, or applicable federal laws or  
547 regulations or other state laws or rules governing drugs,  
548 devices, or cosmetics.

549 (b) The department may deny an application for a permit or  
550 certification, or suspend or revoke a permit or certification,  
551 if the department finds that:

552 1. The applicant is not of good moral character or that it  
553 would be a danger or not in the best interest of the public  
554 health, safety, and welfare if the applicant were issued a  
555 permit or certification.

556 2. The applicant has not met the requirements for the  
557 permit or certification.

558 3. The applicant is not eligible for a permit or  
559 certification for any of the reasons enumerated in s. 499.012.

560 4. The applicant, permittee, or person certified under s.  
561 499.012(16) demonstrates any of the conditions enumerated in s.  
562 499.012.



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563           5. The applicant, permittee, or person certified under s.  
564 499.012(16) has committed any violation of this chapter ~~ss.~~  
565 ~~499.005-499.0054~~.

566           (2) The department may deny, suspend, or revoke any  
567 registration required by ~~the provisions of~~ this chapter part for  
568 the violation of any provision of this chapter part or of any  
569 rules adopted under this chapter part.

570           (3) The department may revoke or suspend a permit:

571           (a) If the permit was obtained by misrepresentation or  
572 fraud or through a mistake of the department;

573           (b) If the permit was procured, or attempted to be  
574 procured, for any other person by making or causing to be made  
575 any false representation; or

576           (c) If the permittee has violated ~~any provision of~~ this  
577 chapter part or rules adopted under this chapter part.

578           (4) If a ~~any~~ permit issued under this chapter part is  
579 revoked or suspended, the owner, manager, operator, or  
580 proprietor of the establishment shall cease to operate as the  
581 permit authorized, from the effective date of the suspension or  
582 revocation until the person is again registered with the  
583 department and possesses the required permit. If a permit is  
584 revoked or suspended, the owner, manager, or proprietor shall  
585 remove all signs and symbols that identify the operation as  
586 premises permitted as a drug wholesaling establishment; drug,  
587 device, or cosmetic manufacturing establishment; or retail  
588 establishment. The department shall determine the length of time  
589 for which the permit is to be suspended. If a permit is revoked,  
590 the person that owns or operates the establishment may not apply  
591 for a ~~any~~ permit under this chapter part for a period of 1 year



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592 after the date of the revocation. A revocation of a permit may  
593 be permanent if the department considers that to be in the best  
594 interest of the public health.

595 (5) The department may deny, suspend, or revoke a permit  
596 issued under this part which authorizes the permittee to  
597 purchase prescription drugs if an ~~any~~ owner, officer, employee,  
598 or other person who participates in administering or operating  
599 the establishment has been found guilty of a ~~any~~ violation of  
600 this chapter part or chapter 465, chapter 501, or chapter 893,  
601 any rules adopted under ~~this part~~ or those chapters, or any  
602 federal or state drug law, regardless of whether the person has  
603 been pardoned, had her or his civil rights restored, or had  
604 adjudication withheld.

605 (6) The department shall deny, suspend, or revoke the  
606 permit of a ~~any~~ person or establishment if the assignment, sale,  
607 transfer, or lease of an establishment permitted under this  
608 chapter part will avoid an administrative penalty, civil action,  
609 or criminal prosecution.

610 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
611 comply with s. 499.012(6) or s. 499.833, as applicable, the  
612 department may revoke the permit of the permittee and shall  
613 provide notice of the intended agency action by posting a notice  
614 at the department's headquarters and by mailing a copy of the  
615 notice of intended agency action by certified mail to the most  
616 recent mailing address on record with the department and, if the  
617 permittee is not a natural person, to the permittee's registered  
618 agent on file with the Department of State.

619 (8) The department may deny, suspend, or revoke a permit  
620 under this part if it finds the permittee has not complied with



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621 the credentialing requirements of s. 499.0121(15).

622 (9) The department may deny, suspend, or revoke a permit  
623 under this part if it finds the permittee has not complied with  
624 the reporting requirements of, or knowingly made a false  
625 statement in a report required by, s. 499.0121(14).

626 Section 12. Part III of chapter 499, Florida Statutes,  
627 consisting of ss. 499.81-499.94, Florida Statutes, is created  
628 and entitled "Medical Gas."

629 Section 13. Section 499.81, Florida Statutes, is created to  
630 read:

631 499.81 Administration and enforcement.-

632 (1) This part is cumulative and shall be construed and  
633 applied as being in addition to, and not in substitution for or  
634 limiting any powers, duties, or authority of the department  
635 under any other law of this state; except that, with respect to  
636 the regulation of medical gas, this part controls over any  
637 conflicting provisions.

638 (2) The department shall administer and enforce this part  
639 to prevent fraud, adulteration, misbranding, or false  
640 advertising in the manufacture and distribution of medical  
641 gases.

642 (3) For the purpose of an investigation or proceeding  
643 conducted by the department under this part, the department may  
644 administer oaths, take depositions, subpoena witnesses, and  
645 compel the production of books, papers, documents, or other  
646 records. Challenges to, and enforcement of, subpoenas and orders  
647 shall be handled as provided in s. 120.569.

648 (4) Each state attorney, county attorney, or municipal  
649 attorney to whom the department or its designated agent reports





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650 a violation of this part shall cause appropriate proceedings to  
651 be instituted in the proper courts without delay and prosecuted  
652 as required by law.

653 (5) This part does not require the department to report,  
654 for the purpose of instituting proceedings under this part,  
655 minor violations of this part when the department believes that  
656 the public interest will be adequately served by a written  
657 notice or warning.

658 Section 14. Section 499.82, Florida Statutes, is created to  
659 read:

660 499.82 Definitions.—As used in this part, the term:

661 (1) "Adulterated," means a medical gas that:

662 (a) Consists, in whole or in part, of impurities or  
663 deleterious substances exceeding normal specifications;

664 (b) Is produced, prepared, packed, or held under conditions  
665 whereby the medical gas may have been contaminated causing it to  
666 be rendered injurious to health; or if the methods used in, or  
667 the facilities or controls used for, its manufacture,  
668 processing, packing, or holding do not conform to or are not  
669 operated or administered in conformity with current good  
670 manufacturing practices to ensure that the medical gas meets the  
671 requirements of this part as to safety and has the identity and  
672 strength and meets the quality and purity characteristics that  
673 the medical gas is represented to possess;

674 (c) Is held in a container with an interior that is  
675 composed in whole or in part of a poisonous or deleterious  
676 substance that may render the contents injurious to health; or

677 (d) Is represented as having a strength differing from, or  
678 quality or purity falling below, the standard set forth in the



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679 USP-NF. A medical gas defined in USP-NF may not be deemed to be  
680 adulterated under this paragraph merely because it differs from  
681 the standard of strength, quality, or purity set forth in the  
682 USP-NF if its difference in strength, quality, or purity from  
683 that standard is plainly stated on its label. The determination  
684 as to strength, quality, or purity shall be made:

685 1. In accordance with the tests or methods of assay in the  
686 USP-NF or its validated equivalent; or

687 2. In the absence or inadequacy of such tests or methods of  
688 assay, in accordance with the tests or methods of assay  
689 prescribed under the federal act.

690 (2) "Department" means the Department of Business and  
691 Professional Regulation.

692 (3) "Distribute" or "distribution" means to sell; offer to  
693 sell; deliver; offer to deliver; transfer by either the passage  
694 of title, physical movement, or both; broker; or give away a  
695 medical gas. The term does not include:

696 (a) The dispensing or administration of a medical gas;

697 (b) The delivery of, or an offer to deliver, a medical gas  
698 by a common carrier in its usual course of business; or

699 (c) Sales activities taking place in a location owned,  
700 controlled, or staffed by persons employed by a person or entity  
701 permitted in this state to distribute a medical gas, if that  
702 location is not used to physically store or move a medical gas.

703 (4) "Emergency medical reasons" include:

704 (a) Transfers between wholesale distributors or between a  
705 wholesale distributor and a retail pharmacy or health care  
706 entity to alleviate a temporary shortage of a medical gas  
707 arising from a long-term delay or interruption of regular



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708 distribution schedules.

709 (b) Sales or transfers to licensed emergency medical  
710 services in this state, including ambulance companies and  
711 firefighting organizations.

712 (c) The provision of emergency supplies of medical gases to  
713 nursing homes during the hours of the day when necessary medical  
714 gases cannot normally be obtained from the nursing home's  
715 regular distributors.

716 (d) The transfer of medical gases between retail pharmacies  
717 to alleviate a temporary shortage.

718 (5) "Emergency use oxygen" means oxygen USP administered in  
719 emergency situations without a prescription for oxygen  
720 deficiency and resuscitation. The container must be labeled in  
721 accordance with requirements of the United States Food and Drug  
722 Administration.

723 (6) "Federal act" means the Federal Food, Drug, and  
724 Cosmetic Act.

725 (7) "Medical gas" means a liquefied or vaporized gas that  
726 is a prescription drug, whether alone or in combination with  
727 other gases, and as defined in the federal act.

728 (8) "Medical gas-related equipment" means a device used as  
729 a component part or accessory used to contain or control the  
730 flow, delivery, or pressure during the administration of a  
731 medical gas, such as liquid oxygen base and portable units,  
732 pressure regulators and flow meters, and oxygen concentrators.

733 (9) "Misbranded" means having a label that is false or  
734 misleading; a label without the name and address of the  
735 manufacturer, repackager, or distributor and without an accurate  
736 statement of the quantities of active ingredients; or a label



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737 without an accurate monograph for the medical gas, except in the  
738 case of mixtures of designated medical gases where the label  
739 identifies the component percentages of each designated medical  
740 gas used to make the mixture.

741 (10) "Medical oxygen" means oxygen USP which must be  
742 labeled in compliance with labeling requirements for oxygen  
743 under the federal act.

744 (11) "Product labeling" means the labels and other written,  
745 printed, or graphic matter upon an article, or the containers or  
746 wrappers that accompany an article, except for letters, numbers,  
747 and symbols stamped into the container as required by the  
748 federal Department of Transportation.

749 (12) "USP" means United States Pharmacopeial Convention.

750 (13) "USP-NF" means United States Pharmacopeia-National  
751 Formulary.

752 (14) "Wholesale distribution" means the distribution of  
753 medical gas to a person other than a consumer or patient.

754 Wholesale distribution of medical gases does not include:

755 (a) The sale, purchase, or trade of a medical gas; an offer  
756 to sell, purchase, or trade a medical gas; or the dispensing of  
757 a medical gas pursuant to a prescription;

758 (b) Activities exempt from the definition of wholesale  
759 distribution in s. 499.003; or

760 (c) Other transactions excluded from the definition of  
761 wholesale distribution under the federal act or regulations  
762 implemented under the federal act related to medical gas.

763 (15) "Wholesale distributor" means any person or entity  
764 engaged in wholesale distribution of medical gas within or into  
765 this state, including, but not limited to, manufacturers; own-



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766 label distributors; private-label distributors; warehouses,  
767 including manufacturers' and distributors' warehouses; and  
768 wholesale medical gas warehouses.

769 Section 15. Section 499.83, Florida Statutes, is created to  
770 read:

771 499.83 Permits.—

772 (1) A person or entity that intends to distribute medical  
773 gas within or into this state, unless exempted under this part,  
774 must obtain the applicable permit before operating as:

775 (a) A medical gas wholesale distributor;

776 (b) A medical gas manufacturer; or

777 (c) A medical oxygen retail establishment.

778 (2) The following permits are established:

779 (a) Medical gas wholesale distributor permit.—A medical gas  
780 wholesale distributor permit is required for wholesale  
781 distribution, whether within or into this state. A medical gas  
782 must remain in the original container obtained by the wholesale  
783 distributor and the wholesale distributor may not engage in  
784 further manufacturing operations unless it possesses a medical  
785 gas manufacturer permit. A medical gas wholesale distributor may  
786 not possess or engage in the wholesale distribution of a  
787 prescription drug that is not a medical gas or distribute a  
788 medical gas other than by wholesale distribution unless  
789 otherwise authorized.

790 (b) Medical gas manufacturer permit.—A medical gas  
791 manufacturer permit is required for a person or entity located  
792 in this state which engages in the manufacture of medical gases  
793 by physical air separation, chemical action, purification, or  
794 filling containers by a liquid-to-liquid, liquid-to-gas, or gas-



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795 to-gas process and distributes those medical gases within this  
796 state.

797 1. A permitted medical gas manufacturer may not manufacture  
798 or possess a prescription drug other than a medical gas, unless  
799 otherwise authorized.

800 2. A permitted medical gas manufacturer may not distribute  
801 a medical gas without obtaining the applicable permit, except  
802 that it may engage in wholesale distribution of medical gases  
803 that it manufactured without obtaining a medical gas wholesale  
804 distributor permit if it complies with this part and the rules  
805 adopted under this part that apply to a wholesale distributor.

806 3. A permitted medical gas manufacturer shall comply with  
807 all of the requirements applicable to a wholesale distributor  
808 under this part and all appropriate state and federal good  
809 manufacturing practices.

810 (c) *Medical oxygen retail establishment permit.*—A medical  
811 oxygen retail establishment permit is required for an entity  
812 that is located in the state and that dispenses medical oxygen  
813 directly to patients in this state. The sale and delivery must  
814 be based on an order from a practitioner authorized by law to  
815 prescribe. A pharmacy licensed under chapter 465 does not  
816 require a permit as a medical oxygen retail establishment.

817 1. A medical oxygen retail establishment may not possess,  
818 purchase, sell, or trade a medical gas other than medical  
819 oxygen, unless otherwise authorized.

820 2. A medical oxygen retail establishment may fill and  
821 deliver medical oxygen to an individual patient based on an  
822 order from a practitioner authorized by law to prescribe. The  
823 medical oxygen retail establishment must comply with all



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824 appropriate state and federal good manufacturing practices.  
825 Medical oxygen sold or delivered by a medical oxygen retail  
826 establishment pursuant to an order from a practitioner may not  
827 be returned into the retail establishment's inventory.

828 3. A medical oxygen retail establishment shall comply with  
829 all of the requirements applicable to a wholesale distributor  
830 under this part, except for those requirements that pertain  
831 solely to nitrous oxide.

832 (3) An out-of-state wholesale distributor that engages in  
833 wholesale distribution into this state must be legally  
834 authorized to engage in the wholesale distribution of medical  
835 gases as a wholesale distributor in the state in which it  
836 resides or is incorporated and provide proof of registration as  
837 set forth in s. 499.93(3), if required.

838 (4) A wholesale distributor may not operate from a place of  
839 residence, and a place of residence may not be granted a permit  
840 or operate under this part, except for the on-call delivery of  
841 home care oxygen for wholesale distributors that also maintain a  
842 medical oxygen retail establishment permit.

843 (5) If wholesale distribution is conducted at more than one  
844 location within this state or more than one location  
845 distributing into this state, each location must be permitted by  
846 the department.

847 Section 16. Section 499.831, Florida Statutes, is created  
848 to read:

849 499.831 Permit application.—

850 (1) The department shall adopt rules to establish the form  
851 and content of the application to obtain a permit and to renew a  
852 permit listed under this part.



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853       (2) An applicant must be at least 18 years of age or be  
854 managed, controlled, or overseen, directly or indirectly, by a  
855 natural person who is at least 18 years of age.

856       (3) An application for a permit must be filed with the  
857 department and must include all of the following information:

858       (a) The trade or business name of the applicant, including  
859 a fictitious name, which may not be identical to a name used by  
860 an unrelated entity permitted in this state to dispense or  
861 distribute medical gas.

862       (b) The name or names of the owner and operator of the  
863 applicant, if not the same person or entity. The application  
864 must also include:

865       1. If the applicant is an individual, the applicant's name,  
866 business address, and date of birth.

867       2. If the applicant is a sole proprietorship, the business  
868 address of the sole proprietor and the name and federal employer  
869 identification number of the business entity.

870       3. If the applicant is a partnership, the name, business  
871 address, date of birth of each partner, the name of the  
872 partnership, and the partnership's federal employer  
873 identification number.

874       4. If the applicant is a limited liability company, the  
875 name, business address, and title of each company officer, the  
876 name of the limited liability company and federal employer  
877 identification number, and the name of the state in which the  
878 limited liability company was organized.

879       5. If the applicant is a corporation, the name, business  
880 address, and title of each corporate officer and director, the  
881 corporate names, the state of incorporation, the federal





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882 employer identification number, and, if applicable, the name and  
883 business address of the parent company.

884 (c) A list of disciplinary actions pertinent to wholesale  
885 distributors, manufacturers, and retailers of prescription drugs  
886 or controlled substances by a state or federal agency against  
887 the applicant seeking to distribute into this state and any such  
888 disciplinary actions against such applicant's principals,  
889 owners, directors, or officers.

890 (d) A complete disclosure of all of the applicant's past  
891 felony convictions.

892 (e) An address and description of each facility and  
893 warehouse, including all locations used for medical gas storage  
894 or wholesale distribution including a description of each  
895 facility's security system.

896 (4) An applicant shall attest in writing that the  
897 information contained in its application is complete and  
898 accurate.

899 (5) An applicant must submit a reasonable fee, to be  
900 determined by the department, in order to obtain a permit.

901 (a) The fee for a medical gas wholesale distributor permit  
902 may not be less than \$200 or more than \$300 annually.

903 (b) The fee for a medical gas manufacturer permit may not  
904 be less than \$400 or more than \$500 annually.

905 (c) The fee for a medical oxygen retail establishment  
906 permit may not be less than \$200 or more than \$300 annually.

907 (6) Upon approval of the application by the department and  
908 payment of the required fee, the department shall issue a permit  
909 to the applicant pursuant to the rules adopted under this part.

910 Section 17. Section 499.832, Florida Statutes, is created



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911 to read:

912 499.832 Expiration and renewal of a permit.—

913 (1) A permit issued under this part automatically expires 2  
914 years after the last day of the month in which the permit was  
915 originally issued.

916 (2) A permit issued under this part may be renewed by  
917 submitting an application for renewal on a form furnished by the  
918 department and paying the appropriate fee. The application for  
919 renewal must contain a statement by the applicant attesting that  
920 the information is true and correct. Upon approval of a renewal  
921 application by the department and payment of the required  
922 renewal fee, the department shall renew a permit issued under  
923 this part pursuant to the rules adopted under this part.

924 (3) A renewal application may be accepted up to 60 days  
925 after the expiration date of the permit if, along with the  
926 permit renewal fee, the applicant submits an additional renewal  
927 delinquent fee of \$100. A permit that expired more than 60 days  
928 before a renewal application was submitted or postmarked may not  
929 be renewed.

930 (4) Failure to renew a permit in accordance with this  
931 section precludes future renewal. If a permit has expired and  
932 cannot be renewed, the person, entity, or establishment holding  
933 the permit must cease all permit related activities. In order to  
934 engage in activities that require a permit the person, entity,  
935 or establishment must submit an application for a new permit,  
936 pay the applicable application fee, the initial permit fee, and  
937 all applicable penalties, and be issued a new permit by the  
938 department before engaging in an activity that requires a permit  
939 under this part.



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940           (5) The department shall adopt rules to administer this  
941 section, including setting a reasonable fee for a renewal  
942 application.

943           Section 18. Section 499.833, Florida Statutes, is created  
944 to read:

945           499.833 Permitholder changes.—

946           (1) A permit issued under this part is valid only for the  
947 person or entity to which it is issued and is not subject to  
948 sale, assignment, or other transfer, voluntarily or  
949 involuntarily.

950           (2) A permit issued under this part is not valid for an  
951 establishment other than the establishment for which it was  
952 originally issued.

953           (3) The department may approve the following permit  
954 changes:

955           (a) Change of location.—A person or entity permitted under  
956 this part must notify and receive approval from the department  
957 before changing location. The department shall set a change-of-  
958 location fee not to exceed \$100.

959           (b) Change in ownership.—If a majority of the ownership or  
960 controlling interest of a permitted establishment is transferred  
961 or assigned or if a lessee agrees to undertake or provide  
962 services such that legal liability for operation of the  
963 establishment will rest with the lessee, an application for a  
964 new permit is required. Such application must be submitted and  
965 approved by the department before the change of ownership takes  
966 place. However, if a permitted wholesale distributor or  
967 manufacturer is changing ownership and the new owner has held  
968 another permit that allows the wholesale distribution of medical



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969 gas under this chapter for the preceding 18 months without  
970 having been found in violation of the provisions of this chapter  
971 relating to medical gases, then the new owner may operate under  
972 the permit of the acquired entity if the new owner submits the  
973 application for a new permit by the first business day after  
974 ownership is transferred or assigned. A new owner operating  
975 under the original permit is responsible for compliance with all  
976 laws and regulations governing medical gas. If the application  
977 is denied, the new owner shall immediately cease operation at  
978 the establishment until a permit is issued to the new owner.

979 (c) *Change of name.*—A permitholder may make a change of  
980 business name without submitting a new permit application.  
981 However, the permitholder must notify the department before  
982 making the name change.

983 (d) *Closure.*—If an establishment permitted under this part  
984 closes, the owner must notify the department, in writing, before  
985 the effective date of the closure and must:

- 986 1. Return the permit to the department; and  
987 2. Indicate the disposition of any medical gas authorized  
988 to be distributed or dispensed under the permit, including the  
989 name, address, and inventory, and provide the name and address  
990 of a person to contact regarding access to the records that are  
991 required to be maintained under this part. Transfer of ownership  
992 of medical gas may be made only to persons authorized to receive  
993 medical gas pursuant to this part.

994 (e) *Change in information.*—Any change in the information  
995 required under this part, other than the changes in paragraphs  
996 (a)-(d), shall be submitted to the department within 30 days  
997 after such change occurs.



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998           (4) A permitholder in good standing may change the type of  
999 permit issued by completing a new application for the requested  
1000 permit, meeting the applicable permitting requirements for the  
1001 new permit type, and paying any difference between the permit  
1002 fees. A refund may not be issued if the fee for the new permit  
1003 is less than the fee that was paid for the original permit. The  
1004 new permit retains the expiration date of the original permit.

1005           Section 19. Section 499.834, Florida Statutes, is created  
1006 to read:

1007           499.834 Minimum qualifications.—The department shall  
1008 consider all of the following factors in determining eligibility  
1009 for, and renewal of, a permit for a person or entity under this  
1010 part:

1011           (1) A finding by the department that the applicant has  
1012 violated or been disciplined by a regulatory agency in any state  
1013 for violating a federal, state, or local law relating to  
1014 prescription drugs.

1015           (2) Felony convictions of the applicant under a federal,  
1016 state, or local law.

1017           (3) The applicant's past experience in the manufacture,  
1018 retail, or distribution of medical gases.

1019           (4) False or fraudulent material provided by the applicant  
1020 in an application made in connection with the manufacturing,  
1021 retailing, or distribution of prescription drugs.

1022           (5) Any suspension, sanction, or revocation by a federal,  
1023 state, or local government against a license or permit currently  
1024 or previously held by the applicant or its owners for violations  
1025 of a federal, state, or local law regarding prescription drugs.

1026           (6) Compliance with previously granted licenses or permits.



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1027 (7) Compliance with the requirements that distributors or  
1028 retailers of medical gases maintain records and make records  
1029 available to the department licensing authority or federal,  
1030 state, or local law enforcement officials.

1031 (8) Other factors or qualifications the department  
1032 considers relevant to and consistent with the public health and  
1033 safety.

1034 Section 20. Section 499.84, Florida Statutes, is created to  
1035 read:

1036 499.84 Minimum requirements for the storage and handling of  
1037 medical gases.-

1038 (1) A facility where a medical gas is received, stored,  
1039 warehoused, handled, held, offered, marketed, displayed, or  
1040 transported, to avoid any negative effect on the identity,  
1041 strength, quality, or purity of the medical gas, must:

1042 (a) Be of suitable construction to ensure that medical  
1043 gases are maintained in accordance with the product labeling of  
1044 the medical gas or in compliance with the USP-NF;

1045 (b) Be of suitable size and construction to facilitate  
1046 cleaning, maintenance, and proper permitted operations;

1047 (c) Have adequate storage areas with appropriate lighting,  
1048 ventilation, space, equipment, and security conditions.

1049 (d) Have a quarantined area for storage of medical gases  
1050 that are suspected of being misbranded, adulterated, or  
1051 otherwise unfit for distribution;

1052 (e) Be maintained in an orderly condition;

1053 (f) Be located in a commercial location and not in a  
1054 personal dwelling or residence location, except that a personal  
1055 dwelling location used for on-call delivery of oxygen USP for



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1056 homecare use if the person providing on-call delivery is  
1057 employed by or acting under a written contract with an entity  
1058 that holds a medical oxygen retailer permit;

1059 (g) Provide for the secure and confidential storage of  
1060 patient information, if applicable, with restricted access and  
1061 policies and procedures to protect the integrity and  
1062 confidentiality of patient information; and

1063 (h) Provide and maintain appropriate inventory controls to  
1064 detect and document any theft of nitrous oxide.

1065 (2) Medical gas shall be stored under appropriate  
1066 conditions in accordance with the manufacturer's recommendations  
1067 on product labeling and department rules or, in the absence of  
1068 rules, in accordance with applicable industry standards.

1069 (3) Medical gas shall be packaged in accordance with  
1070 official compendium standards, such as the USP-NF.

1071 Section 21. Section 499.85, Florida Statutes, is created to  
1072 read:

1073 499.85 Security.-

1074 (1) A permitholder that has a facility used for the  
1075 distribution or retailing of medical gases shall protect such  
1076 gases from unauthorized access by implementing all of the  
1077 following security measures:

1078 (a) Keeping access from outside the premises well-  
1079 controlled and to a minimum.

1080 (b) Ensuring the outside perimeter of the premises is well  
1081 lit.

1082 (c) Limiting access into areas where medical gases are held  
1083 to authorized personnel.

1084 (d) Equipping all facilities with a fence or other system



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1085 to detect or deter entry after hours.

1086 (2) A facility used for distributing or retailing medical  
1087 gases shall be equipped with a system that provides suitable  
1088 protection against theft, including if appropriate, protection  
1089 against theft of computers or electronic records and the  
1090 protection of the integrity and confidentiality of data and  
1091 documents.

1092 (3) A facility used for wholesale distribution of medical  
1093 gases shall be equipped with inventory management and control  
1094 systems that protect against, detect, and document any instances  
1095 of theft of nitrous oxide.

1096 (4) If a wholesale distributor uses electronic distribution  
1097 records, the wholesale distributor shall employ, train, and  
1098 document the training of personnel in the proper use of such  
1099 technology and equipment.

1100 (5) Vehicles used for on-call delivery of oxygen USP and  
1101 oxygen-related equipment for home care use by home care  
1102 providers may be parked at a place of residence and must be  
1103 locked and equipped with an audible alarm when not attended.

1104 (6) The department shall adopt rules that govern the  
1105 distribution of medical oxygen for emergency use by persons  
1106 authorized to receive emergency use oxygen. Unless the laws of  
1107 this state specifically direct otherwise, such rules must be  
1108 consistent with federal regulations, including the labeling  
1109 requirements of oxygen under the federal act.

1110 Section 22. Section 499.86, Florida Statutes, is created to  
1111 read:

1112 499.86 Examination of materials.-

1113 (1) A wholesale distributor must visually examine a medical





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1114 gas container upon receipt from the manufacturer in order to  
1115 identify the medical gas stored within and to determine if the  
1116 container has been damaged or is otherwise unfit for  
1117 distribution. Such examination must occur in a manner that would  
1118 reveal damage to the container which could suggest possible  
1119 adulteration or misbranding.

1120 (2) A medical gas container that is found to be damaged or  
1121 otherwise unfit pursuant to subsection (1) must be quarantined  
1122 from the stock of medical gas until a determination is made that  
1123 the medical gas in question is not misbranded or adulterated.

1124 (3) An outgoing shipment must be inspected to identify the  
1125 medical gases in the shipment to ensure that medical gas  
1126 containers that have been damaged in storage or held under  
1127 improper conditions are not distributed or dispensed.

1128 (4) A wholesale distributor must review records documenting  
1129 the acquisition of medical gas upon receipt for accuracy and  
1130 completeness.

1131 Section 23. Section 499.87, Florida Statutes, is created to  
1132 read:

1133 499.87 Returned, damaged, and outdated medical gas.—

1134 (1) A medical gas that has left the control of the  
1135 wholesale distributor may be returned to the wholesale  
1136 distributor or manufacturer from which it was acquired, but may  
1137 not be resold as a medical gas unless it is reprocessed by a  
1138 manufacturer using proper and adequate controls to ensure the  
1139 identity, strength, quality, and purity of the reprocessed  
1140 medical gas.

1141 (2) A medical gas that has been subjected to improper  
1142 conditions, such as a fire, accident, or natural disaster, may



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1143 not be salvaged or reprocessed.

1144 (3) A medical gas, including its container, which is  
1145 damaged, misbranded, or adulterated must be quarantined from  
1146 other medical gases until it is destroyed or returned to the  
1147 manufacturer or wholesale distributor from which it was  
1148 acquired. External contamination of a medical gas container or  
1149 closure system which does not impact the integrity of the  
1150 medical gas is not considered damaged or adulterated for  
1151 purposes of this subsection. If a medical gas is adulterated or  
1152 misbranded or suspected of being adulterated or misbranded,  
1153 notice shall be provided to the manufacturer or wholesale  
1154 distributor from which the medical gas was acquired and to the  
1155 appropriate boards and federal regulatory bodies.

1156 (4) A medical gas container that has been opened or used  
1157 but is not adulterated or misbranded is considered empty and  
1158 must be quarantined from nonempty medical gas containers and  
1159 returned to the manufacturer or wholesale distributor from which  
1160 it was acquired for destruction or reprocessing.

1161 (5) A medical gas, its container, or its associated  
1162 documentation or labeling that is suspected of being used in  
1163 criminal activity must be retained until its disposition is  
1164 authorized by the department or an applicable law enforcement  
1165 agency.

1166 Section 24. Section 499.88, Florida Statutes, is created to  
1167 read:

1168 499.88 Due diligence.—

1169 (1) A wholesale distributor shall obtain, before the  
1170 initial acquisition of medical gas, the following information  
1171 from the supplying wholesale distributor or manufacturer:



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1172           (a) If a manufacturer is distributing to a wholesale  
1173 distributor, evidence that the manufacturer is registered and  
1174 the medical gas is listed with the United States Food and Drug  
1175 Administration;

1176           (b) If a wholesale distributor is distributing to a  
1177 wholesale distributor, evidence that the wholesale distributor  
1178 supplying the medical gas is legally authorized to distribute  
1179 medical gas within or into the state;

1180           (c) The name of the responsible facility contact person for  
1181 the supplying manufacturer or wholesale distributor; and

1182           (d) Certification that the manufacturer's or wholesale  
1183 distributor's policies and procedures comply with this part.

1184           (2) A wholesale distributor is exempt from obtaining the  
1185 information from a manufacturer, as required under subsection  
1186 (1), if the manufacturer is registered with the United States  
1187 Food and Drug Administration in accordance with s. 510 of the  
1188 federal act and the manufacturer provides:

1189           (a) Proof of such registration; and

1190           (b) Proof of inspection by the United States Food and Drug  
1191 Administration or other regulatory body within the past 3 years  
1192 demonstrating substantial compliance with current good  
1193 manufacturing practices applicable to medical gases.

1194           (3) A manufacturer or wholesale distributor that  
1195 distributes to or acquires medical gas from another wholesale  
1196 distributor shall provide to or obtain from the distributing or  
1197 acquiring manufacturer or distributor the information required  
1198 by s. 499.89(1), as applicable.

1199           Section 25. Section 499.89, Florida Statutes, is created to  
1200 read:



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1201           499.89 Recordkeeping.-  
1202           (1) A permitholder under this part shall establish and  
1203 maintain a record of transactions regarding the receipt and the  
1204 distribution, or other disposition, of medical gases, as  
1205 applicable. Such records constitute an audit trail and must  
1206 contain information sufficient to perform a recall of medical  
1207 gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s.  
1208 820.160(b). Such records must include all of the following  
1209 information, which may be kept in two separate documents one  
1210 related to the distribution of medical gas and the other related  
1211 to the receipt of medical gas:  
1212           (a) The dates of receipt and distribution or other  
1213 disposition of the medical gas.  
1214           (b) The name, address, license or permit number and its  
1215 expiration date for the person or entity purchasing the medical  
1216 gas from the wholesale distributor.  
1217           (c) The name, address, license or permit number and its  
1218 expiration date for the person or entity receiving the medical  
1219 gas, if different from the information required under paragraph  
1220 (b).  
1221           (d) Information sufficient to perform a recall of all  
1222 medical gas received, distributed, or dispensed.  
1223           (2) Such records shall be made available for inspection and  
1224 copying by an authorized official of any federal, state, or  
1225 local governmental agency for a period of:  
1226           (a) Three years following the distribution date of high  
1227 pressure medical gases.  
1228           (b) Two years following the distribution date for cryogenic  
1229 or refrigerated liquid medical gases.



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1230           (3) Records kept at the inspection site or that can be  
1231 immediately retrieved by computer or other electronic means  
1232 shall be readily available for authorized inspection during the  
1233 retention period. Records kept at a central location apart from  
1234 the inspection site and not electronically retrievable shall be  
1235 made available for inspection within 2 working days of a request  
1236 by an authorized official of any state or federal governmental  
1237 agency charged with enforcement of these rules.

1238           (4) A pedigree paper is not required for distributing or  
1239 dispensing medical gas.

1240           (5) A wholesale distributor shall maintain records  
1241 sufficient to aid in the mandatory reporting of any theft,  
1242 suspected theft, or other significant loss of nitrous oxide to  
1243 the department and other appropriate law enforcement agencies.

1244           Section 26. Section 499.90, Florida Statutes, is created to  
1245 read:

1246           499.90 Policies and procedures.—A wholesale distributor  
1247 shall establish, maintain, and adhere to written policies and  
1248 procedures for the receipt, security, storage, transport,  
1249 shipping, and distribution of medical gases and shall establish,  
1250 maintain, and adhere to procedures for maintaining inventories;  
1251 for identifying, recording, and reporting losses or thefts; and  
1252 for correcting all errors and inaccuracies in inventories  
1253 associated with nitrous oxide. A wholesale distributor shall  
1254 include in its written policies and procedures the following:

1255           (1) A procedure for handling recalls and withdrawals of  
1256 medical gas. Such procedure must deal with recalls and  
1257 withdrawals due to:

1258           (a) Action initiated at the request of the United States



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1259 Food and Drug Administration or any federal, state, or local law  
1260 enforcement or other government agency, including the  
1261 department; or

1262 (b) Voluntary action by a manufacturer of medical gases to  
1263 remove defective or potentially defective medical gases from the  
1264 market.

1265 (2) A procedure that includes preparation for, protection  
1266 against, and responding to a crisis that affects the security or  
1267 operation of a facility that stores medical gases in the event  
1268 of a strike; a fire, flood, or other natural disaster; or other  
1269 local, state, or national emergency.

1270 (3) A procedure for reporting criminal or suspected  
1271 criminal activity involving the inventory of nitrous oxide to  
1272 the department and to applicable law enforcement agencies within  
1273 3 business days after becoming aware of the criminal or  
1274 suspected criminal activity.

1275 Section 27. Section 499.91, Florida Statutes, is created to  
1276 read:

1277 499.91 Prohibited acts.—A person may not perform or cause  
1278 the performance of, or aid and abet in, any of the following  
1279 acts in this state:

1280 (1) The manufacture, sale, or delivery, or the holding or  
1281 offering for sale, of a medical gas that is adulterated,  
1282 misbranded, or is otherwise unfit for distribution.

1283 (2) The adulteration or misbranding of a medical gas.

1284 (3) The receipt of a medical gas that is adulterated,  
1285 misbranded, stolen, or obtained by fraud or deceit, or the  
1286 delivery or proffered delivery of such medical gas for pay or  
1287 otherwise.



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1288           (4) The alteration, mutilation, destruction, obliteration,  
1289 or removal of all or any part of the product labeling of a  
1290 medical gas, or the willful commission of any other act with  
1291 respect to a medical gas that results in it being misbranded.

1292           (5) The purchase or receipt of a medical gas from a person  
1293 not authorized to distribute or dispense medical gas or who is  
1294 not exempted from permitting requirements to wholesale  
1295 distribute medical gas to such purchaser or recipient.

1296           (6) The knowing and willful sale or transfer of a medical  
1297 gas to a recipient who is not legally authorized to receive a  
1298 medical gas, except that a violation does not exist if a  
1299 permitted wholesale distributor provides oxygen to a permitted  
1300 medical oxygen retail establishment that is out of compliance  
1301 with the notice of location change requirements of s. 499.834,  
1302 provided that the wholesale distributor with knowledge of the  
1303 violation notifies the department of the transaction by the next  
1304 business day.

1305           (7) The failure to maintain or provide records required  
1306 under this part and the rules adopted under this part.

1307           (8) Providing the department or any of its representatives  
1308 or any state or federal official with false or fraudulent  
1309 records or making false or fraudulent statements regarding this  
1310 part or the rules adopted under this part.

1311           (9) The distribution of a medical gas that was:

1312           (a) Purchased by a public or private hospital or other  
1313 health care entity, except for the physical distribution of such  
1314 medical gas to an authorized recipient at the direction of a  
1315 hospital or other health care entity;

1316           (b) Donated or supplied at a reduced price to a charitable



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1317 organization; or  
1318 (c) Stolen or obtained by fraud or deceit.  
1319 (10) The failure to obtain a license or permit or operating  
1320 without a valid license or permit, if one is required.  
1321 (11) The obtaining of, or attempt to obtain, a medical gas  
1322 by fraud, deceit, or misrepresentation or engaging in  
1323 misrepresentation or fraud in the distribution of a medical gas.  
1324 (12) Except for emergency use oxygen, the distribution of a  
1325 medical gas to a patient without a prescription from a  
1326 practitioner authorized by law to prescribe a medical gas.  
1327 (13) The distribution or dispensing of a medical gas that  
1328 was previously dispensed by a pharmacy or a practitioner  
1329 authorized by law to prescribe.  
1330 (14) The distribution or dispensing of a medical gas or  
1331 medical gas-related equipment to a patient, unless the patient  
1332 has been provided with the appropriate information and  
1333 counseling on the use, storage, and disposal the medical gas.  
1334 (15) Failure to report an act prohibited under this part or  
1335 the rules adopted under this part.  
1336 (16) Failure to exercise due diligence as provided in s.  
1337 499.88.  
1338 Section 28. Section 499.92, Florida Statutes, is created to  
1339 read:  
1340 499.92 Criminal acts.—  
1341 (1) A person commits a felony of the third degree,  
1342 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
1343 if he or she:  
1344 (a) Adulterates or misbrands a medical gas with intent to  
1345 defraud or deceive;





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1346 (b) Knowingly purchases or receives a medical gas from a  
1347 person not legally authorized to distribute or dispense medical  
1348 gas;

1349 (c) Knowingly engages in the wholesale distribution of, or  
1350 sells, barter, brokers, or transfers, a medical gas to a person  
1351 not legally authorized to purchase or receive medical gas in the  
1352 jurisdiction in which the person receives the medical gas. A  
1353 permitted wholesale distributor that, at its location, provides  
1354 oxygen to a permitted medical oxygen retail establishment that  
1355 is out of compliance with only the change of location notice  
1356 requirement under s. 499.834, does not commit a violation of  
1357 this subsection if the wholesale distributor notifies the  
1358 department of the transaction no later than the next business  
1359 day; or

1360 (d) Knowingly falsely creates a label for a medical gas or  
1361 knowingly falsely misrepresents a factual matter contained in a  
1362 label for a medical gas.

1363 (2) A person found guilty of an offense under this section,  
1364 under the authority of the court convicting and sentencing the  
1365 person, shall be ordered to forfeit to the state any real or  
1366 personal property:

1367 (a) Used or intended to be used to commit, to facilitate,  
1368 or to promote the commission of such offense; and

1369 (b) Constituting, derived from, or traceable to the gross  
1370 proceeds that the defendant obtained directly or indirectly as a  
1371 result of the offense.

1372 (3) Property or assets subject to forfeiture under  
1373 subsection (2) may be seized pursuant to a warrant obtained in  
1374 the same manner as a search warrant or as otherwise authorized



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1375 by law, and held until the case against a defendant is  
1376 adjudicated. Monies ordered forfeited, or proceeds from the sale  
1377 of other assets ordered forfeited, shall be equitably divided  
1378 between the department and other agencies involved in the  
1379 investigation and prosecution that led to the conviction. Other  
1380 property ordered forfeited after conviction of a defendant may,  
1381 at the discretion of the investigating agencies, be placed into  
1382 official use by the department or the agencies involved in the  
1383 investigation and prosecution that led to the conviction.

1384 Section 29. Section 499.93, Florida Statutes, is created to  
1385 read:

1386 499.93 Inspections.—

1387 (1) The department may require a facility that engages in  
1388 the manufacture, retail sale, or wholesale distribution of  
1389 medical gas to undergo an inspection in accordance with a  
1390 schedule to be determined by the department, including  
1391 inspections for initial permitting, permit renewal, and a  
1392 permitholder's change of location. The department may recognize  
1393 a third party to inspect wholesale distributors in this state or  
1394 other states pursuant to a schedule to be determined by the  
1395 department.

1396 (2) The department may recognize another state's  
1397 inspections of a manufacturer or wholesale distributor located  
1398 in that state if such state's laws are deemed to be  
1399 substantially equivalent to the laws of this state by the  
1400 department.

1401 (3) A manufacturing facility of medical gases is exempt  
1402 from inspection by the department if:

1403 (a) The manufacturing facility is currently registered with



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1404 the United States Food and Drug Administration under s. 510 of  
1405 the federal act and can provide proof of registration, such as a  
1406 copy of the Internet verification page; and

1407 (b) The manufacturing facility can provide proof of  
1408 inspection by the Food and Drug Administration, or if the  
1409 facility is located in another state, inspection by the Food and  
1410 Drug Administration or other governmental entity charged with  
1411 regulation of good manufacturing practices related to medical  
1412 gases in that state within the past 3 years, which demonstrates  
1413 substantial compliance with current good manufacturing practices  
1414 applicable to medical gases.

1415 (4) A permitholder under this part shall exhibit or have  
1416 readily available its state permits and its most recent  
1417 inspection report administered by the department.

1418 Section 30. Section 499.931, Florida Statutes, is created  
1419 to read:

1420 499.931 Trade secret information.—Information required to  
1421 be submitted under this part which is a trade secret as defined  
1422 in s. 812.081(1)(c) and designated as a trade secret by an  
1423 applicant or permitholder must be maintained as required under  
1424 s. 499.051.

1425 Section 31. Section 499.94, Florida Statutes, is created to  
1426 read:

1427 499.94 Fees.—A fee collected for a permit under this part  
1428 shall be deposited into the Professional Regulation Trust Fund.  
1429 Moneys collected under this part shall be used for administering  
1430 this part. The department shall maintain a separate account in  
1431 the trust fund for the Drugs, Devices, and Cosmetics program.

1432 Section 32. Paragraph (a) of subsection (1) of section



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1433 409.9201, Florida Statutes, is amended to read:

1434 409.9201 Medicaid fraud.—

1435 (1) As used in this section, the term:

1436 (a) "Prescription drug" means any drug, including, but not  
1437 limited to, finished dosage forms or active ingredients that are  
1438 subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the  
1439 Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s.  
1440 499.003(52), ~~s. 499.003(46) or (53) or s. 499.007(13), or s.~~  
1441 499.82(10).

1442

1443 The value of individual items of the legend drugs or goods or  
1444 services involved in distinct transactions committed during a  
1445 single scheme or course of conduct, whether involving a single  
1446 person or several persons, may be aggregated when determining  
1447 the punishment for the offense.

1448 Section 33. Paragraph (c) of subsection (9) of section  
1449 460.403, Florida Statutes, is amended to read:

1450 460.403 Definitions.—As used in this chapter, the term:

1451 (9)

1452 (c)1. Chiropractic physicians may adjust, manipulate, or  
1453 treat the human body by manual, mechanical, electrical, or  
1454 natural methods; by the use of physical means or physiotherapy,  
1455 including light, heat, water, or exercise; by the use of  
1456 acupuncture; or by the administration of foods, food  
1457 concentrates, food extracts, and items for which a prescription  
1458 is not required and may apply first aid and hygiene, but  
1459 chiropractic physicians are expressly prohibited from  
1460 prescribing or administering to any person any legend drug  
1461 except as authorized under subparagraph 2., from performing any



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1462 surgery except as stated herein, or from practicing obstetrics.

1463 2. Notwithstanding the prohibition against prescribing and  
1464 administering legend drugs under subparagraph 1. or s.

1465 499.83(2)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule

1466 chiropractic physicians may order, store, and administer, for  
1467 emergency purposes only at the chiropractic physician's office  
1468 or place of business, prescription medical oxygen and may also  
1469 order, store, and administer the following topical anesthetics  
1470 in aerosol form:

1471 a. Any solution consisting of 25 percent ethylchloride and  
1472 75 percent dichlorodifluoromethane.

1473 b. Any solution consisting of 15 percent  
1474 dichlorodifluoromethane and 85 percent  
1475 trichloromonofluoromethane.

1476  
1477 However, this paragraph does not authorize a chiropractic  
1478 physician to prescribe medical oxygen as defined in chapter 499.

1479 Section 34. Subsection (3) of section 465.0265, Florida  
1480 Statutes, is amended to read:

1481 465.0265 Centralized prescription filling.—

1482 (3) The filling, delivery, and return of a prescription by  
1483 one pharmacy for another pursuant to this section shall not be  
1484 construed as the filling of a transferred prescription as  
1485 described set forth in s. 465.026 or as a wholesale distribution  
1486 as defined set forth in s. 499.003 ~~s. 499.003(54)~~.

1487 Section 35. Paragraph (b) of subsection (2) of section  
1488 499.01212, Florida Statutes, is amended to read:

1489 499.01212 Pedigree paper.—

1490 (2) FORMAT.—A pedigree paper must contain the following



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1491 information:

1492 (b) For all other wholesale distributions of prescription  
1493 drugs:

1494 1. The quantity, dosage form, and strength of the  
1495 prescription drugs.

1496 2. The lot numbers of the prescription drugs.

1497 3. The name and address of each owner of the prescription  
1498 drug and his or her signature.

1499 4. Shipping information, including the name and address of  
1500 each person certifying delivery or receipt of the prescription  
1501 drug.

1502 5. An invoice number, a shipping document number, or  
1503 another number uniquely identifying the transaction.

1504 6. A certification that the recipient wholesale distributor  
1505 has authenticated the pedigree papers.

1506 7. The unique serialization of the prescription drug, if  
1507 the manufacturer or repackager has uniquely serialized the  
1508 individual prescription drug unit.

1509 8. The name, address, telephone number, and, if available,  
1510 e-mail contact information of each wholesale distributor  
1511 involved in the chain of the prescription drug's custody.

1512

1513 When an affiliated group member obtains title to a prescription  
1514 drug before distributing the prescription drug as the  
1515 manufacturer as defined in s. 499.003(30) (e) under s.  
1516 ~~499.003(31) (e)~~, information regarding the distribution between  
1517 those affiliated group members may be omitted from a pedigree  
1518 paper required under this paragraph for subsequent distributions  
1519 of that prescription drug.



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1520 Section 36. Paragraph (a) of subsection (1) and subsection  
1521 (3) of section 499.015, Florida Statutes, are amended to read:

1522 499.015 Registration of drugs, devices, and cosmetics;  
1523 issuance of certificates of free sale.-

1524 (1) (a) Except for those persons exempted from the  
1525 definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, any  
1526 person who manufactures, packages, repackages, labels, or  
1527 relabels a drug, device, or cosmetic in this state must register  
1528 such drug, device, or cosmetic biennially with the department;  
1529 pay a fee in accordance with the fee schedule provided by s.  
1530 499.041; and comply with this section. The registrant must list  
1531 each separate and distinct drug, device, or cosmetic at the time  
1532 of registration.

1533 (3) Except for those persons exempted from the definition  
1534 of manufacturer in s. 499.003 ~~s. 499.003(31)~~, a person may not  
1535 sell any product that he or she has failed to register in  
1536 conformity with this section. Such failure to register subjects  
1537 such drug, device, or cosmetic product to seizure and  
1538 condemnation as provided in s. 499.062, and subjects such person  
1539 to the penalties and remedies provided in this part.

1540 Section 37. Subsection (3) of section 499.024, Florida  
1541 Statutes, is amended to read:

1542 499.024 Drug product classification.-The department shall  
1543 adopt rules to classify drug products intended for use by humans  
1544 which the United States Food and Drug Administration has not  
1545 classified in the federal act or the Code of Federal  
1546 Regulations.

1547 (3) Any product that falls under the definition of drug in  
1548 s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority



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1549 of this section. This section does not subject portable  
1550 emergency oxygen inhalators to classification; however, this  
1551 section does not exempt any person from ss. 499.01 and 499.015.

1552 Section 38. This act shall take effect October 1, 2014.  
1553

1554 ===== T I T L E A M E N D M E N T =====

1555 And the title is amended as follows:

1556 Delete everything before the enacting clause  
1557 and insert:

1558 A bill to be entitled  
1559 An act relating to medical gas; amending s. 499.001,  
1560 F.S.; conforming provisions to changes made by this  
1561 act; amending s. 499.003, F.S.; revising terms;  
1562 amending ss. 499.01 and 499.0121, F.S.; conforming  
1563 provisions to changes made by this act; amending s.  
1564 499.01211, F.S.; adding a member of to the Drug  
1565 Wholesale Distributor Advisory Council; authorizing  
1566 the Compressed Gas Association to recommend one person  
1567 to the council for appointment; amending ss. 499.041,  
1568 499.05, 499.051, 499.066, 499.0661, and 499.067, F.S.;  
1569 conforming provisions to changes made by this act;  
1570 creating part III of ch. 499, F.S., entitled "Medical  
1571 Gas"; creating s. 499.81, F.S.; providing for the  
1572 administration and enforcement of this part; creating  
1573 s. 499.82, F.S.; defining terms; creating s. 499.83,  
1574 F.S.; requiring a person or entity that intends to  
1575 distribute medical gas within or into this state to  
1576 obtain an applicable permit before operating;  
1577 establishing categories of permits and setting





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1578 requirements for each; creating s. 499.831, F.S.;

1579 requiring the Department of Business and Professional

1580 Regulation to establish the form and content of an

1581 application; authorizing the department to set fees

1582 within certain parameters; creating s. 499.832, F.S.;

1583 providing that a permit expires 2 years after the last

1584 day of the month in which the permit was originally

1585 issued; providing requirements for the renewal of a

1586 permit; requiring the department to adopt rules for

1587 the renewal of permits; creating s. 499.833, F.S.;

1588 authorizing the department to approve certain

1589 permitholder changes; creating s. 499.834, F.S.;

1590 authorizing the department to consider certain factors

1591 in determining the eligibility of an applicant;

1592 creating s. 499.84, F.S.; setting the minimum

1593 requirements for the storage and handling of medical

1594 gas; creating s. 499.85, F.S.; setting facility

1595 requirements for security purposes; authorizing a

1596 vehicle used for on-call delivery of oxygen USP and

1597 oxygen-related equipment to be parked at a place of

1598 residence; requiring the department to adopt rules

1599 governing the distribution of medical oxygen; creating

1600 s. 499.86, F.S.; requiring a wholesale distributor of

1601 medical gases to visually examine a medical gas

1602 container upon receipt in order to identify the

1603 medical gas stored within and to determine if the

1604 container has been damaged or is otherwise unfit for

1605 distribution; requiring a medical gas container that

1606 is damaged or otherwise unfit for distribution to be



1607        quarantined; requiring outgoing shipments of medical  
1608        gas to be inspected; requiring wholesale distributors  
1609        to review certain records; creating s. 499.87, F.S.;  
1610        authorizing the return of medical gas that has left  
1611        the control of a wholesale distributor; requiring that  
1612        medical gas that is damaged, misbranded, or  
1613        adulterated be quarantined from other medical gases  
1614        until it is destroyed or returned to the manufacturer  
1615        or wholesale distributor from which it was acquired;  
1616        creating s. 499.88, F.S.; requiring a wholesale  
1617        distributor to obtain certain information before the  
1618        initial acquisition of a medical gas; providing  
1619        certain exemptions; creating s. 499.89, F.S.;  
1620        requiring a permitholder under this part to establish  
1621        and maintain transactional records; providing a  
1622        retention period for certain records and requiring  
1623        that such records be available for inspection during  
1624        that period; creating s. 499.90, F.S.; requiring a  
1625        wholesale distributor to establish, maintain, and  
1626        adhere to certain written policies and procedures;  
1627        creating s. 499.91, F.S.; prohibiting certain acts;  
1628        creating s. 499.92, F.S.; establishing criminal  
1629        penalties; authorizing property or assets subject to  
1630        forfeiture to be seized pursuant to a warrant;  
1631        creating s. 499.93, F.S.; authorizing the department  
1632        to require a facility that engages in in the  
1633        manufacture, retail sale, or wholesale distribution of  
1634        medical to undergo an inspection; authorizing the  
1635        department to authorize a third party to inspect such



1636 facilities; creating s. 499.931, F.S.; providing that  
1637 trade secret information required to be submitted  
1638 pursuant to this part must be maintained by the  
1639 department; creating s. 499.94, F.S.; requiring fees  
1640 collected pursuant to this part to be deposited into  
1641 the Professional Regulation Trust Fund; amending ss.  
1642 409.9201, 460.403, 465.0265, 499.01212, 499.015, and  
1643 499.024, F.S.; conforming cross references; providing  
1644 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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12 state.

13 1. A permitted medical gas manufacturer may not manufacture  
14 or possess a prescription drug other than a medical gas, unless  
15 otherwise authorized under this chapter.

16 2. A permitted medical gas manufacturer may not distribute  
17 a medical gas without obtaining the applicable permit, except  
18 that it may engage in wholesale distribution of medical gases  
19 that it manufactured without obtaining a medical gas wholesale  
20 distributor permit if it complies with this part and the rules  
21 adopted under this part that apply to a wholesale distributor.

22 3. A permitted medical gas manufacturer shall comply with  
23 all of the requirements applicable to a wholesale distributor  
24 under this part and all appropriate state and federal good  
25 manufacturing practices.

26 (c) Medical oxygen retail establishment permit.—A medical  
27 oxygen retail establishment permit is required for an entity  
28 that is located in the state and that dispenses medical oxygen  
29 directly to patients in this state. The sale and delivery must  
30 be based on a prescription or an order from a practitioner  
31 authorized by law to prescribe. A pharmacy licensed under  
32 chapter 465 does not require a permit as a medical oxygen retail  
33 establishment.

34 1. A medical oxygen retail establishment may not possess,  
35 purchase, sell, or trade a medical gas other than medical  
36 oxygen, unless otherwise authorized under this chapter.

37 2. A medical oxygen retail establishment may fill and  
38 deliver medical oxygen to an individual patient based on an  
39 order from a practitioner authorized by law to prescribe. The  
40 medical oxygen retail establishment must comply with all



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41 appropriate state and federal good manufacturing practices.  
42 Medical oxygen sold or delivered by a medical oxygen retail  
43 establishment pursuant to an order from a practitioner may not  
44 be returned into the retail establishment's inventory.

45 3. A medical oxygen retail establishment shall comply with  
46 all of the requirements applicable to a wholesale distributor  
47 under this part, except for those requirements that pertain  
48 solely to nitrous oxide.

49 (3) An out-of-state wholesale distributor that engages in  
50 wholesale distribution into this state must be legally  
51 authorized to engage in the wholesale distribution of medical  
52 gases as a wholesale distributor in the state in which it  
53 resides or is incorporated and provide proof of registration as  
54 set forth in s. 499.93(3), if required.

55 (4) A wholesale distributor may not operate from a place of  
56 residence, and a place of residence may not be granted a permit  
57 or operate under this part, except for the on-call delivery of  
58 home care oxygen for wholesale distributors that also maintain a  
59 medical oxygen retail establishment permit.

60 (5) If wholesale distribution is conducted at more than one  
61 location within this state or more than one location  
62 distributing into this state, each location must be permitted by  
63 the department.

64 Section 16. Section 499.831, Florida Statutes, is created  
65 to read:

66 499.831 Permit application.—

67 (1) The department shall adopt rules to establish the form  
68 and content of the application to obtain a permit and to renew a  
69 permit listed under this part.



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70           (2) An applicant must be at least 18 years of age or be  
71 managed, controlled, or overseen, directly or indirectly, by a  
72 natural person who is at least 18 years of age.

73           (3) An application for a permit must be filed with the  
74 department and must include all of the following information:

75           (a) The trade or business name of the applicant, including  
76 a fictitious name, which may not be identical to a name used by  
77 an unrelated entity permitted in this state to dispense or  
78 distribute medical gas.

79           (b) The name or names of the owner and operator of the  
80 applicant, if not the same person or entity. The application  
81 must also include:

82           1. If the applicant is an individual, the applicant's name,  
83 business address, and date of birth.

84           2. If the applicant is a sole proprietorship, the business  
85 address of the sole proprietor and the name and federal employer  
86 identification number of the business entity.

87           3. If the applicant is a partnership, the name, business  
88 address, date of birth of each partner, the name of the  
89 partnership, and the partnership's federal employer  
90 identification number.

91           4. If the applicant is a limited liability company, the  
92 name, business address, and title of each company officer, the  
93 name of the limited liability company and federal employer  
94 identification number, and the name of the state in which the  
95 limited liability company was organized.

96           5. If the applicant is a corporation, the name, business  
97 address, and title of each corporate officer and director, the  
98 corporate names, the state of incorporation, the federal



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99 employer identification number, and, if applicable, the name and  
100 business address of the parent company.

101 (c) A list of disciplinary actions pertinent to wholesale  
102 distributors, manufacturers, and retailers of prescription drugs  
103 or controlled substances by a state or federal agency against  
104 the applicant seeking to distribute into this state and any such  
105 disciplinary actions against such applicant's principals,  
106 owners, directors, or officers.

107 (d) A complete disclosure of all of the applicant's past  
108 felony convictions.

109 (e) An address and description of each facility and  
110 warehouse, including all locations used for medical gas storage  
111 or wholesale distribution including a description of each  
112 facility's security system.

113 (4) An applicant shall attest in writing that the  
114 information contained in its application is complete and  
115 accurate.

116 (5) An applicant must submit a reasonable fee, to be  
117 determined by the department, in order to obtain a permit.

118 (a) The fee for a medical gas wholesale distributor permit  
119 may not be less than \$200 or more than \$300 annually.

120 (b) The fee for a medical gas manufacturer permit may not  
121 be less than \$400 or more than \$500 annually.

122 (c) The fee for a medical oxygen retail establishment  
123 permit may not be less than \$200 or more than \$300 annually.

124 (6) Upon approval of the application by the department and  
125 payment of the required fee, the department shall issue a permit  
126 to the applicant pursuant to the rules adopted under this part.

127 Section 17. Section 499.832, Florida Statutes, is created





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128 to read:

129 499.832 Expiration and renewal of a permit.—

130 (1) A permit issued under this part automatically expires 2  
131 years after the last day of the month in which the permit was  
132 originally issued.

133 (2) A permit issued under this part may be renewed by  
134 submitting an application for renewal on a form furnished by the  
135 department and paying the appropriate fee. The application for  
136 renewal must contain a statement by the applicant attesting that  
137 the information is true and correct. Upon approval of a renewal  
138 application by the department and payment of the required  
139 renewal fee, the department shall renew a permit issued under  
140 this part pursuant to the rules adopted under this part.

141 (3) A renewal application may be accepted up to 60 days  
142 after the expiration date of the permit if, along with the  
143 permit renewal fee, the applicant submits an additional renewal  
144 delinquent fee of \$100. A permit that expired more than 60 days  
145 before a renewal application was submitted or postmarked may not  
146 be renewed.

147 (4) Failure to renew a permit in accordance with this  
148 section precludes future renewal. If a permit has expired and  
149 cannot be renewed, the person, entity, or establishment holding  
150 the permit must cease all permit related activities. In order to  
151 engage in activities that require a permit the person, entity,  
152 or establishment must submit an application for a new permit,  
153 pay the applicable application fee, the initial permit fee, and  
154 all applicable penalties, and be issued a new permit by the  
155 department before engaging in an activity that requires a permit  
156 under this part.



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157       (5) The department shall adopt rules to administer this  
158 section, including setting a reasonable fee for a renewal  
159 application.

160       Section 18. Section 499.833, Florida Statutes, is created  
161 to read:

162       499.833 Permitholder changes.—

163       (1) A permit issued under this part is valid only for the  
164 person or entity to which it is issued and is not subject to  
165 sale, assignment, or other transfer, voluntarily or  
166 involuntarily.

167       (2) A permit issued under this part is not valid for an  
168 establishment other than the establishment for which it was  
169 originally issued.

170       (3) The department may approve the following permit  
171 changes:

172       (a) Change of location.—A person or entity permitted under  
173 this part must notify and receive approval from the department  
174 before changing location. The department shall set a change-of-  
175 location fee not to exceed \$100.

176       (b) Change in ownership.—If a majority of the ownership or  
177 controlling interest of a permitted establishment is transferred  
178 or assigned or if a lessee agrees to undertake or provide  
179 services such that legal liability for operation of the  
180 establishment will rest with the lessee, an application for a  
181 new permit is required. Such application must be submitted and  
182 approved by the department before the change of ownership takes  
183 place. However, if a permitted wholesale distributor or  
184 manufacturer is changing ownership and the new owner has held  
185 another permit that allows the wholesale distribution of medical



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186 gas under this chapter for the preceding 18 months without  
187 having been found in violation of the provisions of this chapter  
188 relating to medical gases, then the new owner may operate under  
189 the permit of the acquired entity if the new owner submits the  
190 application for a new permit by the first business day after  
191 ownership is transferred or assigned. A new owner operating  
192 under the original permit is responsible for compliance with all  
193 laws and regulations governing medical gas. If the application  
194 is denied, the new owner shall immediately cease operation at  
195 the establishment until a permit is issued to the new owner.

196 (c) *Change of name.*—A permitholder may make a change of  
197 business name without submitting a new permit application.  
198 However, the permitholder must notify the department before  
199 making the name change.

200 (d) *Closure.*—If an establishment permitted under this part  
201 closes, the owner must notify the department, in writing, before  
202 the effective date of the closure and must:

- 203 1. Return the permit to the department; and  
204 2. Indicate the disposition of any medical gas authorized  
205 to be distributed or dispensed under the permit, including the  
206 name, address, and inventory, and provide the name and address  
207 of a person to contact regarding access to the records that are  
208 required to be maintained under this part. Transfer of ownership  
209 of medical gas may be made only to persons authorized to receive  
210 medical gas pursuant to this part.

211 (e) *Change in information.*—Any change in the information  
212 required under this part, other than the changes in paragraphs  
213 (a)-(d), shall be submitted to the department within 30 days  
214 after such change occurs.



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215       (4) A permitholder in good standing may change the type of  
216 permit issued by completing a new application for the requested  
217 permit, meeting the applicable permitting requirements for the  
218 new permit type, and paying any difference between the permit  
219 fees. A refund may not be issued if the fee for the new permit  
220 is less than the fee that was paid for the original permit. The  
221 new permit retains the expiration date of the original permit.

222       Section 19. Section 499.834, Florida Statutes, is created  
223 to read:

224       499.834 Minimum qualifications.—The department shall  
225 consider all of the following factors in determining eligibility  
226 for, and renewal of, a permit for a person or entity under this  
227 part:

228       (1) A finding by the department that the applicant has  
229 violated or been disciplined by a regulatory agency in any state  
230 for violating a federal, state, or local law relating to  
231 prescription drugs.

232       (2) Felony convictions of the applicant under a federal,  
233 state, or local law.

234       (3) The applicant's past experience in the manufacture,  
235 retail, or distribution of medical gases.

236       (4) False or fraudulent material provided by the applicant  
237 in an application made in connection with the manufacturing,  
238 retailing, or distribution of prescription drugs.

239       (5) Any suspension, sanction, or revocation by a federal,  
240 state, or local government against a license or permit currently  
241 or previously held by the applicant or its owners for violations  
242 of a federal, state, or local law regarding prescription drugs.

243       (6) Compliance with previously granted licenses or permits.



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244 (7) Compliance with the requirements that distributors or  
245 retailers of medical gases maintain records and make records  
246 available to the department licensing authority or federal,  
247 state, or local law enforcement officials.

248 (8) Other factors or qualifications the department  
249 considers relevant to and consistent with the public health and  
250 safety.

251 Section 20. Section 499.84, Florida Statutes, is created to  
252 read:

253 499.84 Minimum requirements for the storage and handling of  
254 medical gases.-

255 (1) A facility where a medical gas is received, stored,  
256 warehoused, handled, held, offered, marketed, displayed, or  
257 transported, to avoid any negative effect on the identity,  
258 strength, quality, or purity of the medical gas, must:

259 (a) Be of suitable construction to ensure that medical  
260 gases are maintained in accordance with the product labeling of  
261 the medical gas or in compliance with the USP-NF;

262 (b) Be of suitable size and construction to facilitate  
263 cleaning, maintenance, and proper permitted operations;

264 (c) Have adequate storage areas with appropriate lighting,  
265 ventilation, space, equipment, and security conditions.

266 (d) Have a quarantined area for storage of medical gases  
267 that are suspected of being misbranded, adulterated, or  
268 otherwise unfit for distribution;

269 (e) Be maintained in an orderly condition;

270 (f) Be located in a commercial location and not in a  
271 personal dwelling or residence location, except that a personal  
272 dwelling location used for on-call delivery of oxygen USP for



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273 homecare use if the person providing on-call delivery is  
274 employed by or acting under a written contract with an entity  
275 that holds a medical oxygen retailer permit;

276 (g) Provide for the secure and confidential storage of  
277 patient information, if applicable, with restricted access and  
278 policies and procedures to protect the integrity and  
279 confidentiality of patient information; and

280 (h) Provide and maintain appropriate inventory controls to  
281 detect and document any theft of nitrous oxide.

282 (2) Medical gas shall be stored under appropriate  
283 conditions in accordance with the manufacturer's recommendations  
284 on product labeling and department rules or, in the absence of  
285 rules, in accordance with applicable industry standards.

286 (3) Medical gas shall be packaged in accordance with  
287 official compendium standards, such as the USP-NF.

288 Section 21. Section 499.85, Florida Statutes, is created to  
289 read:

290 499.85 Security.-

291 (1) A permitholder that has a facility used for the  
292 distribution or retailing of medical gases shall protect such  
293 gases from unauthorized access by implementing all of the  
294 following security measures:

295 (a) Keeping access from outside the premises well-  
296 controlled and to a minimum.

297 (b) Ensuring the outside perimeter of the premises is well  
298 lit.

299 (c) Limiting access into areas where medical gases are held  
300 to authorized personnel.

301 (d) Equipping all facilities with a fence or other system



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302 to detect or deter entry after hours.

303 (2) A facility used for distributing or retailing medical  
304 gases shall be equipped with a system that provides suitable  
305 protection against theft, including if appropriate, protection  
306 against theft of computers or electronic records and the  
307 protection of the integrity and confidentiality of data and  
308 documents.

309 (3) A facility used for wholesale distribution of medical  
310 gases shall be equipped with inventory management and control  
311 systems that protect against, detect, and document any instances  
312 of theft of nitrous oxide.

313 (4) If a wholesale distributor uses electronic distribution  
314 records, the wholesale distributor shall employ, train, and  
315 document the training of personnel in the proper use of such  
316 technology and equipment.

317 (5) Vehicles used for on-call delivery of oxygen USP and  
318 oxygen-related equipment for home care use by home care  
319 providers may be parked at a place of residence and must be  
320 locked and equipped with an audible alarm when not attended.

321 (6) The department shall adopt rules that govern the  
322 distribution of medical oxygen for emergency use by persons  
323 authorized to receive emergency use oxygen. Unless the laws of  
324 this state specifically direct otherwise, such rules must be  
325 consistent with federal regulations, including the labeling  
326 requirements of oxygen under the federal act.

327 Section 22. Section 499.86, Florida Statutes, is created to  
328 read:

329 499.86 Examination of materials.-

330 (1) A wholesale distributor must visually examine a medical



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331 gas container upon receipt from the manufacturer in order to  
332 identify the medical gas stored within and to determine if the  
333 container has been damaged or is otherwise unfit for  
334 distribution. Such examination must occur in a manner that would  
335 reveal damage to the container which could suggest possible  
336 adulteration or misbranding.

337 (2) A medical gas container that is found to be damaged or  
338 otherwise unfit pursuant to subsection (1) must be quarantined  
339 from the stock of medical gas until a determination is made that  
340 the medical gas in question is not misbranded or adulterated.

341 (3) An outgoing shipment must be inspected to identify the  
342 medical gases in the shipment to ensure that medical gas  
343 containers that have been damaged in storage or held under  
344 improper conditions are not distributed or dispensed.

345 (4) A wholesale distributor must review records documenting  
346 the acquisition of medical gas upon receipt for accuracy and  
347 completeness.

348 Section 23. Section 499.87, Florida Statutes, is created to  
349 read:

350 499.87 Returned, damaged, and outdated medical gas.—

351 (1) A medical gas that has left the control of the  
352 wholesale distributor may be returned to the wholesale  
353 distributor or manufacturer from which it was acquired, but may  
354 not be resold as a medical gas unless it is reprocessed by a  
355 manufacturer using proper and adequate controls to ensure the  
356 identity, strength, quality, and purity of the reprocessed  
357 medical gas.

358 (2) A medical gas that has been subjected to improper  
359 conditions, such as a fire, accident, or natural disaster, may





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360 not be salvaged or reprocessed.

361 (3) A medical gas, including its container, which is  
362 damaged, misbranded, or adulterated must be quarantined from  
363 other medical gases until it is destroyed or returned to the  
364 manufacturer or wholesale distributor from which it was  
365 acquired. External contamination of a medical gas container or  
366 closure system which does not impact the integrity of the  
367 medical gas is not considered damaged or adulterated for  
368 purposes of this subsection. If a medical gas is adulterated or  
369 misbranded or suspected of being adulterated or misbranded,  
370 notice shall be provided to the manufacturer or wholesale  
371 distributor from which the medical gas was acquired and to the  
372 appropriate boards and federal regulatory bodies.

373 (4) A medical gas container that has been opened or used  
374 but is not adulterated or misbranded is considered empty and  
375 must be quarantined from nonempty medical gas containers and  
376 returned to the manufacturer or wholesale distributor from which  
377 it was acquired for destruction or reprocessing.

378 (5) A medical gas, its container, or its associated  
379 documentation or labeling that is suspected of being used in  
380 criminal activity must be retained until its disposition is  
381 authorized by the department or an applicable law enforcement  
382 agency.

383 Section 24. Section 499.88, Florida Statutes, is created to  
384 read:

385 499.88 Due diligence.—

386 (1) A wholesale distributor shall obtain, before the  
387 initial acquisition of medical gas, the following information  
388 from the supplying wholesale distributor or manufacturer:



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389       (a) If a manufacturer is distributing to a wholesale  
390 distributor, evidence that the manufacturer is registered and  
391 the medical gas is listed with the United States Food and Drug  
392 Administration;

393       (b) If a wholesale distributor is distributing to a  
394 wholesale distributor, evidence that the wholesale distributor  
395 supplying the medical gas is legally authorized to distribute  
396 medical gas within or into the state;

397       (c) The name of the responsible facility contact person for  
398 the supplying manufacturer or wholesale distributor; and

399       (d) Certification that the manufacturer's or wholesale  
400 distributor's policies and procedures comply with this part.

401       (2) A wholesale distributor is exempt from obtaining the  
402 information from a manufacturer, as required under subsection  
403 (1), if the manufacturer is registered with the United States  
404 Food and Drug Administration in accordance with s. 510 of the  
405 federal act and the manufacturer provides:

406       (a) Proof of such registration; and

407       (b) Proof of inspection by the United States Food and Drug  
408 Administration or other regulatory body within the past 3 years  
409 demonstrating substantial compliance with current good  
410 manufacturing practices applicable to medical gases.

411       (3) A manufacturer or wholesale distributor that  
412 distributes to or acquires medical gas from another wholesale  
413 distributor shall provide to or obtain from the distributing or  
414 acquiring manufacturer or distributor the information required  
415 by s. 499.89(1), as applicable.

416       Section 25. Section 499.89, Florida Statutes, is created to  
417 read:



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418           499.89 Recordkeeping.-  
419           (1) A permitholder under this part shall establish and  
420 maintain a record of transactions regarding the receipt and the  
421 distribution, or other disposition, of medical gases, as  
422 applicable. Such records constitute an audit trail and must  
423 contain information sufficient to perform a recall of medical  
424 gas in compliance with 21 C.F.R. s. 211.196 and 21 C.F.R. s.  
425 820.160(b). Such records must include all of the following  
426 information, which may be kept in two separate documents one  
427 related to the distribution of medical gas and the other related  
428 to the receipt of medical gas:  
429           (a) The dates of receipt and distribution or other  
430 disposition of the medical gas.  
431           (b) The name, address, license or permit number and its  
432 expiration date for the person or entity purchasing the medical  
433 gas from the wholesale distributor.  
434           (c) The name, address, license or permit number and its  
435 expiration date for the person or entity receiving the medical  
436 gas, if different from the information required under paragraph  
437 (b).  
438           (d) Information sufficient to perform a recall of all  
439 medical gas received, distributed, or dispensed.  
440           (2) Such records shall be made available for inspection and  
441 copying by an authorized official of any federal, state, or  
442 local governmental agency for a period of:  
443           (a) Three years following the distribution date of high  
444 pressure medical gases.  
445           (b) Two years following the distribution date for cryogenic  
446 or refrigerated liquid medical gases.



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447 (3) Records kept at the inspection site or that can be  
448 immediately retrieved by computer or other electronic means  
449 shall be readily available for authorized inspection during the  
450 retention period. Records kept at a central location apart from  
451 the inspection site and not electronically retrievable shall be  
452 made available for inspection within 2 working days of a request  
453 by an authorized official of any state or federal governmental  
454 agency charged with enforcement of these rules.

455 (4) A pedigree paper is not required for distributing or  
456 dispensing medical gas.

457 (5) A wholesale distributor shall maintain records  
458 sufficient to aid in the mandatory reporting of any theft,  
459 suspected theft, or other significant loss of nitrous oxide to  
460 the department and other appropriate law enforcement agencies.

461 Section 26. Section 499.90, Florida Statutes, is created to  
462 read:

463 499.90 Policies and procedures.—A wholesale distributor  
464 shall establish, maintain, and adhere to written policies and  
465 procedures for the receipt, security, storage, transport,  
466 shipping, and distribution of medical gases and shall establish,  
467 maintain, and adhere to procedures for maintaining inventories;  
468 for identifying, recording, and reporting losses or thefts; and  
469 for correcting all errors and inaccuracies in inventories  
470 associated with nitrous oxide. A wholesale distributor shall  
471 include in its written policies and procedures the following:

472 (1) A procedure for handling recalls and withdrawals of  
473 medical gas. Such procedure must deal with recalls and  
474 withdrawals due to:

475 (a) Action initiated at the request of the United States



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476 Food and Drug Administration or any federal, state, or local law  
477 enforcement or other government agency, including the  
478 department; or

479 (b) Voluntary action by a manufacturer of medical gases to  
480 remove defective or potentially defective medical gases from the  
481 market.

482 (2) A procedure that includes preparation for, protection  
483 against, and responding to a crisis that affects the security or  
484 operation of a facility that stores medical gases in the event  
485 of a strike; a fire, flood, or other natural disaster; or other  
486 local, state, or national emergency.

487 (3) A procedure for reporting criminal or suspected  
488 criminal activity involving the inventory of nitrous oxide to  
489 the department and to applicable law enforcement agencies within  
490 3 business days after becoming aware of the criminal or  
491 suspected criminal activity.

492 Section 27. Section 499.91, Florida Statutes, is created to  
493 read:

494 499.91 Prohibited acts.—A person may not perform or cause  
495 the performance of, or aid and abet in, any of the following  
496 acts:

497 (1) The manufacture, sale, or delivery, or the holding or  
498 offering for sale, of a medical gas that is adulterated,  
499 misbranded, or is otherwise unfit for distribution.

500 (2) The adulteration or misbranding of a medical gas.

501 (3) The receipt of a medical gas that is adulterated,  
502 misbranded, stolen, or obtained by fraud or deceit, and the  
503 delivery or proffered delivery of such medical gas for pay or  
504 otherwise.



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505       (4) The alteration, mutilation, destruction, obliteration,  
506 or removal of all or any part of the product labeling of a  
507 medical gas, or the willful commission of any other act with  
508 respect to a medical gas that results in it being misbranded.

509       (5) The purchase or receipt of a medical gas from a person  
510 not authorized to distribute or dispense medical gas or who is  
511 not exempted from permitting requirements to wholesale  
512 distribute medical gas to such purchaser or recipient.

513       (6) The knowing and willful sale or transfer of a medical  
514 gas to a recipient who is not legally authorized to receive a  
515 medical gas, except that a violation does not exist if a  
516 permitted wholesale distributor provides oxygen to a permitted  
517 medical oxygen retail establishment that is out of compliance  
518 with the notice of location change requirements of s. 499.834,  
519 provided that the wholesale distributor with knowledge of the  
520 violation notifies the department of the transaction by the next  
521 business day.

522       (7) The failure to maintain or provide records required  
523 under this part and the rules adopted under this part.

524       (8) Providing the department or any of its representatives  
525 or any state or federal official with false or fraudulent  
526 records or making false or fraudulent statements regarding this  
527 part or the rules adopted under this part.

528       (9) The distribution of a medical gas that was:

529       (a) Purchased by a public or private hospital or other  
530 health care entity, except for the physical distribution of such  
531 medical gas to an authorized recipient at the direction of a  
532 hospital or other health care entity;

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



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534 organization; or  
535 (c) Stolen or obtained by fraud or deceit.  
536 (10) The failure to obtain a license or permit or operating  
537 without a valid license or permit, if one is required.  
538 (11) The obtaining of, or attempt to obtain, a medical gas  
539 by fraud, deceit, or misrepresentation or engaging in  
540 misrepresentation or fraud in the distribution of a medical gas.  
541 (12) Except for emergency use oxygen, the distribution of a  
542 medical gas to a patient without a prescription from a  
543 practitioner authorized by law to prescribe a medical gas.  
544 (13) The distribution or dispensing of a medical gas that  
545 was previously dispensed by a pharmacy or a practitioner  
546 authorized by law to prescribe.  
547 (14) The distribution or dispensing of a medical gas or  
548 medical gas-related equipment to a patient, unless the patient  
549 has been provided with the appropriate information and  
550 counseling on the use, storage, and disposal of the medical gas.  
551 (15) Failure to report an act prohibited under this part or  
552 the rules adopted under this part.  
553 (16) Failure to exercise due diligence as provided in s.  
554 499.88.  
555 Section 28. Section 499.92, Florida Statutes, is created to  
556 read:  
557 499.92 Criminal acts.—  
558 (1) A person commits a felony of the third degree,  
559 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
560 if he or she:  
561 (a) Adulterates or misbrands a medical gas with intent to  
562 defraud or deceive;



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563 (b) Knowingly purchases or receives a medical gas from a  
564 person not legally authorized to distribute or dispense medical  
565 gas;

566 (c) Knowingly engages in the wholesale distribution of, or  
567 sells, barter, brokers, or transfers, a medical gas to a person  
568 not legally authorized to purchase or receive medical gas in the  
569 jurisdiction in which the person receives the medical gas. A  
570 permitted wholesale distributor that, at its location, provides  
571 oxygen to a permitted medical oxygen retail establishment that  
572 is out of compliance with only the change of location notice  
573 requirement under s. 499.834, does not commit a violation of  
574 this subsection if the wholesale distributor notifies the  
575 department of the transaction no later than the next business  
576 day; or

577 (d) Knowingly falsely creates a label for a medical gas or  
578 knowingly falsely misrepresents a factual matter contained in a  
579 label for a medical gas.

580 (2) A person found guilty of an offense under this section,  
581 under the authority of the court convicting and sentencing the  
582 person, shall be ordered to forfeit to the state any real or  
583 personal property:

584 (a) Used or intended to be used to commit, to facilitate,  
585 or to promote the commission of such offense; and

586 (b) Constituting, derived from, or traceable to the gross  
587 proceeds that the defendant obtained directly or indirectly as a  
588 result of the offense.

589 (3) Property or assets subject to forfeiture under  
590 subsection (2) may be seized pursuant to a warrant obtained in  
591 the same manner as a search warrant or as otherwise authorized





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592 by law, and held until the case against a defendant is  
593 adjudicated. Monies ordered forfeited, or proceeds from the sale  
594 of other assets ordered forfeited, shall be equitably divided  
595 between the department and other agencies involved in the  
596 investigation and prosecution that led to the conviction. Other  
597 property ordered forfeited after conviction of a defendant may,  
598 at the discretion of the investigating agencies, be placed into  
599 official use by the department or the agencies involved in the  
600 investigation and prosecution that led to the conviction.

601 Section 29. Section 499.93, Florida Statutes, is created to  
602 read:

603 499.93 Inspections.—

604 (1) The department may require a facility that engages in  
605 the manufacture, retail sale, or wholesale distribution of  
606 medical gas to undergo an inspection in accordance with a  
607 schedule to be determined by the department, including  
608 inspections for initial permitting, permit renewal, and a  
609 permitholder's change of location. The department may recognize  
610 a third party to inspect wholesale distributors in this state or  
611 other states pursuant to a schedule to be determined by the  
612 department.

613 (2) The department may recognize another state's  
614 inspections of a manufacturer or wholesale distributor located  
615 in that state if such state's laws are deemed to be  
616 substantially equivalent to the laws of this state by the  
617 department.

618 (3) A manufacturing facility of medical gases is exempt  
619 from routine inspection by the department if:

By the Committee on Regulated Industries; and Senator Bean

580-02206-14

2014836c1

1 A bill to be entitled  
 2 An act relating to medical gas; creating part III of  
 3 ch. 499, F.S., entitled "Medical Gas"; creating s.  
 4 499.81, F.S.; defining terms; creating s. 499.82,  
 5 F.S.; requiring a person or establishment located  
 6 inside or outside the state which intends to  
 7 distribute medical gas within or into this state to  
 8 obtain an applicable permit before operating; listing  
 9 the people or entities that are legally authorized to  
 10 receive medical gas; establishing categories of  
 11 permits and setting requirements for each; creating s.  
 12 499.821, F.S.; requiring the Department of Business  
 13 and Professional Regulation to establish the form and  
 14 content of an application; stating that an applicant  
 15 who is denied a permit has a right of review pursuant  
 16 to ch. 120, F.S.; authorizing the department to set  
 17 fees within certain parameters; creating s. 499.822,  
 18 F.S.; requiring a permit to expire 2 years after the  
 19 last day of the month in which the permit was issued;  
 20 providing requirements for the renewal of a permit;  
 21 requiring the department to adopt rules for the  
 22 renewal of permits; creating s. 499.823, F.S.;  
 23 authorizing the department to consider certain factors  
 24 in determining the eligibility of an applicant;  
 25 creating s. 499.824, F.S.; authorizing the department  
 26 to approve certain permitholder changes; authorizing  
 27 the department to revoke the permit of a person that  
 28 fails to comply with this section; creating s. 499.83,  
 29 F.S.; requiring an applicant for or a holder of a

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

580-02206-14

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30 permit as a wholesale distributor of medical gas or as  
 31 a medical oxygen retailer to designate a registered  
 32 agent; creating s. 499.84, F.S.; setting the minimum  
 33 requirements for the storage and handling of medical  
 34 gas; creating s. 499.85, F.S.; requiring a wholesale  
 35 distributor of medical gas to implement measures to  
 36 secure the location from unauthorized entry; setting  
 37 facility requirements for security purposes;  
 38 authorizing a vehicle used for on-call delivery of  
 39 oxygen USP and oxygen-related equipment to be parked  
 40 at a place of residence; requiring the department to  
 41 adopt rules governing the wholesale distribution of  
 42 prescription medical oxygen; creating s. 499.86, F.S.;  
 43 requiring a wholesale distributor of medical gases to  
 44 visually examine an immediate container upon receipt  
 45 for identity and to determine if the medical gas  
 46 container has been damaged or is otherwise unfit for  
 47 distribution; requiring a medical gas container that  
 48 is damaged or otherwise unfit for distribution to be  
 49 quarantined; requiring outgoing shipments to be  
 50 inspected; requiring wholesale distributors to review  
 51 certain records; creating s. 499.87, F.S.; authorizing  
 52 the return of medical gas that has left the control of  
 53 the wholesale distributor; requiring that medical gas  
 54 that is damaged, misbranded, or adulterated be  
 55 quarantined from other medical gases until it is  
 56 destroyed or returned to the manufacturer or wholesale  
 57 distributor from which it was acquired; creating s.  
 58 499.88, F.S.; requiring a wholesale distributor to

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59 obtain certain information before the initial  
60 acquisition of the medical gas; providing certain  
61 exemptions; creating s. 499.89, F.S.; requiring a  
62 wholesale distributor to establish and maintain  
63 transactional records; providing a retention period  
64 for certain records and requiring that the records be  
65 available for inspection during that period; creating  
66 s. 499.90, F.S.; requiring a wholesale distributor to  
67 establish, maintain, and adhere to certain written  
68 policies and procedures; creating s. 499.91, F.S.;  
69 prohibiting certain acts; creating s. 499.92, F.S.;  
70 establishing criminal penalties; authorizing property  
71 or assets subject to forfeiture to be seized pursuant  
72 to a warrant; creating s. 499.93, F.S.; authorizing  
73 the department to require a facility that engages in  
74 wholesale distribution to undergo an inspection;  
75 authorizing the department to authorize a third party  
76 to inspect wholesale distributors; creating s.  
77 499.931, F.S.; providing that trade secret information  
78 required to be submitted pursuant to this part must be  
79 maintained by the department; creating s. 499.94,  
80 F.S.; requiring fees collected pursuant to this part  
81 to be deposited into the Professional Regulation Trust  
82 Fund; creating s. 499.95, F.S.; authorizing the  
83 department for the purpose of initiating an  
84 investigation or proceeding under this part to  
85 administer oaths, take depositions, issue and serve  
86 subpoenas, and compel attendance of witnesses and the  
87 production of books, papers, documents or other

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88 evidence; requiring an attorney to whom the department  
89 reports a violation of this part to timely institute  
90 proceedings in the court of competent jurisdiction;  
91 exempting minor violations from reporting requirements  
92 at the department's discretion; providing that this  
93 part is cumulative and does not repeal or affect the  
94 power, duty, or authority of the department; amending  
95 ss. 409.9201, 460.403, and 465.0265; conforming  
96 provisions to changes made by the act; amending s.  
97 499.001, F.S.; conforming a provision to changes made  
98 by the act; amending s. 499.003, F.S.; conforming  
99 terminology, deleting a definition, and defining the  
100 term "medical gas"; amending ss. 499.01 and 499.0121,  
101 F.S.; conforming provisions to changes made by the  
102 act; amending s. 499.01211, F.S.; changing the  
103 membership of the Drug Wholesale Distributor Advisory  
104 Council; requiring the Compressed Gas Association to  
105 appoint one person to the council; amending ss.  
106 499.01212, 499.015, 499.024, 499.041, 499.05, 499.051,  
107 499.066, 499.0661, and 499.067, F.S.; conforming  
108 provisions to changes made by the act; providing an  
109 effective date.

110  
111 Be It Enacted by the Legislature of the State of Florida:

112  
113 Section 1. Part III of chapter 499, Florida Statutes,  
114 consisting of ss. 499.81-499.95, Florida Statutes, is created  
115 and is entitled "Medical Gas."

116 Section 2. Section 499.81, Florida Statutes, is created to

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117 read:

118 499.81 Definitions.-As used in this part, the term:119 (1) "Adulterated" with respect to medical gas means medical  
120 gas that:121 (a) Consists, in whole or in part, of impurities or  
122 deleterious substances that exceed normal specifications;123 (b) Has been produced, prepared, packed, or held under  
124 conditions whereby the gas may have been contaminated, causing  
125 it to be rendered injurious to health; or was manufactured,  
126 processed, packed, or held using methods, facilities, or  
127 controls that do not conform to or are not operated or  
128 administered in conformity with current good manufacturing  
129 practices;130 (c) Has a container interior that is composed, in whole or  
131 in part, of a poisonous or deleterious substance that may render  
132 the container contents injurious to health; or133 (d) Has a strength that differs from, or that is of a  
134 quality or purity that fails to meet, the standards established  
135 in the USP-NF, if the gas is purported to be, or is represented  
136 as, medical gas as recognized in the USP-NF. Such a  
137 determination as to strength, quality, or purity must be made in  
138 accordance with the tests or methods of assay set forth in the  
139 USP-NF or a validated equivalent, or, in the absence or  
140 inadequacy of these tests or methods of assay, those prescribed  
141 under the authority of the federal act shall be used. However, a  
142 gas that is purported to be, or is represented as, medical gas  
143 as recognized in the USP-NF but that differs in strength,  
144 quality, or purity from the standards established in the USP-NF  
145 may not be deemed adulterated for purposes of this paragraph if

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146 the difference is plainly stated on its label.147 (2) "Department" means the Department of Business and  
148 Professional Regulation.149 (3) "Distribute" or "distribution" means to sell or offer  
150 to sell, deliver or offer to deliver, broker, give away, or  
151 transfer medical gas, by passage of title or by physical  
152 movement. The term does not include:153 (a) Dispensing or administering medical gas;154 (b) Delivering or offering to deliver medical gas by a  
155 common carrier in its usual course of business; or156 (c) A sales activity that takes place in an establishment  
157 that is owned or controlled by a person or business entity  
158 authorized to distribute medical gas within or into this state  
159 or staffed by persons employed by such person, if the location  
160 where the sales activity takes place does not physically store  
161 or transport medical gas.162 (4) "Emergency use oxygen" means oxygen USP that is  
163 administered without a prescription for an emergency situation  
164 concerning oxygen deficiency or resuscitation and that is in a  
165 container labeled in accordance with FDA standards.166 (5) "FDA" means the federal Food and Drug Administration.167 (6) "Federal act" means the federal Food, Drug, and  
168 Cosmetic Act, 21 U.S.C. ss. 301 et seq.169 (7) "Health care entity" means a person, including an  
170 organization business entity, which provides diagnostic,  
171 medical, surgical, or dental treatment or rehabilitative care.  
172 The term includes a home respiratory care provider or a person  
173 or entity authorized to administer emergency use oxygen, but  
174 does not include a retail pharmacy or wholesale distributor.

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175 (8) "Immediate container" means a compressed gas cylinder  
 176 or liquid container that contains medical gas. The term does not  
 177 include a large-bulk liquid or high pressure container, such as  
 178 a storage tank, vehicle-mounted vessel, trailer, or railcar.

179 (9) "Intracompany transaction" means a transaction between  
 180 divisions, subsidiaries, parents, or affiliated or related  
 181 companies under the common ownership and control of a single  
 182 corporate entity.

183 (10) "Label" means a display of a written, printed, or  
 184 graphic matter upon an immediate container. The term does not  
 185 include the letters, numbers, or symbols stamped onto a  
 186 container as required by the United States Department of  
 187 Transportation.

188 (11) "Manufacturer" means a person or entity that  
 189 manufactures medical gas in bulk or that transfers the gas or  
 190 liquefied gas product from one container to another.

191 (12) "Medical gas" is defined in accordance with the  
 192 federal act and means a liquefied or vaporized gas that is a  
 193 prescription drug, regardless of whether it is alone or combined  
 194 with other gases.

195 (13) "Medical gas-related equipment" means a device used as  
 196 an accessory or component part to contain or control flow,  
 197 delivery, or pressure during the administration of medical gas,  
 198 such as liquid-oxygen base and portable units, pressure  
 199 regulators, flow meters, and oxygen concentrators.

200 (14) "Misbranded" means medical gas that has a label that  
 201 is false or misleading or a label that does not:

202 (a) Display the name and address of the manufacturer,  
 203 packer, or distributor;

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204 (b) Provide an accurate statement of the quantity of active  
 205 ingredients or show an accurate monograph for the medical gas;  
 206 or

207 (c) In the case of mixtures of designated medical gases,  
 208 identify the component percentages of each designated medical  
 209 gas used to make the mixture.

210 (15) "Prescription medical oxygen" means oxygen USP, a drug  
 211 that may be sold only by the order or prescription of a licensed  
 212 practitioner authorized by law to prescribe.

213 (16) "USP-NF" or "USP" means the standards published in the  
 214 official book, "The United States Pharmacopeia and the National  
 215 Formulary."

216 (17) "Wholesale distribution" means the distribution of  
 217 medical gas by a wholesale distributor of medical gas to a  
 218 person other than a consumer or patient. The term does not  
 219 include:

220 (a) The sale, purchase, or trade of a medical gas, an offer  
 221 to sell, purchase, or trade a prescription drug or device, or  
 222 the dispensing of medical gas pursuant to a prescription;

223 (b) The sale, purchase, or trade of a medical gas or an  
 224 offer to sell, purchase, or trade medical gas for an emergency  
 225 medical reason that includes, but is not limited to:

226 1. A transfer of a medical gas between wholesale  
 227 distributors or between a wholesale distributor and a retail  
 228 pharmacy or health care entity to alleviate a temporary shortage  
 229 of medical gas resulting from a delay in or an interruption of a  
 230 regular distribution schedule;

231 2. Sales to a licensed emergency medical service provider,  
 232 such as an ambulance company, a firefighting organization, or a

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233 licensed practitioner authorized to prescribe medical gases;  
 234 3. Provision of minimal emergency supplies of medical gas  
 235 to a nursing home for use in an emergency or during the hours of  
 236 the day when necessary medical gas cannot be obtained; or  
 237 4. Transfers of medical gases to alleviate a temporary  
 238 shortage between retail pharmacies;  
 239 (c) An intracompany transaction;  
 240 (d) The sale, purchase, or trade of medical gas or an offer  
 241 to sell, purchase, or trade medical gas among hospitals,  
 242 pharmacies, or other health care entities that are under common  
 243 control;  
 244 (e) The sale, purchase, or trade of medical gas, or the  
 245 offer to sell, purchase, or trade medical gas by a charitable  
 246 organization that has been granted an exemption under s.  
 247 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate  
 248 of the organization, to the extent otherwise permitted by law;  
 249 (f) The purchase or other acquisition of medical gas by a  
 250 hospital or other similar health care entity that is a member of  
 251 a group purchasing organization, for the hospital's or the  
 252 health care entity's own use, from the group purchasing  
 253 organization or from another hospital or similar health care  
 254 entity that is a member of such organization;  
 255 (g) The return of residual medical gas that may be  
 256 reprocessed in accordance with the manufacturer's procedures or  
 257 the return of recalled, expired, damaged, or otherwise  
 258 nonsalable medical gas, when returned by a hospital, health care  
 259 entity, pharmacy, or charitable institution to a wholesale  
 260 distributor;  
 261 (h) An activity that is exempt from the definition of the

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262 term "wholesale distribution" as provided in s. 499.003; or  
 263 (i) A transaction that is excluded from the definition of  
 264 the term "wholesale distribution" under the federal act or  
 265 regulations implemented under the federal act related to medical  
 266 gas.  
 267 (18) "Wholesale distributor" means a person or entity  
 268 engaged in the wholesale distribution of medical gas within or  
 269 into this state, including, but not limited to, a manufacturer,  
 270 an own-label distributor, a private-label distributor, a  
 271 warehouse, including a manufacturers' and distributors'  
 272 warehouse, and a wholesale medical gas warehouse.  
 273 Section 3. Section 499.82, Florida Statutes, is created to  
 274 read:  
 275 499.82 Permits.—  
 276 (1) A person or establishment, located inside or outside  
 277 the state, which intends to distribute medical gas within or  
 278 into this state must obtain the applicable permit before  
 279 operating.  
 280 (2) All of the following are legally authorized to receive  
 281 medical gas: permitted medical gas manufacturers or permitted  
 282 wholesale distributors, licensed pharmacies or health care  
 283 entities, people authorized to receive emergency use oxygen  
 284 without a prescription, locations with automated external  
 285 defibrillation machines where emergency use oxygen is intended  
 286 to be used with such machines, or companies that need medical  
 287 gas in the installation and refurbishment of piping and  
 288 equipment used to contain or administer medical gas.  
 289 (3) An applicant who is a natural person must be at least  
 290 18 years of age or an applicant must be managed, controlled, or

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291 overseen, directly or indirectly, by a natural person who is at  
 292 least 18 years of age.

293 (4) An out-of-state wholesale distributor that provides  
 294 services in this state must be legally authorized as a wholesale  
 295 distributor in the state in which it resides or is incorporated.

296 (5) A wholesale distributor may not operate from a place of  
 297 residence, and a place of residence may not be granted a permit  
 298 or operate under this part, except for the on-call delivery of  
 299 home care oxygen by a home respiratory care technician.

300 (6) If wholesale distribution is conducted at more than one  
 301 location within this state or more than one location  
 302 distributing into this state, each location must be permitted by  
 303 the department.

304 (7) The following permits are established:

305 (a) Medical gas wholesale distributor permit.—A medical gas  
 306 wholesale distributor permit is required for wholesale  
 307 distribution within or into this state.

308 1. Such permit does not authorize distribution to a  
 309 consumer or patient.

310 2. The medical gas must be in the container that was  
 311 obtained by that wholesale distributor without further  
 312 manufacturing operations being performed.

313 3. A wholesale distributor may not possess or engage in the  
 314 wholesale distribution of any prescription drug other than  
 315 medical gas.

316 (b) Medical gas manufacturer permit.—A medical gas  
 317 manufacturer permit is required for a person who engages in the  
 318 manufacture of medical gas by physical air separation, chemical  
 319 action, purification, or filling containers using a liquid-to-

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320 liquid, liquid-to-gas, or gas-to-gas process and distributes  
 321 such medical gas within or into this state. A medical gas  
 322 manufacturer:

323 1. May not manufacture or possess a prescription drug other  
 324 than medical gas unless the appropriate permit is obtained.

325 2. May engage in the wholesale distribution of medical gas  
 326 that is manufactured at the permitted establishment without  
 327 obtaining a medical gas wholesale distributor permit, but shall  
 328 comply with this part and applicable rules.

329 3. Shall comply with all appropriate state and federal good  
 330 manufacturing practices.

331 (c) Medical oxygen retail establishment permit.—A medical  
 332 oxygen retail establishment permit is required for a person who  
 333 sells prescription medical oxygen directly to patients. Such  
 334 sales must be based upon an order or prescription from a  
 335 licensed practitioner authorized by law to prescribe. A pharmacy  
 336 licensed under chapter 465 is exempt from this paragraph. A  
 337 medical oxygen retail establishment:

338 1. May not possess, purchase, sell, or trade a prescription  
 339 drug other than medical oxygen unless other appropriate permits  
 340 are obtained.

341 2. May refill a prescription medical oxygen container for a  
 342 patient based on an order or prescription from a licensed  
 343 practitioner authorized by law to prescribe. A medical oxygen  
 344 retail establishment that refills prescription medical oxygen  
 345 shall comply with all appropriate state and federal good  
 346 manufacturing practices.

347 3. Shall comply with the storage and handling requirements  
 348 under s. 499.84.

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349 4. May not receive back into its inventory any prescription  
 350 medical oxygen that it sold pursuant to a licensed  
 351 practitioner's order.

352 Section 4. Section 499.821, Florida Statutes, is created to  
 353 read:

354 499.821 Permit application.—

355 (1) The department shall establish by rule the form and  
 356 content of an application to obtain a permit listed under s.  
 357 499.82.

358 (a) An application for a permit must be filed with the  
 359 department and must include the following information:

360 1. The trade or business names, including fictitious names,  
 361 currently and formerly used by the applicant, which may not be  
 362 identical to a name used by an unrelated wholesale distributor  
 363 authorized in this state to purchase medical gas.

364 2. The name or names of the owner and operator of the  
 365 permittee, if not the same person or entity. The application  
 366 must also include the following if the applicant is:

367 a. An individual: the applicant's business address and date  
 368 of birth.

369 b. A sole proprietorship: the business address of the sole  
 370 proprietor and the name and federal employer identification  
 371 number of the business entity.

372 c. A partnership: the business address and date of birth of  
 373 each partner and the name and federal employer identification  
 374 number of the partnership.

375 d. A limited liability company: the business address and  
 376 title of each company officer, the name and federal employer  
 377 identification number of the limited liability company, and the

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378 state of incorporation.

379 e. A corporation: the business address and title of each  
 380 corporate officer and director; the name, state of  
 381 incorporation, and federal employer identification number of the  
 382 corporation; and the name and business address of any parent  
 383 company.

384 3. A list of disciplinary actions pertinent to wholesale  
 385 distributors of prescription drugs or controlled substances by a  
 386 state or federal agency against the applicant seeking to  
 387 distribute into this state and against a principal, owner,  
 388 director, or officer.

389 4. An address and description of each facility or  
 390 warehouse, including a description of the security system for  
 391 any location used for medical gas storage or wholesale  
 392 distribution.

393 (b) The applicant shall attest in writing that the  
 394 information contained in the application is complete and  
 395 accurate, that the applicant has not been convicted of or  
 396 disciplined for a criminal or prohibited act, and that the  
 397 application contains complete disclosure of any past criminal  
 398 convictions or violations of state or federal law relating to  
 399 medical gases.

400 (2) An applicant that is denied a permit has the right to  
 401 review of the department's decision pursuant to chapter 120.

402 (3) An applicant must submit a reasonable fee, to be  
 403 determined by the department, in order to obtain a permit. The  
 404 fee for a medical gas wholesale distributor permit may not be  
 405 less than \$200 or more than \$300 annually. The fee for a medical  
 406 gas manufacturer permit may not be less than \$400 or more than



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407 \$500 annually. The fee for a medical oxygen retail establishment  
 408 permit may not be less than \$200 or more than \$300 annually.

409 Section 5. Section 499.822, Florida Statutes, is created to  
 410 read:

411 499.822 Expiration and renewal of a permit.—

412 (1) A permit issued under this part automatically expires 2  
 413 years after the last day of the month in which the permit was  
 414 originally issued unless the permit is suspended or revoked  
 415 before the automatic expiration date.

416 (2) A permit issued under this part may be renewed by  
 417 submitting an application for renewal on a form furnished by the  
 418 department and paying the appropriate fee. The application for  
 419 renewal must contain a statement by the applicant attesting that  
 420 the information is true and correct. If a renewal application  
 421 and renewal fee are submitted and postmarked after the  
 422 expiration date of the permit, the permit may be renewed only  
 423 upon payment of a late renewal delinquent fee of \$100, plus the  
 424 required renewal fee, within 60 days after the expiration date.

425 (3) Failure to renew a permit in accordance with this  
 426 section precludes future renewal. If a permit has expired and  
 427 cannot be renewed, the person or establishment must submit an  
 428 application for a new permit, pay the applicable application  
 429 fee, the initial permit fee, and all applicable penalties, and  
 430 be issued a new permit by the department before engaging in an  
 431 activity that requires a permit under this part.

432 (4) The department shall adopt rules to administer this  
 433 section, including setting a reasonable fee for a renewal  
 434 application.

435 Section 6. Section 499.823, Florida Statutes, is created to

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436 read:

437 499.823 Minimum qualifications.—The department may deny an  
 438 application for a permit or refuse to renew a permit based upon:

439 (1) Whether the applicant has violated, or has been  
 440 disciplined by a regulatory agency in any state for violating, a  
 441 federal, state, or local law relating to wholesale distribution;

442 (2) The applicant's criminal convictions;

443 (3) The applicant's past experience in manufacturing or  
 444 distributing medical gas;

445 (4) Any false or fraudulent material contained in an  
 446 application;

447 (5) Suspension, sanction, or revocation of a permit  
 448 currently or previously held by the applicant for violations of  
 449 a state or federal law relating to medical gas;

450 (6) Compliance with previously granted permit requirements;

451 (7) Compliance with the requirements to maintain or make  
 452 available to the department or permitting authority or to a  
 453 federal, state, or local law enforcement official records

454 required to be maintained by a wholesale distributor; and

455 (8) Any other factors or qualifications that the department  
 456 considers relevant to and consistent with public health and  
 457 safety.

458 Section 7. Section 499.824, Florida Statutes, is created to  
 459 read:

460 499.824 Permitholder changes.—

461 (1) A permit issued by the department is valid only for the  
 462 person or entity to which it is issued and is not subject to  
 463 sale, assignment, or other transfer, voluntarily or  
 464 involuntarily, and is not valid for an establishment other than

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465 the establishment for which it was originally issued, except as  
 466 provided in this part. The department may approve the following  
 467 changes, and a person or entity may continue to operate in the  
 468 following manner:

469 (a) Change of location.—A person or entity permitted under  
 470 this part must notify the department 30 days before changing  
 471 location. The department shall set a change-of-location fee not  
 472 to exceed \$100.

473 (b) Change in ownership.—If a majority of the ownership or  
 474 controlling interest of a permitted establishment is transferred  
 475 or assigned or if a lessee agrees to undertake or provide  
 476 services such that legal liability for operation of the  
 477 establishment will rest with the lessee, an application for a  
 478 new permit is required. The application for the new permit must  
 479 be submitted 30 days before the change of ownership. However, if  
 480 an applicant is a permitholder or is wholly owned by or wholly  
 481 owns a permitholder under this part, the application for the new  
 482 permit must be made by the date of the sale, transfer,  
 483 assignment, or lease. Between the date of the change of  
 484 ownership and the date of the application approval or denial by  
 485 the department, an applicant may distribute under the permit  
 486 number of the previous owner.

487 (c) Change of name.—A permitholder may change its name  
 488 without submitting a new permit application. However, the  
 489 permitholder must notify the department 30 days before changing  
 490 its name. The permitholder may continue to operate the  
 491 establishment while the notification is being processed.

492 (d) Closure.—If an establishment permitted under this part  
 493 closes, the owner must notify the department, in writing, before

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494 the effective date of the closure and must:

- 495 1. Return the permit to the department; and
- 496 2. If the permittee is authorized to distribute medical  
 497 gas, indicate the disposition of such medical gas, including the  
 498 name, address, and inventory, and provide the name and address  
 499 of a person to contact regarding access to the records that are  
 500 required to be maintained under this part. Transfer of ownership  
 501 of medical gas may be made only to persons authorized to receive  
 502 medical gas pursuant to this part.

503 (e) Change in information.—Any change in information  
 504 required under this part, other than a change of information as  
 505 set forth in paragraphs (a)-(d), must be submitted to the  
 506 department within 30 days after such change.

507 (2) Notwithstanding paragraph (1)(a), a permitholder in  
 508 good standing may change the type of permit issued by completing  
 509 a new application for the requested permit, paying the amount of  
 510 the difference in the permit fees, and meeting the applicable  
 511 permitting requirements for the new permit type. A refund may  
 512 not be issued if the fee for the new permit is less than the fee  
 513 that was paid for the original permit. The new permit expires on  
 514 the expiration date of the original permit being changed.

515 (3) The department may revoke a permit for failure to  
 516 comply with this section.

517 Section 8. Section 499.83 Florida Statutes, is created to  
 518 read:

519 499.83 Registered agent.—An applicant for or a holder of a  
 520 permit as a medical gas wholesale distributor or as a medical  
 521 oxygen retail establishment shall designate a registered agent  
 522 in this state for purposes of service of process. If an

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523 applicant or a permitted wholesale distributor or medical oxygen  
 524 retailer fails to designate a registered agent, the Secretary of  
 525 State shall be deemed the true and lawful attorney of the  
 526 applicant or the permitted wholesale distributor or medical  
 527 oxygen retailer, and, in such case, the legal processes in any  
 528 action or proceeding against an applicant or permitted wholesale  
 529 distributor or medical oxygen retailer which grows out of or  
 530 arising from wholesale distribution or retail may be served upon  
 531 the Secretary of State. A copy of the service of process shall  
 532 be mailed to the applicant or the permitted wholesale  
 533 distributor or medical oxygen retailer by the department by  
 534 certified mail, return receipt requested, postage prepaid, at  
 535 the address of the applicant or the distributor or retailer as  
 536 designated on the application for a permit in this state.

537 Section 9. Section 499.84, Florida Statutes, is created to  
 538 read:

539 499.84 Minimum requirements for the storage and handling of  
 540 medical gas.-

541 (1) A facility that receives, stores, warehouses, handles,  
 542 holds, offers, markets, displays, or transports medical gas must  
 543 avoid any negative effect on the identity, strength, quality, or  
 544 purity of medical gas by:

545 (a) Being constructed in a way that ensures that medical  
 546 gas is maintained in accordance with its product labeling  
 547 recommendations or in compliance with official compendium  
 548 standards, such as the USP-NF;

549 (b) Being of a suitable size and construction that  
 550 facilitates cleaning, maintenance, and proper wholesale  
 551 distribution;

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552 (c) Having an adequate storage area with appropriate  
 553 lighting, ventilation, space, equipment, and security  
 554 conditions;  
 555 (d) Having a quarantine area for the storage of medical gas  
 556 that is suspected of being misbranded, adulterated, or otherwise  
 557 unfit for distribution;  
 558 (e) Being maintained in an orderly condition;  
 559 (f) Being in a commercial location, except if a personal  
 560 dwelling location is used for the on-call delivery of oxygen USP  
 561 for home care use and the person providing on-call delivery is  
 562 employed by or acting under a written contract with a permittee;  
 563 (g) Providing for the secure storage of patient  
 564 information, if applicable, by restricting access and  
 565 implementing policies and procedures that protect the integrity  
 566 and confidentiality of patient information; and  
 567 (h) Providing and maintaining appropriate inventory  
 568 controls in order to detect and document any theft of nitrous  
 569 oxide.  
 570 (2) Medical gas must be stored under appropriate conditions  
 571 in accordance with the manufacturers' recommendations on product  
 572 labeling and department rules or, in the absence of rules, in  
 573 accordance with applicable industry standards. Medical gas must  
 574 be packaged in accordance with official compendium standards,  
 575 such as the USP-NF.  
 576 Section 10. Section 499.85, Florida Statutes, is created to  
 577 read:  
 578 499.85 Security.-  
 579 (1) A facility that engages in wholesale distribution shall  
 580 implement measures to secure its facility from unauthorized

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581 entry. Such measures must include the following:  
 582 (a) Access from outside the premises must be well-  
 583 controlled and kept to a minimum.  
 584 (b) The outside perimeter of the premises must be well-  
 585 lighted.  
 586 (c) Areas in which medical gas is held must be restricted  
 587 by a fence or other system that detects or deters entry after  
 588 hours and limits access only to authorized personnel.  
 589 (2) A facility that engages in wholesale distribution must  
 590 have:  
 591 (a) A security system that provides protection against  
 592 theft and, if appropriate, theft that is enabled or obscured by  
 593 tampering with computers or electronic records.  
 594 (b) A security system that protects the integrity and  
 595 confidentiality of data and documents.  
 596 (3) If a wholesale distributor uses electronic distribution  
 597 records, he or she must employ, train, and document the training  
 598 of personnel for the proper use of the applicable technology and  
 599 equipment.  
 600 (4) A vehicle used for on-call delivery of oxygen USP and  
 601 oxygen-related equipment for home care use by a home care  
 602 provider may be parked at a place of residence. Such vehicle  
 603 while unattended must be locked and equipped with an audible  
 604 alarm.  
 605 (5) The department shall adopt rules that govern the  
 606 wholesale distribution of prescription medical oxygen for  
 607 emergency use by persons authorized to receive emergency use  
 608 oxygen. Unless the laws of this state specifically direct  
 609 otherwise, such rules must be consistent with federal rules and

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610 regulations, including the labeling requirements of oxygen under  
 611 the federal act.  
 612 Section 11. Section 499.86, Florida Statutes, is created to  
 613 read:  
 614 499.86 Examination of materials.-  
 615 (1) A wholesale distributor must visually examine an  
 616 immediate container upon receipt from the manufacturer in order  
 617 to identify the medical gas and to determine if the container  
 618 has been damaged or is otherwise unfit for wholesale  
 619 distribution. Such examination must occur in a manner that would  
 620 reveal damage to the container which could suggest possible  
 621 adulteration or misbranding.  
 622 (2) A medical gas container that is damaged (2) or otherwise  
 623 unfit pursuant to subsection (1) must be quarantined from the  
 624 rest of the stock of medical gas until it is determined that the  
 625 medical gas in question was not misbranded or adulterated.  
 626 (3) An outgoing shipment must be inspected for identity and  
 627 to ensure that medical gas containers that have been damaged in  
 628 storage or held under improper conditions are not delivered.  
 629 (4) A wholesale distributor must review records documenting  
 630 the acquisition of medical gas upon receipt for accuracy and  
 631 completeness.  
 632 Section 12. Section 499.87, Florida Statutes, is created to  
 633 read:  
 634 499.87 Returned, damaged, and outdated medical gas.-  
 635 (1) Medical gas that has left the control of a wholesale  
 636 distributor may be returned to the manufacturer or wholesale  
 637 distributor from which it was acquired.  
 638 (2) Unless medical gas is reprocessed by a manufacturer

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639 employing proper and adequate controls to ensure the identity,  
 640 strength, quality, and purity of the reprocessed medical gas,  
 641 the gas may not be resold as a medical gas even if its integrity  
 642 was maintained.

643 (3) Medical gas that has been subjected to improper  
 644 conditions, such as a fire, accident, or natural disaster, may  
 645 not be salvaged or reprocessed.

646 (4) Medical gas, including its container, which is damaged,  
 647 misbranded, or adulterated must be quarantined from other  
 648 medical gases until it is destroyed or returned to the  
 649 manufacturer or wholesale distributor from which it was  
 650 acquired. External contamination to a medical gas container or  
 651 closure system which does not impact the integrity of the  
 652 medical gas is not considered damage or adulteration for  
 653 purposes of this subsection. If medical gas is adulterated or  
 654 misbranded or suspected of being adulterated or misbranded,  
 655 notice shall be provided to the manufacturer or wholesale  
 656 distributor from which the medical gas was acquired and to the  
 657 appropriate boards and federal regulatory bodies.

658 (5) A medical gas container that has been opened or used  
 659 but is not adulterated or misbranded is considered empty and  
 660 must be quarantined from nonempty medical gas containers and  
 661 returned to the manufacturer or wholesale distributor from which  
 662 it was acquired for destruction or reprocessing.

663 (6) Medical gas, its container, or its associated  
 664 documentation or labeling that is suspected of being used in  
 665 criminal activity must be retained until its disposition is  
 666 authorized by the department or an applicable law enforcement  
 667 agency.

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668 Section 13. Section 499.88, Florida Statutes, is created to  
 669 read:

670 499.88 Due diligence.—

671 (1) A wholesale distributor shall obtain, before the  
 672 initial acquisition of medical gas, the following information  
 673 from the supplying wholesale distributor or manufacturer:

674 (a) If a manufacturer is distributing to a wholesale  
 675 distributor, evidence that the manufacturer is registered and  
 676 the medical gas is listed with the FDA;

677 (b) If a wholesale distributor is distributing to a  
 678 wholesale distributor, evidence that the wholesale distributor  
 679 supplying the medical gas is permitted to distribute medical gas  
 680 within or into the state;

681 (c) The name of the contact person for the supplying  
 682 manufacturer or wholesale distributor; and

683 (d) Certification that the manufacturer's or wholesale  
 684 distributor's policies and procedures comply with this part.

685 (2) A wholesale distributor is exempt from obtaining the  
 686 information from a manufacturer as required under subsection (1)  
 687 if the manufacturer is registered with the FDA in accordance  
 688 with s. 510 of the federal act and provides:

689 (a) Proof of such registration; and

690 (b) Proof of inspection within the past 3 years by the FDA  
 691 or other regulatory body or proof of conformance with industry  
 692 standards or guidelines as identified by the department.

693 (3) A manufacturer or wholesale distributor that  
 694 distributes to or acquires medical gas from another wholesale  
 695 distributor shall provide to or obtain from the distributing or  
 696 acquiring manufacturer or distributor the information required

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697 by s. 499.89(1), as applicable.

698 Section 14. Section 499.89, Florida Statutes, is created to  
699 read:

700 499.89 Recordkeeping.—

701 (1) A wholesale distributor shall establish and maintain a  
702 record of transactions regarding the receipt and the  
703 distribution, or other disposition, of medical gases. Such  
704 records constitute an audit trail and must contain information  
705 sufficient to perform a recall of medical gas in compliance with  
706 21 C.F.R. s. 211.196 and 21 C.F.R. s. 820.160(b). Such records  
707 must include all the following information, which need not  
708 appear in the same document:

709 (a) The dates of receipt and wholesale distribution, or  
710 other disposition, of the medical gas.

711 (b) The name, address, permit number, and permit expiration  
712 date for the entity purchasing the medical gas from the  
713 wholesale distributor.

714 (c) The name, address, permit number, and permit expiration  
715 date for the entity receiving the medical gas from the wholesale  
716 distributor, if different from the information required under  
717 paragraph (b).

718 (d) Information sufficient to perform a recall of all  
719 medical gas received or distributed.

720 (2) From the time of their creation, such records shall be  
721 kept for 3 years for high pressure medical gas and for 1 year  
722 for cryogenic or refrigerated liquid medical gas.

723 (3) During the retention period, such records shall be made  
724 available for inspection and photocopying by an authorized  
725 official of a state, federal, or local governmental agency. If

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726 such records are kept at the inspection site or could be  
727 immediately retrieved by electronic means, they shall be made  
728 readily available for authorized inspection during the retention  
729 period. Records kept at a central location apart from the  
730 inspection site and not electronically retrievable shall be made  
731 available for inspection within 2 business days of a request.

732 (4) A pedigree paper is not required for the wholesale  
733 distribution of medical gas.

734 Section 15. Section 499.90, Florida Statutes, is created to  
735 read:

736 499.90 Policies and procedures.—A wholesale distributor  
737 shall establish, maintain, and adhere to written policies and  
738 procedures for the receipt, security, storage, transport,  
739 shipping, and wholesale distribution of medical gas and shall  
740 establish, maintain, and adhere to procedures for maintaining  
741 inventories; for identifying, recording, and reporting losses or  
742 thefts; and for correcting all errors and inaccuracies in  
743 inventories associated with nitrous oxide. A wholesale  
744 distributor shall include in its written policies and procedures  
745 the following:

746 (1) A procedure for handling recalls and withdrawals of  
747 medical gas. Such procedure must deal with recalls and  
748 withdrawals due to:

749 (a) Action initiated at the request of the FDA or any  
750 federal, state, or local law enforcement or other government  
751 agency, including the department; or

752 (b) Voluntary action by the manufacturer of medical gas to  
753 remove defective or potentially defective medical gases from the  
754 market.

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755 (2) A procedure preparing for, protecting against, and  
 756 handling a crisis that affects the security or operation of a  
 757 facility in the event of a strike, fire, flood, or other natural  
 758 disaster or other situations of local, state, or national  
 759 emergency.

760 (3) A procedure for reporting criminal or suspected  
 761 criminal activity involving the inventory of nitrous oxide to  
 762 the department and to applicable law enforcement agencies within  
 763 3 business days after becoming aware of the criminal or  
 764 suspected criminal activity.

765 Section 16. Section 499.91, Florida Statutes, is created to  
 766 read:

767 499.91 Prohibited acts.—A person may not perform or cause  
 768 the performance of, or aid and abet in, any of the following  
 769 acts in this state:

770 (1) The manufacture, sale, or delivery, or the holding or  
 771 offering for sale, of medical gas that is adulterated,  
 772 misbranded, or has otherwise been rendered unfit for  
 773 distribution.

774 (2) The adulteration or misbranding of medical gas.

775 (3) The receipt of medical gas that is adulterated,  
 776 misbranded, stolen, or obtained by fraud or deceit or the  
 777 delivery or proffered delivery of such medical gas for pay or  
 778 otherwise.

779 (4) The alteration, mutilation, destruction, obliteration,  
 780 or removal of the whole or any part of the product labeling of  
 781 medical gas or the willful commission of any other act with  
 782 respect to medical gas that results in it being misbranded.

783 (5) The purchase or receipt of medical gas from a person

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784 who is not authorized by permit to distribute wholesale medical  
 785 gas or who is exempted from permitting requirements to  
 786 distribute wholesale medical gas to such purchaser or recipient.

787 (6) The knowing and willful sale or transfer of medical gas  
 788 to a recipient who is not legally authorized to receive medical  
 789 gas, except that a violation does not exist as to a distributor  
 790 that provides oxygen to a permitted medical oxygen retail  
 791 establishment if the distributor is out of compliance with only  
 792 the change of location notice requirement under s. 499.824.

793 (7) The failure to maintain or provide records required  
 794 under this part and its implementing regulations.

795 (8) Providing the department or any of its representatives  
 796 or any state or federal official with false or fraudulent  
 797 records or making false or fraudulent statements regarding this  
 798 part and its implementing regulations.

799 (9) The wholesale distribution of medical gas that was:

800 (a) Purchased by a public or private hospital or other  
 801 health care entity, except for the physical distribution of such  
 802 medical gas to an authorized recipient at the direction of a  
 803 hospital or other health care entity;

804 (b) Donated or supplied at a reduced price to a charitable  
 805 organization; or

806 (c) Stolen or obtained by fraud or deceit.

807 (10) The failure to obtain a permit or operating without a  
 808 valid permit when a permit is required.

809 (11) The obtaining of or attempt to obtain medical gas by  
 810 fraud, deceit, or misrepresentation or engaging in  
 811 misrepresentation or fraud in the distribution of medical gas.

812 (12) Except for oxygen USP in emergency situations, the

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813 distribution of medical gas to a patient without an order or  
 814 prescription from a licensed practitioner authorized by law to  
 815 prescribe.

816 (13) The distribution of medical gas that was previously  
 817 dispensed by a pharmacy or a licensed practitioner authorized by  
 818 law to prescribe.

819 (14) The distribution of medical gas or medical gas-related  
 820 equipment to a patient, unless the patient has been provided  
 821 with the appropriate information and counseling on the use,  
 822 storage, and disposal of medical gas.

823 (15) The failure to report an act prohibited under this  
 824 part and its implementing regulations.

825 (16) The failure to exercise due diligence as provided in  
 826 s. 499.88.

827 Section 17. Section 499.92, Florida Statutes, is created to  
 828 read:

829 499.92 Criminal acts.—

830 (1) A person commits a felony of the third degree,  
 831 punishable as provided in s. 775.082, s. 775.083, or s. 775.084,  
 832 if he or she:

833 (a) With intent to defraud or deceive adulterates or  
 834 misbrands medical gas.

835 (b) Engages in the wholesale distribution of, and knowingly  
 836 purchases or receives, medical gas from a person not legally  
 837 authorized to distribute medical gas.

838 (c) Engages in the wholesale distribution of, and knowingly  
 839 sells, barter, brokers, or transfers, medical gas to a person  
 840 not legally authorized to purchase medical gas in the  
 841 jurisdiction in which the person receives the medical gas,

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842 except that a violation does not exist as to a distributor that  
 843 provides oxygen to a permitted medical oxygen retail  
 844 establishment if the distributor is out of compliance with only  
 845 the change of location notice requirement under s. 499.824.

846 (d) Knowingly, falsely creates a label for medical gas or  
 847 knowingly, falsely represents a factual matter contained in a  
 848 label for medical gas.

849 (2) A court that has authority over a person who violates  
 850 this section and that convicts such person shall order him or  
 851 her to forfeit to the state real or personal property or assets:

852 (a) Used or intended to be used to commit, facilitate, or  
 853 promote the commission of such violation; and

854 (b) Constituting, derived from, or traceable to the gross  
 855 proceeds that the defendant obtained as a result of the  
 856 violation.

857 (3) Property or assets subject to forfeiture under  
 858 subsection (2) may be seized pursuant to a warrant obtained in  
 859 the same manner as a search warrant or as otherwise authorized  
 860 by law and held until the case against the defendant is  
 861 adjudicated. Moneys ordered to be forfeited or proceeds from the  
 862 sale of assets ordered to be forfeited shall be equitably  
 863 divided between the department and agencies involved in the  
 864 investigation and prosecution that led to the conviction. Other  
 865 property ordered to be forfeited after conviction of a defendant  
 866 may, at the discretion of the investigating agencies, be placed  
 867 into official use by the department or the agencies involved in  
 868 the investigation and prosecution.

869 Section 18. Section 499.93, Florida Statutes, is created to  
 870 read:



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871 499.93 Inspections.-

872 (1) The department may require a facility that engages in the  
 873 manufacture, retail sale, or wholesale distribution of medical  
 874 gas to undergo an inspection in accordance with a schedule to be  
 875 determined by the department.

876 (2) The department may recognize other state inspections of  
 877 a manufacturer or wholesale distributor in another state if such  
 878 state's laws are deemed to be substantially equivalent to the  
 879 laws of this state.

880 (3) A manufacturing facility is exempt from inspection by  
 881 the department if the facility:

882 (a) Is currently registered with the FDA in accordance with  
 883 s. 510 of the federal act and can provide proof of such  
 884 registration, such as a copy of the online verification page;  
 885 and

886 (b) Can provide proof of inspection within the past 3 years  
 887 by the FDA or, if the facility is located in another state, by  
 888 another governmental entity charged with regulation of good  
 889 manufacturing practices related to medical gas.

890 (4) A wholesale distributor must exhibit or have readily  
 891 available its state permits and its most recent inspection  
 892 report administered by the department. The department may  
 893 authorize a third party to inspect wholesale distributors who  
 894 distribute within or into this state.

895 Section 19. Section 499.931, Florida Statutes, is created  
 896 to read:

897 499.931 Trade secret information.-Information required to  
 898 be submitted under this part which is a trade secret as defined  
 899 in s. 812.081(1)(c) and designated as a trade secret by an

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900 applicant or permit holder must be maintained as required under  
 901 s. 499.051.

902 Section 20. Section 499.94, Florida Statutes, is created to  
 903 read:

904 499.94 Fees.-A fee collected for a permit under this part  
 905 shall be deposited into the Professional Regulation Trust Fund.  
 906 Moneys collected under this part shall be used for administering  
 907 this part. The department shall maintain a separate account in  
 908 the trust fund for the Drugs, Devices, and Cosmetics program.

909 Section 21. Section 499.95, Florida Statutes, is created to  
 910 read:

911 499.95 Enforcement and construction of this part.-

912 (1) For the purpose of initiating an investigation or  
 913 proceeding under this part, the department may administer oaths,  
 914 take depositions, issue and serve subpoenas, and compel the  
 915 attendance of witnesses and the production of books, papers,  
 916 documents, or other evidence. Challenges to, and enforcement of,  
 917 a subpoena and an order shall be conducted in accordance with s.  
 918 120.569.

919 (2) A state, county, or municipal attorney to whom the  
 920 department or its designated agent reports a violation of this  
 921 part shall timely institute proceedings in the court of  
 922 competent jurisdiction and shall prosecute in the manner  
 923 required by law.

924 (3) The department is not required to report minor  
 925 violations to a state, county, or municipal attorney if the  
 926 department determines that the public interest is best served by  
 927 issuance of a written notice or warning to the violator.

928 (4) This part is cumulative and does not repeal or affect

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929 the power, duty, or authority of the department. However,  
 930 relating to the regulation of medical gas, if this part  
 931 conflicts with other law, this part controls.

932 Section 22. Section 499.001, Florida Statutes, is amended  
 933 to read:

934 499.001 Florida Drug and Cosmetic Act; short title.-  
 935 Sections 499.001-499.95 ~~499.001-499.081~~ may be cited as the  
 936 "Florida Drug and Cosmetic Act."

937 Section 23. Present subsections (11) through (32) and (46)  
 938 through (55) of section 499.003, Florida Statutes, are amended,  
 939 and a new subsection (32) is added to that section, to read:

940 499.003 Definitions of terms used in this part.-As used in  
 941 this part, the term:

942 ~~(11) "Compressed medical gas" means any liquefied or~~  
 943 ~~vaporized gas that is a prescription drug, whether it is alone~~  
 944 ~~or in combination with other gases.~~

945 (11)-(12) "Contraband prescription drug" means any  
 946 adulterated drug, as defined in s. 499.006, any counterfeit  
 947 drug, as defined in this section, and also means any  
 948 prescription drug for which a pedigree paper does not exist, or  
 949 for which the pedigree paper in existence has been forged,  
 950 counterfeited, falsely created, or contains any altered, false,  
 951 or misrepresented matter.

952 (12)-(13) "Cosmetic" means an article, with the exception of  
 953 soap, that is:

954 (a) Intended to be rubbed, poured, sprinkled, or sprayed  
 955 on; introduced into; or otherwise applied to the human body or  
 956 any part thereof for cleansing, beautifying, promoting  
 957 attractiveness, or altering the appearance; or

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958 (b) Intended for use as a component of any such article.

959 (13)-(14) "Counterfeit drug," "counterfeit device," or  
 960 "counterfeit cosmetic" means a drug, device, or cosmetic which,  
 961 or the container, seal, or labeling of which, without  
 962 authorization, bears the trademark, trade name, or other  
 963 identifying mark, imprint, or device, or any likeness thereof,  
 964 of a drug, device, or cosmetic manufacturer, processor, packer,  
 965 or distributor other than the person that in fact manufactured,  
 966 processed, packed, or distributed that drug, device, or cosmetic  
 967 and which thereby falsely purports or is represented to be the  
 968 product of, or to have been packed or distributed by, that other  
 969 drug, device, or cosmetic manufacturer, processor, packer, or  
 970 distributor.

971 (14)-(15) "Department" means the Department of Business and  
 972 Professional Regulation.

973 (15)-(16) "Device" means any instrument, apparatus,  
 974 implement, machine, contrivance, implant, in vitro reagent, or  
 975 other similar or related article, including its components,  
 976 parts, or accessories, which is:

977 (a) Recognized in the current edition of the United States  
 978 Pharmacopoeia and National Formulary, or any supplement  
 979 thereof;;

980 (b) Intended for use in the diagnosis, cure, mitigation,  
 981 treatment, therapy, or prevention of disease in humans or other  
 982 animals;; or

983 (c) Intended to affect the structure or any function of the  
 984 body of humans or other animals,

985 and that does not achieve any of its principal intended purposes

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987 through chemical action within or on the body of humans or other  
 988 animals and which is not dependent upon being metabolized for  
 989 the achievement of any of its principal intended purposes.

990 (16)~~(17)~~ "Distribute" or "distribution" means to sell;  
 991 offer to sell; give away; transfer, whether by passage of title,  
 992 physical movement, or both; deliver; or offer to deliver. The  
 993 term does not mean to administer or dispense and does not  
 994 include the billing and invoicing activities that commonly  
 995 follow a wholesale distribution transaction.

996 (17)~~(18)~~ "Drop shipment" means the sale of a prescription  
 997 drug from a manufacturer to a wholesale distributor, where the  
 998 wholesale distributor takes title to, but not possession of, the  
 999 prescription drug, and the manufacturer of the prescription drug  
 1000 ships the prescription drug directly to a chain pharmacy  
 1001 warehouse or a person authorized by law to purchase prescription  
 1002 drugs for the purpose of administering or dispensing the drug,  
 1003 as defined in s. 465.003.

1004 (18)~~(19)~~ "Drug" means an article that is:

1005 (a) Recognized in the current edition of the United States  
 1006 Pharmacopoeia and National Formulary, official Homeopathic  
 1007 Pharmacopoeia of the United States, or any supplement to any of  
 1008 those publications;

1009 (b) Intended for use in the diagnosis, cure, mitigation,  
 1010 treatment, therapy, or prevention of disease in humans or other  
 1011 animals;

1012 (c) Intended to affect the structure or any function of the  
 1013 body of humans or other animals; or

1014 (d) Intended for use as a component of any article  
 1015 specified in paragraph (a), paragraph (b), or paragraph (c), and

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1016 includes active pharmaceutical ingredients, but does not include  
 1017 devices or their nondrug components, parts, or accessories. For  
 1018 purposes of this paragraph, an "active pharmaceutical  
 1019 ingredient" includes any substance or mixture of substances  
 1020 intended, represented, or labeled for use in drug manufacturing  
 1021 that furnishes or is intended to furnish, in a finished dosage  
 1022 form, any pharmacological activity or other direct effect in the  
 1023 diagnosis, cure, mitigation, treatment, therapy, or prevention  
 1024 of disease in humans or other animals, or to affect the  
 1025 structure or any function of the body of humans or other  
 1026 animals.

1027 (19)~~(20)~~ "Establishment" means a place of business which is  
 1028 at one general physical location and may extend to one or more  
 1029 contiguous suites, units, floors, or buildings operated and  
 1030 controlled exclusively by entities under common operation and  
 1031 control. Where multiple buildings are under common exclusive  
 1032 ownership, operation, and control, an intervening thoroughfare  
 1033 does not affect the contiguous nature of the buildings. For  
 1034 purposes of permitting, each suite, unit, floor, or building  
 1035 must be identified in the most recent permit application.

1036 (20)~~(21)~~ "Federal act" means the Federal Food, Drug, and  
 1037 Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

1038 (21)~~(22)~~ "Freight forwarder" means a person who receives  
 1039 prescription drugs which are owned by another person and  
 1040 designated by that person for export, and exports those  
 1041 prescription drugs.

1042 (22)~~(23)~~ "Health care entity" means a closed pharmacy or  
 1043 any person, organization, or business entity that provides  
 1044 diagnostic, medical, surgical, or dental treatment or care, or

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1045 chronic or rehabilitative care, but does not include any  
 1046 wholesale distributor or retail pharmacy licensed under state  
 1047 law to deal in prescription drugs. However, a blood  
 1048 establishment is a health care entity that may engage in the  
 1049 wholesale distribution of prescription drugs under s.  
 1050 499.01(2)(g)1.c.

1051 (23)~~(24)~~ "Health care facility" means a health care  
 1052 facility licensed under chapter 395.

1053 (24)~~(25)~~ "Hospice" means a corporation licensed under part  
 1054 IV of chapter 400.

1055 (25)~~(26)~~ "Hospital" means a facility as defined in s.  
 1056 395.002 and licensed under chapter 395.

1057 (26)~~(27)~~ "Immediate container" does not include package  
 1058 liners.

1059 (27)~~(28)~~ "Label" means a display of written, printed, or  
 1060 graphic matter upon the immediate container of any drug, device,  
 1061 or cosmetic. A requirement made by or under authority of this  
 1062 part or rules adopted under this part that any word, statement,  
 1063 or other information appear on the label is not complied with  
 1064 unless such word, statement, or other information also appears  
 1065 on the outside container or wrapper, if any, of the retail  
 1066 package of such drug, device, or cosmetic or is easily legible  
 1067 through the outside container or wrapper.

1068 (28)~~(29)~~ "Labeling" means all labels and other written,  
 1069 printed, or graphic matters:

1070 (a) Upon a drug, device, or cosmetic, or any of its  
 1071 containers or wrappers; or

1072 (b) Accompanying or related to such drug, device, or  
 1073 cosmetic.

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1074 (29)~~(30)~~ "Manufacture" means the preparation, deriving,  
 1075 compounding, propagation, processing, producing, or fabrication  
 1076 of any drug, device, or cosmetic.

1077 (30)~~(31)~~ "Manufacturer" means:

1078 (a) A person who prepares, derives, manufactures, or  
 1079 produces a drug, device, or cosmetic;

1080 (b) The holder or holders of a New Drug Application (NDA),  
 1081 an Abbreviated New Drug Application (ANDA), a Biologics License  
 1082 Application (BLA), or a New Animal Drug Application (NADA),  
 1083 provided such application has become effective or is otherwise  
 1084 approved consistent with s. 499.023;

1085 (c) A private label distributor for whom the private label  
 1086 distributor's prescription drugs are originally manufactured and  
 1087 labeled for the distributor and have not been repackaged;

1088 (d) A person registered under the federal act as a  
 1089 manufacturer of a prescription drug, who is described in  
 1090 paragraph (a), paragraph (b), or paragraph (c), who has entered  
 1091 into a written agreement with another prescription drug  
 1092 manufacturer that authorizes either manufacturer to distribute  
 1093 the prescription drug identified in the agreement as the  
 1094 manufacturer of that drug consistent with the federal act and  
 1095 its implementing regulations;

1096 (e) A member of an affiliated group that includes, but is  
 1097 not limited to, persons described in paragraph (a), paragraph  
 1098 (b), paragraph (c), or paragraph (d), which member distributes  
 1099 prescription drugs, whether or not obtaining title to the drugs,  
 1100 only for the manufacturer of the drugs who is also a member of  
 1101 the affiliated group. As used in this paragraph, the term  
 1102 "affiliated group" means an affiliated group as defined in s.

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1103 1504 of the Internal Revenue Code of 1986, as amended. The  
 1104 manufacturer must disclose the names of all of its affiliated  
 1105 group members to the department; or

1106 (f) A person permitted as a third party logistics provider,  
 1107 only while providing warehousing, distribution, or other  
 1108 logistics services on behalf of a person described in paragraph  
 1109 (a), paragraph (b), paragraph (c), paragraph (d), or paragraph  
 1110 (e).

1111

1112 The term does not include a pharmacy that is operating in  
 1113 compliance with pharmacy practice standards as defined in  
 1114 chapter 465 and rules adopted under that chapter.

1115 (31)~~(32)~~ "Medical convenience kit" means packages or units  
 1116 that contain combination products as defined in 21 C.F.R. s.  
 1117 3.2(e)(2).

1118 (32) "Medical gas" is defined in accordance with the  
 1119 federal act and means a liquefied or vaporized gas that is a  
 1120 prescription drug, regardless of whether it is alone or combined  
 1121 with other gases.

1122 ~~(46) "Prescription medical oxygen" means oxygen USP which~~  
 1123 ~~is a drug that can only be sold on the order or prescription of~~  
 1124 ~~a practitioner authorized by law to prescribe. The label of~~  
 1125 ~~prescription medical oxygen must comply with current labeling~~  
 1126 ~~requirements for oxygen under the Federal Food, Drug, and~~  
 1127 ~~Cosmetic Act.~~

1128 ~~(47)~~ "Primary wholesale distributor" means any wholesale  
 1129 distributor that:

1130 (a) Purchased 90 percent or more of the total dollar volume  
 1131 of its purchases of prescription drugs directly from

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1132 manufacturers in the previous year; and

1133 (b)1. Directly purchased prescription drugs from not fewer  
 1134 than 50 different prescription drug manufacturers in the  
 1135 previous year; or

1136 2. Has, or the affiliated group, as defined in s. 1504 of  
 1137 the Internal Revenue Code, of which the wholesale distributor is  
 1138 a member has, not fewer than 250 employees.

1139 (c) For purposes of this subsection, "directly from  
 1140 manufacturers" means:

1141 1. Purchases made by the wholesale distributor directly  
 1142 from the manufacturer of prescription drugs; and

1143 2. Transfers from a member of an affiliated group, as  
 1144 defined in s. 1504 of the Internal Revenue Code, of which the  
 1145 wholesale distributor is a member, if:

1146 a. The affiliated group purchases 90 percent or more of the  
 1147 total dollar volume of its purchases of prescription drugs from  
 1148 the manufacturer in the previous year; and

1149 b. The wholesale distributor discloses to the department  
 1150 the names of all members of the affiliated group of which the  
 1151 wholesale distributor is a member and the affiliated group  
 1152 agrees in writing to provide records on prescription drug  
 1153 purchases by the members of the affiliated group not later than  
 1154 48 hours after the department requests access to such records,  
 1155 regardless of the location where the records are stored.

1156 (47)~~(48)~~ "Proprietary drug," or "OTC drug," means a patent  
 1157 or over-the-counter drug in its unbroken, original package,  
 1158 which drug is sold to the public by, or under the authority of,  
 1159 the manufacturer or primary distributor thereof, is not  
 1160 misbranded under the provisions of this part, and can be

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1161 purchased without a prescription.

1162 (48)~~(49)~~ "Repackage" includes repacking or otherwise  
1163 changing the container, wrapper, or labeling to further the  
1164 distribution of the drug, device, or cosmetic.

1165 (49)~~(50)~~ "Repackager" means a person who repackages. The  
1166 term excludes pharmacies that are operating in compliance with  
1167 pharmacy practice standards as defined in chapter 465 and rules  
1168 adopted under that chapter.

1169 (50)~~(51)~~ "Retail pharmacy" means a community pharmacy  
1170 licensed under chapter 465 that purchases prescription drugs at  
1171 fair market prices and provides prescription services to the  
1172 public.

1173 (51)~~(52)~~ "Secondary wholesale distributor" means a  
1174 wholesale distributor that is not a primary wholesale  
1175 distributor.

1176 (52)~~(53)~~ "Veterinary prescription drug" means a  
1177 prescription drug intended solely for veterinary use. The label  
1178 of the drug must bear the statement, "Caution: Federal law  
1179 restricts this drug to sale by or on the order of a licensed  
1180 veterinarian."

1181 (53)~~(54)~~ "Wholesale distribution" means distribution of  
1182 prescription drugs to persons other than a consumer or patient,  
1183 but does not include:

1184 (a) Any of the following activities, which is not a  
1185 violation of s. 499.005(21) if such activity is conducted in  
1186 accordance with s. 499.01(2)(g):

1187 1. The purchase or other acquisition by a hospital or other  
1188 health care entity that is a member of a group purchasing  
1189 organization of a prescription drug for its own use from the

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1190 group purchasing organization or from other hospitals or health  
1191 care entities that are members of that organization.

1192 2. The sale, purchase, or trade of a prescription drug or  
1193 an offer to sell, purchase, or trade a prescription drug by a  
1194 charitable organization described in s. 501(c)(3) of the  
1195 Internal Revenue Code of 1986, as amended and revised, to a  
1196 nonprofit affiliate of the organization to the extent otherwise  
1197 permitted by law.

1198 3. The sale, purchase, or trade of a prescription drug or  
1199 an offer to sell, purchase, or trade a prescription drug among  
1200 hospitals or other health care entities that are under common  
1201 control. For purposes of this subparagraph, "common control"  
1202 means the power to direct or cause the direction of the  
1203 management and policies of a person or an organization, whether  
1204 by ownership of stock, by voting rights, by contract, or  
1205 otherwise.

1206 4. The sale, purchase, trade, or other transfer of a  
1207 prescription drug from or for any federal, state, or local  
1208 government agency or any entity eligible to purchase  
1209 prescription drugs at public health services prices pursuant to  
1210 Pub. L. No. 102-585, s. 602 to a contract provider or its  
1211 subcontractor for eligible patients of the agency or entity  
1212 under the following conditions:

1213 a. The agency or entity must obtain written authorization  
1214 for the sale, purchase, trade, or other transfer of a  
1215 prescription drug under this subparagraph from the Secretary of  
1216 Business and Professional Regulation or his or her designee.

1217 b. The contract provider or subcontractor must be  
1218 authorized by law to administer or dispense prescription drugs.

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1219 c. In the case of a subcontractor, the agency or entity  
 1220 must be a party to and execute the subcontract.

1221 d. The contract provider and subcontractor must maintain  
 1222 and produce immediately for inspection all records of movement  
 1223 or transfer of all the prescription drugs belonging to the  
 1224 agency or entity, including, but not limited to, the records of  
 1225 receipt and disposition of prescription drugs. Each contractor  
 1226 and subcontractor dispensing or administering these drugs must  
 1227 maintain and produce records documenting the dispensing or  
 1228 administration. Records that are required to be maintained  
 1229 include, but are not limited to, a perpetual inventory itemizing  
 1230 drugs received and drugs dispensed by prescription number or  
 1231 administered by patient identifier, which must be submitted to  
 1232 the agency or entity quarterly.

1233 e. The contract provider or subcontractor may administer or  
 1234 dispense the prescription drugs only to the eligible patients of  
 1235 the agency or entity or must return the prescription drugs for  
 1236 or to the agency or entity. The contract provider or  
 1237 subcontractor must require proof from each person seeking to  
 1238 fill a prescription or obtain treatment that the person is an  
 1239 eligible patient of the agency or entity and must, at a minimum,  
 1240 maintain a copy of this proof as part of the records of the  
 1241 contractor or subcontractor required under sub-subparagraph d.

1242 f. In addition to the departmental inspection authority  
 1243 described ~~set forth~~ in s. 499.051, the establishment of the  
 1244 contract provider and subcontractor and all records pertaining  
 1245 to prescription drugs subject to this subparagraph shall be  
 1246 subject to inspection by the agency or entity. All records  
 1247 relating to prescription drugs of a manufacturer under this

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1248 subparagraph shall be subject to audit by the manufacturer of  
 1249 those drugs, without identifying individual patient information.

1250 (b) Any of the following activities, which is not a  
 1251 violation of s. 499.005(21) if such activity is conducted in  
 1252 accordance with rules established by the department:

1253 1. The sale, purchase, or trade of a prescription drug  
 1254 among federal, state, or local government health care entities  
 1255 that are under common control and are authorized to purchase  
 1256 such prescription drug.

1257 2. The sale, purchase, or trade of a prescription drug or  
 1258 an offer to sell, purchase, or trade a prescription drug for  
 1259 emergency medical reasons. For purposes of this subparagraph,  
 1260 the term "emergency medical reasons" includes transfers of  
 1261 prescription drugs by a retail pharmacy to another retail  
 1262 pharmacy to alleviate a temporary shortage.

1263 3. The transfer of a prescription drug acquired by a  
 1264 medical director on behalf of a licensed emergency medical  
 1265 services provider to that emergency medical services provider  
 1266 and its transport vehicles for use in accordance with the  
 1267 provider's license under chapter 401.

1268 4. The revocation of a sale or the return of a prescription  
 1269 drug to the person's prescription drug wholesale supplier.

1270 5. The donation of a prescription drug by a health care  
 1271 entity to a charitable organization that has been granted an  
 1272 exemption under s. 501(c)(3) of the Internal Revenue Code of  
 1273 1986, as amended, and that is authorized to possess prescription  
 1274 drugs.

1275 6. The transfer of a prescription drug by a person  
 1276 authorized to purchase or receive prescription drugs to a person

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1277 licensed or permitted to handle reverse distributions or  
 1278 destruction under the laws of the jurisdiction in which the  
 1279 person handling the reverse distribution or destruction receives  
 1280 the drug.

1281 7. The transfer of a prescription drug by a hospital or  
 1282 other health care entity to a person licensed under this part to  
 1283 repackage prescription drugs for the purpose of repackaging the  
 1284 prescription drug for use by that hospital, or other health care  
 1285 entity and other health care entities that are under common  
 1286 control, if ownership of the prescription drugs remains with the  
 1287 hospital or other health care entity at all times. In addition  
 1288 to the recordkeeping requirements of s. 499.0121(6), the  
 1289 hospital or health care entity that transfers prescription drugs  
 1290 pursuant to this subparagraph must reconcile all drugs  
 1291 transferred and returned and resolve any discrepancies in a  
 1292 timely manner.

1293 (c) The distribution of prescription drug samples by  
 1294 manufacturers' representatives or distributors' representatives  
 1295 conducted in accordance with s. 499.028.

1296 (d) The sale, purchase, or trade of blood and blood  
 1297 components intended for transfusion. As used in this paragraph,  
 1298 the term "blood" means whole blood collected from a single donor  
 1299 and processed for transfusion or further manufacturing, and the  
 1300 term "blood components" means that part of the blood separated  
 1301 by physical or mechanical means.

1302 (e) The lawful dispensing of a prescription drug in  
 1303 accordance with chapter 465.

1304 (f) The sale, purchase, or trade of a prescription drug  
 1305 between pharmacies as a result of a sale, transfer, merger, or

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1306 consolidation of all or part of the business of the pharmacies  
 1307 from or with another pharmacy, whether accomplished as a  
 1308 purchase and sale of stock or of business assets.

1309 ~~(54)-(55)~~ "Wholesale distributor" means any person engaged  
 1310 in wholesale distribution of prescription drugs in or into this  
 1311 state, including, but not limited to, manufacturers;  
 1312 repackagers; own-label distributors; jobbers; private-label  
 1313 distributors; brokers; warehouses, including manufacturers' and  
 1314 distributors' warehouses, chain drug warehouses, and wholesale  
 1315 drug warehouses; independent wholesale drug traders; exporters;  
 1316 retail pharmacies; and the agents thereof that conduct wholesale  
 1317 distributions.

1318 Section 24. Paragraph (a) of subsection (1) of section  
 1319 409.9201, Florida Statutes, is amended to read:

1320 409.9201 Medicaid fraud.—

1321 (1) As used in this section, the term:

1322 (a) "Prescription drug" means any drug, including, but not  
 1323 limited to, finished dosage forms or active ingredients that are  
 1324 subject to, defined in ~~by~~, or described in ~~by~~ s. 503(b) of the  
 1325 Federal Food, Drug, and Cosmetic Act or in ~~by~~ s. 465.003(8), s.  
 1326 499.003(52), ~~s. 499.003(46) or (53) or~~ s. 499.007(13), or s.  
 1327 499.81(15).

1328  
 1329 The value of individual items of the legend drugs or goods or  
 1330 services involved in distinct transactions committed during a  
 1331 single scheme or course of conduct, whether involving a single  
 1332 person or several persons, may be aggregated when determining  
 1333 the punishment for the offense.

1334 Section 25. Paragraph (c) of subsection (9) of section

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1335 460.403, Florida Statutes, is amended to read:  
 1336 460.403 Definitions.—As used in this chapter, the term:  
 1337 (9)  
 1338 (c)1. Chiropractic physicians may adjust, manipulate, or  
 1339 treat the human body by manual, mechanical, electrical, or  
 1340 natural methods; by the use of physical means or physiotherapy,  
 1341 including light, heat, water, or exercise; by the use of  
 1342 acupuncture; or by the administration of foods, food  
 1343 concentrates, food extracts, and items for which a prescription  
 1344 is not required and may apply first aid and hygiene, but  
 1345 chiropractic physicians are expressly prohibited from  
 1346 prescribing or administering to any person any legend drug  
 1347 except as authorized under subparagraph 2., from performing any  
 1348 surgery except as stated herein, or from practicing obstetrics.  
 1349 2. Notwithstanding the prohibition against prescribing and  
 1350 administering legend drugs under subparagraph 1. or s.  
 1351 499.82(7)(c) ~~s. 499.01(2)(m)~~, pursuant to board rule  
 1352 chiropractic physicians may order, store, and administer, for  
 1353 emergency purposes only at the chiropractic physician's office  
 1354 or place of business, prescription medical oxygen and may also  
 1355 order, store, and administer the following topical anesthetics  
 1356 in aerosol form:  
 1357 a. Any solution consisting of 25 percent ethylchloride and  
 1358 75 percent dichlorodifluoromethane.  
 1359 b. Any solution consisting of 15 percent  
 1360 dichlorodifluoromethane and 85 percent  
 1361 trichloromonofluoromethane.  
 1362  
 1363 However, this paragraph does not authorize a chiropractic

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1364 physician to prescribe medical oxygen as defined in chapter 499.  
 1365 Section 26. Subsection (3) of section 465.0265, Florida  
 1366 Statutes, is amended to read:  
 1367 465.0265 Centralized prescription filling.—  
 1368 (3) The filling, delivery, and return of a prescription by  
 1369 one pharmacy for another pursuant to this section ~~may shall~~ not  
 1370 be construed as the filling of a transferred prescription as  
 1371 described set forth in s. 465.026 or as a wholesale distribution  
 1372 as defined set forth in s. 499.003 ~~s. 499.003(54)~~.  
 1373 Section 27. Subsection (1), paragraphs (a), (c), (g), (m),  
 1374 (n), and (o) of subsection (2), and subsection (5) of section  
 1375 499.01, Florida Statutes, are amended to read:  
 1376 499.01 Permits.—  
 1377 (1) Before ~~Prior to~~ operating, a permit is required for  
 1378 each person and establishment that intends to operate as:  
 1379 (a) A prescription drug manufacturer;  
 1380 (b) A prescription drug repackager;  
 1381 (c) A nonresident prescription drug manufacturer;  
 1382 (d) A prescription drug wholesale distributor;  
 1383 (e) An out-of-state prescription drug wholesale  
 1384 distributor;  
 1385 (f) A retail pharmacy drug wholesale distributor;  
 1386 (g) A restricted prescription drug distributor;  
 1387 (h) A complimentary drug distributor;  
 1388 (i) A freight forwarder;  
 1389 (j) A veterinary prescription drug retail establishment;  
 1390 (k) A veterinary prescription drug wholesale distributor;  
 1391 (l) A limited prescription drug veterinary wholesale  
 1392 distributor;

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1393 ~~(m)~~ A medical oxygen retail establishment;

1394 ~~(n)~~ A compressed medical gas wholesale distributor;

1395 ~~(e)~~ A compressed medical gas manufacturer;

1396 ~~(m)~~ ~~(p)~~ An over-the-counter drug manufacturer;

1397 ~~(n)~~ ~~(q)~~ A device manufacturer;

1398 ~~(o)~~ ~~(r)~~ A cosmetic manufacturer;

1399 ~~(p)~~ ~~(s)~~ A third party logistics provider; or

1400 ~~(q)~~ ~~(t)~~ A health care clinic establishment.

1401 (2) The following permits are established:

1402 (a) *Prescription drug manufacturer permit.*—A prescription

1403 drug manufacturer permit is required for any person that is a

1404 manufacturer of a prescription drug and that manufactures or

1405 distributes such prescription drugs in this state.

1406 1. A person that operates an establishment permitted as a

1407 prescription drug manufacturer may engage in wholesale

1408 distribution of prescription drugs manufactured at that

1409 establishment and must comply with all of the provisions of this

1410 part, except s. 499.01212, and the rules adopted under this

1411 part, except s. 499.01212, which apply to a wholesale

1412 distributor.

1413 2. A prescription drug manufacturer must comply with all

1414 appropriate state and federal good manufacturing practices.

1415 3. A blood establishment, as defined in s. 381.06014,

1416 operating in a manner consistent with the provisions of 21

1417 C.F.R. parts 211 and 600-640, and manufacturing only the

1418 prescription drugs described in s. 499.003(53)(d) ~~s.~~

1419 ~~499.003(54)(d)~~ is not required to be permitted as a prescription

1420 drug manufacturer under this paragraph or to register products

1421 under s. 499.015.

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1422 (c) *Nonresident prescription drug manufacturer permit.*—A

1423 nonresident prescription drug manufacturer permit is required

1424 for any person that is a manufacturer of prescription drugs,

1425 unless permitted as a third party logistics provider, located

1426 outside of this state or outside the United States and that

1427 engages in the wholesale distribution in this state of such

1428 prescription drugs. Each such manufacturer must be permitted by

1429 the department and comply with all of the provisions required of

1430 a wholesale distributor under this part, except s. 499.01212.

1431 1. A person that distributes prescription drugs for which

1432 the person is not the manufacturer must also obtain an out-of-

1433 state prescription drug wholesale distributor permit or third

1434 party logistics provider permit pursuant to this section to

1435 engage in the wholesale distribution of such prescription drugs.

1436 This subparagraph does not apply to a manufacturer as defined in

1437 s. 499.003(30)(e) ~~s. 499.003(31)(e)~~.

1438 2. Any such person must comply with the licensing or

1439 permitting requirements of the jurisdiction in which the

1440 establishment is located and the federal act, and any product

1441 wholesaled into this state must comply with this part. If a

1442 person intends to import prescription drugs from a foreign

1443 country into this state, the nonresident prescription drug

1444 manufacturer must provide to the department a list identifying

1445 each prescription drug it intends to import and document

1446 approval by the United States Food and Drug Administration for

1447 such importation.

1448 (g) *Restricted prescription drug distributor permit.*—

1449 1. A restricted prescription drug distributor permit is

1450 required for:

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1451 a. Any person located in this state who engages in the  
 1452 distribution of a prescription drug, which distribution is not  
 1453 considered "wholesale distribution" under s. 499.003(53)(a) ~~or~~  
 1454 ~~499.003(54)(a)~~.

1455 b. Any person located in this state who engages in the  
 1456 receipt or distribution of a prescription drug in this state for  
 1457 the purpose of processing its return or its destruction if such  
 1458 person is not the person initiating the return, the prescription  
 1459 drug wholesale supplier of the person initiating the return, or  
 1460 the manufacturer of the drug.

1461 c. A blood establishment located in this state which  
 1462 collects blood and blood components only from volunteer donors  
 1463 as defined in s. 381.06014 or pursuant to an authorized  
 1464 practitioner's order for medical treatment or therapy and  
 1465 engages in the wholesale distribution of a prescription drug not  
 1466 described in s. 499.003(53)(d) ~~or 499.003(54)(d)~~ to a health  
 1467 care entity. A mobile blood unit operated by a blood  
 1468 establishment permitted under this sub-subparagraph is not  
 1469 required to be separately permitted. The health care entity  
 1470 receiving a prescription drug distributed under this sub-  
 1471 subparagraph must be licensed as a closed pharmacy or provide  
 1472 health care services at that establishment. The blood  
 1473 establishment must operate in accordance with s. 381.06014 and  
 1474 may distribute only:

1475 (I) Prescription drugs indicated for a bleeding or clotting  
 1476 disorder or anemia;

1477 (II) Blood-collection containers approved under s. 505 of  
 1478 the federal act;

1479 (III) Drugs that are blood derivatives, or a recombinant or

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1480 synthetic form of a blood derivative;

1481 (IV) Prescription drugs that are identified in rules  
 1482 adopted by the department and that are essential to services  
 1483 performed or provided by blood establishments and authorized for  
 1484 distribution by blood establishments under federal law; or

1485 (V) To the extent authorized by federal law, drugs  
 1486 necessary to collect blood or blood components from volunteer  
 1487 blood donors; for blood establishment personnel to perform  
 1488 therapeutic procedures under the direction and supervision of a  
 1489 licensed physician; and to diagnose, treat, manage, and prevent  
 1490 any reaction of a volunteer blood donor or a patient undergoing  
 1491 a therapeutic procedure performed under the direction and  
 1492 supervision of a licensed physician,

1493  
 1494 as long as all of the health care services provided by the blood  
 1495 establishment are related to its activities as a registered  
 1496 blood establishment or the health care services consist of  
 1497 collecting, processing, storing, or administering human  
 1498 hematopoietic stem cells or progenitor cells or performing  
 1499 diagnostic testing of specimens if such specimens are tested  
 1500 together with specimens undergoing routine donor testing. The  
 1501 blood establishment may purchase and possess the drugs described  
 1502 in this sub-subparagraph without a health care clinic  
 1503 establishment permit.

1504 2. Storage, handling, and recordkeeping of these  
 1505 distributions by a person required to be permitted as a  
 1506 restricted prescription drug distributor must be in accordance  
 1507 with the requirements for wholesale distributors under s.  
 1508 499.0121, but not those described ~~set forth~~ in s. 499.01212 if

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1509 the distribution occurs pursuant to sub-subparagraph 1.a. or  
1510 sub-subparagraph 1.b.

1511 3. A person who applies for a permit as a restricted  
1512 prescription drug distributor, or for the renewal of such a  
1513 permit, must provide to the department the information required  
1514 under s. 499.012.

1515 4. The department may adopt rules regarding the  
1516 distribution of prescription drugs by hospitals, health care  
1517 entities, charitable organizations, other persons not involved  
1518 in wholesale distribution, and blood establishments, which rules  
1519 are necessary for the protection of the public health, safety,  
1520 and welfare.

1521 ~~(m) Medical oxygen retail establishment permit. A medical~~  
1522 ~~oxygen retail establishment permit is required for any person~~  
1523 ~~that sells medical oxygen to patients only. The sale must be~~  
1524 ~~based on an order from a practitioner authorized by law to~~  
1525 ~~prescribe. The term does not include a pharmacy licensed under~~  
1526 ~~chapter 465.~~

1527 1. ~~A medical oxygen retail establishment may not possess,~~  
1528 ~~purchase, sell, or trade any prescription drug other than~~  
1529 ~~medical oxygen.~~

1530 2. ~~A medical oxygen retail establishment may refill medical~~  
1531 ~~oxygen for an individual patient based on an order from a~~  
1532 ~~practitioner authorized by law to prescribe. A medical oxygen~~  
1533 ~~retail establishment that refills medical oxygen must comply~~  
1534 ~~with all appropriate state and federal good manufacturing~~  
1535 ~~practices.~~

1536 3. ~~A medical oxygen retail establishment must comply with~~  
1537 ~~all of the wholesale distribution requirements of s. 499.0121.~~

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1538 4. ~~Prescription medical oxygen sold by a medical oxygen~~  
1539 ~~retail establishment pursuant to a practitioner's order may not~~  
1540 ~~be returned into the retail establishment's inventory.~~

1541 ~~(n) Compressed medical gas wholesale distributor permit. A~~  
1542 ~~compressed medical gas wholesale distributor is a wholesaale~~  
1543 ~~distributor that is limited to the wholesale distribution of~~  
1544 ~~compressed medical gases to other than the consumer or patient.~~  
1545 ~~The compressed medical gas must be in the original sealed~~  
1546 ~~container that was purchased by that wholesale distributor. A~~  
1547 ~~compressed medical gas wholesale distributor may not possess or~~  
1548 ~~engage in the wholesale distribution of any prescription drug~~  
1549 ~~other than compressed medical gases. The department shall adopt~~  
1550 ~~rules that govern the wholesale distribution of prescription~~  
1551 ~~medical oxygen for emergency use. With respect to the emergency~~  
1552 ~~use of prescription medical oxygen, those rules may not be~~  
1553 ~~inconsistent with rules and regulations of federal agencies~~  
1554 ~~unless the Legislature specifically directs otherwise.~~

1555 ~~(o) Compressed medical gas manufacturer permit. A~~  
1556 ~~compressed medical gas manufacturer permit is required for any~~  
1557 ~~person that engages in the manufacture of compressed medical~~  
1558 ~~gases or repackages compressed medical gases from one container~~  
1559 ~~to another.~~

1560 1. ~~A compressed medical gas manufacturer may not~~  
1561 ~~manufacture or possess any prescription drug other than~~  
1562 ~~compressed medical gases.~~

1563 2. ~~A compressed medical gas manufacturer may engage in~~  
1564 ~~wholesale distribution of compressed medical gases manufactured~~  
1565 ~~at that establishment and must comply with all the provisions of~~  
1566 ~~this part and the rules adopted under this part that apply to a~~

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1567 ~~wholesale distributor.~~1568 ~~3. A compressed medical gas manufacturer must comply with~~  
1569 ~~all appropriate state and federal good manufacturing practices.~~1570 (5) A prescription drug repackager permit issued under this  
1571 part is not required for a restricted prescription drug  
1572 distributor permitholder that is a health care entity to  
1573 repackage prescription drugs in this state for its own use or  
1574 for distribution to hospitals or other health care entities in  
1575 the state for their own use, pursuant to s. 499.003(53)(a)3. ~~s.~~  
1576 ~~499.003(54)(a)3.~~, if:1577 (a) The prescription drug distributor notifies the  
1578 department, in writing, of its intention to engage in  
1579 repackaging under this exemption, 30 days before engaging in the  
1580 repackaging of prescription drugs at the permitted  
1581 establishment;1582 (b) The prescription drug distributor is under common  
1583 control with the hospitals or other health care entities to  
1584 which the prescription drug distributor is distributing  
1585 prescription drugs. As used in this paragraph, "common control"  
1586 means the power to direct or cause the direction of the  
1587 management and policies of a person or an organization, whether  
1588 by ownership of stock, voting rights, contract, or otherwise;1589 (c) The prescription drug distributor repackages the  
1590 prescription drugs in accordance with current state and federal  
1591 good manufacturing practices; and1592 (d) The prescription drug distributor labels the  
1593 prescription drug it repackages in accordance with state and  
1594 federal laws and rules.

1595

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1596 The prescription drug distributor is exempt from the product  
1597 registration requirements of s. 499.015 with regard to the  
1598 prescription drugs that it repackages and distributes under this  
1599 subsection.1600 Section 28. Paragraph (b) of subsection (2) of section  
1601 499.0121, Florida Statutes, is amended to read:1602 499.0121 Storage and handling of prescription drugs;  
1603 recordkeeping.—The department shall adopt rules to implement  
1604 this section as necessary to protect the public health, safety,  
1605 and welfare. Such rules shall include, but not be limited to,  
1606 requirements for the storage and handling of prescription drugs  
1607 and for the establishment and maintenance of prescription drug  
1608 distribution records.

1609 (2) SECURITY.—

1610 (b) An establishment that is used for wholesale drug  
1611 distribution must be equipped with:1612 1. An alarm system to detect entry after hours; however,  
1613 the department may exempt by rule establishments that only hold  
1614 a permit as prescription drug wholesale distributor-brokers ~~and~~  
1615 ~~establishments that only handle medical oxygen;~~ and1616 2. A security system that will provide suitable protection  
1617 against theft and diversion. When appropriate, the security  
1618 system must provide protection against theft or diversion that  
1619 is facilitated or hidden by tampering with computers or  
1620 electronic records.1621 Section 29. Section 499.01211, Florida Statutes, is amended  
1622 to read:

1623 499.01211 Drug Wholesale Distributor Advisory Council.—

1624 (1) There is created the Drug Wholesale Distributor

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1625 Advisory Council within the department. The council shall meet  
 1626 at least once each calendar quarter. Staff for the council shall  
 1627 be provided by the department. The council shall consist of 12  
 1628 ~~14~~ members who shall serve without compensation. The council  
 1629 shall elect a chairperson and a vice chairperson annually.

1630 (2) The Secretary of Business and Professional Regulation  
 1631 or his or her designee and the Secretary of Health Care  
 1632 Administration or her or his designee shall be members of the  
 1633 council. The Secretary of Business and Professional Regulation  
 1634 shall appoint nine additional members to the council who shall  
 1635 be appointed to a term of 4 years each, as follows:

1636 (a) Three different persons each of whom is employed by a  
 1637 different prescription drug wholesale distributor licensed under  
 1638 this part which operates nationally and is a primary wholesale  
 1639 distributor, as defined in s. 499.003 ~~s. 499.003(47)~~.

1640 (b) One person employed by a prescription drug wholesale  
 1641 distributor licensed under this part which is a secondary  
 1642 wholesale distributor, as defined in s. 499.003 ~~s. 499.003(52)~~.

1643 (c) One person employed by a retail pharmacy chain located  
 1644 in this state.

1645 (d) One person who is a member of the Board of Pharmacy and  
 1646 is a pharmacist licensed under chapter 465.

1647 (e) One person who is a physician licensed pursuant to  
 1648 chapter 458 or chapter 459.

1649 (f) One person who is an employee of a hospital licensed  
 1650 pursuant to chapter 395 and is a pharmacist licensed pursuant to  
 1651 chapter 465.

1652 (g) One person who is an employee of a pharmaceutical  
 1653 manufacturer.

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1654 (3) The Compressed Gas Association shall appoint one person  
 1655 to the council who is an employee of a permitted medical gas  
 1656 wholesale distributor or manufacturer.

1657 ~~(4)(3)~~ The council shall review this part and the rules  
 1658 adopted to administer this part annually, provide input to the  
 1659 department regarding all proposed rules to administer this part,  
 1660 make recommendations to the department to improve the protection  
 1661 of the prescription drugs and public health, make  
 1662 recommendations to improve coordination with other states'  
 1663 regulatory agencies and the federal government concerning the  
 1664 wholesale distribution of drugs, and make recommendations to  
 1665 minimize the impact of regulation of the wholesale distribution  
 1666 industry while ensuring protection of the public health.

1667 Section 30. Paragraph (b) of subsection (2) of section  
 1668 499.01212, Florida Statutes, is amended to read:  
 1669 499.01212 Pedigree paper.—

1670 (2) FORMAT.—A pedigree paper must contain the following  
 1671 information:

1672 (b) For all other wholesale distributions of prescription  
 1673 drugs:

1674 1. The quantity, dosage form, and strength of the  
 1675 prescription drugs.

1676 2. The lot numbers of the prescription drugs.

1677 3. The name and address of each owner of the prescription  
 1678 drug and his or her signature.

1679 4. Shipping information, including the name and address of  
 1680 each person certifying delivery or receipt of the prescription  
 1681 drug.

1682 5. An invoice number, a shipping document number, or

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1683 another number uniquely identifying the transaction.

1684 6. A certification that the recipient wholesale distributor  
1685 has authenticated the pedigree papers.

1686 7. The unique serialization of the prescription drug, if  
1687 the manufacturer or repackager has uniquely serialized the  
1688 individual prescription drug unit.

1689 8. The name, address, telephone number, and, if available,  
1690 e-mail contact information of each wholesale distributor  
1691 involved in the chain of the prescription drug's custody.

1692

1693 When an affiliated group member obtains title to a prescription  
1694 drug before distributing the prescription drug as the  
1695 manufacturer as defined in s. 499.003(30)(e) ~~under s.~~  
1696 ~~499.003(31)(e)~~, information regarding the distribution between  
1697 those affiliated group members may be omitted from a pedigree  
1698 paper required under this paragraph for subsequent distributions  
1699 of that prescription drug.

1700 Section 31. Paragraph (a) of subsection (1) and subsection  
1701 (3) of section 499.015, Florida Statutes, are amended to read:

1702 499.015 Registration of drugs, devices, and cosmetics;  
1703 issuance of certificates of free sale.—

1704 (1)(a) Except for those persons exempted from the  
1705 definition of manufacturer in s. 499.003 ~~s. 499.003(31)~~, any  
1706 person who manufactures, packages, repackages, labels, or  
1707 relabels a drug, device, or cosmetic in this state must register  
1708 such drug, device, or cosmetic biennially with the department;  
1709 pay a fee in accordance with the fee schedule provided by s.  
1710 499.041; and comply with this section. The registrant must list  
1711 each separate and distinct drug, device, or cosmetic at the time

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1712 of registration.

1713 (3) Except for those persons exempted from the definition  
1714 of manufacturer in s. 499.003 ~~s. 499.003(31)~~, a person may not  
1715 sell any product that he or she has failed to register in  
1716 conformity with this section. Such failure to register subjects  
1717 such drug, device, or cosmetic product to seizure and  
1718 condemnation as provided in s. 499.062, and subjects such person  
1719 to the penalties and remedies provided in this part.

1720 Section 32. Subsection (3) of section 499.024, Florida  
1721 Statutes, is amended to read:

1722 499.024 Drug product classification.—The department shall  
1723 adopt rules to classify drug products intended for use by humans  
1724 which the United States Food and Drug Administration has not  
1725 classified in the federal act or the Code of Federal  
1726 Regulations.

1727 (3) Any product that falls under the definition of drug in  
1728 s. 499.003 ~~s. 499.003(19)~~ may be classified under the authority  
1729 of this section. This section does not subject portable  
1730 emergency oxygen inhalators to classification; however, this  
1731 section does not exempt any person from ss. 499.01 and 499.015.

1732 Section 33. Paragraph (e) of subsection (1), paragraph (b)  
1733 of subsection (2), and paragraph (b) of subsection (3) of  
1734 section 499.041, Florida Statutes, are amended to read:

1735 499.041 Schedule of fees for drug, device, and cosmetic  
1736 applications and permits, product registrations, and free-sale  
1737 certificates.—

1738 (1) The department shall assess applicants requiring a  
1739 manufacturing permit an annual fee within the ranges established  
1740 in this section for the specific type of manufacturer.

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1741 ~~(e) The fee for a compressed medical gas manufacturer~~  
 1742 ~~permit may not be less than \$400 or more than \$500 annually.~~

1743 (2) The department shall assess an applicant that is  
 1744 required to have a wholesaling permit an annual fee within the  
 1745 ranges established in this section for the specific type of  
 1746 wholesaling.

1747 ~~(b) The fee for a compressed medical gas wholesale~~  
 1748 ~~distributor permit may not be less than \$200 or more than \$300~~  
 1749 ~~annually.~~

1750 (3) The department shall assess an applicant that is  
 1751 required to have a retail establishment permit an annual fee  
 1752 within the ranges established in this section for the specific  
 1753 type of retail establishment.

1754 ~~(b) The fee for a medical oxygen retail establishment~~  
 1755 ~~permit may not be less than \$200 or more than \$300 annually.~~

1756 Section 34. Paragraphs (i) and (m) of subsection (1) of  
 1757 section 499.05, Florida Statutes, are amended to read:

1758 499.05 Rules.—

1759 (1) The department shall adopt rules to implement and  
 1760 enforce this chapter part with respect to:

1761 (i) Additional conditions that qualify as an emergency  
 1762 medical reason under s. 499.003(53)(b)2. ~~s. 499.003(54)(b)2.~~

1763 (m) The recordkeeping, storage, and handling with respect  
 1764 to each of the distributions of prescription drugs specified in  
 1765 s. 499.003(53)(a)-(d) ~~s. 499.003(54)(a)-(d).~~

1766 Section 35. Subsections (1) through (4) of section 499.051,  
 1767 Florida Statutes, are amended to read:

1768 499.051 Inspections and investigations.—

1769 (1) The agents of the department and of the Department of

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1770 Law Enforcement, after they present proper identification, may  
 1771 inspect, monitor, and investigate any establishment permitted  
 1772 pursuant to this chapter part during business hours for the  
 1773 purpose of enforcing this chapter part, chapters 465, 501, and  
 1774 893, and the rules of the department that protect the public  
 1775 health, safety, and welfare.

1776 (2) In addition to the authority set forth in subsection  
 1777 (1), the department and any duly designated officer or employee  
 1778 of the department may enter and inspect any other establishment  
 1779 for the purpose of determining compliance with this part and  
 1780 rules adopted under this chapter part regarding any drug,  
 1781 device, or cosmetic product.

1782 (3) Any application for a permit or product registration or  
 1783 for renewal of such permit or registration made pursuant to this  
 1784 chapter part and rules adopted under this chapter part  
 1785 constitutes permission for any entry or inspection of the  
 1786 premises in order to verify compliance with this chapter part  
 1787 and rules; to discover, investigate, and determine the existence  
 1788 of compliance; or to elicit, receive, respond to, and resolve  
 1789 complaints and violations.

1790 (4) Any application for a permit made pursuant to s.  
 1791 499.012 or s. 499.821 and rules adopted under those sections  
 1792 ~~that section~~ constitutes permission for agents of the department  
 1793 and the Department of Law Enforcement, after presenting proper  
 1794 identification, to inspect, review, and copy any financial  
 1795 document or record related to the manufacture, repackaging, or  
 1796 distribution of a drug as is necessary to verify compliance with  
 1797 this chapter part and the rules adopted by the department to  
 1798 administer this chapter part, in order to discover, investigate,



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1799 and determine the existence of compliance, or to elicit,  
1800 receive, respond to, and resolve complaints and violations.

1801 Section 36. Section 499.066, Florida Statutes, is amended  
1802 to read:

1803 499.066 Penalties; remedies.—In addition to other penalties  
1804 and other enforcement provisions:

1805 (1) The department may institute such suits or other legal  
1806 proceedings as are required to enforce any provision of this  
1807 chapter part. If it appears that a person has violated any  
1808 provision of this chapter part for which criminal prosecution is  
1809 provided, the department may provide the appropriate state  
1810 attorney or other prosecuting agency having jurisdiction with  
1811 respect to such prosecution with the relevant information in the  
1812 department's possession.

1813 (2) If any person engaged in any activity covered by this  
1814 chapter part violates any provision of this chapter part, any  
1815 rule adopted under this chapter part, or a cease and desist  
1816 order as provided by this chapter part, the department may  
1817 obtain an injunction in the circuit court of the county in which  
1818 the violation occurred or in which the person resides or has its  
1819 principal place of business, and may apply in that court for  
1820 such temporary and permanent orders as the department considers  
1821 necessary to restrain the person from engaging in any such  
1822 activities until the person complies with this chapter part, the  
1823 rules adopted under this chapter part, and the orders of the  
1824 department authorized by this chapter part or to mandate  
1825 compliance with this chapter part, the rules adopted under this  
1826 chapter part, and any order or permit issued by the department  
1827 under this chapter part.

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1828 (3) The department may impose an administrative fine, not  
1829 to exceed \$5,000 per violation per day, for the violation of any  
1830 provision of this chapter part or rules adopted under this  
1831 chapter part. Each day a violation continues constitutes a  
1832 separate violation, and each separate violation is subject to a  
1833 separate fine. All amounts collected pursuant to this section  
1834 shall be deposited into the Professional Regulation Trust Fund  
1835 and are appropriated for the use of the department in  
1836 administering this chapter part. In determining the amount of  
1837 the fine to be levied for a violation, the department shall  
1838 consider:

1839 (a) The severity of the violation;

1840 (b) Any actions taken by the person to correct the  
1841 violation or to remedy complaints; and

1842 (c) Any previous violations.

1843 (4) The department shall deposit any rewards, fines, or  
1844 collections that are due the department and which derive from  
1845 joint enforcement activities with other state and federal  
1846 agencies which relate to this chapter part, chapter 893, or the  
1847 federal act, into the Professional Regulation Trust Fund. The  
1848 proceeds of those rewards, fines, and collections are  
1849 appropriated for the use of the department in administering this  
1850 chapter part.

1851 (5) The department may issue an emergency order immediately  
1852 suspending or revoking a permit if it determines that any  
1853 condition in the establishment presents a danger to the public  
1854 health, safety, and welfare.

1855 (6) The department may issue an emergency order to  
1856 immediately remove from commerce and public access any drug,

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1857 device, or cosmetic, if the department determines that the drug,  
1858 device, or cosmetic presents a clear and present danger to the  
1859 public health, safety, and welfare.

1860 (7) Resignation or termination of an affiliated party does  
1861 not affect the department's jurisdiction or discretion to  
1862 proceed with action to suspend or revoke a permit or to impose  
1863 other penalties or enforcement actions authorized by law.

1864 Section 37. Paragraph (a) of subsection (1) and paragraph  
1865 (a) of subsection (2) of section 499.0661, Florida Statutes, are  
1866 amended to read:

1867 499.0661 Cease and desist orders; removal of certain  
1868 persons.—

1869 (1) CEASE AND DESIST ORDERS.—

1870 (a) In addition to any authority otherwise provided in this  
1871 chapter, the department may issue and serve a complaint stating  
1872 charges upon any permittee or upon any affiliated party,  
1873 whenever the department has reasonable cause to believe that the  
1874 person or individual named therein is engaging in or has engaged  
1875 in conduct that is:

1876 1. An act that demonstrates a lack of fitness or  
1877 trustworthiness to engage in the business authorized under the  
1878 permit issued pursuant to this chapter part, is hazardous to the  
1879 public health, or constitutes business operations that are a  
1880 detriment to the public health;

1881 2. A violation of any provision of this chapter part;

1882 3. A violation of any rule of the department;

1883 4. A violation of any order of the department; or

1884 5. A breach of any written agreement with the department.

1885 (2) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

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1886 (a) The department may issue and serve a complaint stating  
1887 charges upon any affiliated party and upon the permittee  
1888 involved whenever the department has reason to believe that an  
1889 affiliated party is engaging in or has engaged in conduct that  
1890 constitutes:

1891 1. An act that demonstrates a lack of fitness or  
1892 trustworthiness to engage in the business authorized under the  
1893 permit issued pursuant to this chapter part, is hazardous to the  
1894 public health, or constitutes business operations that are a  
1895 detriment to the public health;

1896 2. A willful violation of this chapter part; however, if  
1897 the violation constitutes a misdemeanor, a complaint may not be  
1898 served as provided in this section until the affiliated party is  
1899 notified in writing of the matter of the violation and has been  
1900 afforded a reasonable period of time, as set forth in the  
1901 notice, to correct the violation and has failed to do so;

1902 3. A violation of any other law involving fraud or moral  
1903 turpitude which constitutes a felony;

1904 4. A willful violation of any rule of the department;

1905 5. A willful violation of any order of the department; or

1906 6. A material misrepresentation of fact, made knowingly and  
1907 willfully or made with reckless disregard for the truth of the  
1908 matter.

1909 Section 38. Section 499.067, Florida Statutes, is amended  
1910 to read:

1911 499.067 Denial, suspension, or revocation of permit,  
1912 certification, or registration.—

1913 (1)(a) The department may deny, suspend, or revoke a permit  
1914 if it finds that there has been a substantial failure to comply

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1915 with this ~~chapter part~~ or chapter 465, chapter 501, or chapter  
 1916 893, the rules adopted under this ~~chapter part~~ or those  
 1917 chapters, any final order of the department, or applicable  
 1918 federal laws or regulations or other state laws or rules  
 1919 governing drugs, devices, or cosmetics.

1920 (b) The department may deny an application for a permit or  
 1921 certification, or suspend or revoke a permit or certification,  
 1922 if the department finds that:

1923 1. The applicant is not of good moral character or that it  
 1924 would be a danger or not in the best interest of the public  
 1925 health, safety, and welfare if the applicant were issued a  
 1926 permit or certification.

1927 2. The applicant has not met the requirements for the  
 1928 permit or certification.

1929 3. The applicant is not eligible for a permit or  
 1930 certification for any of the reasons enumerated in s. 499.012.

1931 4. The applicant, permittee, or person certified under s.  
 1932 499.012(16) demonstrates any of the conditions enumerated in s.  
 1933 499.012.

1934 5. The applicant, permittee, or person certified under s.  
 1935 499.012(16) has committed any violation of ss. 499.005-499.0054.

1936 (2) The department may deny, suspend, or revoke any  
 1937 registration required by the provisions of this ~~chapter part~~ for  
 1938 the violation of any provision of this ~~chapter part~~ or of any  
 1939 rules adopted under this ~~chapter part~~.

1940 (3) The department may revoke or suspend a permit:

1941 (a) If the permit was obtained by misrepresentation or  
 1942 fraud or through a mistake of the department;

1943 (b) If the permit was procured, or attempted to be

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1944 procured, for any other person by making or causing to be made  
 1945 any false representation; or

1946 (c) If the permittee has violated any provision of this  
 1947 ~~chapter part~~ or rules adopted under this ~~chapter part~~.

1948 (4) If any permit issued under this ~~chapter part~~ is revoked  
 1949 or suspended, the owner, manager, operator, or proprietor of the  
 1950 establishment shall cease to operate as the permit authorized,  
 1951 from the effective date of the suspension or revocation until  
 1952 the person is again registered with the department and possesses  
 1953 the required permit. If a permit is revoked or suspended, the  
 1954 owner, manager, or proprietor shall remove all signs and symbols  
 1955 that identify the operation as premises permitted as a drug  
 1956 wholesaling establishment; drug, device, or cosmetic  
 1957 manufacturing establishment; or retail establishment. The  
 1958 department shall determine the length of time for which the  
 1959 permit is to be suspended. If a permit is revoked, the person  
 1960 that owns or operates the establishment may not apply for any  
 1961 permit under this ~~chapter part~~ for a period of 1 year after the  
 1962 date of the revocation. A revocation of a permit may be  
 1963 permanent if the department considers that to be in the best  
 1964 interest of the public health.

1965 (5) The department may deny, suspend, or revoke a permit  
 1966 issued under this ~~chapter part~~ which authorizes the permittee to  
 1967 purchase prescription drugs if any owner, officer, employee, or  
 1968 other person who participates in administering or operating the  
 1969 establishment has been found guilty of any violation of this  
 1970 ~~chapter part~~ or chapter 465, chapter 501, or chapter 893, any  
 1971 rules adopted under this ~~chapter part~~ or those chapters, or any  
 1972 federal or state drug law, regardless of whether the person has

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1973 been pardoned, had her or his civil rights restored, or had  
1974 adjudication withheld.

1975 (6) The department shall deny, suspend, or revoke the  
1976 permit of any person or establishment if the assignment, sale,  
1977 transfer, or lease of an establishment permitted under this  
1978 ~~chapter part~~ will avoid an administrative penalty, civil action,  
1979 or criminal prosecution.

1980 (7) Notwithstanding s. 120.60(5), if a permittee fails to  
1981 comply with s. 499.012(6) or s. 499.83, as applicable, the  
1982 department may revoke the permit of the permittee and shall  
1983 provide notice of the intended agency action by posting a notice  
1984 at the department's headquarters and by mailing a copy of the  
1985 notice of intended agency action by certified mail to the most  
1986 recent mailing address on record with the department and, if the  
1987 permittee is not a natural person, to the permittee's registered  
1988 agent on file with the Department of State.

1989 (8) The department may deny, suspend, or revoke a permit  
1990 under this part if it finds the permittee has not complied with  
1991 the credentialing requirements of s. 499.0121(15).

1992 (9) The department may deny, suspend, or revoke a permit  
1993 under this part if it finds the permittee has not complied with  
1994 the reporting requirements of, or knowingly made a false  
1995 statement in a report required by, s. 499.0121(14).

1996 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

Phone 850 224-7000

Street

TLH  
City

FL  
State

32301  
Zip

E-mail \_\_\_\_\_

Speaking:  For  Against  Information

Representing Compiessed 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.**

**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.)

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

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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

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**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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup>

### 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."<sup>6</sup>

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.

---

<sup>1</sup> 410 U.S. 113 (1973).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> 505 U.S. 833 (1992).

<sup>6</sup> 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.<sup>7</sup>

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.<sup>8</sup> A termination of pregnancy must be performed by a physician<sup>9</sup> 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.<sup>10</sup>

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.<sup>11</sup> 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.<sup>12</sup>

### **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.<sup>13</sup>

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

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<sup>7</sup> *Id.*

<sup>8</sup> Section 390.011(1), F.S.

<sup>9</sup> Section 390.0111(2), F.S.

<sup>10</sup> Section 390.011(8), F.S.

<sup>11</sup> Section 390.011(7), F.S.

<sup>12</sup> Section 797.03(3), F.S.

<sup>13</sup> 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.<sup>14</sup>

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.<sup>15,16</sup>

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.<sup>17</sup>

### **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<sup>18</sup> 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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<sup>14</sup> 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)

<sup>15</sup> Wolters Kluwer Health, UpToDate, available at: <http://www.uptodate.com/contents/limit-of-viability#H8144843>, (Last visited Feb. 26, 2014).

<sup>16</sup> 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](http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx), (Last visited Feb. 26, 2014).

<sup>17</sup> 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](http://www.guttmacher.org/statecenter/spibs/spib_PLTA.pdf) (Last visited Feb. 25, 2014).

<sup>18</sup> 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<sup>19</sup> 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.

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<sup>19</sup> 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,<sup>20</sup> 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

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<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup> 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.<sup>23</sup> 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.<sup>24</sup>

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.<sup>25</sup>

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."<sup>26</sup>

In *In re T.W.*, the Florida Supreme Court determined that:

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<sup>21</sup> 410 U.S. 113 (1973).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> 505 U.S. 833 (1992).

<sup>26</sup> 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.<sup>27</sup>

**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.

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<sup>27</sup> *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.



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LEGISLATIVE ACTION

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

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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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11 that would be made by a reasonably prudent physician,  
12 knowledgeable about the case and treatment possibilities with  
13 respect to the medical conditions involved.

14 (10) "Standard medical measure" means the medical care that  
15 a physician would provide based on the particular facts of the  
16 pregnancy, the information available to the physician, and the  
17 technology reasonably available in a hospital, as defined in s.  
18 395.002, with an obstetrical department, to preserve the life  
19 and health of the fetus, with or without temporary artificial  
20 life sustaining support, if the fetus were born at the same  
21 stage of fetal development.

22 (12) "Viable" or "viability" means the stage of fetal  
23 development when the life of a fetus is sustainable outside the  
24 womb through standard medical measures.

25 Section 2. Subsections (1), (4), (10), and (13) of section  
26 390.0111, Florida Statutes, are amended to read:

27 390.0111 Termination of pregnancies.—

28 (1) TERMINATION IN THIRD TRIMESTER; WHEN ALLOWED.—No  
29 termination of pregnancy shall be performed on any human being  
30 in the third trimester of pregnancy unless one of the following  
31 conditions is met:

32 (a) Two physicians certify in writing ~~to the fact that, in~~  
33 reasonable medical judgment ~~to a reasonable degree of medical~~  
34 ~~probability,~~ the termination of the pregnancy is necessary to  
35 save the pregnant woman's life or avert a serious risk of  
36 substantial and irreversible physical impairment of a major  
37 bodily function of the pregnant woman other than a psychological  
38 condition. ~~or preserve the health of the pregnant woman; or~~

39 (b) The physician certifies in writing that, in reasonable





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40 medical judgment, there is a to the medical necessity for  
41 legitimate emergency medical procedures for termination of the  
42 pregnancy to save the pregnant woman's life or avert a serious  
43 risk of imminent substantial and irreversible physical  
44 impairment of a major bodily function of the pregnant woman  
45 other than a psychological condition in the third trimester, and  
46 another physician is not available for consultation.

47 (4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER  
48 DURING VIABILITY.—If a termination of pregnancy is performed in  
49 the third trimester, the physician performing during viability,  
50 no person who performs or induces the termination of pregnancy  
51 must exercise the same shall fail to use that degree of  
52 professional skill, care, and diligence to preserve the life and  
53 health of the fetus which the physician such person would be  
54 required to exercise in order to preserve the life and health of  
55 a any fetus intended to be born and not aborted. However, if  
56 preserving the life and health of the fetus conflicts with  
57 preserving the life and health of the pregnant woman, the  
58 physician must consider preserving the woman's life and health  
59 the overriding and superior concern "Viability" means that stage  
60 of fetal development when the life of the unborn child may with  
61 a reasonable degree of medical probability be continued  
62 indefinitely outside the womb. Notwithstanding the provisions of  
63 this subsection, the woman's life and health shall constitute an  
64 overriding and superior consideration to the concern for the  
65 life and health of the fetus when such concerns are in conflict.

66 (10) PENALTIES FOR VIOLATION.—Except as provided in  
67 subsections (3), (7), and (12):

68 (a) Any person who willfully performs, or actively



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69 participates in, a termination of pregnancy ~~procedure~~ in  
70 violation of the requirements of this section or s. 390.01112  
71 commits a felony of the third degree, punishable as provided in  
72 s. 775.082, s. 775.083, or s. 775.084.

73 (b) Any person who performs, or actively participates in, a  
74 termination of pregnancy ~~procedure~~ in violation of ~~the~~  
75 ~~provisions of~~ this section or s. 390.01112 which results in the  
76 death of the woman commits a felony of the second degree,  
77 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

78 (13) FAILURE TO COMPLY.—Failure to comply with the  
79 requirements of this section or s. 390.01112 constitutes grounds  
80 for disciplinary action under each respective practice act and  
81 under s. 456.072.

82 Section 3. Section 390.01112, Florida Statutes, is created  
83 to read:

84 390.01112 Termination of pregnancies during viability.—

85 (1) No termination of pregnancy shall be performed on any  
86 human being if the physician determines that, in reasonable  
87 medical judgment, the fetus has achieved viability, unless:

88 (a) Two physicians certify in writing that, in reasonable  
89 medical judgment, the termination of the pregnancy is necessary  
90 to save the pregnant woman's life or avert a serious risk of  
91 substantial and irreversible physical impairment of a major  
92 bodily function of the pregnant woman other than a psychological  
93 condition; or

94 (b) The physician certifies in writing that, in reasonable  
95 medical judgment, there is a medical necessity for legitimate  
96 emergency medical procedures for termination of the pregnancy to  
97 save the pregnant woman's life or avert a serious risk of



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98 imminent substantial and irreversible physical impairment of a  
99 major bodily function of the pregnant woman other than a  
100 psychological condition, and another physician is not available  
101 for consultation.

102 (2) Before performing a termination of pregnancy, a  
103 physician must determine if the fetus is viable by, at a  
104 minimum, performing a medical examination of the pregnant woman  
105 and, to the maximum extent possible through reasonably available  
106 tests and the ultrasound required under s. 390.0111(3), an  
107 examination of the fetus. The physician must document in the  
108 pregnant woman's medical file the physician's determination and  
109 the method, equipment, fetal measurements, and any other  
110 information used to determine the viability of the fetus.

111 (3) If a termination of pregnancy is performed during  
112 viability, the physician performing the termination of pregnancy  
113 must exercise the same degree of professional skill, care, and  
114 diligence to preserve the life and health of the fetus that the  
115 physician would be required to exercise in order to preserve the  
116 life and health of a fetus intended to be born and not aborted.  
117 However, if preserving the life and health of the fetus  
118 conflicts with preserving the life and health of the woman, the  
119 physician must consider preserving the woman's life and health  
120 the overriding and superior concern.

121 Section 4. Subsection (3) of section 797.03, Florida  
122 Statutes, is amended to read:

123 797.03 Prohibited acts; penalties.—

124 (3) It is unlawful for any person to perform or assist in  
125 performing an abortion on a person during viability or in the  
126 third trimester other than in a hospital.



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127 Section 5. Severability and reversion.—

128 (1) If any provision of this act or its application to any  
129 person or circumstance is held invalid, the invalidity does not  
130 affect other provisions or applications of this act which can be  
131 given effect without the invalid provision or application, and  
132 to this end the provisions of this act are severable.

133 (2) Notwithstanding subsection (1), if s. 390.01112,  
134 Florida Statutes, is held unconstitutional and severed by a  
135 court having jurisdiction, the amendments made by this act to s.  
136 390.011, Florida Statutes, and subsections (4), (10), and (13)  
137 of s. 390.0111, Florida Statutes, will be repealed and will  
138 revert to the law as it existed on January 1, 2014.

139 Section 6. This act shall take effect July 1, 2014.

140  
141 ===== T I T L E A M E N D M E N T =====

142 And the title is amended as follows:

143 Delete everything before the enacting clause  
144 and insert:

145 A bill to be entitled  
146 An act relating to the termination of pregnancies;  
147 amending s. 390.011, F.S.; defining the terms  
148 "reasonable medical judgment" and "standard medical  
149 measure" and redefining the term "viability"; amending  
150 s. 390.0111, F.S.; revising the circumstances under  
151 which a pregnancy in the third trimester may be  
152 terminated; providing the standard of medical care for  
153 the termination of a pregnancy during the third  
154 trimester; providing criminal penalties for a  
155 violation of s. 390.01112, F.S.; authorizing



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156 administrative discipline for a violation of s.  
157 390.01112, F.S., by certain licensed professionals;  
158 creating s. 390.01112, F.S.; prohibiting the  
159 termination of a viable fetus; providing exceptions;  
160 requiring a physician to perform certain examinations  
161 to determine the viability of a fetus; providing the  
162 standard of care for the termination of a viable  
163 fetus; amending s. 797.03, F.S.; prohibiting an  
164 abortion of a viable fetus outside of a hospital;  
165 providing for severability; providing for a contingent  
166 future repeal and reversion of law; providing an  
167 effective date.

By Senator Flores

37-01090C-14

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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:

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

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(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

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

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59 physical impairment of a major bodily function of the pregnant  
 60 woman other than a psychological condition in the third  
 61 trimester, and another physician is not available for  
 62 consultation.

63 (4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER  
 64 DURING VIABILITY.—If a termination of pregnancy is performed in  
 65 the third trimester, the physician performing during viability,  
 66 no person who performs or induces the termination of pregnancy  
 67 must exercise the same shall fail to use that degree of  
 68 professional skill, care, and diligence to preserve the life and  
 69 health of the fetus which the physician such person would be  
 70 required to exercise in order to preserve the life and health of  
 71 a any fetus intended to be born and not aborted. However, if  
 72 preserving the life and health of the fetus conflicts with  
 73 preserving the life and health of the pregnant woman, the  
 74 physician must consider preserving the woman's life and health  
 75 the overriding and superior concern "Viability" means that stage  
 76 of fetal development when the life of the unborn child may with  
 77 a reasonable degree of medical probability be continued  
 78 indefinitely outside the womb. Notwithstanding the provisions of  
 79 this subsection, the woman's life and health shall constitute an  
 80 overriding and superior consideration to the concern for the  
 81 life and health of the fetus when such concerns are in conflict.

82 (10) PENALTIES FOR VIOLATION.—Except as provided in  
 83 subsections (3), (7), and (12):

84 (a) Any person who willfully performs, or actively  
 85 participates in, a termination of pregnancy procedure in  
 86 violation of the requirements of this section or s. 390.01112  
 87 commits a felony of the third degree, punishable as provided in

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88 s. 775.082, s. 775.083, or s. 775.084.

89 (b) Any person who performs, or actively participates in, a  
 90 termination of pregnancy procedure in violation of the  
 91 provisions of this section or s. 390.01112 which results in the  
 92 death of the woman commits a felony of the second degree,  
 93 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

94 (13) FAILURE TO COMPLY.—Failure to comply with the  
 95 requirements of this section or s. 390.01112 constitutes grounds  
 96 for disciplinary action under each respective practice act and  
 97 under s. 456.072.

98 Section 3. Section 390.01112, Florida Statutes, is created  
 99 to read:

100 390.01112 Termination of pregnancies during viability.—

101 (1) No termination of pregnancy shall be performed on any  
 102 human being if the physician reasonably determines that, in the  
 103 physician's good faith medical judgment, the fetus has achieved  
 104 viability, unless:

105 (a) Two physicians certify in writing that, to a reasonable  
 106 degree of medical probability, the termination of the pregnancy  
 107 is necessary to save the pregnant woman's life or avert a  
 108 serious risk of substantial and irreversible physical impairment  
 109 of a major bodily function of the pregnant woman other than a  
 110 psychological condition; or

111 (b) The physician certifies in writing to the medical  
 112 necessity for legitimate emergency medical procedures for  
 113 termination of the pregnancy to save the pregnant woman's life  
 114 or avert a serious risk of imminent substantial and irreversible  
 115 physical impairment of a major bodily function of the pregnant  
 116 woman other than a psychological condition, and another

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117 physician is not available for consultation.

118 (2) Before performing a termination of pregnancy, a  
 119 physician must determine if the fetus is viable by, at a  
 120 minimum, performing a medical examination of the pregnant woman  
 121 and, to the maximum extent possible through reasonably available  
 122 tests and the ultrasound required under s. 390.0111(3), an  
 123 examination of the fetus. The physician must document in the  
 124 pregnant woman's medical file the physician's determination and  
 125 the method, equipment, fetal measurements, and any other  
 126 information used to determine the viability of the fetus.

127 (3) If a termination of pregnancy is performed during  
 128 viability, the physician performing the termination of pregnancy  
 129 must exercise the same degree of professional skill, care, and  
 130 diligence to preserve the life and health of the fetus that the  
 131 physician would be required to exercise in order to preserve the  
 132 life and health of a fetus intended to be born and not aborted.  
 133 However, if preserving the life and health of the fetus  
 134 conflicts with preserving the life and health of the woman, the  
 135 physician must consider preserving the woman's life and health  
 136 the overriding and superior concern.

137 Section 4. Subsection (3) of section 797.03, Florida  
 138 Statutes, is amended to read:

139 797.03 Prohibited acts; penalties.—

140 (3) It is unlawful for any person to perform or assist in  
 141 performing an abortion on a person during viability or in the  
 142 third trimester other than in a hospital.

143 Section 5. Severability and reversion.—

144 (1) If any provision of this act or its application to any  
 145 person or circumstance is held invalid, the invalidity does not

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2014918\_\_

146 affect other provisions or applications of this act which can be  
 147 given effect without the invalid provision or application, and  
 148 to this end the provisions of this act are severable.

149 (2) Notwithstanding subsection (1), if s. 390.01112,  
 150 Florida Statutes, is held unconstitutional and severed by a  
 151 court having jurisdiction, the amendments made by this act to s.  
 152 390.011, Florida Statutes, and subsections (4), (10), and (13)  
 153 of s. 390.0111, Florida Statutes, will be repealed and will  
 154 revert to the law as it existed on January 1, 2014.

155 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 Respondees

Bill Number SB918  
*(if applicable)*

Name Barbara DeVane

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title \_\_\_\_\_

Address 1625 E. Brevard St

Phone 850-222-3969

Tallahassee FL 32308  
*City State Zip*

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.*

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4/1/2014

Meeting Date

Topic Termination of Pregnancies

Bill Number SB 918  
(if applicable)

Name Richard Polzangin

Amendment Barcode \_\_\_\_\_  
(if applicable)

Job Title —

Address 1300 N Duval St

Phone 850 224-4206

Tallahassee FL 32303  
City State Zip

E-mail richardpolzangin@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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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

Phone 813.264.2977

Street

TAMPA FL 33699

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.*

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**APPEARANCE RECORD**

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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.*

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**APPEARANCE RECORD**

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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

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.*

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S-001 (10/20/11)

THE FLORIDA SENATE  
**APPEARANCE RECORD**



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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  
*Street*

Phone 850-320-4208

Tallahassee FL 32301  
*City State Zip*

E-mail Stef.Kunkel@gmail.com

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.*

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**APPEARANCE RECORD**



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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 Bismayne Blvd. Suite 1  
Street

Phone 305-321-4573

Miami FL 33138  
City State Zip

E-mail MONI@FLNEWMAJORITY.ORG

Speaking:  For  Against  Information

Representing Florida New Majority

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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THE FLORIDA SENATE  
**APPEARANCE RECORD**



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4/1/14

Meeting Date

Topic Termination of Pregnancy

Bill Number SB 918  
*(if applicable)*

Name Malloy Garner-Wells

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Public Policy Director

Address 737 NW 24<sup>th</sup> Ave

Phone \_\_\_\_\_

Street

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

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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

Phone 561-472-9934

Nest Palm Beach, FL 33435  
*Street City State Zip*

E-mail beth.swickard@ppsofla.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.*

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THE FLORIDA SENATE  
**APPEARANCE RECORD**



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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

Phone 850-425-1344

Tallahassee FL 32301  
City State Zip

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

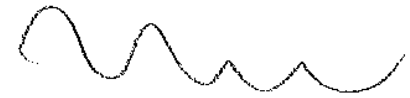
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S-001 (10/20/11)

THE FLORIDA SENATE

APPEARANCE RECORD



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

1 Apr 14  
Meeting Date

Topic Termination of Pregnancy

Bill Number SB918  
*(if applicable)*

Name Benjamin David-Arrow

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title \_\_\_\_\_

Address 1010 Shaver Ct 19

Phone 850 321 0660

*Street*

Tallahassee

FL

32312

*City*

*State*

*Zip*

E-mail bjh12@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.*

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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*

Phone 850-567-8143

Orlando  
*City*

FL  
*State*

32806  
*Zip*

E-mail saraj@fffamily

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.*

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**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.)

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

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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.	<u>Gudeman</u>	<u>Uchino</u>	<u>EP</u>	<b>Fav/CS</b>
2.	<u>Peterson</u>	<u>Stovall</u>	<u>HP</u>	<b>Favorable</b>
3.	_____	_____	<u>AG</u>	_____

---

**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 interceptors, 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.<sup>1</sup> The DOH estimates there are approximately 2.6 million septic tanks in use statewide.<sup>2</sup> An onsite sewage treatment and disposal system is:<sup>3</sup>

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

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<sup>1</sup> See s. 381.006(7), F.S.

<sup>2</sup> Fla. Dept. of Health, *Onsite Sewage*, <http://www.floridahealth.gov/healthy-environments/onsite-sewage/index.html> (last visited Mar. 29, 2014).

<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup>

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.<sup>6</sup>

### **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.<sup>7</sup> Septage is defined as a mixture of sludge, fatty materials, human feces, and wastewater removed during the pumping of an OSTDS.<sup>8</sup> Approximately 100,000 septic tanks are pumped each year, generating 100 million gallons of septage requiring treatment and disposal.<sup>9</sup> 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.<sup>10</sup> The treated septage is then spread over the land at DOH-regulated land application sites.<sup>11</sup> 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

---

<sup>4</sup> 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](http://water.epa.gov/aboutow/owm/upload/2005_08_19_primer.pdf) (last visited Mar. 29, 2014).

<sup>5</sup> Fla. Dept. of Health, *Resource Manual*, 169 (FY 2012 – 2013) (on file with the Senate Health Policy Committee).

<sup>6</sup> Fla. Dept. of Environmental Protection, *Septic Systems*, <http://www.dep.state.fl.us/water/wastewater/dom/septic.htm> (last visited Mar. 29, 2014).

<sup>7</sup> 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](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).

<sup>8</sup> Section 381.0065(2)(n), F.S.

<sup>9</sup> *Supra* note 6, at 1.

<sup>10</sup> Rule 64E-6.010(7)(a), F.A.C.

<sup>11</sup> *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.<sup>12</sup>

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.<sup>13</sup> The law required the DOH to adopt rules and begin initial inspections of OSTDSs by January 1, 2011.<sup>14</sup>

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.<sup>15</sup> 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.<sup>16</sup>

In 2012, the statewide inspection program and the DOH's rulemaking authority were repealed. A county or municipality with a first magnitude spring<sup>17</sup> 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.<sup>18</sup> 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;

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<sup>12</sup> *Supra* note 6 at 1.

<sup>13</sup> Chapter 2010-205, s. 35, Laws of Fla.

<sup>14</sup> *Id.*

<sup>15</sup> Chapter 2010-283, Laws of Fla.

<sup>16</sup> Chapter 2011-47, s. 13, Laws of Fla.

<sup>17</sup> "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.)

<sup>18</sup> 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:  $AAR = N \div 0.0026$ , 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:
  - $AAR = P \div 0.0076$  (if crop demand is calculated for  $P_2O_5$ ); and
  - $AAR = P \div 0.0033$  (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.<sup>19</sup>

### **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.<sup>20</sup>

### ***Wastewater Treatment Facilities***

There are approximately 2,100 domestic wastewater treatment facilities in Florida.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup>

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

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<sup>19</sup> Rule 64E—6.010, F.A.C.

<sup>20</sup> *Supra* note 6 at 2-4.

<sup>21</sup> 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).

<sup>22</sup> *Supra* note 6 at 2-3.

<sup>23</sup> *Supra* note 6 at 2-3.

various treatment points in the system as capacity allows.<sup>24</sup> The average rate for this disposal method is 6 to 12 cents per gallon.<sup>25</sup>

### ***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.<sup>26</sup>

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.<sup>27</sup>

### **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;

---

<sup>24</sup> *Supra* note 6, at 2-3.

<sup>25</sup> *Supra* note 6, at 3.

<sup>26</sup> *Supra* note 6, at 3.

<sup>27</sup> *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

1 A bill to be entitled  
2 An act relating to onsite sewage treatment and  
3 disposal systems; amending s. 381.0065, F.S.; delaying  
4 the effective date of the prohibition against the land  
5 application of septage from onsite sewage treatment  
6 and disposal systems; requiring the Department of  
7 Environmental Protection to examine and report on  
8 potential options for safely and appropriately  
9 disposing or reusing septage; requiring the department  
10 to submit a report of its findings and  
11 recommendations; providing an effective date.  
12  
13 Be It Enacted by the Legislature of the State of Florida:  
14  
15 Section 1. Subsection (6) of section 381.0065, Florida  
16 Statutes, is amended to read:  
17 381.0065 Onsite sewage treatment and disposal systems;  
18 regulation.—  
19 (6) LAND APPLICATION OF SEPTAGE PROHIBITED.—  
20 (a) Effective January 1, 2017 ~~2016~~, the land application of  
21 septage from onsite sewage treatment and disposal systems is  
22 prohibited.  
23 (b) The Department of Environmental Protection, in  
24 consultation with the Department of Health, the Department of  
25 Agriculture and Consumer Services, the Department of Economic  
26 Opportunity, the University of Florida Institute of Food and  
27 Agricultural Sciences, local governments, and other  
28 stakeholders, shall examine and report on the potential options  
29 for safely and appropriately disposing of or reusing septage and

Page 1 of 3

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

592-03286-14

20141160c1

30 the contents of portable toilets, grease interceptors, and  
31 holding tanks, including, but not limited to:  
32 1. An inventory of domestic wastewater utilities and solid  
33 waste management facilities that are known to receive and treat  
34 septage or the contents of portable toilets, grease  
35 interceptors, and holding tanks.  
36 2. An inventory of permitted septage land application  
37 sites.  
38 3. An analysis of the nutrient concentrations of septage.  
39 4. An analysis of the technical limitations for domestic  
40 wastewater utilities and solid waste management facilities to  
41 receive and treat septage or the contents of portable toilets,  
42 grease interceptors, and holding tanks.  
43 5. An analysis of the sufficiency of chapter 64E-6, Florida  
44 Administrative Code, in managing nutrient loading from land  
45 application sites, with emphasis on high recharge areas of the  
46 aquifer and other sensitive surface waters or groundwaters.  
47 6. An analysis of compliance rates with chapter 64E-6,  
48 Florida Administrative Code, and the sufficiency of operator  
49 oversight to ensure compliance.  
50 7. An analysis of the sufficiency of penalties for  
51 noncompliance.  
52 8. The transfer of regulatory authority over the land  
53 application of septage or the contents of portable toilets,  
54 grease interceptors, and holding tanks from the Department of  
55 Health to the Department of Environmental Protection, including  
56 the environmental benefits of applying the nutrient management  
57 plan requirements, setbacks, site-monitoring requirements, and  
58 provisions of chapter 62-640, Florida Administrative Code, to

Page 2 of 3

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

592-03286-14

20141160c1

59 the land application of septage.

60 (c) The Department of Environmental Protection shall submit  
61 a report of its findings and recommendations, pursuant to  
62 paragraph (b), to the Governor, the President of the Senate, and  
63 the Speaker of the House of Representatives by February 1, 2015.

64 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,

A handwritten signature in black ink that reads "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](http://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)

3-1-14

Meeting Date

Topic Onsite Septic Disposal Bill Number 1160  
Name Chris Doolin Amendment Barcode \_\_\_\_\_ (if applicable)  
Job Title Consultant (if applicable)  
Address 1118-B Thomasville Rd. Phone 850-508-5492  
*Street* Tallahassee, Fla. 32303 E-mail \_\_\_\_\_  
*City* *State* *Zip*

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.**

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

Phone (843)-533-8383

Street

Barton

City

State

Zip

E-mail JMANNSEPTIC@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.*

**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 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

Phone 863 956 5540

Street LAKE ALFRED FL 33850  
City State Zip

E-mail rgroover@fouronsite.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.

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 onsite treatment & disposal systems

Bill Number 1160 (if applicable)

Name Jarla 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 prettyposhy@yahoo.com

Speaking:  For  Against  Information

Representing FAWA, 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.

**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.)

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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	<b>Fav/CS</b>
2.			AHS	
3.			AP	

---

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup>

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.<sup>4</sup>

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:<sup>5</sup>

- 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.<sup>6</sup>

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<sup>1</sup> Alliance for the Prudent Use of Antibiotics, *General Background: About Antibiotic Resistance*, [http://www.tufts.edu/med/apua/about\\_issue/about\\_antibioticres.shtml](http://www.tufts.edu/med/apua/about_issue/about_antibioticres.shtml) (last visited Mar. 27, 2014).

<sup>2</sup> 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](http://www.tufts.edu/med/apua/about_issue/what_can_be_done.shtml) (last visited Mar. 27, 2014).

<sup>3</sup> 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=0CCYOFjAA&url=http%3A%2F%2Fwww.cdc.gov%2Fdrugresistance%2Fthreat-report-2013%2Fpdf%2Far-threats-2013-508.pdf&ei=I0o0U5qAH6jA0OG5zYG0BQ&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.

<sup>4</sup> *Id.* at 11.

<sup>5</sup> *Id.* at 20.

<sup>6</sup> *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.<sup>7</sup> 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.<sup>8</sup>

### Communicable Diseases

The DOH is responsible for implementing a communicable disease<sup>9</sup> prevention and control program.<sup>10</sup> 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.<sup>11</sup>

The DOH is also granted authority to conduct epidemiological studies of diseases of public health significance.<sup>12</sup> 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.<sup>13</sup> Likewise, a laboratory must report to the DOH when a test suggests or diagnoses a notifiable disease or condition.<sup>14</sup> Information submitted in reports is confidential and exempt from the public records laws and may be disclosed only when necessary to public health.<sup>15</sup>

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

<sup>7</sup> 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).

<sup>8</sup> 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&usq=AFQjCNFz-uyFsgpL6Db3jGW951Xv2mWWVA> (last visited Mar. 27, 2014).

<sup>9</sup> “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).

<sup>10</sup> Section 381.003(1), F.S.

<sup>11</sup> Section 381.003(8), F.S.

<sup>12</sup> Section 381.0031(1), F.S.

<sup>13</sup> Rule 64D-3.030, F.A.C.

<sup>14</sup> Rule 64D-3.030, F.A.C.

<sup>15</sup> Section 381.0031(6), F.S.

population or an institution is of urgent public health significance.<sup>16,17</sup> The list is based on the notifiable diseases recommended by the Council of State and Territorial Epidemiologists<sup>18</sup> and the CDC, but may be expanded by the DOH.<sup>19</sup> Currently the table includes five of the 18 threats identified by the CDC in its 2013 report.<sup>20</sup> The DOH has initiated rulemaking to add four additional bacteria<sup>21</sup> 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.<sup>22</sup> 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.<sup>23</sup>

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.<sup>24</sup>

The State Surgeon General has specific responsibility for declaring public health emergencies and issuing public health advisories.<sup>25</sup> Before issuing an advisory, the State Surgeon General must consult with affected state agencies or local governments regarding areas of responsibility.<sup>26</sup> 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.<sup>27</sup> Before declaring a public health emergency, the State Surgeon General must consult with the Governor and the Chief of Domestic Security.<sup>28</sup>

### **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

---

<sup>16</sup> Rule 64D-3.029(3), F.A.C.

<sup>17</sup> "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.)

<sup>18</sup> The list is available at: <http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/CSTENotifiableConditionListA.pdf> (last visited Mar. 27, 2014).

<sup>19</sup> Section 381.0031(\$), F.S.

<sup>20</sup> MRSA, multi-drug resistant Gonorrhea, VRSA, and *Streptococcus pneumoniae*.

<sup>21</sup> Carbapenem-resistant enterobacteriaceae, ESBLs, VRE, and Acinetobacter.

<sup>22</sup> 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).

<sup>23</sup> Fla. Dept. of Health, *supra* note 11. See <http://www.floridacharts.com/merlin/freqrpt.asp> (last visited Mar. 27, 2014).

<sup>24</sup> *Id.*

<sup>25</sup> Section 381.00315, F.S.

<sup>26</sup> Section 381.00315(1)(a), F.S.

<sup>27</sup> Section 381.00315(1)(b), F.S.

<sup>28</sup> *Id.*



two of the infections appearing on the CDC threat list, MRSA Bacteremia, and *C.diff*.<sup>29</sup> This information is posted on the Hospital Compare website, which allows consumers to compare hospital performance on specific quality of care indicators.<sup>30</sup>

In addition, current law requires hospitals to report data about infections to the Agency for Health Care Administration (AHCA).<sup>31</sup> 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.<sup>32</sup>

### **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.<sup>33</sup>

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.<sup>34</sup> There are two types of pneumococcal vaccines available for adults: a pneumococcal polysaccharide vaccine (PPSV23) and a pneumococcal conjugate vaccine (PCV13).<sup>35</sup>

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,

<sup>29</sup> Medicare.gov Hospital Compare, *Healthcare-associated infections*, <http://www.medicare.gov/hospitalcompare/Data/Healthcare-Associated-Infections.html?AspxAutoDetectCookieSupport=1> (last visited Mar. 28, 2014).

<sup>30</sup> Medicare.gov Hospital Compare, *What Is Hospital Compare?*, <http://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html> (last visited Mar. 28, 2014).

<sup>31</sup> Section 408.0361(5)(a)2., F.S.

<sup>32</sup> 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).

<sup>33</sup> National Foundation for Infectious Disease, *Pneumococcal Disease*, [http://www.adultvaccination.com/pneumococcal\\_vaccine\\_vaccination\\_adult\\_immunization.htm](http://www.adultvaccination.com/pneumococcal_vaccine_vaccination_adult_immunization.htm) (last visited April 2, 2014).

<sup>34</sup> 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).

<sup>35</sup> *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.



164560

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. 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

12 practitioners licensed under chapter 458, chapter 459, chapter  
13 464, and chapter 474, the Agency for Health Care Administration,  
14 and the Department of Health. At least two members of the work  
15 group must be certified infection control practitioners. Members  
16 of the study group may be reimbursed for travel expenses. The  
17 work group shall evaluate the list of currently reportable  
18 antibiotic-resistant bacteria; reporting procedures, including  
19 content and format of the reports; notification procedures,  
20 including the modes and the network of distribution; and  
21 response procedures, including coordination with other  
22 departments and agencies of state government, with county and  
23 municipal governments, school boards, the Centers for Disease  
24 Control and Prevention, facilities that may be affected by an  
25 outbreak, and the public. The work group may evaluate other  
26 issues it deems necessary and appropriate. The study group shall  
27 submit a report of its findings and an action plan for  
28 implementation, together with any recommendations of necessary  
29 legislation, to the Governor, the President of the Senate, and  
30 the Speaker of the House of Representatives no later than July  
31 1, 2015.

32 Section 2. Paragraph (t) of subsection (1) of section  
33 400.141, Florida Statutes, is amended to read:

34 400.141 Administration and management of nursing home  
35 facilities.-

36 (1) Every licensed facility shall comply with all  
37 applicable standards and rules of the agency and shall:

38 (t) Assess all residents within 5 working days after  
39 admission for eligibility for pneumococcal ~~polysaccharide~~  
40 vaccination or revaccination ~~(PPV)~~ and vaccinate residents when



164560

41 ~~indicated within 60 days after the effective date of this act in~~  
42 ~~accordance with the recommendations of the United States Centers~~  
43 ~~for Disease Control and Prevention, subject to exemptions for~~  
44 ~~medical contraindications and religious or personal beliefs.~~  
45 ~~Residents admitted after the effective date of this act shall be~~  
46 ~~assessed within 5 working days of admission and, when indicated,~~  
47 ~~vaccinated within 60 days in accordance with the recommendations~~  
48 ~~of the United States Centers for Disease Control and Prevention,~~  
49 ~~subject to exemptions for medical contraindications and~~  
50 ~~religious or personal beliefs.~~ Immunization shall not be  
51 provided to any resident who provides documentation that he or  
52 she has been immunized as required by this paragraph. This  
53 paragraph does not prohibit a resident from receiving the  
54 immunization from his or her personal physician if he or she so  
55 chooses. A resident who chooses to receive the immunization from  
56 his or her personal physician shall provide proof of  
57 immunization to the facility. The agency may adopt and enforce  
58 any rules necessary to comply with or implement this paragraph.

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

60  
61 ===== T I T L E A M E N D M E N T =====

62 And the title is amended as follows:

63 Delete everything before the enacting clause  
64 and insert:

65 A bill to be entitled  
66 An act relating to infectious disease control;  
67 creating a study group to evaluate activities related  
68 to antibiotic-resistant bacteria; specifying  
69 appointments; providing duties and responsibilities of



164560

70 the study group; providing for a report and  
71 recommendations to be submitted to the Governor,  
72 President of the Senate, and Speaker of the House of  
73 Representatives; amending s. 400.141, F.S.; revising  
74 the type of pneumococcal vaccine given to nursing home  
75 residents; deleting obsolete language; providing an  
76 effective date.

By Senator Bean

4-01194-14

2014992\_\_

1 A bill to be entitled  
 2 An act relating to infectious disease control;  
 3 amending s. 381.0011, F.S.; providing duties of the  
 4 Department of Health relating to the dissemination of  
 5 information regarding treatment-resistant bacterial  
 6 infections; providing for the establishment of a  
 7 research panel and an interagency task force;  
 8 requiring the department to adopt and enforce minimum  
 9 standards for infection control practices in certain  
 10 licensed facilities; providing an effective date.  
 11  
 12 Be It Enacted by the Legislature of the State of Florida:  
 13  
 14 Section 1. Section 381.0011, Florida Statutes, is amended  
 15 to read:  
 16 381.0011 Duties and powers of the Department of Health.—It  
 17 is the duty of the Department of Health to:  
 18 (1) Assess the public health status and needs of the state.  
 19 (2) Administer and enforce laws and rules relating to  
 20 sanitation, control of infectious ~~communicable~~ diseases,  
 21 illnesses and hazards to health among humans and from animals to  
 22 humans, and the general health of the people of the state.  
 23 (3) Coordinate with federal, state, and local officials for  
 24 the prevention and suppression of infectious ~~communicable~~ and  
 25 other diseases, illnesses, injuries, and hazards to human  
 26 health.  
 27 (4) Provide for a thorough investigation and study of the  
 28 incidence, causes, modes of propagation and transmission, and  
 29 means of prevention, control, and cure of diseases, illnesses,

Page 1 of 3

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

4-01194-14

2014992\_\_

30 and hazards to human health.  
 31 (5) Provide for the dissemination of information to the  
 32 public ~~relating relative~~ to the prevention, control, and cure of  
 33 diseases, illnesses, and hazards to human health, including  
 34 information reported by licensed health care practitioners under  
 35 subsection (6).  
 36 (6) Establish an Internet website for health care  
 37 practitioners licensed under chapter 458, chapter 459, or  
 38 chapter 464 to report the presence of confirmed treatment-  
 39 resistant bacterial infections. The website shall require the  
 40 practitioner to enter his or her license number, the location of  
 41 the confirmed treatment-resistant bacterial infection, and the  
 42 type of bacterial infection. The department shall adopt rules  
 43 establishing a method to ensure that only one report per  
 44 confirmed case is displayed on the publicly accessible part of  
 45 the website. The department shall adopt rules requiring that the  
 46 identity of the practitioner not be displayed on the publicly  
 47 accessible part of the website and that the report not disclose  
 48 protected health information but only document the presence,  
 49 type, and location of a confirmed treatment-resistant bacterial  
 50 infection.  
 51 ~~(7)-(6)~~ Act as registrar of vital statistics.  
 52 ~~(8)-(7)~~ Manage and coordinate emergency preparedness and  
 53 disaster response functions to: investigate and control the  
 54 spread of disease; coordinate the availability and staffing of  
 55 special needs shelters; support patient evacuation; ensure the  
 56 safety of food and drugs; provide critical incident stress  
 57 debriefing; and provide surveillance and control of  
 58 radiological, chemical, biological, and other environmental

Page 2 of 3

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



4-01194-14

2014992\_\_

59 hazards.

60 (9) Establish a research panel composed of experts in the  
61 field of treatment-resistant bacterial infections, which shall  
62 make recommendations to state agencies regarding biomedical  
63 research programs designed to improve treatment outcomes and  
64 develop protocols to control the incidence of treatment-  
65 resistant bacterial infections.

66 (10) Establish and lead an interagency task force that  
67 includes representatives from health care providers, interested  
68 trade associations, and other state agencies to:

69 (a) Identify emergency response protocols for facilities  
70 licensed under part II of chapter 408 when an outbreak of a  
71 treatment-resistant bacterial infection occurs in such a  
72 facility.

73 (b) Establish a volunteer statewide emergency response team  
74 to investigate, document, and report the presence and outbreak  
75 of a treatment-resistant bacterial infection to the department  
76 and the Centers for Disease Control and Prevention.

77 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 De Castro

Amendment Barcode 104560  
(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  Against  Information  
*Amendment*

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.

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 912  
*(if applicable)*

Name Mona Alesnik

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Infectious Diseases

Address 4802 E Fowler Ave

Phone 813 977 4837

Street

Tampa FL 33620

City

State

Zip

E-mail mmanti30@health.usf.edu

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.**

**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.)

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

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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

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**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.<sup>1</sup>

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.<sup>2</sup> 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.<sup>3</sup>

### 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.<sup>4</sup> 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.<sup>5</sup> The revised guidelines seek to achieve four objectives:<sup>6</sup>

- 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:<sup>7</sup>

- Opt-out HIV screening<sup>8</sup> in all health-care settings;<sup>9</sup>

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<sup>1</sup> Centers for Disease Control and Prevention, *About HIV/AIDS*, <http://www.cdc.gov/hiv/basics/whatishiv.html> (last visited Mar. 26, 2014).

<sup>2</sup> Centers for Disease Control and Prevention, *Basic Statistics*, <http://www.cdc.gov/hiv/basics/statistics.html> (last visited Mar. 26, 2014).

<sup>3</sup> Centers for Disease Control and Prevention, *Florida 2010 Profile*, [http://www.cdc.gov/nchhstp/stateprofiles/pdf/Florida\\_profile.pdf](http://www.cdc.gov/nchhstp/stateprofiles/pdf/Florida_profile.pdf) (last visited Mar. 26, 2014).

<sup>4</sup> Id.

<sup>5</sup> 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](http://www.cdc.gov/hiv/testing/HIVStandardCare/resources/brochures/MMWR-Annotated%20508C_Full.pdf) (last visited Mar. 26, 2014).

<sup>6</sup> Id.

<sup>7</sup> Id.

<sup>8</sup> Opt-out screening means the patient must be notified that the screening will be done; the patient may decline the test.

<sup>9</sup> 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](http://www.cdc.gov/hiv/pdf/evaluation_HIVTesting_BudgetAllocation.pdf) (last visited Mar. 28, 2014). 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.<sup>10</sup>

### **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:<sup>11</sup>

- 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.<sup>12</sup>

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.<sup>13</sup>

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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.

<sup>10</sup> Center for Disease Control and Prevention, *Testing*, <http://www.cdc.gov/hiv/basics/testing.html> (last visited Mar. 26, 2014).

<sup>11</sup> Rule 64D-2.004, F.A.C.

<sup>12</sup> Section 384.30, F.S. and Rule 64D-2.004(4), F.A.C.

<sup>13</sup> 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.<sup>14</sup>

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.

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<sup>14</sup> 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.



246082

LEGISLATIVE ACTION

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

11

nonhealth care setting; amending s. 456.032, F.S.;

By Senator Thompson

12-01300A-14

20141470\_\_

1 A bill to be entitled  
 2 An act relating to HIV testing; amending s. 381.004,  
 3 F.S.; revising and adding definitions; differentiating  
 4 between the notification and consent procedures for  
 5 performing an HIV test in a health care setting and a  
 6 nonhealth care setting; deleting the exemption from  
 7 the requirement to obtain informed consent before  
 8 testing a pregnant woman; amending s. 456.032, F.S.;  
 9 conforming a cross-reference; providing an effective  
 10 date.  
 11  
 12 Be It Enacted by the Legislature of the State of Florida:  
 13  
 14 Section 1. Subsection (1), paragraphs (a), (b), (g), and  
 15 (h) of subsection (2), and paragraph (d) of subsection (4) of  
 16 section 381.004, Florida Statutes, are amended, and subsection  
 17 (1) of that section is reordered, to read:  
 18 381.004 HIV testing.—  
 19 (1) DEFINITIONS.—As used in this section:  
 20 (a) "Health care setting" means a setting devoted to both  
 21 the diagnosis and care of persons, such as county health  
 22 department clinics, hospital emergency departments, urgent care  
 23 clinics, substance abuse treatment clinics, primary care  
 24 settings, community clinics, mobile medical clinics, and  
 25 correctional health care facilities.  
 26 (b)(a) "HIV test" means a test ordered after July 6, 1988,  
 27 to determine the presence of the antibody or antigen to human  
 28 immunodeficiency virus or the presence of human immunodeficiency  
 29 virus infection.

Page 1 of 14

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

12-01300A-14

20141470\_\_

30 (c)(b) "HIV test result" means a laboratory report of a  
 31 human immunodeficiency virus test result entered into a medical  
 32 record on or after July 6, 1988, or any report or notation in a  
 33 medical record of a laboratory report of a human  
 34 immunodeficiency virus test. ~~As used in this section,~~ The term  
 35 "HIV test result" does not include test results reported to a  
 36 health care provider by a patient.  
 37 (d) "Nonhealth care setting" means a site that conducts HIV  
 38 testing for the sole purpose of identifying HIV infection. Such  
 39 setting does not provide medical treatment but may include  
 40 community-based organizations, outreach settings, county health  
 41 department HIV testing programs, and mobile vans.  
 42 (f)(e) "Significant exposure" means:  
 43 1. Exposure to blood or body fluids through needlestick,  
 44 instruments, or sharps;  
 45 2. Exposure of mucous membranes to visible blood or body  
 46 fluids, to which universal precautions apply according to the  
 47 National Centers for Disease Control and Prevention, including,  
 48 without limitations, the following body fluids:  
 49 a. Blood.  
 50 b. Semen.  
 51 c. Vaginal secretions.  
 52 d. Cerebrospinal ~~Cerebro-spinal~~ fluid (CSF).  
 53 e. Synovial fluid.  
 54 f. Pleural fluid.  
 55 g. Peritoneal fluid.  
 56 h. Pericardial fluid.  
 57 i. Amniotic fluid.  
 58 j. Laboratory specimens that contain HIV (e.g., suspensions

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

12-01300A-14

20141470\_\_

59 of concentrated virus); or

60 3. Exposure of skin to visible blood or body fluids,  
61 especially when the exposed skin is chapped, abraded, or  
62 afflicted with dermatitis or the contact is prolonged or  
63 involving an extensive area.

64 ~~(e)(d)~~ "Preliminary HIV test" means an antibody or  
65 antibody-antigen screening test, such as the ~~enzyme-linked~~  
66 immunosorbent assays (IA), or a rapid test approved by the  
67 federal Food and Drug Administration (ELISAs) or the Single-Use  
68 Diagnostic System (SUDS).

69 (g)(e) "Test subject" or "subject of the test" means the  
70 person upon whom an HIV test is performed, or the person who has  
71 legal authority to make health care decisions for the test  
72 subject.

73 (2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT;  
74 RESULTS; COUNSELING; CONFIDENTIALITY.—

75 (a) Before performing an HIV test:

76 1. In a health care setting, the health care provider shall  
77 notify the person to be tested that the test is planned, provide  
78 information about the test, and advise the person that he or she  
79 has the right to decline the test. The health care provider  
80 shall also explain the right to confidential treatment of  
81 information identifying the subject of the test and the results  
82 of the test as provided by law. If a person declines the test,  
83 the health care provider shall note that fact in the person's  
84 medical record. ~~No person in this state shall order a test~~  
85 ~~designed to identify the human immunodeficiency virus, or its~~  
86 ~~antigen or antibody, without first obtaining the informed~~  
87 ~~consent of the person upon whom the test is being performed,~~

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20141470\_\_

88 ~~except as specified in paragraph (h). Informed consent shall be~~  
89 ~~preceded by an explanation of the right to confidential~~  
90 ~~treatment of information identifying the subject of the test and~~  
91 ~~the results of the test to the extent provided by law.~~

92 ~~Information shall also be provided on the fact that a positive~~  
93 ~~HIV test result will be reported to the county health department~~  
94 ~~with sufficient information to identify the test subject and on~~  
95 ~~the availability and location of sites at which anonymous~~  
96 ~~testing is performed. As required in paragraph (3)(c), each~~  
97 ~~county health department shall maintain a list of sites at which~~  
98 ~~anonymous testing is performed, including the locations, phone~~  
99 ~~numbers, and hours of operation of the sites. Consent need not~~  
100 ~~be in writing provided there is documentation in the medical~~  
101 ~~record that the test has been explained and the consent has been~~  
102 ~~obtained.~~

103 2. In a nonhealth care setting, a provider shall obtain the  
104 informed consent of the person upon whom the test is being  
105 performed. Informed consent shall be preceded by an explanation  
106 of the right to confidential treatment of information  
107 identifying the subject of the test and the results of the test  
108 as provided by law.

109  
110 The test subject shall also be informed that a positive HIV test  
111 result will be reported to the county health department with  
112 sufficient information to identify the test subject and on the  
113 availability and location of sites at which anonymous testing is  
114 performed. As required in paragraph (3)(c), each county health  
115 department shall maintain a list of sites at which anonymous  
116 testing is performed, including the locations, telephone

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117 numbers, and hours of operation of the sites.

118 (b) Except as provided in paragraph (h), informed consent  
119 must be obtained from a legal guardian or other person  
120 authorized by law ~~if when~~ the person:

121 1. Is not competent, is incapacitated, or is otherwise  
122 unable to make an informed judgment; or

123 2. Has not reached the age of majority, except as provided  
124 in s. 384.30.

125 (g) Human immunodeficiency virus test results contained in  
126 the medical records of a hospital licensed under chapter 395 may  
127 be released in accordance with s. 395.3025 without being subject  
128 to ~~the requirements of~~ subparagraph (e)2., subparagraph (e)9.,  
129 or paragraph (f) if, provided the hospital has notified the  
130 patient of the limited confidentiality protections afforded HIV  
131 test results contained in hospital medical records ~~obtained~~  
132 written informed consent for the HIV test in accordance with  
133 provisions of this section.

134 (h) Notwithstanding ~~the provisions of~~ paragraph (a),  
135 informed consent is not required:

136 1. When testing for sexually transmissible diseases is  
137 required by state or federal law, or by rule including the  
138 following situations:

139 a. HIV testing pursuant to s. 796.08 of persons convicted  
140 of prostitution or of procuring another to commit prostitution.

141 b. HIV testing of inmates pursuant to s. 945.355 before  
142 ~~prior to their~~ release from prison by reason of parole,  
143 accumulation of gain-time credits, or expiration of sentence.

144 c. Testing for HIV by a medical examiner in accordance with  
145 s. 406.11.

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146 ~~d. HIV testing of pregnant women pursuant to s. 384.31.~~

147 2. Those exceptions provided for blood, plasma, organs,  
148 skin, semen, or other human tissue pursuant to s. 381.0041.

149 3. For the performance of an HIV-related test by licensed  
150 medical personnel in bona fide medical emergencies ~~if when~~ the  
151 test results are necessary for medical diagnostic purposes to  
152 provide appropriate emergency care or treatment to the person  
153 being tested and the patient is unable to consent, as supported  
154 by documentation in the medical record. Notification of test  
155 results in accordance with paragraph (c) is required.

156 4. For the performance of an HIV-related test by licensed  
157 medical personnel for medical diagnosis of acute illness where,  
158 in the opinion of the attending physician, providing  
159 notification ~~obtaining informed consent~~ would be detrimental to the  
160 patient, as supported by documentation in the medical  
161 record, and the test results are necessary for medical  
162 diagnostic purposes to provide appropriate care or treatment to  
163 the person being tested. Notification of test results in  
164 accordance with paragraph (c) is required if it would not be  
165 detrimental to the patient. This subparagraph does not authorize  
166 the routine testing of patients for HIV infection without  
167 notification ~~informed consent~~.

168 5. ~~If when~~ HIV testing is performed as part of an autopsy  
169 for which consent was obtained pursuant to s. 872.04.

170 6. For the performance of an HIV test upon a defendant  
171 pursuant to the victim's request in a prosecution for any type  
172 of sexual battery where a blood sample is taken from the  
173 defendant voluntarily, pursuant to court order for any purpose,  
174 or pursuant to ~~the provisions of~~ s. 775.0877, s. 951.27, or s.

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 175 960.003; however, the results of an any HIV test performed shall  
 176 be disclosed solely to the victim and the defendant, except as  
 177 provided in ss. 775.0877, 951.27, and 960.003.

178 7. ~~If when~~ an HIV test is mandated by court order.

179 8. For epidemiological research pursuant to s. 381.0031,  
 180 for research consistent with institutional review boards created  
 181 by 45 C.F.R. part 46, or for the performance of an HIV-related  
 182 test for the purpose of research, if the testing is performed in  
 183 a manner by which the identity of the test subject is not known  
 184 and may not be retrieved by the researcher.

185 9. ~~If when~~ human tissue is collected lawfully without the  
 186 consent of the donor for corneal removal as authorized by s.  
 187 765.5185 or enucleation of the eyes as authorized by s. 765.519.

188 10. For the performance of an HIV test upon an individual  
 189 who comes into contact with medical personnel in such a way that  
 190 a significant exposure has occurred during the course of  
 191 employment or within the scope of practice and where a blood  
 192 sample is available which that was taken from that individual  
 193 voluntarily by medical personnel for other purposes. The term  
 194 "medical personnel" includes a licensed or certified health care  
 195 professional; an employee of a health care professional or  
 196 health care facility; employees of a laboratory licensed under  
 197 chapter 483; personnel of a blood bank or plasma center; a  
 198 medical student or other student who is receiving training as a  
 199 health care professional at a health care facility; and a  
 200 paramedic or emergency medical technician certified by the  
 201 department to perform life-support procedures under s. 401.23.

202 a. Before performing ~~Prior to performance of~~ an HIV test on  
 203 a voluntarily obtained blood sample, the individual from whom

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 204 the blood was obtained shall be requested to consent to the  
 205 performance of the test and to the release of the results. If  
 206 consent cannot be obtained within the time necessary to perform  
 207 the HIV test and begin prophylactic treatment of the exposed  
 208 medical personnel, all information concerning the performance of  
 209 an HIV test and any HIV test result shall be documented only in  
 210 the medical personnel's record unless the individual gives  
 211 written consent to entering this information on the individual's  
 212 medical record.

213 b. Reasonable attempts to locate the individual and to  
 214 obtain consent shall be made, and all attempts must be  
 215 documented. If the individual cannot be found or is incapable of  
 216 providing consent, an HIV test may be conducted on the available  
 217 blood sample. If the individual does not voluntarily consent to  
 218 the performance of an HIV test, the individual shall be informed  
 219 that an HIV test will be performed, and counseling shall be  
 220 furnished as provided in this section. However, HIV testing  
 221 shall be conducted only after appropriate medical personnel  
 222 under the supervision of a licensed physician documents, in the  
 223 medical record of the medical personnel, that there has been a  
 224 significant exposure and that, in accordance with the written  
 225 protocols based on the National Centers for Disease Control and  
 226 Prevention guidelines on HIV postexposure prophylaxis and in the  
 227 physician's medical judgment, the information is medically  
 228 necessary to determine the course of treatment for the medical  
 229 personnel.

230 c. Costs of an any HIV test of a blood sample performed  
 231 with or without the consent of the individual, as provided in  
 232 this subparagraph, shall be borne by the medical personnel or

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233 the employer of the medical personnel. However, costs of testing  
 234 or treatment not directly related to the initial HIV tests or  
 235 costs of subsequent testing or treatment may not be borne by the  
 236 medical personnel or the employer of the medical personnel.

237 d. In order to ~~use~~ utilize the provisions of this  
 238 subparagraph, the medical personnel must ~~either~~ be tested for  
 239 HIV pursuant to this section or provide the results of an HIV  
 240 test taken within 6 months before ~~prior to~~ the significant  
 241 exposure if such test results are negative.

242 e. A person who receives the results of an HIV test  
 243 pursuant to this subparagraph shall maintain the confidentiality  
 244 of the information received and of the persons tested. Such  
 245 confidential information is exempt from s. 119.07(1).

246 f. If the source of the exposure will not voluntarily  
 247 submit to HIV testing and a blood sample is not available, the  
 248 medical personnel or the employer of such person acting on  
 249 behalf of the employee may seek a court order directing the  
 250 source of the exposure to submit to HIV testing. A sworn  
 251 statement by a physician licensed under chapter 458 or chapter  
 252 459 that a significant exposure has occurred and that, in the  
 253 physician's medical judgment, testing is medically necessary to  
 254 determine the course of treatment constitutes probable cause for  
 255 the issuance of an order by the court. The results of the test  
 256 shall be released to the source of the exposure and to the  
 257 person who experienced the exposure.

258 11. For the performance of an HIV test upon an individual  
 259 who comes into contact with medical personnel in such a way that  
 260 a significant exposure has occurred during the course of  
 261 employment or within the scope of practice of the medical

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262 personnel while the medical personnel provides emergency medical  
 263 treatment to the individual; or notwithstanding s. 384.287, an  
 264 individual who comes into contact with nonmedical personnel in  
 265 such a way that a significant exposure has occurred while the  
 266 nonmedical personnel provides emergency medical assistance  
 267 during a medical emergency. For the purposes of this  
 268 subparagraph, a medical emergency means an emergency medical  
 269 condition outside of a hospital or health care facility that  
 270 provides physician care. The test may be performed only during  
 271 the course of treatment for the medical emergency.

272 a. An individual who is capable of providing consent shall  
 273 be requested to consent to an HIV test before ~~prior to the~~  
 274 testing. If consent cannot be obtained within the time necessary  
 275 to perform the HIV test and begin prophylactic treatment of the  
 276 exposed medical personnel and nonmedical personnel, all  
 277 information concerning the performance of an HIV test and its  
 278 result, shall be documented only in the medical personnel's or  
 279 nonmedical personnel's record unless the individual gives  
 280 written consent to entering this information in ~~on~~ the  
 281 individual's medical record.

282 b. HIV testing shall be conducted only after appropriate  
 283 medical personnel under the supervision of a licensed physician  
 284 documents, in the medical record of the medical personnel or  
 285 nonmedical personnel, that there has been a significant exposure  
 286 and that, in accordance with the written protocols based on the  
 287 National Centers for Disease Control and Prevention guidelines  
 288 on HIV postexposure prophylaxis and in the physician's medical  
 289 judgment, the information is medically necessary to determine  
 290 the course of treatment for the medical personnel or nonmedical



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291 personnel.

292 c. Costs of any HIV test performed with or without the  
 293 consent of the individual, as provided in this subparagraph,  
 294 shall be borne by the medical personnel or the employer of the  
 295 medical personnel or nonmedical personnel. However, costs of  
 296 testing or treatment not directly related to the initial HIV  
 297 tests or costs of subsequent testing or treatment may not be  
 298 borne by the medical personnel or the employer of the medical  
 299 personnel or nonmedical personnel.

300 d. In order to use ~~utilize~~ the provisions of this  
 301 subparagraph, the medical personnel or nonmedical personnel  
 302 shall be tested for HIV pursuant to this section or shall  
 303 provide the results of an HIV test taken within 6 months before  
 304 ~~prior to~~ the significant exposure if such test results are  
 305 negative.

306 e. A person who receives the results of an HIV test  
 307 pursuant to this subparagraph shall maintain the confidentiality  
 308 of the information received and of the persons tested. Such  
 309 confidential information is exempt from s. 119.07(1).

310 f. If the source of the exposure will not voluntarily  
 311 submit to HIV testing and a blood sample was not obtained during  
 312 treatment for the medical emergency, the medical personnel, the  
 313 employer of the medical personnel acting on behalf of the  
 314 employee, or the nonmedical personnel may seek a court order  
 315 directing the source of the exposure to submit to HIV testing. A  
 316 sworn statement by a physician licensed under chapter 458 or  
 317 chapter 459 that a significant exposure has occurred and that,  
 318 in the physician's medical judgment, testing is medically  
 319 necessary to determine the course of treatment constitutes

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320 probable cause for the issuance of an order by the court. The  
 321 results of the test shall be released to the source of the  
 322 exposure and to the person who experienced the exposure.

323 12. For the performance of an HIV test by the medical  
 324 examiner or attending physician upon an individual who expired  
 325 or could not be resuscitated while receiving emergency medical  
 326 assistance or care and who was the source of a significant  
 327 exposure to medical or nonmedical personnel providing such  
 328 assistance or care.

329 a. HIV testing may be conducted only after appropriate  
 330 medical personnel under the supervision of a licensed physician  
 331 documents in the medical record of the medical personnel or  
 332 nonmedical personnel that there has been a significant exposure  
 333 and that, in accordance with the written protocols based on the  
 334 National Centers for Disease Control and Prevention guidelines  
 335 on HIV postexposure prophylaxis and in the physician's medical  
 336 judgment, the information is medically necessary to determine  
 337 the course of treatment for the medical personnel or nonmedical  
 338 personnel.

339 b. Costs of an ~~any~~ HIV test performed under this  
 340 subparagraph may not be charged to the deceased or to the family  
 341 of the deceased person.

342 c. For ~~the provisions of~~ this subparagraph to be  
 343 applicable, the medical personnel or nonmedical personnel must  
 344 be tested for HIV under this section or must provide the results  
 345 of an HIV test taken within 6 months before the significant  
 346 exposure if such test results are negative.

347 d. A person who receives the results of an HIV test  
 348 pursuant to this subparagraph shall comply with paragraph (e).

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349 13. For the performance of an HIV-related test medically  
 350 indicated by licensed medical personnel for medical diagnosis of  
 351 a hospitalized infant as necessary to provide appropriate care  
 352 and treatment of the infant ~~if when~~, after a reasonable attempt,  
 353 a parent cannot be contacted to provide consent. The medical  
 354 records of the infant ~~must shall~~ reflect the reason consent of  
 355 the parent was not initially obtained. Test results shall be  
 356 provided to the parent when the parent is located.

357 14. For the performance of HIV testing conducted to monitor  
 358 the clinical progress of a patient previously diagnosed to be  
 359 HIV positive.

360 15. For the performance of repeated HIV testing conducted  
 361 to monitor possible conversion from a significant exposure.

362 (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS;  
 363 REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM  
 364 REGISTRATION.—No county health department and no other person in  
 365 this state shall conduct or hold themselves out to the public as  
 366 conducting a testing program for acquired immune deficiency  
 367 syndrome or human immunodeficiency virus status without first  
 368 registering with the Department of Health, reregistering each  
 369 year, complying with all other applicable provisions of state  
 370 law, and meeting the following requirements:

371 (d) A program in a health care setting shall meet the  
 372 notification criteria contained in subparagraph (2)(a)1. A  
 373 program in a nonhealth care setting shall meet all informed  
 374 consent criteria contained in subparagraph (2)(a)2. ~~The program~~  
 375 must meet all the informed consent criteria contained in  
 376 subsection (2).

377 Section 2. Subsection (2) of section 456.032, Florida

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378 Statutes, is amended to read:

379 456.032 Hepatitis B or HIV carriers.—

380 (2) Any person licensed by the department and any other  
 381 person employed by a health care facility who contracts a blood-  
 382 borne infection shall have a rebuttable presumption that the  
 383 illness was contracted in the course and scope of his or her  
 384 employment, provided that the person, as soon as practicable,  
 385 reports to the person's supervisor or the facility's risk  
 386 manager any significant exposure, as that term is defined in s.  
 387 381.004(1)(e), to blood or body fluids. The employer may test  
 388 the blood or body fluid to determine if it is infected with the  
 389 same disease contracted by the employee. The employer may rebut  
 390 the presumption by the preponderance of the evidence. Except as  
 391 expressly provided in this subsection, there shall be no  
 392 presumption that a blood-borne infection is a job-related injury  
 393 or illness.

394 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  
City State Zip

E-mail nulandlwe@aol.com

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. #1217

Phone 850-408-4512

Tallahassee FL 32301  
*City State 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.**

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 APALACHOE PARKWAY

Phone 878-7364

Street  
TALLAHASSEE, FL 32301  
City State Zip

E-mail \_\_\_\_\_

Speaking:  For  Against  Information

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

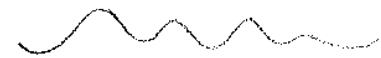
Appearing at request of Chair:  Yes  No

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.

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

City

State

Zip

E-mail mjacquis@flmedical.org

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.**

**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.)

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

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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	<b>Fav/CS</b>
2.			RI	
3.			AP	

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**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**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.<sup>1</sup> 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.”<sup>2</sup> 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.<sup>3</sup>

### 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.<sup>4</sup>

As part of its credentialing program, the BACB has developed:<sup>5</sup>

- 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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<sup>1</sup> Behavior Analyst Certification Board, *About Behavior Analysis* <http://www.bacb.com/index.php?page=2> (last visited Mar. 29, 2014).

<sup>2</sup> 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.

<sup>3</sup> *Supra* note 1.

<sup>4</sup> Behavior Analyst Certification Board, *About the BACB* <http://www.bacb.com/index.php?page=1> (last visited Mar. 29, 2014).

<sup>5</sup> *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.<sup>6</sup>

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.<sup>7</sup> 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.<sup>8</sup>

Currently, there are 1,821 behavior analysts or assistant behavior analysts in Florida who are board-certified by the BACB.<sup>9</sup>

### **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.<sup>10</sup> 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.<sup>11</sup>

### **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

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<sup>6</sup> Behavior Analyst Certification Board, *Standards for Board Certified Behavior Analysts (BCBA)* <http://www.bacb.com/index.php?page=158> (last visited Mar. 30, 2014).

<sup>7</sup> Behavior Analyst Certification Board, *About BACB Credentials* <http://www.bacb.com/index.php?page=4> (last visited Mar. 29, 2014).

<sup>8</sup> 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).

<sup>9</sup> Behavior Analyst Certification Board, *Certificant Registry* <http://www.bacb.com/index.php?page=100155&by=state> (last visited Mar. 30, 2014).

<sup>10</sup> See *Infra* note 20 at 2.

<sup>11</sup> 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.<sup>12</sup> The agency has opted not to create a separate certification process.<sup>13</sup>

- 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.<sup>14</sup> 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:<sup>15</sup>

- 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.<sup>16</sup>

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.<sup>17</sup> In general, boards are responsible for approving or denying applications for

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<sup>12</sup> See *Supra* note 4.

<sup>13</sup> Rule 65G-4.0011, F.A.C.

<sup>14</sup> Section 20.43(1)(g), F.S.

<sup>15</sup> Section 456.003(2), F.S.

<sup>16</sup> Fla. Dept. of Health, *Resource Manual for the Florida Department of Health*, 252 (FY 2012–2013) (on file with the Senate Health Policy Committee).

<sup>17</sup> Section 456.001(1), F.S.

licensure, establishing continuing education requirements, and disciplining practitioners for violations of the relevant practice act.<sup>18</sup> 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.<sup>19</sup>

### **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,

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<sup>18</sup> 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.

<sup>19</sup> *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.<sup>20</sup> 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.<sup>21</sup>

#### ***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.<sup>22</sup>

#### ***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.<sup>23</sup>

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

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<sup>20</sup> 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.

<sup>21</sup> *Id.* at 4 – 7.

<sup>22</sup> *Id.* at 19 – 23.

<sup>23</sup> *Id.* at 25.

certification under the bill.<sup>24</sup> In addition, behavior analysis is an element of the practice of psychology, thus it may be provided by a psychologist.<sup>25</sup>

### ***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).<sup>26</sup>

### ***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.<sup>27</sup>

### **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.”<sup>28</sup> 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.

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<sup>24</sup> *Id.* at 18.

<sup>25</sup> Section 490.003(4), F.S.

<sup>26</sup> *Supra* note 20 at 4 – 5.

<sup>27</sup> *Id.* at 23.

<sup>28</sup> 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<sup>29</sup>**

The DOH estimates it will receive 4,000 applications,<sup>30</sup> which will be subject to an application fee of \$100; a licensure fee of \$300; and an unlicensed activity fee of \$5,<sup>31</sup> 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<sup>32</sup>**

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.

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<sup>29</sup> Fla. Dept. of Health, *Senate Bill 1212 Fiscal Analysis* (Feb. 25, 2014) (on file with the Senate Committee on Health Policy).

<sup>30</sup> 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.)

<sup>31</sup> Section 456.065(3), F.S.

<sup>32</sup> *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 licensee’s 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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12 from any harmful conduct of unqualified, unprofessional, or  
13 unethical applied behavior analysts.

14 Section 3. Section 470.41, Florida Statutes, is created to  
15 read:

16 470.41 Definitions.—As used in this chapter, the term:

17 (1) "Applied behavior analysis" means the design,  
18 implementation, and evaluation of instructional and  
19 environmental modifications to produce socially significant  
20 improvements in human behavior and includes functional  
21 assessment and analysis. The term does not include psychological  
22 testing, the diagnosis of a mental or physical disorder,  
23 neuropsychology, psychotherapy, cognitive therapy, sex therapy,  
24 psychoanalysis, hypnotherapy, or long-term counseling.

25 (2) "Board" means the Board of Applied Behavior Analysis  
26 established in s. 470.415, except when the term is used in the  
27 context of board certification.

28 (3) "Board-certified behavior analyst" means a practitioner  
29 who is certified as a Board Certified Behavior Analyst, or is  
30 recognized as a "Florida-certified behavior analyst," by the  
31 national Behavior Analyst Certification Board (BACB), or its  
32 successor pursuant to s. 470.42.

33 (4) "Board-certified assistant behavior analyst" means a  
34 practitioner who is certified by the national Behavior Analyst  
35 Certification Board, or its successor pursuant to s. 470.42, as  
36 a Board Certified Assistant Behavior Analyst.

37 (5) "Department" means the Department of Health.

38 (6) "Licensed behavior analyst" means an individual who is  
39 licensed by the board and meets the requirements of this  
40 chapter.



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41 (7) "Licensed assistant behavior analyst" means an  
42 individual who:

43 (a) Is licensed by the board as an assistant behavior  
44 analyst and meets the requirements of this chapter; and

45 (b) Works under the supervision of a licensed behavior  
46 analyst.

47 (8) "Supervised experience" means an individual has  
48 completed the training necessary to satisfy the eligibility  
49 requirements for BACB certification.

50 Section 4. Section 470.415, Florida Statutes, is created to  
51 read:

52 470.415 Board of Applied Behavior Analysis.—

53 (1) The Board of Applied Behavior Analysis is created  
54 within the department. The board consists of seven members who  
55 must be appointed by the Governor and confirmed by the Senate.

56 (2) The initial board members, who are not required to be  
57 licensed as a condition of appointment, shall be appointed as  
58 follows:

59 (a) Three board-certified behavior analysts, which may  
60 include board-certified behavior analysts who are at the  
61 doctoral level, two of whom shall be selected from a list of six  
62 nominations submitted by the Florida Association for Behavior  
63 Analysis. One shall be appointed to a 1-year term, and two shall  
64 be appointed to 3-year terms;

65 (b) One board-certified assistant behavior analyst, who  
66 shall be appointed to a 1-year term;

67 (c) One health care practitioner licensed in this state,  
68 who shall be appointed to a 2-year term. The majority of the  
69 appointed health care practitioner's practice must be related to



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70 the treatment of behavior disorders, including, but not limited  
71 to, autism spectrum disorders; and

72 (d) Two laypersons, who may include a parent or guardian of  
73 an individual who is a recipient of applied behavior analysis  
74 services, one of whom shall serve a 1-year term, and one of whom  
75 shall serve a 2-year term.

76 (3) As the terms of the initial members expire, the  
77 Governor shall appoint successors for 4-year terms. Each  
78 successor, except for the laypersons, must be licensed. A member  
79 may not serve more than two consecutive terms.

80 Section 5. Section 470.42, Florida Statutes, is created to  
81 read:

82 470.42 Authority of the board; board duties; authority of  
83 the department.—

84 (1) The board may adopt rules pursuant to ss. 120.536(1)  
85 and 120.54 to implement the provisions of this chapter  
86 conferring duties upon it. Such rules must include, but are not  
87 limited to, rules relating to all of the following:

88 (a) Standards of practice for licensed behavior analysts  
89 and licensed assistant behavior analysts.

90 (b) Supervision of licensed assistant behavior analysts or  
91 students in training to be licensed behavior analysts, including  
92 the number of persons that a licensed behavior analyst or  
93 licensed assistant behavior analyst may supervise at one time.

94 (2) If the Behavior Analyst Certification Board stops  
95 certifying practitioners of applied behavior analysis in this  
96 state, the board shall approve a successor certification board  
97 that is accredited by the National Commission for Certifying  
98 Agencies or the American National Standards Institute to certify



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99 applied behavior analysts.

100 (3) The department may adopt rules pursuant to ss.  
101 120.536(1) and 120.54 to implement the provisions of this  
102 chapter conferring duties upon it. Such rules must include, but  
103 are not limited to, rules relating to all of the following:

104 (a) Licensure and licensure renewal applications and  
105 processes, including licensure fees.

106 (b) Educational qualifications for licensure.

107 (c) Continuing education requirements for biennial renewal  
108 of licensure not to exceed 30 hours biennially as a condition  
109 for renewal of a license.

110 Section 6. Section 470.43, Florida Statutes, is created to  
111 read:

112 470.43 Licensure and renewal.—

113 (1) A person applying for an initial or renewal license as  
114 a licensed behavior analyst or licensed assistant behavior  
115 analyst shall apply to the department on such form and in such  
116 manner as the department prescribes. The person shall furnish  
117 evidence to the department that he or she:

118 (a) Is a board-certified behavior analyst;

119 (b) Has paid the licensure fee or the biennial renewal fee;

120 and

121 (c) Has passed a criminal background check after submitting  
122 fingerprints and a fee pursuant to s. 456.0135.

123 (2) A person applying for an initial or renewal license as  
124 an assistant behavior analyst shall apply to the department upon  
125 such form and in such manner as the department prescribes and  
126 shall furnish evidence to the department that such person:

127 (a) Is a board-certified assistant behavior analyst;





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128 (b) Is supervised by a licensed behavior analyst in a  
129 manner consistent with BACB requirements and this chapter;

130 (c) Has paid the licensure fee or the biennial renewal fee;  
131 and

132 (d) Has passed a criminal background check after submitting  
133 fingerprints and a fee pursuant to s. 456.0135.

134 (3) The board may issue a license to a person who holds an  
135 active license as a behavior analyst or assistant behavior  
136 analyst in another state if the person:

137 (a) Submits proof of licensure and board certification;

138 (b) Passes a criminal background check after submitting  
139 fingerprints and a fee pursuant to s. 456.0135; and

140 (c) Pays the licensure fee.

141 Section 7. Section 470.44, Florida Statutes, is created to  
142 read:

143 470.44 Fees.—

144 (1) The board shall establish by rule a fee not to exceed  
145 \$100 for an application and a fee not to exceed \$300 for an  
146 initial license or license renewal.

147 (2) All moneys collected by the department under this  
148 chapter shall be deposited as provided under s. 456.025.

149 Section 8. Section 470.45, Florida Statutes, is created to  
150 read:

151 470.45 Disciplinary grounds and actions.—The board may  
152 enter an order imposing any of the penalties provided under s.  
153 456.072(2) against a licensee who violates any provision of s.  
154 456.072(1).

155 Section 9. Section 470.46, Florida Statutes, is created to  
156 read:



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157 470.46 Violations and penalties.-

158 (1) Unless licensed or authorized under this chapter, a  
159 person who engages in the practice of applied behavior analysis,  
160 assists in the practice of applied behavior analysis, renders  
161 services designated as applied behavior analysis, or represents  
162 himself or herself as a practitioner of applied behavior  
163 analysis in this state commits a felony of the third degree,  
164 punishable as provided under s. 775.082, s. 775.083, or s.  
165 775.084.

166 (2) Unless licensed or authorized under this chapter, a  
167 person who uses the title "licensed behavior analyst," "licensed  
168 assistant behavior analyst," or any other title that is  
169 substantially similar commits a misdemeanor of the second  
170 degree, punishable as provided in s. 775.082 or s. 775.083.

171 Section 10. Section 470.47, Florida Statutes, is created to  
172 read:

173 470.47 Exceptions to applicability.-This chapter does not  
174 prohibit or restrict the practice of the following:

175 (1) An individual licensed under chapter 490 to practice  
176 psychology.

177 (2) A certified teacher authorized to practice in this  
178 state who is not a behavior analyst if he or she does not  
179 represent himself or herself as a behavior analyst. The services  
180 provided by a certified teacher must be within his or her  
181 authorized scope of practice and within the scope of his or her  
182 education, training, and experience and must be provided in the  
183 course of his or her employment in a program approved by the  
184 Department of Education. Teaching assistants, other than those  
185 engaged in pupil personnel services, and student support



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186 professionals are exempt from the requirements of this chapter  
187 if they provide applied behavior analysis services under the  
188 supervision of a certified teacher who meets the requirements of  
189 this paragraph.

190 (3) A behavior analyst who practices with nonhuman clients,  
191 including, but not limited to, applied animal behaviorists and  
192 animal trainers.

193 (4) An individual who teaches applied behavior analysis or  
194 who conducts behavior analytic research if such teaching or  
195 research does not involve the delivery of applied behavior  
196 analysis.

197 (5) A matriculated college or university student or  
198 postdoctoral fellow whose activities are part of a defined  
199 behavior analysis program of study, practicum, or intensive  
200 practicum if his or her practice under this subsection is  
201 directly supervised by a licensed behavior analyst or an  
202 instructor of an accredited course sequence approved by the  
203 Behavior Analyst Certification Board (BACB). A student or intern  
204 may not represent himself or herself as a professional behavior  
205 analyst but may use a title indicating his or her trainee  
206 status, such as "behavior analyst student," "behavior analyst  
207 intern," or "behavior analyst trainee."

208 (6) An unlicensed individual pursuing supervised  
209 experiential training to meet eligibility requirements for BACB  
210 certification if such training is supervised by an individual  
211 who is licensed to practice applied behavior analysis and who  
212 meets BACB supervisor requirements and if the supervised  
213 experiential training is conducted in accordance with other BACB  
214 standards and requirements.



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215       (7) A board-certified behavior analyst, a doctoral level  
216 board-certified behavior analyst, or an individual licensed to  
217 practice applied behavior analysis in another state who resides  
218 in another state and provides applied behavior analysis in this  
219 state or to a resident of this state for less than 12 days per  
220 year.

221       (8) A family member of a recipient of applied behavior  
222 analysis services who implements certain procedures with the  
223 recipient. Such a family member may not represent himself or  
224 herself as a professional behavior analyst.

225       (9) A behavior analyst who provides general behavior  
226 analysis services to organizations if the services are for the  
227 benefit of the organizations and do not involve direct services  
228 to individuals.

229       (10) A physician licensed pursuant to chapter 458 or  
230 chapter 459.

231       (11) An occupational therapist licensed pursuant to chapter  
232 468 if he or she does not represent himself or herself as a  
233 behavior analyst.

234       (12) An individual licensed pursuant to chapter 491 as a  
235 clinical social worker, marriage and family therapist, or mental  
236 health counselor.

237       (13) A salaried employee of a private, nonprofit  
238 organization providing behavior analysis services to children,  
239 youth, and families if the services are provided for no charge,  
240 the employee is performing duties for which he or she was  
241 trained and hired, and the employee does not represent himself  
242 or herself as a professional behavior analyst.

243       (14) A school psychologist certified in school psychology



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244 by the Department of Education who performs behavior analysis  
245 services as an employee of a public or private educational  
246 institution. Such exemption does not authorize unlicensed  
247 practice that is not performed directly as an employee of an  
248 educational institution.

249 (15) A rabbi, priest, minister, or member of the clergy of  
250 a religious denomination or sect if engaging in activities that  
251 are within the scope of the performance of his or her regular or  
252 specialized ministerial duties and for which no separate fee is  
253 charged, or if such activities are performed, with or without a  
254 fee, for or under the auspices or sponsorship, individually or  
255 in conjunction with others, of an established and legally  
256 cognizable church, denomination, or sect; and if the person  
257 rendering service remains accountable to the established  
258 authority thereof.

259 Section 11. Paragraph (g) of subsection (3) of section  
260 20.43, Florida Statutes, is amended to read:

261 20.43 Department of Health.—There is created a Department  
262 of Health.

263 (3) The following divisions of the Department of Health are  
264 established:

265 (g) Division of Medical Quality Assurance, which is  
266 responsible for the following boards and professions established  
267 within the division:

- 268 1. The Board of Acupuncture, created under chapter 457.
- 269 2. The Board of Medicine, created under chapter 458.
- 270 3. The Board of Osteopathic Medicine, created under chapter  
271 459.
- 272 4. The Board of Chiropractic Medicine, created under



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273 chapter 460.  
274       5. The Board of Podiatric Medicine, created under chapter  
275 461.  
276       6. Naturopathy, as provided under chapter 462.  
277       7. The Board of Optometry, created under chapter 463.  
278       8. The Board of Nursing, created under part I of chapter  
279 464.  
280       9. Nursing assistants, as provided under part II of chapter  
281 464.  
282       10. The Board of Pharmacy, created under chapter 465.  
283       11. The Board of Dentistry, created under chapter 466.  
284       12. Midwifery, as provided under chapter 467.  
285       13. The Board of Speech-Language Pathology and Audiology,  
286 created under part I of chapter 468.  
287       14. The Board of Nursing Home Administrators, created under  
288 part II of chapter 468.  
289       15. The Board of Occupational Therapy, created under part  
290 III of chapter 468.  
291       16. Respiratory therapy, as provided under part V of  
292 chapter 468.  
293       17. Dietetics and nutrition practice, as provided under  
294 part X of chapter 468.  
295       18. The Board of Athletic Training, created under part XIII  
296 of chapter 468.  
297       19. The Board of Orthotists and Prosthetists, created under  
298 part XIV of chapter 468.  
299       20. The Board of Applied Behavior Analysis, created under  
300 chapter 470.  
301       21.20. Electrolysis, as provided under chapter 478.



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302        ~~22.21.~~ The Board of Massage Therapy, created under chapter  
303 480.

304        ~~23.22.~~ The Board of Clinical Laboratory Personnel, created  
305 under part III of chapter 483.

306        ~~24.23.~~ Medical physicists, as provided under part IV of  
307 chapter 483.

308        ~~25.24.~~ The Board of Opticianry, created under part I of  
309 chapter 484.

310        ~~26.25.~~ The Board of Hearing Aid Specialists, created under  
311 part II of chapter 484.

312        ~~27.26.~~ The Board of Physical Therapy Practice, created  
313 under chapter 486.

314        ~~28.27.~~ The Board of Psychology, created under chapter 490.

315        ~~29.28.~~ School psychologists, as provided under chapter 490.

316        ~~30.29.~~ The Board of Clinical Social Work, Marriage and  
317 Family Therapy, and Mental Health Counseling, created under  
318 chapter 491.

319        ~~31.30.~~ Emergency medical technicians and paramedics, as  
320 provided under part III of chapter 401.

321        Section 12. Subsection (4) of section 456.001, Florida  
322 Statutes, is amended to read:

323        456.001 Definitions.—As used in this chapter, the term:

324        (4) "Health care practitioner" means any person licensed  
325 under chapter 457; chapter 458; chapter 459; chapter 460;  
326 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;  
327 chapter 466; chapter 467; part I, part II, part III, part V,  
328 part X, part XIII, or part XIV of chapter 468; chapter 470;  
329 chapter 478; chapter 480; part III or part IV of chapter 483;  
330 chapter 484; chapter 486; chapter 490; or chapter 491.



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331 Section 13. Section 456.0135, Florida Statutes, is amended  
332 to read:

333 456.0135 General background screening provisions.—

334 (1) An application for initial licensure received on or  
335 after January 1, 2013, under chapter 458, chapter 459, chapter  
336 460, chapter 461, chapter 464, ~~or~~ s. 465.022, or chapter 470  
337 shall include fingerprints pursuant to procedures established by  
338 the department through a vendor approved by the Department of  
339 Law Enforcement and fees imposed for the initial screening and  
340 retention of fingerprints. Fingerprints must be submitted  
341 electronically to the Department of Law Enforcement for state  
342 processing, and the Department of Law Enforcement shall forward  
343 the fingerprints to the Federal Bureau of Investigation for  
344 national processing. Each board, or the department if there is  
345 no board, shall screen the results to determine if an applicant  
346 meets licensure requirements. For any subsequent renewal of the  
347 applicant's license that requires a national criminal history  
348 check, the department shall request the Department of Law  
349 Enforcement to forward the retained fingerprints of the  
350 applicant to the Federal Bureau of Investigation.

351 (2) All fingerprints submitted to the Department of Law  
352 Enforcement as required under subsection (1) shall be retained  
353 by the Department of Law Enforcement as provided under s.  
354 943.05(2)(g) and (h) and (3). The department shall notify the  
355 Department of Law Enforcement regarding any person whose  
356 fingerprints have been retained but who is no longer licensed.

357 (3) The costs of fingerprint processing, including the cost  
358 for retaining fingerprints, shall be borne by the applicant  
359 subject to the background screening.





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360 Section 14. This act shall take effect January 1, 2015.

361

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

363 And the title is amended as follows:

364 Delete everything before the enacting clause

365 and insert:

366 A bill to be entitled

367 An act relating to behavior analysts; creating ch.  
368 470, F.S.; entitling the chapter; creating s. 470.40,  
369 F.S.; providing a purpose; creating s. 470.41, F.S.;  
370 defining terms; creating s. 470.415, F.S.; creating  
371 the Board of Applied Behavior Analysis; creating s.  
372 470.42, F.S.; specifying the authority and duties of  
373 the board; creating s. 470.43, F.S.; providing  
374 requirements for licensure and renewal; creating s.  
375 470.44, F.S.; establishing maximum fees for  
376 applications, initial licenses, and license renewals;  
377 providing for the deposit of funds; creating s.  
378 470.45, F.S.; providing grounds for disciplinary  
379 action by the board; creating s. 470.46, F.S.;  
380 providing penalties for practicing applied behavior  
381 analysis without a license or wrongfully identifying  
382 oneself as a licensed behavior analyst; creating s.  
383 470.47, F.S.; providing exceptions to applicability of  
384 the chapter; amending s. 20.43, F.S.; making the  
385 Division of Medical Quality Assurance within the  
386 Department of Health responsible for the board;  
387 amending s. 456.001, F.S.; including licensed behavior  
388 analysts and licensed assistant behavior analysts in



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389 the definition of "health care practitioner"; amending  
390 s. 456.0135, F.S.; requiring an applicant for  
391 licensure under ch. 470, F.S., to submit to certain  
392 fingerprinting requirements; providing an effective  
393 date.



577454

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/01/2014	.	
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The Committee on Health Policy (Bean) recommended the following:

- 1        **Senate Amendment to Amendment (331530)**
- 2
- 3        Delete lines 47 - 49.

By Senator Bean

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1 A bill to be entitled  
 2 An act relating to behavior analysts; creating ch.  
 3 470, F.S.; entitling the chapter; creating s. 470.40,  
 4 F.S.; providing a purpose; creating s. 470.41, F.S.;  
 5 defining terms; creating s. 470.415, F.S.; creating  
 6 the Board of Applied Behavior Analysis; creating s.  
 7 470.42, F.S.; specifying the authority and duties of  
 8 the board; creating s. 470.43, F.S.; providing  
 9 requirements for licensure and renewal; creating s.  
 10 470.44, F.S.; establishing maximum fees for  
 11 applications, initial licenses, and license renewals;  
 12 creating s. 470.45, F.S.; providing grounds for  
 13 disciplinary action by the board; providing for  
 14 reinstatement of a license; creating s. 470.46, F.S.;  
 15 requiring a licensee or his or her employer to report  
 16 to the board certain felony convictions on the part of  
 17 a licensee or suspicions that a licensee has committed  
 18 fraud or deceit; creating s. 470.47, F.S.; providing  
 19 penalties for practicing applied behavior analysis  
 20 without a license or wrongfully identifying oneself as  
 21 a licensed behavior analyst; creating s. 470.48, F.S.;  
 22 providing exceptions to the chapter; amending s.  
 23 456.001, F.S.; including licensed behavior analysts  
 24 and licensed assistant behavior analysts in the  
 25 definition of "health care practitioner"; providing an  
 26 effective date.

27  
 28 Be It Enacted by the Legislature of the State of Florida:  
 29

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30 Section 1. Chapter 470, Florida Statutes, is created and  
 31 entitled "Behavior Analysts."  
 32 Section 2. Section 470.40, Florida Statutes, is created to  
 33 read:  
 34 470.40 Purpose.—The practice of applied behavior analysis  
 35 in this state affects the public health, safety, and welfare of  
 36 its residents, and this act is intended to protect the public  
 37 from any harmful conduct of unqualified, unprofessional, or  
 38 unethical applied behavior analysts.  
 39 Section 3. Section 470.41, Florida Statutes, is created to  
 40 read:  
 41 470.41 Definitions.—As used in this chapter, the term:  
 42 (1) "Applied behavior analysis" means the design,  
 43 implementation, and evaluation of instructional and  
 44 environmental modifications to produce socially significant  
 45 improvements in human behavior and includes functional  
 46 assessment and analysis. The term does not include psychological  
 47 testing, the diagnosis of a mental or physical disorder,  
 48 neuropsychology, psychotherapy, cognitive therapy, sex therapy,  
 49 psychoanalysis, hypnotherapy, or long-term counseling.  
 50 (2) "Board" means the Board of Applied Behavior Analysis  
 51 established in s. 470.415, except when the term is used in the  
 52 context of board certification.  
 53 (3) "Board-certified behavior analyst" means a practitioner  
 54 who is certified by the national Behavior Analyst Certification  
 55 Board (BACB), or its successor pursuant to s. 470.42, as a Board  
 56 Certified Behavior Analyst.  
 57 (4) "Board-certified assistant behavior analyst" means a  
 58 practitioner who is certified by the national Behavior Analyst

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59 Certification Board, or its successor pursuant to s. 470.42, as  
60 a Board Certified Assistant Behavior Analyst.

61 (5) "Department" means the Department of Health.

62 (6) "Licensed behavior analyst" means an individual who is  
63 licensed by the board and meets the requirements of this  
64 chapter.

65 (7) "Licensed assistant behavior analyst" means an  
66 individual who:

67 (a) Is licensed by the board as an assistant behavior  
68 analyst and meets the requirements of this chapter; and

69 (b) Works under the supervision of a licensed behavior  
70 analyst.

71 (8) "Supervised experience" means an individual has  
72 completed the training necessary to satisfy the eligibility  
73 requirements for BACB certification.

74 Section 4. Section 470.415, Florida Statutes, is created to  
75 read:

76 470.415 Board of Applied Behavior Analysis.—

77 (1) The Board of Applied Behavior Analysis is created  
78 within the department. The board consists of seven members who  
79 must be appointed by the Governor and confirmed by the Senate.

80 (2) The initial board members, who are not required to be  
81 licensed as a condition of appointment, shall be appointed as  
82 follows:

83 (a) Three board-certified behavior analysts, which may  
84 include board-certified behavior analysts who are at the  
85 doctoral level, two of whom shall be selected from a list of six  
86 nominations submitted by the Florida Association for Behavior  
87 Analysis. One shall be appointed to a 1-year term, and two shall

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88 be appointed to 3-year terms;

89 (b) One board-certified assistant behavior analyst, who  
90 shall be appointed to a 1-year term;

91 (c) One health care provider licensed in this state, who  
92 shall be appointed to a 2-year term. The majority of the  
93 appointed health care provider's practice must be related to the  
94 treatment of behavior disorders, including, but not limited to,  
95 autism spectrum disorders; and

96 (d) Two laypersons, who may include a parent or guardian of  
97 an individual who is a recipient of applied behavior analysis  
98 services, one of whom shall serve a 1-year term, and one of whom  
99 shall serve a 2-year term.

100 (3) As the terms of the initial members expire, the  
101 Governor shall appoint successors for 3-year terms. Each  
102 successor, except for the laypersons, must be licensed. A member  
103 may not serve more than two consecutive terms.

104 (4) All provisions of chapter 456 relating to the board  
105 apply.

106 Section 5. Section 470.42, Florida Statutes, is created to  
107 read:

108 470.42 Authority of the board; duties.—

109 (1) The board may adopt rules pursuant to ss. 120.536(1)  
110 and 120.54 to implement the provisions of this chapter  
111 conferring duties upon it. Such rules must include, but are not  
112 limited to, rules relating to all of the following:

113 (a) Standards of practice.

114 (b) Licensure, including the suspension and revocation of a  
115 license and the refusal to issue or renew a license.

116 (c) Limitations of activities.

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- 117 (d) Supervision.
- 118 (e) Educational qualifications and continuing education
- 119 requirements.
- 120 (f) The number of persons that a licensed behavior analyst
- 121 or licensed assistant behavior analyst may supervise at one
- 122 time.
- 123 (g) The competency of a person to receive or renew his or
- 124 her license.
- 125 (h) The physical and mental examination of licensed
- 126 behavior analysts and licensed assistant behavior analysts who
- 127 may be impaired by reason of a mental, physical, or other
- 128 condition that impedes their ability to practice competently.
- 129 (2) The board shall perform all of the following:
- 130 (a) Adopt a code of ethical standards and standards of
- 131 practice for licensed behavior analysts and licensed assistant
- 132 behavior analysts.
- 133 (b) Keep a minute book containing a record of all meetings
- 134 of the board.
- 135 (c) Maintain a registry of all persons licensed under this
- 136 chapter. This registry must show the name of every licensee in
- 137 this state, his or her current business and residence address
- 138 and telephone number, and his or her licensure date and license
- 139 number. A licensee shall notify the board of a change of name,
- 140 address, or telephone number within 30 days after the change.
- 141 (d) Update its records annually.
- 142 (e) Publish annually and make available a current directory
- 143 of all licensed behavior analysts and licensed assistant
- 144 behavior analysts in this state.
- 145 (f) Adopt a seal and affix it to every license granted by

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- 146 the board.
- 147 (g) Maintain its official headquarters in Tallahassee.
- 148 (3) If the Behavior Analyst Certification Board stops
- 149 certifying practitioners of applied behavior analysis in this
- 150 state, the board shall approve a successor certification board
- 151 that is accredited by the National Commission for Certifying
- 152 Agencies or the American National Standards Institute to certify
- 153 applied behavior analysts.
- 154 Section 6. Section 470.43, Florida Statutes, is created to
- 155 read:
- 156 470.43 Licensure and renewal.—
- 157 (1) A person applying for an initial or renewal license as
- 158 a licensed behavior analyst or licensed assistant behavior
- 159 analyst shall apply to the board on such form and in such manner
- 160 as the board prescribes. The person shall furnish evidence to
- 161 the board that he or she:
- 162 (a) Is a board-certified behavior analyst;
- 163 (b) Conducts his or her professional activities in
- 164 accordance with accepted standards as required by rule;
- 165 (c) Complies with all applicable rules adopted by the
- 166 board;
- 167 (d) Has paid the licensure fee or the biennial renewal fee;
- 168 and
- 169 (e) Has passed a criminal background check, as determined
- 170 by the board.
- 171 (2) A person applying for an initial or renewal license as
- 172 an assistant behavior analyst shall apply to the board upon such
- 173 form and in such manner as the board prescribes and shall
- 174 furnish evidence to the board that such person:

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175 (a) Is a board-certified assistant behavior analyst;  
 176 (b) Conducts his or her professional activities in  
 177 accordance with accepted standards, as required by rule;  
 178 (c) Complies with all applicable rules promulgated by the  
 179 board;  
 180 (d) Is supervised by a licensed behavior analyst in a  
 181 manner consistent with BACB requirements and this chapter;  
 182 (e) Has paid the licensure fee or the biennial renewal fee;  
 183 and  
 184 (f) Has passed a criminal background check, as determined  
 185 by the board.  
 186 (3) The board may issue a license to a person who holds an  
 187 active license as a behavior analyst or assistant behavior  
 188 analyst in another state that imposes comparable licensure  
 189 requirements to those imposed by this state and that offers  
 190 reciprocity to individuals licensed under this chapter.  
 191 Applicants for reciprocity must:  
 192 (a) Submit proof of licensure and board certification;  
 193 (b) Pass a criminal background check, as determined by the  
 194 board; and  
 195 (c) Pay the licensure fee.  
 196 Section 7. Section 470.44, Florida Statutes, is created to  
 197 read:  
 198 470.44 Fees.—  
 199 (1) The board shall establish by rule a fee not to exceed  
 200 \$100 for an application and a fee not to exceed \$300 for an  
 201 initial license or license renewal.  
 202 (2) In establishing fees pursuant to subsection (1), the  
 203 board shall consider the actual costs incurred in carrying out

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204 its duties under this chapter.  
 205 (3) All moneys collected by the department under this  
 206 chapter shall be deposited as provided under s. 456.025.  
 207 Section 8. Section 470.45, Florida Statutes, is created to  
 208 read:  
 209 470.45 Disciplinary grounds and actions; reinstatement.—  
 210 (1) The board may enter an order imposing any of the  
 211 penalties provided under s. 456.072(2) against a licensee who  
 212 violates any provision of s. 456.072(1), except that the board  
 213 may not do any of the following:  
 214 (a) Place a licensee on probation for more than 5 years.  
 215 (b) Impose a fine that exceeds \$2,500.  
 216 (c) Suspend a license for more than 5 years.  
 217 (d) Limit or restrict a license for an indefinite period.  
 218 (2) The board may reinstate a license that has been  
 219 suspended or revoked if, after a hearing conducted pursuant to  
 220 s. 120.54, the board determines that the applicant is able to  
 221 practice his or her profession with reasonable competency and in  
 222 accordance with the code of ethics and standards of practice  
 223 established by rule under s. 470.42. As a condition of  
 224 reinstatement, the board may impose reasonable restrictions on  
 225 the licensee's license to practice.  
 226 Section 9. Section 470.46, Florida Statutes, is created to  
 227 read:  
 228 470.46 Duty to report felony or suspicion of fraud or  
 229 deceit.—A licensee or employer of a licensee having actual or  
 230 direct knowledge of facts shall report to the board a behavior  
 231 analyst or assistant behavior analyst who:  
 232 (1) Has been charged or convicted of a felony that involved

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233 any act that bears directly on his or her qualifications or  
 234 ability to practice applied behavior analysis or any act that  
 235 bears directly on the public health, safety, or welfare;

236 (2) Is suspected of fraud or deceit in procuring or  
 237 attempting to procure a license to practice applied behavior  
 238 analysis or of negligently performing actions that justify  
 239 action against the license of the behavior analyst or assistant  
 240 behavior analyst;

241 (3) Has had a board certification or a license to practice  
 242 as a behavior analyst or assistant behavior analyst denied,  
 243 limited, suspended, placed on probation, or revoked in another  
 244 jurisdiction on grounds sufficient to cause a license or  
 245 certificate to be denied, limited, suspended, placed on  
 246 probation, or revoked in this state; or

247 (4) Is practicing applied behavior analysis without a  
 248 license issued by the board unless specifically exempted in this  
 249 chapter.

250 Section 10. Section 470.47, Florida Statutes, is created to  
 251 read:

252 470.47 Violations and penalties.-

253 (1) Unless licensed or authorized under this chapter, a  
 254 person who engages in the practice of applied behavior analysis,  
 255 assists in the practice of applied behavior analysis, renders  
 256 services designated as applied behavior analysis, or represents  
 257 himself or herself as a practitioner of applied behavior  
 258 analysis in this state commits a felony of the third degree,  
 259 punishable as provided under s. 775.082, s. 775.083, or s.  
 260 775.084.

261 (2) Unless licensed or authorized under this chapter, a

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262 person who uses the title "licensed behavior analyst," "licensed  
 263 assistant behavior analyst," or any other title that is  
 264 substantially similar commits a misdemeanor of the second  
 265 degree, punishable as provided in s. 775.082 or s. 775.083.

266 Section 11. Section 470.48, Florida Statutes, is created to  
 267 read:

268 470.48 Exceptions to applicability.-This chapter does not  
 269 prohibit or restrict the practice of the following:

270 (1) An individual licensed under chapter 490 to practice  
 271 psychology if the applied behavior analysis services he or she  
 272 provides are within the scope of chapter 490 and his or her  
 273 education, training, and experience.

274 (2) A certified teacher authorized to practice in this  
 275 state who is not a behavior analyst if he or she does not  
 276 represent himself or herself as a behavior analyst. The services  
 277 provided by a certified teacher must be within his or her  
 278 authorized scope of practice and within the scope of his or her  
 279 education, training, and experience and must be provided in the  
 280 course of his or her employment in a program approved by the  
 281 Department of Education. Teaching assistants, other than those  
 282 engaged in pupil personnel services, and student support  
 283 professionals are exempt from the requirements of this chapter  
 284 if they provide behavior analysis services under the supervision  
 285 of a certified teacher who meets the requirements of this  
 286 paragraph.

287 (3) A behavior analyst who practices with nonhuman clients,  
 288 including, but not limited to, applied animal behaviorists and  
 289 animal trainers.

290 (4) An unlicensed individual who provides applied behavior



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291 analysis services under the extended authority and direction of  
 292 a licensed behavior analyst or licensed assistant behavior  
 293 analyst.

294 (5) An individual who teaches applied behavior analysis or  
 295 who conducts behavior analytic research if such teaching or  
 296 research does not involve the delivery of direct behavior  
 297 analysis interventions to individuals.

298 (6) A matriculated college or university student or  
 299 postdoctoral fellow whose activities are part of a defined  
 300 behavior analysis program of study, practicum, or intensive  
 301 practicum if his or her practice under this subsection is  
 302 directly supervised by a licensed behavior analyst or an  
 303 instructor of an accredited course sequence approved by the  
 304 Behavior Analyst Certification Board (BACB). A student or intern  
 305 may not represent himself or herself as a professional behavior  
 306 analyst but may use a title indicating his or her trainee  
 307 status, such as "behavior analyst student," "behavior analyst  
 308 intern," or "behavior analyst trainee."

309 (7) An unlicensed individual pursuing supervised  
 310 experiential training to meet eligibility requirements for BACB  
 311 certification if such training is supervised by an individual  
 312 who is licensed to practice applied behavior analysis and who  
 313 meets BACB supervisor requirements and if the supervised  
 314 experience is conducted in accordance with other BACB standards  
 315 and requirements.

316 (8) A board-certified behavior analyst, a doctoral level  
 317 board-certified behavior analyst, or an individual licensed to  
 318 practice applied behavior analysis in another state who resides  
 319 in another state and provides applied behavior analysis in this

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320 state or to a resident of this state for less than 12 days per  
 321 year.

322 (9) A Florida-certified behavior analyst who is in good  
 323 standing with the Behavior Analyst Certification Board and who  
 324 is not a board-certified behavior analyst.

325 (10) A family member of a recipient of applied behavior  
 326 analysis services who implements certain procedures with the  
 327 recipient under the extended authority and direction of a  
 328 licensed behavior analyst or licensed assistant behavior  
 329 analyst. Such a family member may not represent himself or  
 330 herself as a professional behavior analyst.

331 (11) A behavior analyst who provides general behavior  
 332 analysis services to organizations if the services are for the  
 333 benefit of the organizations and do not involve direct services  
 334 to individuals.

335 (12) A physician licensed pursuant to chapter 458 or  
 336 chapter 459 if he or she does not represent himself or herself  
 337 as a professional behavior analyst.

338 (13) An individual licensed pursuant to chapter 491 as a  
 339 clinical social worker, marriage and family therapist, or mental  
 340 health counselor if he or she does not represent himself or  
 341 herself as a professional behavior analyst.

342 (14) A salaried employee of a private, nonprofit  
 343 organization providing behavior analysis services to children,  
 344 youth, and families if the services are provided for no charge,  
 345 the employee is performing duties for which he or she was  
 346 trained and hired, and the employee does not represent himself  
 347 or herself as a professional behavior analyst.

348 (15) A school psychologist certified in school psychology

4-00250A-14

20141212\_\_

349 by the Department of Education who performs behavior analysis  
350 services as an employee of a public or private educational  
351 institution. Such exemption does not authorize unlicensed  
352 practice that is not performed directly as an employee of an  
353 educational institution.

354 (16) A rabbi, priest, minister, or member of the clergy of  
355 a religious denomination or sect if engaging in activities that  
356 are within the scope of the performance of his or her regular or  
357 specialized ministerial duties and for which no separate fee is  
358 charged, or if such activities are performed, with or without a  
359 fee, for or under the auspices or sponsorship, individually or  
360 in conjunction with others, of an established and legally  
361 cognizable church, denomination, or sect; and if the person  
362 rendering service remains accountable to the established  
363 authority thereof.

364 Section 12. Subsection (4) of section 456.001, Florida  
365 Statutes, is amended to read:

366 456.001 Definitions.—As used in this chapter, the term:

367 (4) "Health care practitioner" means any person licensed  
368 under chapter 457; chapter 458; chapter 459; chapter 460;  
369 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;  
370 chapter 466; chapter 467; part I, part II, part III, part V,  
371 part X, part XIII, or part XIV of chapter 468; chapter 470;  
372 chapter 478; chapter 480; part III or part IV of chapter 483;  
373 chapter 484; chapter 486; chapter 490; or chapter 491.

374 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.

Phone 850-570-6307

Street

Tallahassee

FL

32301

City

State

Zip

E-mail lawgon2@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.

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 Stimmel

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Psychologist

Address 2704 Apalachee Pkwy

Phone 850 385 8116

Street

Tallahassee FL 32301

City

State

Zip

E-mail stimmel@opt.com

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.*

**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 Adam Roberts

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Lobbyist

Address 2924 Quail Rise Court

Phone 591-9293

Street

Tallahassee FL 32309

City

State

Zip

E-mail adam@gma9lobby.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.*

**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)

4/11/14

Meeting Date

Topic Behavior Analysts

Bill Number SB 1212 (if applicable)

Name Ron Watson

Amendment Barcode (if applicable)

Job Title Father

Address 3738 Munden Way

Phone (850) 567-1202

Tallahassee FL 32309

E-mail watson.strategies@comcast.net

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

Representing my son

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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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

Phone 727-947-2066

Jacksonville FL 32256  
*Street City State Zip*

E-mail lynyeaager1@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.**

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. RIOROAN, Ph.D.

Amendment Barcode (if applicable)

Job Title BCBA-D

Address 1010 REDBUD

Phone 850 933 6654

Street

Tallahassee

FL

32303

City

State

Zip

E-mail mmriordan@me.co

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.





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 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 Kdlucker@comcast.net

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.

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 Analysis

Bill Number 1212  
*(if applicable)*

Name AMANDA BROAD FOOT

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Parent

Address 1861 Eastern Forest Dr.

Phone 850 570 7147

Street  
Tallahassee, FL 32317  
City State Zip

E-mail mandi@good  
samaritanallahassee.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.**

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 1200  
*(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.)

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

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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

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**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.<sup>1</sup> 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.<sup>2</sup> Activities of daily living include: ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.<sup>3</sup>

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<sup>1</sup> Section 429.02(5), F.S.

<sup>2</sup> Section 429.02(16), F.S.

<sup>3</sup> 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.<sup>4</sup> The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.<sup>5</sup> 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.<sup>6</sup>

### **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.<sup>7</sup> 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.<sup>8</sup>

### **ALF Administrators**

Administrators and other ALF staff must meet minimum training and education requirements established by rule of the DOEA.<sup>9,10</sup> 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.<sup>11</sup>

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

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<sup>4</sup> For specific minimum standards see Rule 58A-5.0182, F.A.C.

<sup>5</sup> Section 429.26, F.S., and Rule 58A-5.0181, F.A.C.

<sup>6</sup> Section 429.28, F.S.

<sup>7</sup> Section 429.41(1), F.S.

<sup>8</sup> 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).

<sup>9</sup> Rule 58A-5.0191, F.A.C.

<sup>10</sup> Many of the training requirements in rule may be subject to change due to the negotiated rulemaking process undertaken by DOEA.

<sup>11</sup> Section 429.52(1), F.S.

maintained the continuing education requirements must retake the ALF core training and the competency test.<sup>12</sup>

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,<sup>13</sup> 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

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<sup>12</sup> Rule 59A-5.0191, F.A.C.

<sup>13</sup> 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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	.	
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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



794588

12 entity that is approved by the department under this section. An  
13 assisted living facility administrator who fails to be certified  
14 under this section or fails to meet training and educational  
15 requirements of s. 429.52 violates this section and is subject  
16 to an administrative fine as provided under s. 429.19. This  
17 subsection does not apply to an administrator licensed under  
18 part II of chapter 468.

19 (5) GRANDFATHER CLAUSE.—A third-party credentialing entity  
20 shall allow the following persons to enroll in its certification  
21 program, at no cost to the department or the person, in the 12  
22 months immediately after the department approves the third-party  
23 credentialing entity as provided in subsection (3):

24 (a) A person who is employed as of July 1, 2014, as an  
25 assisted living facility administrator and is in compliance with  
26 the requirements under s. 429.52.

27 (b) A person who has completed before July 1, 2014, the  
28 required training as an administrator, including the competency  
29 test and continuing education requirements under s. 429.52.

30 (6) CORE COMPETENCIES.—A third-party credentialing entity  
31 that is approved by the department shall establish the core  
32 competencies for assisted living facility administrators  
33 according to the standards established by the National  
34 Commission for Certifying Agencies.

35 (7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification  
36 program of a third-party credentialing entity that is approved  
37 by the department must:

38 (a) Be established according to the standards set forth by  
39 the National Commission for Certifying Agencies.

40 (b) Be directly related to the core competencies.



794588

41 (c) Establish minimum requirements in each of the following  
42 categories:

- 43 1. Formal education.
- 44 2. Training.
- 45 3. On-the-job work experience.
- 46 4. Supervision.
- 47 5. Testing.
- 48 6. Biennial continuing education.

49 (d) Administer a professional code of ethics and  
50 disciplinary process that applies to all certified persons.

51 (e) Administer and maintain a publicly accessible Internet-  
52 based database that contains information on each person who  
53 applies for certification or is certified.

54 (f) Approve qualified training entities that provide  
55 precertification training to applicants and continuing education  
56 to certified assisted living facility administrators.

57 (8) APPEAL.—An individual who is adversely affected by the  
58 decision of a department-approved, third-party credentialing  
59 entity with regard to the denial of initial certification or an  
60 adverse action on continued certification may appeal such  
61 decision to the department for a final determination.

62 (9) FEES.—A third-party credentialing entity shall  
63 establish a fee for application, examination, certification, and  
64 biennial certification renewal. The fee for application,  
65 examination, and certification may not exceed \$200. The fee for  
66 biennial certification renewal may not exceed \$100.

67  
68 ===== T I T L E A M E N D M E N T =====

69 And the title is amended as follows:



794588

70           Delete line 49  
71 and insert:  
72           certain circumstances; requiring a third-party  
73           credentialing entity to establish fees; providing an  
74           effective date.



211298

LEGISLATIVE ACTION

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

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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:

1           **Senate Substitute for Amendment (794588) (with title**  
2 **amendment)**

3  
4           Delete lines 224 - 278

5 and insert:

6           (g) Establishment of credentialing standards that meet or  
7 exceed the department standards for training and education  
8 programs for assisted living facility administrators.

9           (4) ASSISTED LIVING FACILITY ADMINISTRATOR CERTIFICATION.-  
10 Effective July 1, 2014, an assisted living facility  
11 administrator may be certified by a third-party credentialing



937330

12 entity that is approved by the department under this section. An  
13 assisted living facility administrator who fails to be certified  
14 under this section or fails to meet training and educational  
15 requirements of s. 429.52 violates this section and is subject  
16 to an administrative fine as provided under s. 429.19. This  
17 subsection does not apply to an administrator licensed under  
18 part II of chapter 468.

19 (5) GRANDFATHER CLAUSE.—A third-party credentialing entity  
20 shall allow the following persons to enroll in its certification  
21 program, at no cost to the department or the person, in the 12  
22 months immediately after the department approves the third-party  
23 credentialing entity as provided in subsection (3):

24 (a) A person who is employed as of July 1, 2014, as an  
25 assisted living facility administrator and is in compliance with  
26 the requirements under s. 429.52.

27 (b) A person who has completed before July 1, 2014, the  
28 required training as an administrator, including the competency  
29 test and continuing education requirements under s. 429.52.

30 (6) CORE COMPETENCIES.—A third-party credentialing entity  
31 that is approved by the department shall establish the core  
32 competencies for assisted living facility administrators  
33 according to nationally recognized professional psychometric  
34 standards.

35 (7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification  
36 program of a third-party credentialing entity that is approved  
37 by the department must:

38 (a) Be established according to nationally recognized  
39 professional psychometric standards.

40 (b) Be directly related to the core competencies.



937330

41 (c) Establish minimum requirements in each of the following  
42 categories:

43 1. Formal education.

44 2. Training.

45 3. On-the-job work experience.

46 4. Supervision.

47 5. Testing.

48 6. Biennial continuing education.

49 (d) Administer a professional code of ethics and  
50 disciplinary process that applies to all certified persons.

51 (e) Administer and maintain a publicly accessible Internet-  
52 based database that contains information on each person who  
53 applies for certification or is certified.

54 (f) Approve qualified training entities that provide  
55 precertification training to applicants and continuing education  
56 to certified assisted living facility administrators.

57 (8) APPEAL.—An individual who is adversely affected by the  
58 decision of a department-approved, third-party credentialing  
59 entity with regard to the denial of initial certification or an  
60 adverse action on continued certification may appeal such  
61 decision to the department for a final determination.

62 (9) FEES.—A third-party credentialing entity shall  
63 establish a fee for application, examination, certification, and  
64 biennial certification renewal. The fee for application,  
65 examination, and certification may not exceed \$200. The fee for  
66 biennial certification renewal may not exceed \$100.

67  
68 ===== T I T L E A M E N D M E N T =====

69 And the title is amended as follows:



937330

70           Delete lines 43 - 49  
71 and insert:  
72           nationally recognized professional psychometric  
73           standards; requiring a certification program of a  
74           third-party credentialing entity to meet certain  
75           requirements; authorizing an individual adversely  
76           affected by the decision of a third-part credentialing  
77           entity to appeal the decision under certain  
78           circumstances; requiring a third-party credentialing  
79           entity to establish fees; providing an effective date.

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

586-03141-14

2014316c1

1 A bill to be entitled  
2 An act relating to certification of assisted living  
3 facility administrators; amending s. 429.52, F.S.;  
4 requiring assisted living facility administrators to  
5 meet the training and education requirements  
6 established by a third-party credentialing entity or  
7 by the Department of Elderly Affairs; requiring the  
8 department to establish a competency test; requiring a  
9 third-party credentialing entity to develop a  
10 competency test and a minimum required score to  
11 indicate successful completion of the training and  
12 educational requirements; revising requirements for  
13 facility administrators who are hired on or after a  
14 specified date; authorizing the department to require  
15 additional training and education of any personal care  
16 staff in the facility, except for certain assisted  
17 living facility administrators; requiring training to  
18 be conducted by an entity recognized by a third-party  
19 credentialing entity under s. 429.55, F.S.;  
20 authorizing the department to adopt rules to establish  
21 staff training requirements; creating s. 429.55, F.S.;  
22 providing legislative intent; defining terms;  
23 authorizing the department to approve third-party  
24 credentialing entities for the purpose of developing  
25 and administering a professional credentialing program  
26 for assisted living facility administrators; requiring  
27 the department to approve a third-party credentialing  
28 entity that documents compliance with certain minimum  
29 standards; authorizing an administrator to be

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30 certified by a third-party credentialing entity;  
31 providing that an administrator who fails to be  
32 certified under s. 429.55, F.S., or fails to complete  
33 training and educational requirements under s. 429.55  
34 is subject to an administrative fine; providing an  
35 exemption for an administrator licensed under part II  
36 of ch. 468, F.S.; requiring a third-party  
37 credentialing entity to allow certain persons to  
38 enroll in its certification program for a specified  
39 time after the department approves the third-party  
40 credentialing entity; requiring an approved third-  
41 party credentialing entity to establish the core  
42 competencies for administrators according to the  
43 standards set forth by the National Commission for  
44 Certifying Agencies; requiring a certification program  
45 of a third-party credentialing entity to meet certain  
46 requirements; authorizing an individual adversely  
47 affected by the decision of a third-party  
48 credentialing entity to appeal the decision under  
49 certain circumstances; providing an effective date.

50  
51 Be It Enacted by the Legislature of the State of Florida:

52  
53 Section 1. Section 429.52, Florida Statutes, is amended to  
54 read:

55 429.52 Staff training and educational programs; core  
56 educational requirement.—

57 (1) Effective July 1, 2014, administrators shall meet the  
58 minimum training and education requirements established by a

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59 third-party credentialing entity pursuant to s. 429.55 or by the  
 60 Department of Elderly Affairs by rule. ~~and~~ Other assisted living  
 61 facility staff ~~shall~~ must meet minimum training and education  
 62 requirements established by the department ~~of Elderly Affairs~~ by  
 63 rule. This training and education is intended to assist  
 64 facilities to appropriately respond to the needs of residents,  
 65 to maintain resident care and facility standards, and to meet  
 66 licensure requirements.

67 (2) The department shall establish a competency test and a  
 68 minimum required score to indicate successful completion of the  
 69 training and educational requirements. The department shall  
 70 develop the competency test ~~must be developed by the department~~  
 71 in conjunction with the agency and providers. A third-party  
 72 credentialing entity approved under s. 429.55 must also develop  
 73 a competency test and a minimum required score to indicate  
 74 successful completion of the training and educational  
 75 requirements. The required training and education must cover at  
 76 least the following topics:

77 (a) State law and rules relating to assisted living  
 78 facilities.

79 (b) Resident rights and identifying and reporting abuse,  
 80 neglect, and exploitation.

81 (c) Special needs of elderly persons, persons with mental  
 82 illness, and persons with developmental disabilities and how to  
 83 meet those needs.

84 (d) Nutrition and food service, including acceptable  
 85 sanitation practices for preparing, storing, and serving food.

86 (e) Medication management, recordkeeping, and proper  
 87 techniques for assisting residents with self-administered

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88 medication.

89 (f) Firesafety requirements, including fire evacuation  
 90 drill procedures and other emergency procedures.

91 (g) Care of persons who have ~~with~~ Alzheimer's disease and  
 92 related disorders.

93 (3) ~~Effective January 1, 2004,~~ A new facility administrator  
 94 hired on or after July 1, 2014, must:

95 (a) Complete the required training and education, including  
 96 the competency test, within a reasonable time after being  
 97 employed as an administrator, as determined by the department;  
 98 or

99 (b) Earn and maintain certification as an assisted living  
 100 facility administrator from a third-party credentialing entity  
 101 that is approved by the department as provided in s. 429.55.

102 Failure of a facility administrator to comply with paragraph (a)  
 103 or paragraph (b) ~~de-se~~ is a violation of this part and subjects  
 104 the violator to an administrative fine as prescribed in s.  
 105 429.19. Administrators licensed in accordance with part II of  
 106 chapter 468 are exempt from this requirement. ~~Other licensed~~  
 107 ~~professionals may be exempted, as determined by the department~~  
 108 ~~by rule.~~

109 (4) Administrators ~~shall~~ are required to participate in  
 110 continuing education for a minimum of 12 contact hours every 2  
 111 years.

112 (5) Staff involved with the management of medications and  
 113 assisting with the self-administration of medications under s.  
 114 429.256 must complete a minimum of 4 additional hours of  
 115 training provided by a registered nurse, licensed pharmacist, or  
 116

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117 department staff. The department shall establish by rule the  
118 minimum requirements of this additional training.

119 (6) Other facility staff shall participate in training  
120 relevant to their job duties as specified by rule of the  
121 department.

122 (7) If the department ~~or the agency~~ determines that there  
123 is a need for ~~are problems in a facility that could be reduced~~  
124 ~~through~~ specific staff training or education beyond that already  
125 required under this section, the department ~~or the agency~~ may  
126 require, and provide, or cause to be provided, the training or  
127 education of ~~any~~ personal care staff in the facility. However,  
128 this subsection does not apply to an assisted living facility  
129 administrator certified under s. 429.55.

130 (8) The department shall adopt rules related to these  
131 training requirements, the competency test, necessary  
132 procedures, and competency test fees and shall adopt or contract  
133 with another entity to develop a curriculum, which shall be used  
134 as the minimum core training requirements. The department shall  
135 consult with representatives of stakeholder associations and  
136 agencies in the development of the curriculum.

137 (9) The training required by this section must ~~shall~~ be  
138 conducted by a person who is ~~persons~~ registered with the  
139 department as having the requisite experience and credentials to  
140 conduct the training or by a training entity recognized by a  
141 third-party credentialing entity under s. 429.55(7)(f). A person  
142 seeking to register as a trainer must provide the department  
143 with proof of completion of the minimum core training education  
144 requirements, successful passage of the competency test  
145 established under this section, and proof of compliance with the

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146 continuing education requirement in subsection (4).

147 (10) A person seeking to register as a trainer must also:

148 (a) Provide proof of completion of a 4-year degree from an  
149 accredited college or university and must have worked in a  
150 management position in an assisted living facility for 3 years  
151 after being core certified;

152 (b) Have worked in a management position in an assisted  
153 living facility for 5 years after being core certified and have  
154 1 year of teaching experience as an educator or staff trainer  
155 for persons who work in assisted living facilities or other  
156 long-term care settings;

157 (c) Have been previously employed as a core trainer for the  
158 department; or

159 (d) Meet other qualification criteria as defined in rule,  
160 which the department may ~~is authorized to~~ adopt.

161 (11) The department may ~~shall~~ adopt rules to establish  
162 staff training ~~trainer registration~~ requirements.

163 Section 2. Section 429.55, Florida Statutes, is created to  
164 read:

165 429.55 Assisted living facility administrator;  
166 certification.-

167 (1) LEGISLATIVE INTENT.-It is the intent of the Legislature  
168 that each assisted living facility administrator have the option  
169 to earn and maintain professional certification from a third-  
170 party credentialing entity that is approved by the Department of  
171 Elderly Affairs. The Legislature further intends that  
172 certification ensure that an administrator has the competencies  
173 necessary to appropriately respond to the needs of residents, to  
174 maintain resident care and facility standards, and to meet

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175 licensure requirements for a facility. The Legislature  
 176 recognizes professional certification by a professional  
 177 credentialing organization as an equivalent alternative to a  
 178 state-run licensure program and, therefore, intends that  
 179 certification pursuant to this section is sufficient as an  
 180 acceptable alternative to the training and educational  
 181 requirements of s. 429.52.

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

183 (a) "Assisted living facility administrator certification"  
 184 means a professional credential awarded by a department-approved  
 185 third-party credentialing entity to a person who meets core  
 186 competency requirements in assisted living facility practice  
 187 areas.

188 (b) "Core competency" means the minimum knowledge and  
 189 skills necessary to carry out work responsibilities.

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

191 (d) "Third-party credentialing entity" means an  
 192 organization that develops and administers certification  
 193 programs according to the standards established by the National  
 194 Commission for Certifying Agencies.

195 (3) THIRD-PARTY CREDENTIALING ENTITIES.—The department  
 196 shall approve one or more third-party credentialing entities for  
 197 the purpose of developing and administering a professional  
 198 credentialing program for administrators. Within 90 days after  
 199 receiving documentation from a third-party credentialing entity,  
 200 the department shall approve a third-party credentialing entity  
 201 that demonstrates compliance with the following minimum  
 202 standards:

203 (a) Establishment of assisted living facility administrator

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204 core competencies, certification standards, testing instruments,  
 205 and recertification standards according to national psychometric  
 206 standards.

207 (b) Establishment of a process to administer the  
 208 certification application, award, and maintenance processes  
 209 according to national psychometric standards.

210 (c) Demonstrated ability to administer a professional code  
 211 of ethics and disciplinary process that applies to all certified  
 212 persons.

213 (d) Establishment of, and ability to maintain a publicly  
 214 accessible Internet-based database that contains information on  
 215 each person who applies for and is awarded certification, such  
 216 as the person's first and last name, certification status, and  
 217 ethical or disciplinary history.

218 (e) Demonstrated ability to administer biannual continuing  
 219 education and certification renewal requirements.

220 (f) Demonstrated ability to administer an education  
 221 provider program to approve qualified training entities and to  
 222 provide precertification training to applicants and continuing  
 223 education opportunities to certified professionals.

224 (4) ASSISTED LIVING FACILITY ADMINISTRATOR CERTIFICATION.—  
 225 Effective July 1, 2014, an assisted living facility  
 226 administrator may be certified by a third-party credentialing  
 227 entity that is approved by the department under this section. An  
 228 assisted living facility administrator who fails to be certified  
 229 under this section or fails to meet training and educational  
 230 requirements of s. 429.52 violates this section and is subject  
 231 to an administrative fine as provided under s. 429.19. This  
 232 subsection does not apply to an administrator licensed under



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233 part II of chapter 468.

234 (5) GRANDFATHER CLAUSE.—A third-party credentialing entity  
 235 shall allow the following persons to enroll in its certification  
 236 program, at no cost to the department or the person, in the 12  
 237 months immediately after the department approves the third-party  
 238 credentialing entity as provided in subsection (3):

239 (a) A person who is employed as an assisted living facility  
 240 administrator and is in compliance with the requirements in s.  
 241 429.52, including continuing education requirements in place  
 242 before July 1, 2014.

243 (b) A person who has completed before July 1, 2014, the  
 244 required training as an administrator, including the competency  
 245 test and continuing education requirements established in s.  
 246 429.52.

247 (6) CORE COMPETENCIES.—A third-party credentialing entity  
 248 that is approved by the department shall establish the core  
 249 competencies for assisted living facility administrators  
 250 according to the standards established by the National  
 251 Commission for Certifying Agencies.

252 (7) CERTIFICATION PROGRAM REQUIREMENTS.—A certification  
 253 program of a third-party credentialing entity that is approved  
 254 by the department must:

255 (a) Be established according to the standards set forth by  
 256 the National Commission for Certifying Agencies.

257 (b) Be directly related to the core competencies.

258 (c) Establish minimum requirements in each of the following  
 259 categories:

260 1. Formal education.

261 2. Training.

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262 3. On-the-job work experience.

263 4. Supervision.

264 5. Testing.

265 6. Biannual continuing education.

266 (d) Administer a professional code of ethics and  
 267 disciplinary process that applies to all certified persons.

268 (e) Administer and maintain a publicly accessible Internet-  
 269 based database that contains information on each person who  
 270 applies for certification or is certified.

271 (f) Approve qualified training entities that provide  
 272 precertification training to applicants and continuing education  
 273 to certified assisted living facility administrators.

274 (8) APPEAL.—An individual who is adversely affected by the  
 275 decision of a department-approved, third-party credentialing  
 276 entity with regard to the denial of initial certification or an  
 277 adverse action on continued certification may appeal such  
 278 decision to the department for a final determination.

279 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 Polzangin

Amendment Barcode \_\_\_\_\_  
(if applicable)

Job Title Director of Government Affairs

Address 1300 N Duval St

Phone 850 224-4206

Street

Tallahassee

FL

32303

City

State

Zip

E-mail richardpolzangin@hotmail.com

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 Matillo

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title Executive Director

Address 9445 Buck Haven Tr.

Phone 850-496-2562

1114555e, FL 32312  
*Street City State Zip*

E-mail gmatillo@alfa.org

Speaking:  For  Against  Information

Representing FL ALFA

Appearing at request of Chair:  Yes  No

Lobbyist registered with Legislature:  Yes  No

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

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

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 SB 316

Bill Number 316  
*(if applicable)*

Name Leslie Dughi

Amendment Barcode \_\_\_\_\_  
*(if applicable)*

Job Title \_\_\_\_\_

Address \_\_\_\_\_  
Street

Phone \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

E-mail dughil@gflaw.com

Speaking:  For  Against  Information

Representing Florida Assisted Living 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.**

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

Phone 850-222-6314

Street

Tallahassee FL 32301

City

State

Zip

E-mail neal.mcgarry@flcertificationboard.org

Speaking:  For  Against  Information

Representing Florida Certification Board

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.)

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

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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	<b>Favorable</b>
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.<sup>1</sup> 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.<sup>2</sup> In addition, in 2011 the Legislature passed HB 7107<sup>3</sup> creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The SMMC program

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<sup>1</sup> 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).

<sup>2</sup> Agency for Health Care Administration, *Welcome to Medicaid*, <http://ahca.myflorida.com/Medicaid/index.shtml#about> (last visited Mar. 27, 2014).

<sup>3</sup> 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).<sup>4</sup> 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.<sup>5</sup>

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.<sup>6</sup> 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.<sup>7</sup> Plans are also required to include any providers deemed “essential” by the AHCA.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup>

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<sup>4</sup> Health and Human Services Committee, Fla. House of Representatives, *PCS HHSC 11-01 Staff Analysis*, p.25, (Mar. 25, 2011).

<sup>5</sup> Agency for Health Care Administration, *Florida Medicaid - What Plans are Available in My Region?* [http://ahca.myflorida.com/Medicaid/statewide\\_mc/index.shtml#MMA](http://ahca.myflorida.com/Medicaid/statewide_mc/index.shtml#MMA) (last visited Mar. 27, 2014).

<sup>6</sup> 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](http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/FL_1115_MMA_IP_10-30-2013_Final.pdf) (last visited Nov. 21, 2013).

<sup>7</sup> See s. 409.975(1), F.S.

<sup>8</sup> 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.

<sup>9</sup> See s. 409.975(1)(a) and (b), F.S.

<sup>10</sup> 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](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).

<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup>

Failure to maintain adequate networks or to attain performance goals may result in liquidated damages or performance measure sanctions against the MMA.<sup>14</sup> For example, liquidated damages may be assessed for non-compliance with screening rates or preventive dental service goals.<sup>15</sup> 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.<sup>16</sup>

### Florida's Demographics

Florida has a large and diverse population of over 18.8 million residents.<sup>17</sup> Based on the 2010 Census data, Florida's population racial breakdown includes the following:<sup>18</sup>

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%
<b>Total Population:</b>		<b>18,801,310</b>

Florida's ethnic make-up is 22.5 percent Hispanic or Latino and 77.5 percent non-Hispanic or Latino.<sup>19</sup> 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.<sup>20</sup> The second largest Hispanic and Latino group, 1,213,438 individuals, identify their origins as Cuban.<sup>21</sup>

<sup>12</sup> 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](http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Core_Model_2014-01-31.pdf), p. 74, (last visited Mar. 28, 2014).

<sup>13</sup> *Id.*

<sup>14</sup> Agency for Health Care Administration, *Supra* note 10 at 101-105.

<sup>15</sup> *Id.* at 101.

<sup>16</sup> *Id.* at 98.

<sup>17</sup> 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](http://edr.state.fl.us/Content/population-demographics/2010-census/data/2010SF1_PROFILE_Florida.pdf) (last visited: Mar. 28, 2014).

<sup>18</sup> 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](http://edr.state.fl.us/Content/population-demographics/2010-census/data/2010DP_Florida.pdf) (last visited Mar. 28, 2014).

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *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.<sup>22</sup> This office coordinates the *Reducing Racial and Ethnic Disparities: Closing the Gap Grant Program*.<sup>23</sup> Projects funded under the *Closing the Gap* grant program support public and private entities by:<sup>24</sup>

- 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:<sup>25</sup>

- 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.<sup>26</sup> 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.<sup>27</sup> The partnership between the office and the liaisons are intended to accomplish several objectives, including:<sup>28</sup>

- 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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<sup>22</sup> See s. 20.43(9), F.S.

<sup>23</sup> See s. 381.7351, F.S.

<sup>24</sup> 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).

<sup>25</sup> *Id.*

<sup>26</sup> Department of Health, *American Indian Health Advisory Committee*, <http://www.floridahealth.gov/healthy-people-and-families/minority-health/aihaac.html> (last visited: Mar. 27, 2014).

<sup>27</sup> 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).

<sup>28</sup> *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.<sup>29</sup>

### 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.

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<sup>29</sup> 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](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\_\_

1 A bill to be entitled

2 An act relating to reducing racial and ethnic health  
3 disparities; requiring the Office of Program Policy  
4 Analysis and Government Accountability to conduct a  
5 study and provide recommendations relating to Medicaid  
6 provider networks; requiring a report to the Governor  
7 and Legislature; providing for expiration; providing  
8 an effective date.

9  
10 Be It Enacted by the Legislature of the State of Florida:

11  
12 Section 1. The Office of Program Policy Analysis and  
13 Government Accountability shall conduct a study of obstacles to  
14 achieving an adequate health care provider network for Medicaid  
15 recipients. The office shall consult with the Agency for Health  
16 Care Administration and the Department of Health to develop and  
17 recommend strategies to reduce racial and ethnic health  
18 disparities in this state. The office shall submit its findings  
19 and recommendations to the Governor, the President of the  
20 Senate, and the Speaker of the House of Representatives by  
21 January 1, 2016. This section expires June 30, 2016.

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



## THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

**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

**SENATOR ARTHENIA L. JOYNER**  
19th District

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,

A handwritten signature in black ink, appearing to read "Arthenia L. Joyner".

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](http://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)

4-1-2014

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 SHD Beverly Ct

Phone 850.509.2535

Tallahassee FL 32301  
City State Zip

E-mail jpaul@picoflorida.org

Speaking:  For  Against  Information

Representing PICO 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)

# CourtSmart Tag Report

**Room:** KN 412  
**Caption:** Senate Health Policy

**Case:**  
**Judge:**

**Type:**

**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 Health 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 passing  
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 Builders 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 Kershner, 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 Stimmel FI Psychological Assn.  
5:09:24 PM Question by Sen. Joyner  
5:10:45 PM Dr. Stimmel responds  
5:10:48 PM Follow-up question by Sen. Joyner  
5:10:56 PM Dr. Stimmel responds  
5:12:13 PM Question by Sen. Sobel  
5:12:27 PM Dr. Stimmel responds  
5:12:42 PM Follow-up question by Sen. Sobel  
5:12:58 PM Dr. Stimmel responds  
5:14:20 PM Question by Sen. Joyner  
5:14:46 PM Dr. Stimmel 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