

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Tuesday, December 5, 2017

TIME: 10:00 a.m.—12:00 noon

PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Young, Chair; Senator Passidomo, Vice Chair; Senators Benacquisto, Book, Hukill, Hutson, Montford, and Powell

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	SB 250 Steube (Compare H 23)	Ambulatory Surgical Centers and Mobile Surgical Facilities; Revising the definition of the terms "ambulatory surgical center" and "mobile surgical facility", etc. HP 12/05/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
2	SB 408 Flores (Similar H 283, Compare H 597, S 622)	Licensure of Cardiovascular Programs; Establishing additional criteria that must be included by the Agency for Health Care Administration in rules relating to adult cardiovascular services at hospitals seeking licensure for a Level I program, etc. HP 12/05/2017 Favorable AHS AP	Favorable Yeas 8 Nays 0
3	SB 488 Grimsley (Identical H 285)	Emergency Medical Services; Exempting certain governmental entities from the requirement to obtain a certificate of public convenience and necessity to provide certain emergency services under specified conditions, etc. HP 12/05/2017 Fav/CS CA RC	Fav/CS Yeas 7 Nays 0
4	SB 520 Latvala	Optometrists; Revising the requirements that applicants must meet in order to qualify to take optometric licensure and certification examinations; specifying that applicants must graduate from an accredited school or college of optometry in order to obtain a license and practice as optometrists, etc. HP 12/05/2017 Fav/CS AP RC	Fav/CS Yeas 8 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Tuesday, December 5, 2017, 10:00 a.m.—12:00 noon

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
5	SB 622 Grimsley (Similar H 597, Compare H 27, H 119, H 213, H 283, S 144, S 408)	Health Care Facility Regulation; Providing that a designated facility owned or operated by a public health trust and located within the boundaries of a municipality is under the exclusive jurisdiction of the county creating the public health trust; eliminating state licensure requirements for clinical laboratories; requiring a birth center to be federally certified and meet specified requirements to perform certain laboratory tests, etc. HP 12/05/2017 Favorable AHS AP RC	Favorable Yeas 7 Nays 0
6	SB 710 Book (Identical H 291)	Prescription Drug Donation Program; Renaming the Cancer Drug Donation Program as the Prescription Drug Donation Program; authorizing the donation of prescription drugs, including cancer drugs, and supplies to eligible patients; authorizing nursing home facilities to participate in the program, etc. HP 12/05/2017 Fav/CS AHS AP	Fav/CS Yeas 8 Nays 0

Other Related Meeting Documents



588182

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
12/05/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Between lines 30 and 31

insert:

Section 2. Present subsections (3) through (10) of section 395.1055, Florida Statutes, are redesignated as subsections (4) through (11), respectively, and a new subsection (3) is added to that section, to read:

395.1055 Rules and enforcement.—

(3) (a) The agency, in consultation with the Board of



11 Medicine and the Board of Osteopathic Medicine, shall adopt
12 rules that establish requirements for practitioners and
13 facilities to ensure the safe and effective delivery of surgical
14 care to children in ambulatory surgical centers. The rules must
15 be consistent with the American College of Surgeons' standards
16 document entitled "Optimal Resources for Children's Surgical
17 Care" and must establish minimum standards for pediatric patient
18 care treatment practices, including at least all of the
19 following: surgical risk assessment; anesthetic care;
20 resuscitation; transfer agreements; and training and
21 certification requirements for pediatric health care providers.

22 (b) Ambulatory surgical centers may provide operative
23 procedures that require a length of stay past midnight on the
24 day of surgery on children younger than 18 years of age only if
25 the agency authorizes the performance of such procedures by
26 rule.

27
28 ===== T I T L E A M E N D M E N T =====

29 And the title is amended as follows:

30 Between lines 5 and 6

31 insert:

32 amending s. 395.1055, F.S.; requiring the Agency for
33 Health Care Administration, in consultation with the
34 Board of Medicine and the Board of Osteopathic
35 Medicine to adopt rules that establish requirements
36 for practitioners and facilities related to the
37 delivery of surgical care to children in ambulatory
38 surgical centers, in accordance with specified
39 standards; requiring that the rules establish minimum



588182

40 standards for certain pediatric patient care
41 practices; specifying that ambulatory surgical centers
42 may only provide certain procedures if authorized by
43 agency rule;



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Judiciary, *Chair*
Banking and Insurance, *Vice Chair*
Agriculture
Appropriations Subcommittee on Finance and Tax
Appropriations Subcommittee on Pre-K - 12 Education
Children, Families, and Elder Affairs
Regulated Industries

JOINT COMMITTEE:

Joint Committee on Public Counsel Oversight

SENATOR GREG STEUBE

23rd District

September 25, 2017

The Honorable Dana Young
Florida Senate
316 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Senator Young,

I am writing this letter because my bill, SB 250 – Ambulatory Surgical Centers and Mobile Surgical Facilities, has been referred to the Senate Health Policy Committee. I am respectfully requesting that you place the bill on your committee's calendar for the next committee week.

Thank you for your consideration. Please contact me if you have any questions.

Very respectfully yours,

A handwritten signature in black ink, appearing to read "W. Gregory Steube".

W. Gregory Steube, District 23

REPLY TO:

- 6230 University Parkway, Suite 202, Sarasota, Florida 34240 (941) 342-9162
- 326 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5023

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

12/5/17
Meeting Date

250

Bill Number (if applicable)

588182

Amendment Barcode (if applicable)

Topic Amberatay Surgical Centers - amendment

Name Anita Berry

Job Title Lobbyist

Address 21748 SR 04, Ste 102

Phone 301-524-0172

Street

Wtz
City

FL
State

Zip

Email anita@carcoranfirm.com

Speaking: For Against Information

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

Representing Johns Hopkins AllChildren's Hospital

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)

12/05/2017

Meeting Date

SB 250

Bill Number (if applicable)

588182

Amendment Barcode (if applicable)

Topic Ambulatory Surgical Centers/Pediatric Amendment

Name Brian Jogerst

Job Title _____

Address PO Box 11094

Street

Tallahassee

City

FL

State

32302

Zip

Phone 850-222-0191

Email brian@bhandassociates.com

Speaking: For Against Information

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

Representing Miami Children's Health System

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

12/5/17
Meeting Date

250
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title _____

Address 1000 Riverside Ave #240
Street

Phone 904-233-3051

City _____ State _____ Zip _____

Email nulandlaw@aol.com

Speaking: For Against Information

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

Representing Florida Chapter, American College of 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.

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THE FLORIDA SENATE
APPEARANCE RECORD

12/05/17
Meeting Date

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

SB 250
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name DAVID SHAPIRO, M.D.

Job Title PHYSICIAN

Address 1400 VILLAGE SQ BLVD.

Phone 8505086787

Street

TALLAHASSEE FL 32312

City

State

Zip

Email dshapiromd@yahoo.com

Speaking: For Against Information

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

Representing FLORIDA SOCIETY OF AMBULATORY SURGERY CENTERS

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)

12/5/17
Meeting Date

250
Bill Number (if applicable)

Topic Am Surg

Amendment Barcode (if applicable)

Name Toni Large

Job Title ~~XXXXXXXXXXXX~~

Address P.O. Box 1737

Phone (850) 556-1461

Tallahassee, FL 32302
Street
City State Zip

Email toni@sulaw.net

Speaking: For Against Information

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

Representing FL Orthopedic Society

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)

12/5/17 Meeting Date

SB250 Bill Number (if applicable)

Topic Ambulatory Surgical Centers

Amendment Barcode (if applicable)

Name Logan Pike

Job Title Director of Public Affairs

Address 100 N Duval Street

Phone 880-386-3131

City TLH State FL Zip 32301

Email lpikere@jamesmadison.org

Speaking: For Against Information

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

Representing The James Madison 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.

THE FLORIDA SENATE

APPEARANCE RECORD

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

12.5.17

Meeting Date

SB 250

Bill Number (if applicable)

Topic Ambulatory Surgical Centers

Amendment Barcode (if applicable)

Name Monica Corbett

Job Title VP of Public Affairs

Address 300 E. College Ave

Phone 222-9800

Street

Tallahassee FL 32301

City

State

Zip

Email monica.c@fha.org

Speaking: [] For [] Against [] Information

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

Representing Florida Hospital Association

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

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

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 250

INTRODUCER: Health Policy Committee and Senator Steube

SUBJECT: Ambulatory Surgical Centers and Mobile Surgical Facilities

DATE: December 5, 2017 **REVISED:** _____

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

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 250 amends the definition of “ambulatory surgical center” (ASC) or “mobile surgical facility”¹ in s. 395.002, F.S., to allow patients to remain in the ASC for up to 24 hours rather than requiring that patients be admitted and discharged from the ASC within the same working day. This change conforms to the federal definition of an ACS as part of the conditions of participation in the Medicare program.

The bill also requires the Agency for Health Care Administration (AHCA), in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules consistent with the American College of Surgeons’ standards document entitled “Optimal Resources for Children’s Surgical Care” to ensure the safe and effective delivery of surgical care to children in ASCs. The bill specifies that ASCs may only provide procedures requiring a length of stay past midnight to children under the age of 18 if specifically authorized by the AHCA.

¹ Chapter 395, Part I, F.S., also includes a provision for mobile surgical facility licensure, which is a portable ASC contracted with the Department of Corrections (DOC) or private correctional facility to serve as the surgery department of a prison hospital. To date, no applications have been received for a mobile surgical facility license and none are anticipated. AHCA, *Senate Bill 250 Analysis* (Oct. 19, 2017) (on file with the Senate Committee on Health Policy).

II. Present Situation:

Ambulatory Surgical Centers

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.² Currently there are 442 licensed ASCs in Florida.³ Between April 2016 and March 2017, there were 3,068,350 visits to ASCs in Florida.⁴ Two of the most popular procedures to have performed at an ASC include cataract procedures with 269,807 performed on adults and colonoscopies with 238,997 performed on adults, also during the same time period.⁵ Average charges for procedures performed at an ASC over this period range from \$2,201 to \$15, 961.⁶

Ambulatory surgical centers are licensed and regulated by the AHCA under the same regulatory framework as hospitals.⁷ In addition, ASCs may seek voluntary accreditation by the Joint Commission or the Accreditation Association for Ambulatory Health Care. The AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.⁸

Ambulatory surgical centers are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.⁹

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body, or licensed by a state agency, and CMS determines that such accreditation or licensure provides reasonable assurance that the conditions

² Section 395.002(3), F.S., defines “Ambulatory surgical center” to mean a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003, F.S.

³ Supra note 1

⁴ AHCA, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last viewed Nov. 30, 2017).

⁵ Supra note 4

⁶ Supra note 4

⁷ Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.

⁸ Rule 59A-5.004, F.A.C.

⁹ 42 C.F.R. s. 416.2.

for coverage are met.¹⁰ All of the CMS conditions for coverage requirements are specifically required in Rule 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

- Governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- Quality assessment and performance improvement program;
- Transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- Disaster preparedness plan;
- Organized medical staff;
- Fire control plan;
- Sanitary environment;
- Infection control program; and
- Procedure for patient admission, assessment and discharge.

American College of Surgeons Document: Optimal Resources for Children's Surgical Care

The standards document Optimal Resources for Children's Surgical Care was released in 2015 based on the findings of the Task Force for Children's Surgical Care. The Task Force was an ad hoc multidisciplinary group of invited leaders in relevant disciplines assembled initially from April 30 to May 1, 2012, in Rosemont, IL, and subsequently in 2013, 2014, and 2015 to consider approaches to optimize the delivery of children's surgical care in today's competitive national health care environment.¹¹

The document contains specific standards for children's ambulatory surgical centers. The ambulatory surgery standards were developed because a large proportion of children's surgical needs today are managed on an outpatient basis; the number of children involved may be half or more of all children who undergo surgical procedures. Although these children are generally healthy and do well, the uncommon consequences of perioperative problems, particularly related to anesthesia, may be life threatening. The standards were developed in an effort to minimize this risk. The standards require children's ambulatory surgical centers to have treatment protocols for resuscitation, transfer protocols, and data reporting, and must participate in systems for performance improvement.¹²

III. Effect of Proposed Changes:

CS/SB 250 amends the definition of ASC in s. 395.002, F.S., to allow patients to remain in the ASC for up to 24 hours rather than requiring that patients be admitted and discharged from the ASC within the same working day. This change conforms to the federal definition of an ACS as part of the conditions of participation in the Medicare program.

¹⁰ 42 C.F.R. s. 416.26(a)(1).

¹¹ Optimal Resources for Children's Surgical Care, p. 4, available at https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx, (last visited on Dec. 5, 2017).

¹² Id. A p. 12

The bill also amends s. 395.1055, F.S., to require the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules consistent with the American College of Surgeons' standards document entitled "Optimal Resources for Children's Surgical Care" to ensure the safe and effective delivery of surgical care to children in ASCs. The rules must, at a minimum, address surgical risk assessments, anesthetic care, resuscitation, transfer agreements, and training and certification requirements for pediatric health care providers. The bill also specifies that ASCs may only provide procedures requiring a length of stay past midnight to children under the age of 18 if specifically authorized pursuant to an AHCA's rule.

The bill establishes an effective date of July 1, 2018.

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 250 may have an indeterminate negative fiscal impact on hospitals if more patients choose to have their procedures performed in an ASC.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

CS/SB 250 requires the AHCA to establish rules consistent with the American College of Surgeon's standards document entitled "Optimal Resources for Children's Surgical Care." The bill does not specify a specific version of the document to be used. This reference based on the

title of the document may be problematic for future rulemaking if the title of the document changes or if the standards are significantly changed. It may be advisable to specify a version of the document or to allow for updates to these rules.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.002 and 395.1055.

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 December 5, 2017:

The CS requires the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules consistent with the American College of Surgeons' standards document entitled "Optimal Resources for Children's Surgical Care" to ensure the safe and effective delivery of surgical care to children in ASCs. The bill specifies that ASCs may only provide procedures requiring a length of stay past midnight to children under the age of 18 if specifically authorized by rule.

- B. **Amendments:**

None.

By Senator Steube

23-00004-18

2018250__

1 A bill to be entitled
2 An act relating to ambulatory surgical centers and
3 mobile surgical facilities; amending s. 395.002, F.S.;
4 revising the definition of the terms "ambulatory
5 surgical center" and "mobile surgical facility";
6 providing an effective date.

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

9
10 Section 1. Subsection (3) of section 395.002, Florida
11 Statutes, is amended to read:

12 395.002 Definitions.—As used in this chapter:

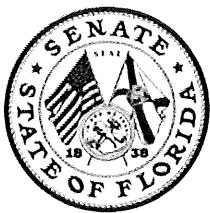
13 (3) "Ambulatory surgical center" or "mobile surgical
14 facility" means a facility the primary purpose of which is to
15 provide elective surgical care, in which the patient is admitted
16 to and discharged from such facility within 24 hours ~~the same~~
17 ~~working day and is not permitted to stay overnight~~, and which is
18 not part of a hospital. However, a facility existing for the
19 primary purpose of performing terminations of pregnancy, an
20 office maintained by a physician for the practice of medicine,
21 or an office maintained for the practice of dentistry shall not
22 be construed to be an ambulatory surgical center, provided that
23 any facility or office which is certified or seeks certification
24 as a Medicare ambulatory surgical center shall be licensed as an
25 ambulatory surgical center pursuant to s. 395.003. Any structure
26 or vehicle in which a physician maintains an office and
27 practices surgery, and which can appear to the public to be a
28 mobile office because the structure or vehicle operates at more
29 than one address, shall be construed to be a mobile surgical

23-00004-18

2018250__

30 facility.

31 Section 2. This act shall take effect July 1, 2018.



The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 6, 2017

I respectfully request that **Senate Bill #408**, relating to Licensure Cardiovascular Program, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 39

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: SB 408

INTRODUCER: Senator Flores

SUBJECT: Licensure of Cardiovascular Programs

DATE: December 4, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Favorable
2.			AHS	
3.			AP	

I. Summary:

SB 408 reduces the number of adult inpatient and outpatient diagnostic cardiac catheterizations, from 300 to 100, that a hospital located more than 100 road miles from the nearest hospital offering Level II adult cardiovascular services (ACS) must provide in a 12-month period in order to become licensed as a Level I ACS program. A Level I program performs adult percutaneous cardiac interventions without onsite cardiac surgery.¹

Currently, only the Lower Keys Medical Center would qualify for this exemption.²

Additionally, the bill amends the requirements for the licensure of all Level I programs to include both inpatients and outpatients when determining the volume of patients that have been discharged or transferred with a principal diagnosis of ischemic heart disease.

II. Present Situation:

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of part II of ch. 408, F.S. Hospitals are subject to the certificate of need (CON) provisions in part I of ch. 408, F.S. A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.³

¹ Percutaneous coronary intervention, also known as coronary angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina, acute myocardial infarction, and multivessel coronary artery disease. See Medscape: Percutaneous cardiac intervention, available at <http://emedicine.medscape.com/article/161446-overview>, (last visited Dec. 1, 2017).

² AHCA, *Senate Bill 408 Analysis* (Nov. 8, 2017) (on file with the Senate Committee on Health Policy).

³ Section 408.032(3), F.S.

Adult Cardiovascular Services were previously regulated through the CON program.⁴ However, in 2004, the Legislature established a licensure process for adult interventional cardiology services (the predecessor terminology for ACS), dependent upon rulemaking, in lieu of the CON procedure.⁵

Among other things, that law required the rules to establish two hospital program licensure levels: a Level I program and a Level II program.⁶

Hospitals with Level I adult cardiovascular services designation on their license provide diagnostic and therapeutic cardiac catheterization procedures on a routine and emergency basis. Level I hospitals do not have the capability to perform open heart surgery, and by rule can provide the same routine and emergency cardiac catheterization services as Level II (with open heart surgery capability) hospitals except for the higher risk trans septal punctures and lead extractions of implanted devices. Level I hospitals qualify for the designation by confirming compliance with national guidelines established by the American College of Cardiology and the American Heart Association, and having a transfer agreement with a Level II hospital in which a patient needing the higher level of care can be transferred within 60 minutes.⁷

Currently, in order to be designated as a Level I hospital, the hospital must perform at least 300 diagnostic cardiac catheterization sessions during the most recent 12-month period, or transfer or discharge at least 300 inpatients with the principal diagnosis of ischemic heart disease. For these metrics, the diagnostic cardiac catheterization sessions may include inpatients and outpatients in the total count, but the patients with ischemic heart disease must be inpatients. The criteria cannot be met by combining the two volume options - either the sessions volume is met or the inpatient principle diagnosis volume is met. Once a hospital obtains the designation it does not need to verify volume thresholds to maintain the designation.⁸ Subsection 408.0361(3), F.S., allows a hospital more than 100 road miles from the closest Level II hospital to qualify for Level I designation if all criteria is met except for the emergency transfer of patients within 60 minutes.

III. Effect of Proposed Changes:

SB 408 amends s. 408.0361, F.S., to exempt a hospital that is more than 100 road miles from the nearest hospital offering Level II ACS from patient or procedure volume requirements in order to be licensed as a Level I ACS provider. The hospital must still demonstrate, for the most recent 12-month period as reported to the AHCA, that:

- It has provided a minimum of 100 adult inpatient and outpatient cardiac catheterizations rather than 300; or

⁴ See s. 408.036(3)(m) and (n), F.S., allowing for an exemption from the full review process for certain adult open-heart services and PCI services.

⁵ Chapter 2004-383, s. 7, Laws of Fla.

⁶ Level I and Level II ACS programs may also perform adult diagnostic cardiac catheterization in accordance with Rule 59A-3.2085(13), F.A.C. Adult diagnostic cardiac catheterization involves the insertion of a catheter into one or more heart chambers for the purpose of diagnosing cardiovascular diseases.

⁷ Supra note 2

⁸ Supra note 2

- It has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease.

Currently, only the Lower Keys Medical Center would qualify for this exemption.⁹

Additionally, the bill amends the requirements for the licensure of all Level I programs to include both inpatients and outpatients when determining the volume of patients that have been discharged or transferred with a principal diagnosis of ischemic heart disease. This will allow patients who have been transferred prior to admission to the hospital as an inpatient to be included in the counts.

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:

SB 408 may have a positive fiscal impact on a hospital that is able to be licensed as a Level I program under the changes made in the bill.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

⁹ Supra note 2

VIII. Statutes Affected:

This bill substantially amends section 408.0361 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.

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

By Senator Flores

39-00427-18

2018408__

1 A bill to be entitled
2 An act relating to licensure of cardiovascular
3 programs; amending s. 408.0361, F.S.; establishing
4 additional criteria that must be included by the
5 Agency for Health Care Administration in rules
6 relating to adult cardiovascular services at hospitals
7 seeking licensure for a Level I program; providing an
8 effective date.

9
10 Be It Enacted by the Legislature of the State of Florida:

11
12 Section 1. Paragraph (b) of subsection (3) of section
13 408.0361, Florida Statutes, is amended to read:

14 408.0361 Cardiovascular services and burn unit licensure.—

15 (3) In establishing rules for adult cardiovascular
16 services, the agency shall include provisions that allow for:

17 (b) For a hospital seeking a Level I program, demonstration
18 that, for the most recent 12-month period as reported to the
19 agency, it has provided a minimum of 300 adult inpatient and
20 outpatient diagnostic cardiac catheterizations or, for the most
21 recent 12-month period, has discharged or transferred at least
22 300 patients ~~inpatients~~ with the principal diagnosis of ischemic
23 heart disease and that it has a formalized, written transfer
24 agreement with a hospital that has a Level II program, including
25 written transport protocols to ensure safe and efficient
26 transfer of a patient within 60 minutes. However, a hospital
27 located more than 100 road miles from the closest Level II adult
28 cardiovascular services program:

29 1. May demonstrate that, for the most recent 12-month

39-00427-18

2018408__

30 period as reported to the agency, it has provided a minimum of
31 100 adult inpatient and outpatient diagnostic cardiac
32 catheterizations, or for the most recent 12-month period has
33 discharged or transferred at least 300 patients with the
34 principal diagnosis of ischemic heart disease.

35 2. Does not need to meet the 60-minute transfer time
36 protocol if the hospital demonstrates that it has a formalized,
37 written transfer agreement with a hospital that has a Level II
38 program. The agreement must include written transport protocols
39 to ensure the safe and efficient transfer of a patient, taking
40 into consideration the patient's clinical and physical
41 characteristics, road and weather conditions, and viability of
42 ground and air ambulance service to transfer the patient.

43 Section 2. This act shall take effect July 1, 2018.



257094

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
12/05/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 16 - 87

and insert:

Section 1. Present subsections (2) through (21) of section 401.23, Florida Statutes, are redesignated as subsections (3) through (22), respectively, a new subsection (2) is added to that section, present subsection (19) of that section is amended, and subsection (1) of that section is republished, to read:



257094

11 401.23 Definitions.—As used in this part, the term:
12 (1) “Advanced life support” means assessment or treatment
13 by a person qualified under this part through the use of
14 techniques such as endotracheal intubation, the administration
15 of drugs or intravenous fluids, telemetry, cardiac monitoring,
16 cardiac defibrillation, and other techniques described in the
17 EMT-Paramedic National Standard Curriculum or the National EMS
18 Education Standards, pursuant to rules of the department.
19 (2) “Advanced life support nontransport services” means the
20 provision of services defined in subsection (1) in an emergency
21 by a licensee until the arrival of an air ambulance or ambulance
22 provided by another entity that is used for, or intended to be
23 used for, land, air, or water transportation of sick or injured
24 persons requiring or likely to require medical attention during
25 transport. For the purpose of this definition, “emergency” means
26 a situation in which a person has a medical condition that
27 manifests itself by acute symptoms of such severity, including
28 severe pain, that the absence of immediate medical attention
29 could reasonably be expected to jeopardize the person’s health
30 or result in serious impairment to bodily functions or serious
31 dysfunction of any bodily organ or part. The term “emergency”
32 includes a response to a 911 call.
33 (20) (19) “Physician” means a practitioner who is licensed
34 under ~~the provisions of~~ chapter 458 or chapter 459. For the
35 purpose of providing medical direction ~~“medical direction” as~~
36 ~~defined in subsection (14)~~ for the treatment of patients
37 immediately prior to or during transportation to a United States
38 Department of Veterans Affairs medical facility, the term
39 ~~“physician”~~ also means a practitioner employed by the United



257094

40 States Department of Veterans Affairs.

41 Section 2. Paragraph (d) of subsection (2) is amended and
42 new subsection (8) is added to section 401.25, Florida Statutes,
43 to read:

44 401.25 Licensure as a basic life support or an advanced
45 life support service.—

46 (2) The department shall issue a license for operation to
47 any applicant who complies with the following requirements:

48 (d) The applicant has obtained a certificate of public
49 convenience and necessity from each county in which the
50 applicant will operate. However, notwithstanding, any general
51 law, special act, or ordinance of a local government to the
52 contrary, except as provided in subparagraph 4., a governmental
53 entity that maintains fire rescue infrastructure and provides
54 first responders as defined in s. 112.1815 is not required to
55 obtain a certificate of public convenience and necessity or any
56 other authorization from a county to provide advanced life
57 support nontransport services if the governmental entity meets
58 the requirements of this chapter and applicable department rules
59 and uses a countywide common medical protocol, if such a
60 protocol is instituted.

61 1. In issuing the certificate of public convenience and
62 necessity, the governing body of each county shall consider the
63 recommendations of municipalities within its jurisdiction.

64 2. If a countywide common medical protocol restricts or
65 limits the ability of the governmental entity to provide
66 advanced life support nontransport services without a
67 certificate of public convenience and necessity, the
68 governmental entity must meet only the requirements of this



257094

69 chapter and applicable department rules to obtain its license.

70 3. A governmental entity intending to provide advanced life
71 support nontransport services without a certificate of public
72 convenience and necessity must notify the county and
73 municipalities in its proposed service area of its submission of
74 an application to the state.

75 4. The exception to the certificate of public convenience
76 and necessity requirement in this paragraph does not apply to a
77 county in which there is a countywide emergency medical services
78 authority created by special act or a governmental entity that
79 contracts with a private entity to provide fire rescue services.

80 (8) If a license is issued without a certificate of public
81 convenience and necessity, as authorized by paragraph (2) (d),
82 the department shall issue such license so that the licensee is
83 limited to providing advanced life support nontransport
84 services. Vehicle permits issued to such a licensee pursuant to
85 section 401.26 must be for nontransport only.

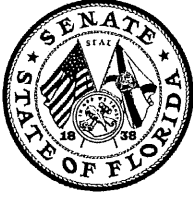
86
87 ===== T I T L E A M E N D M E N T =====

88 And the title is amended as follows:

89 Delete lines 3 - 4

90 and insert:

91 amending s. 401.23, F.S.; defining the term "advanced
92 life support nontransport services";



The Florida Senate

Committee Agenda Request

To: Senator Dana D. Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: October 25, 2017

I respectfully request that **Senate Bill #488**, relating to Emergency Medical Services, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in cursive script that reads "Denise Grimsley".

Senator Denise Grimsley
Florida Senate, District 26

cc: Sandra Stovall, Staff Director
Celia Georgiades, Committee Administrative Assistant

THE FLORIDA SENATE

APPEARANCE RECORD

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

12/5/17

Meeting Date

488

Bill Number (if applicable)

EMS

Topic Certificate of Public Convenience + Necessity (COPEN) Amendment Barcode (if applicable)

Name Greg DeWitt

Job Title Assistant Chief, Bonita Springs Fire

Address 27701 Bonita Grande Dr.

Phone 239-390-7959

Street

Bonita Springs

FL

34135

Email Dewitt@BonitaFire.org

City

State

Zip

Speaking: For Against Information

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

Representing Bonita Springs Fire Control and Rescue District

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

125-17

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

488

Meeting Date

Bill Number (if applicable)

Topic Emergency Services

Amendment Barcode (if applicable)

Name Jim Millican

Job Title Fire Marshal

Address 4360 - 55 AV N

Phone 727-526-5650

Street

St. Pete FL 33714

City

State

Zip

Email jmillican@lealmanfire.com

Speaking: For Against Information

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

Representing Lealman Fire District

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)

12/5/17

Meeting Date

SB 488

Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Bret Jameyson

Job Title VP North Collier Professional Firefighters

Address 89 BUENT PINE DR

Phone 239-272-4517

Street

Naples

City

FL

State

34119

Zip

Email

Speaking: For Against Information

Waive Speaking: In Support Against

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

Representing North Collier Prof Firefighters Local 2297

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)

12/5/17

Meeting Date

488

Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Chris Lyon

Job Title Legislative Counsel

Address 315 S. Calhoun St., Ste. 830

Phone 850/222-5702

Street

Tallahassee

City

FL

State

32301

Zip

Email clyonellw-law.com

Speaking: For Against Information

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

Representing Florida Association of Special Districts

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

12/5/2017
Meeting Date

488
Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Jorge Aguilera

Job Title ASSISTANT CHIEF

Address 1885 Veterans Park Dr
Street

Phone (239) 255-8589

NAPLES FLA 34109
City State Zip

Email Jaguilera@NorthCollieFire.com

Speaking: For Against Information

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

Representing NORTH COLLIE FIRE CONTROL & RESCUE DISTRICT

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)

12/5/17
Meeting Date

488
Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Eric Prutsman

Job Title Florida Fire Chiefs Assoc.

Address P.O. Box 10448

Phone 880-210-2525

Tall FL 32302
City State Zip

Email eric@prutsmanlaw.com

Speaking: For Against Information

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

Representing Florida Fire Chiefs 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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THE FLORIDA SENATE

APPEARANCE RECORD

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

12/5/17

Meeting Date

SB 488

Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name John StanFILL

Job Title DVP North Collier Professional Firefighters

Address 5940 Dogwood way

Phone (239) 404-2947

Street

naples

FL

34116

City

State

Zip

Email

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

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

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)

12/5/17
Meeting Date

488
Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name LISA HURLEY

Job Title

Address 311 E. PARK AVE.

Phone 850.224.5081

Street TAUAHASSEE
City State Zip

Email hurley@smithbryanandmyers

Speaking: For Against Information

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

Representing Collier County Board of County Commissioners

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)

11/5/17
Meeting Date

488
Bill Number (if applicable)

Topic Emergency Medical services

Amendment Barcode (if applicable)

Name Daphnee Sanvil

Job Title Legislative Coordinator

Address 115 S Andrews Ave. Rm. 426

Phone 954-253-7320

Street
City Ft. Lauderdale State FL Zip 33301

Email dsanvil@broward.org

Speaking: For Against Information

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

Representing Broward County

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)

12/5/17
Meeting Date

488
Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Jim Tolley

Job Title President Florida Professional Firefighters

Address 343 West Madison St,
Street

Phone 850 224 7333

Tallahassee FL 32301
City State Zip

Email JimT@FPFP.org

Speaking: For Against Information

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

Representing Firefighters

Appearing at request of Chair: Yes No

Lobbyist registered with Legislature: Yes No

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

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

12-5-17 Meeting Date

SB 488 Bill Number (if applicable)

Topic Emergency Medical Services

Amendment Barcode (if applicable)

Name Mac Kemp

Job Title Deputy Chief

Address 911 Easterwood Drive Street

Phone 850 606 2100

Tallahassee, FL 32311 City State Zip

Email KempM@leoncountyfl.gov

Speaking: For Against Information

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

Representing Florida Council of EMS Chiefs

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.)

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

BILL: CS/SB 488

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Emergency Medical Services

DATE: December 5, 2017 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Fav/CS
2.			CA	
3.			RC	

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 488 exempts certain governmental entities that provide advanced life support nontransport services (ALSNS), as defined in the bill, from the requirement to obtain a certificate of public convenience and necessity (COPCN) as a condition of licensure to provide ALSNS. Governmental entities that maintain fire rescue infrastructure and provide first responders are eligible for this exemption.

The exemption is preemptive in a county unless there is a countywide emergency medical services authority that has been created by special act or a governmental entity that contracts with a private entity to provide fire rescue.¹ The governmental entity must follow other statutory requirements, Department of Health (DOH) rules, and use a countywide common medical protocol if one exists and if the protocol does not restrict or limit the governmental entity's ability to provide ALSNS. The bill requires a governmental entity intending to provide ALSNS without a COPCN to notify the county and municipalities in its proposed service area when it submits its application to the state.

¹ Chapter 75-492, Laws of Fla., established a countywide emergency medical services authority in Pinellas County. It appears as if this is the only such authority created by special act

II. Present Situation:

Advanced Life Support Services

Prehospital life support services fall into two general categories, basic life support services and advanced life support services (ALS). ALS is sophisticated care using invasive methods, such as intravenous fluids, medications and intubation.² ALS can be performed on site, in a ground ambulance, or in a helicopter and is usually implemented by physicians or paramedics.³

In emergency care, two alternative strategies have generally been presented:

- Scoop and run: the patient is transported to a high level hospital as quickly as possible, with minimal prehospital treatments, or
- Stay and play: the patient is stabilized on site before transportation.

The merits of these two strategies are still under debate.⁴

Certificates of Public Convenience and Necessity for the Provision of Basic or Advanced Life Support Services and Air Ambulance Services

A COPCN is defined as a written statement or document, issued by the governing board of a county, granting permission for an applicant or licensee to provide services authorized under such license for the benefit of the population of that county or an area within the county.⁵ In order to be licensed to provide basic or advanced life support services or air ambulance services an applicant must have obtained a COPCN from each county in which the applicant will provide services.⁶ Counties are allowed, but not required, to adopt ordinances to provide reasonable standards for the issuance of COPCNs. In adopting such ordinances, the counties must consider state guidelines, the recommendations of the local or regional trauma agency, and the recommendations of municipalities within their jurisdiction.⁷

County ordinances regarding COPCNs vary in detail from county to county. Of the counties surveyed,⁸ all ordinances detail specific application requirements, typically including forms required to be filed with the county, and application review criteria. The application review criteria typically require that applications be sent to each municipality within the county and the municipalities to make recommendations on the application. Such recommendations must be taken into account when deciding to grant or deny the COPCN.

² Ryyanen, et. al, *Is advanced life support better than basic life support in prehospital care? A systematic review*, Scand J Trauma Resusc. Emerg. Med. 2010; 18: 62, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001418/> (last visited on Nov. 30, 2017).

³ Id.

⁴ Supra note 2

⁵ Rule 64J-1.001, F.A.C.

⁶ Section 401.25(2)(d), F.S.

⁷ Section 401.25(6), F.S.

⁸ Counties surveyed include Volusia (Sec. 46-92 Volusia County Code of Ordinances), Broward (Ch. 3½, Broward County Code of Ordinances), Miami-Dade (Ch. 4 Art. I, Miami-Dade County Code of Ordinances), Wakulla (Ch. 11.5 Art. III, Wakulla County Code of Ordinances), Baker (Ch. 16, Art. III, Baker County Code of Ordinances), and Collier (Ch. 50 Art. III, Collier County Code of Ordinances). Counties without ordinances include, but are not limited to, Columbia, Franklin, Levy, and Gadsden Counties (*Conversation with Susan Harbin, Florida Association of Counties on Nov. 30, 2015*).

The amount of detail required to be filed with a COPCN application also varies from county to county, but generally includes proof that the applicant has all necessary licenses as well as meets all state criteria for the provision of ALS or BLS services. Also included in such ordinances were revocation criteria, responsibilities conveyed on the holder of a COPCN, and a ban on the sale or reassignment of COPCNs. Additionally, the length of time that a COPCN lasts before it expires varies. For example, in Volusia County COPCNs expire after two years, in Broward County after 3 years, and in Miami-Dade County the COPCNs last until they are revoked.

Currently, if a COPCN is denied, there is no specific process for appeal detailed in the Florida statutes. As such, it is likely that any appeals of COPCN denials would be filed with the circuit court with jurisdiction over the county that denied the COPCN.

Licensure Requirements

The application requirements for a license to provide ALS include submission of:

- An application and applicable fees;
- Documentation that ambulances, equipment, vehicles, personnel, communications systems, staffing patterns, and services of the applicant meet the requirements of statute and rules;
- Evidence of insurance coverage or self-insurance; and
- A COPCN.⁹

III. Effect of Proposed Changes:

CS/SB 488 amends various statutes related to medical transportation services:

Section 1 amends s. 401.23, F.S., to define the term “advanced life support nontransport services” as the provision of advanced life support services in an emergency by a licensee until the arrival of an air ambulance or ambulance provided by another entity that is used for, or intended to be used for, land, air, or water transport of sick or injured persons requiring or likely to require medical attention during transport. For the purpose of this definition, “emergency” means a situation in which a person has a medical condition that manifests itself by acute symptoms of such severity including severe pain, that the absence of immediate medical attention could reasonably be expected to jeopardize the person’s health or result in serious impairment to bodily functions or serious dysfunction of any bodily organ or part including a response to a 911 call.

Section 2 amends s. 401.25, F.S., to exempt any governmental entity that provides first responders and that maintains fire rescue infrastructure from the requirement to obtain a COPCN or any other authorization from a county to provide ALSNS notwithstanding any general law, special act, or local government ordinance. In order to be exempt, the governmental entity must follow statutory requirements, DOH rules, and use a countywide common medical protocol if one exists and if the protocol does not restrict or limit the governmental entity’s ability to provide ALSNS. Additionally, the exemption from the requirement to obtain a COPCN does not apply in a county in which there is a countywide emergency medical services authority created

⁹ Section 401.25(2), F.S.

by a special act or a governmental entity that contracts with a private entity to provide fire rescue services.¹⁰ Any governmental entity intending to provide ALSNS without a COPCN must notify the county and municipalities in its proposed service area when it submits its application to the state. The bill specifies that any license issued under the COPCN exemption, as well as any related vehicle permits, must be for ALSNS only.

Sections 3-9 amend ss. 14.33, 125.01045, 166.0446, 252.515, 395.1027, 401.245, and 401.27, F.S., to conform cross references to the changes made by the bill.

Section 10 establishes an effective date of July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 488 may have an indeterminate positive fiscal impact on governmental entities that are able to provide ALSNS services without obtaining a COPCN from not being required to proceed through the COPCN process.

The bill may have an indeterminate negative fiscal impact on local governments with entities that are exempt from the COPCN process from a reduction in fees collected related to COPCN applications.

¹⁰*Supra* note 1.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 401.23, 401.25, 14.33, 125.01045, 166.0446, 252.515, 395.1027, 401.245, and 401.27.

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 December 5, 2017:

The CS addresses multiple technical issues, specifies that the DOH may only issue a nontransport ALS license to entities applying to provide ALS without a COPCN as provided in the bill, and disallows use of the COPCN exemption in counties where there is a governmental entity that contracts with a private entity to provide fire rescue services.

- B. **Amendments:**

None.

By Senator Grimsley

26-00482A-18

2018488__

1 A bill to be entitled
2 An act relating to emergency medical services;
3 amending s. 401.23, F.S.; defining the terms "advanced
4 life support nontransport services" and "emergency";
5 amending s. 401.25, F.S.; exempting certain
6 governmental entities from the requirement to obtain a
7 certificate of public convenience and necessity to
8 provide certain emergency services under specified
9 conditions; providing applicability; amending ss.
10 14.33, 125.01045, 166.0446, 252.515, 395.1027,
11 401.245, and 401.27, F.S.; conforming cross-
12 references; providing an effective date.

13
14 Be It Enacted by the Legislature of the State of Florida:

15
16 Section 1. Present subsections (2) through (10) and (11)
17 through (21) of section 401.23, Florida Statutes, are
18 redesignated as subsections (3) through (11) and (13) through
19 (23), respectively, new subsections (2) and (12) are added to
20 that section, present subsection (19) of that section is
21 amended, and subsection (1) of that section is republished, to
22 read:

23 401.23 Definitions.—As used in this part, the term:

24 (1) "Advanced life support" means assessment or treatment
25 by a person qualified under this part through the use of
26 techniques such as endotracheal intubation, the administration
27 of drugs or intravenous fluids, telemetry, cardiac monitoring,
28 cardiac defibrillation, and other techniques described in the
29 EMT-Paramedic National Standard Curriculum or the National EMS

26-00482A-18

2018488__

30 Education Standards, pursuant to rules of the department.

31 (2) "Advanced life support nontransport services" means the
32 provision of services defined in subsection (1) in an emergency
33 by a licensee until the arrival of an air ambulance or ambulance
34 provided by another entity that is used for, or intended to be
35 used for, land or water transportation of sick or injured
36 persons requiring or likely to require medical attention during
37 transport.

38 (12) "Emergency" means a situation in which a person has a
39 medical condition that manifests itself by acute symptoms of
40 such severity, including severe pain, that the absence of
41 immediate medical attention could reasonably be expected to
42 jeopardize the person's health or result in serious impairment
43 to bodily functions or serious dysfunction of any bodily organ
44 or part. The term "emergency" includes a response to a 911 call.

45 (21) ~~(19)~~ "Physician" means a practitioner who is licensed
46 under ~~the provisions of~~ chapter 458 or chapter 459. For the
47 purpose of providing medical direction ~~"medical direction"~~ as
48 ~~defined in subsection (14)~~ for the treatment of patients
49 immediately prior to or during transportation to a United States
50 Department of Veterans Affairs medical facility, the term
51 ~~"physician"~~ also means a practitioner employed by the United
52 States Department of Veterans Affairs.

53 Section 2. Paragraph (d) of subsection (2) of section
54 401.25, Florida Statutes, is amended to read:

55 401.25 Licensure as a basic life support or an advanced
56 life support service.—

57 (2) The department shall issue a license for operation to
58 any applicant who complies with the following requirements:

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59 (d) The applicant has obtained a certificate of public
60 convenience and necessity from each county in which the
61 applicant will operate. However, notwithstanding, any general
62 law, special act, or ordinance of a local government to the
63 contrary, a governmental entity that maintains fire rescue
64 infrastructure and provides first responders as defined in s.
65 112.1815 is not required to obtain a certificate of public
66 convenience and necessity or any other authorization from a
67 county to provide advanced life support nontransport services if
68 the governmental entity meets the requirements of this chapter
69 and applicable department rules and uses a countywide common
70 medical protocol, if such a protocol is instituted.

71 1. In issuing the certificate of public convenience and
72 necessity, the governing body of each county shall consider the
73 recommendations of municipalities within its jurisdiction.

74 2. If a countywide common medical protocol restricts or
75 limits the ability of the governmental entity to provide
76 advanced life support nontransport services, the governmental
77 entity must meet only the requirements of this chapter and
78 applicable department rules to obtain its license.

79 3. A governmental entity intending to provide advanced life
80 support nontransport services without a certificate of public
81 convenience and necessity must notify the county and
82 municipalities in its proposed service area of its submission of
83 an application to the state.

84 4. The exception to the certificate of public convenience
85 and necessity requirement in this paragraph does not apply to a
86 county in which there is a countywide emergency medical services
87 authority created by special act.

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88 Section 3. Subsection (1) of section 14.33, Florida
89 Statutes, is amended to read:

90 14.33 Medal of Heroism.—

91 (1) The Governor may award a Medal of Heroism of
92 appropriate design, with ribbons and appurtenances, to a law
93 enforcement, correctional, or correctional probation officer, as
94 defined in s. 943.10(14); a firefighter, as defined in s.
95 112.191(1)(b); or an emergency medical technician, ~~as defined in~~
96 ~~s. 401.23(11)~~; or a paramedic, as defined in s. 401.23 ~~s.~~
97 ~~401.23(17)~~. A recipient must have distinguished himself or
98 herself conspicuously by gallantry and intrepidity, must have
99 risked his or her life deliberately above and beyond the call of
100 duty while performing duty in his or her respective position,
101 and must have engaged in hazardous or perilous activities to
102 preserve lives with the knowledge that such activities might
103 result in great personal harm.

104 Section 4. Subsection (1) of section 125.01045, Florida
105 Statutes, is amended to read:

106 125.01045 Prohibition of fees for first responder
107 services.—

108 (1) A county may not impose a fee or seek reimbursement for
109 any costs or expenses that may be incurred for services provided
110 by a first responder, including costs or expenses related to
111 personnel, supplies, motor vehicles, or equipment in response to
112 a motor vehicle accident, except for costs to contain or clean
113 up hazardous materials in quantities reportable to the Florida
114 State Warning Point at the Division of Emergency Management, and
115 costs for transportation and treatment provided by ambulance
116 services as defined in licensed pursuant to s. 401.23(5) and (6)

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117 ~~401.23(4) and (5).~~

118 Section 5. Subsection (1) of section 166.0446, Florida
119 Statutes, is amended to read:

120 166.0446 Prohibition of fees for first responder services.—

121 (1) A municipality may not impose a fee or seek
122 reimbursement for any costs or expenses that may be incurred for
123 services provided by a first responder, including costs or
124 expenses related to personnel, supplies, motor vehicles, or
125 equipment in response to a motor vehicle accident, except for
126 costs to contain or clean up hazardous materials in quantities
127 reportable to the Florida State Warning Point at the Division of
128 Emergency Management, and costs for transportation and treatment
129 provided by ambulance services as defined in licensed pursuant
130 ~~to s. 401.23(5) and (6) 401.23(4) and (5).~~

131 Section 6. Paragraph (a) of subsection (3) of section
132 252.515, Florida Statutes, is amended to read:

133 252.515 Postdisaster Relief Assistance Act; immunity from
134 civil liability.—

135 (3) As used in this section, the term:

136 (a) "Emergency first responder" means:

- 137 1. A physician licensed under chapter 458.
- 138 2. An osteopathic physician licensed under chapter 459.
- 139 3. A chiropractic physician licensed under chapter 460.
- 140 4. A podiatric physician licensed under chapter 461.
- 141 5. A dentist licensed under chapter 466.
- 142 6. An advanced registered nurse practitioner certified
143 under s. 464.012.

144 7. A physician assistant licensed under s. 458.347 or s.
145 459.022.

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146 8. A worker employed by a public or private hospital in the
147 state.

148 9. A paramedic as defined in s. 401.23 ~~s. 401.23(17)~~.

149 10. An emergency medical technician as defined in s. 401.23
150 ~~s. 401.23(11)~~.

151 11. A firefighter as defined in s. 633.102.

152 12. A law enforcement officer as defined in s. 943.10.

153 13. A member of the Florida National Guard.

154 14. Any other personnel designated as emergency personnel
155 by the Governor pursuant to a declared emergency.

156 Section 7. Subsection (5) of section 395.1027, Florida
157 Statutes, is amended to read:

158 395.1027 Regional poison control centers.—

159 (5) By October 1, 1999, each regional poison control center
160 shall develop a prehospital emergency dispatch protocol with
161 each licensee, as defined in s. 401.23, ~~by s. 401.23(13)~~ in the
162 geographic area covered by the regional poison control center.
163 The prehospital emergency dispatch protocol shall be developed
164 by each licensee's medical director in conjunction with the
165 designated regional poison control center responsible for the
166 geographic area in which the licensee operates. The protocol
167 shall define toxic substances and describe the procedure by
168 which the designated regional poison control center may be
169 consulted by the licensee. If a call is transferred to the
170 designated regional poison control center in accordance with the
171 protocol established under this section and s. 401.268, the
172 designated regional poison control center shall assume
173 responsibility and liability for the call.

174 Section 8. Paragraph (b) of subsection (2) of section

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175 401.245, Florida Statutes, is amended to read:

176 401.245 Emergency Medical Services Advisory Council.—

177 (2)

178 (b) Representation on the Emergency Medical Services
179 Advisory Council shall include: two licensed physicians who are
180 “medical directors” as defined in s. 401.23 ~~s. 401.23(15)~~ or
181 whose medical practice is closely related to emergency medical
182 services; two emergency medical service administrators, one of
183 whom is employed by a fire service; two certified paramedics,
184 one of whom is employed by a fire service; two certified
185 emergency medical technicians, one of whom is employed by a fire
186 service; one emergency medical services educator; one emergency
187 nurse; one hospital administrator; one representative of air
188 ambulance services; one representative of a commercial ambulance
189 operator; and two laypersons who are in no way connected with
190 emergency medical services, one of whom is a representative of
191 the elderly. Ex officio members of the advisory council from
192 state agencies shall include, but shall not be limited to,
193 representatives from the Department of Education, the Department
194 of Management Services, the State Fire Marshal, the Department
195 of Highway Safety and Motor Vehicles, the Department of
196 Transportation, and the Division of Emergency Management.

197 Section 9. Paragraph (a) of subsection (2) of section
198 401.27, Florida Statutes, is amended to read:

199 401.27 Personnel; standards and certification.—

200 (2) The department shall establish by rule educational and
201 training criteria and examinations for the certification and
202 recertification of emergency medical technicians and paramedics.
203 Such rules must require, but need not be limited to:

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204 (a) For emergency medical technicians, proficiency in
205 techniques of basic life support as defined in s. 401.23
206 ~~identified in s. 401.23(7)~~ and in rules of the department.

207 Section 10. This act shall take effect July 1, 2018.



510350

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
12/05/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 463.006, Florida Statutes, is amended to
read:

463.006 Licensure and certification by examination.—

(1) Any person desiring to be a licensed practitioner
pursuant to this chapter must ~~shall~~ apply to the department and
must submit proof to ~~take the licensure and certification~~



510350

11 ~~examinations. the department that she or he shall examine each~~
12 ~~applicant who the board determines has:~~

13 (a) Has completed the application forms as required by the
14 board, remitted an application fee for certification not to
15 exceed \$250, remitted an examination fee for certification not
16 to exceed \$250, and remitted an examination fee for licensure
17 not to exceed \$325, all as set by the board.

18 (b) ~~Submitted proof satisfactory to the department that she~~
19 ~~or he:~~

20 ~~1.~~ Is at least 18 years of age.

21 (c) ~~2.~~ Has graduated from an accredited school or college of
22 optometry approved by rule of the board.

23 (d) ~~3.~~ Is of good moral character.

24 (e) ~~4.~~ Has successfully completed at least 110 hours of
25 transcript-quality coursework and clinical training in general
26 and ocular pharmacology as determined by the board, at an
27 institution that:

28 ~~1.a.~~ Has facilities for both didactic and clinical
29 instructions in pharmacology; and

30 ~~2.b.~~ Is accredited by a regional or professional
31 accrediting organization that is recognized and approved by the
32 Commission on Recognition of Postsecondary Accreditation or the
33 United States Department of Education.

34 (f) ~~5.~~ Has completed at least 1 year of supervised
35 experience in differential diagnosis of eye disease or disorders
36 as part of the optometric training or in a clinical setting as
37 part of the optometric experience.

38 (2) The board shall approve a licensure examination
39 consisting shall consist of the appropriate subjects and



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40 including applicable state laws and rules and general and ocular
41 pharmacology with emphasis on the use and side effects of ocular
42 pharmaceutical agents. The board may by rule substitute a
43 national examination as part or all of the examination and,
44 notwithstanding chapter 456, may by rule offer a practical
45 examination in addition to a the written examination.

46 (3) Each applicant who submits proof satisfactory to the
47 department that he or she has met the requirements of subsection
48 (1), who successfully passes the licensure examination within 3
49 years before the date of application or after the submission of
50 an application, and who otherwise meets the requirements of this
51 chapter is entitled to be licensed as a practitioner and to be
52 certified to administer and prescribe ocular pharmaceutical
53 agents in the diagnosis and treatment of ocular conditions.

54 Section 2. Subsection (3) of section 463.0057, Florida
55 Statutes, is amended to read:

56 463.0057 Optometric faculty certificate.—

57 (3) The holder of a faculty certificate may engage in the
58 practice of optometry as permitted by this section but may not
59 administer or prescribe topical ocular pharmaceutical agents
60 unless the certificateholder has satisfied the requirements of
61 s. 463.006(1)(e) and (f) ~~s. 463.006(1)(b)4. and 5.~~ If a
62 certificateholder wishes to administer or prescribe oral ocular
63 pharmaceutical agents, the certificateholder must also satisfy
64 the requirements of s. 463.0055(1)(b).

65 Section 3. This act shall take effect July 1, 2018.

66
67 ===== T I T L E A M E N D M E N T =====

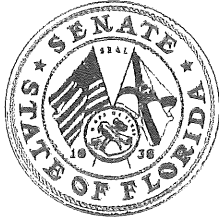
68 And the title is amended as follows:



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69 Delete everything before the enacting clause
70 and insert:

71 A bill to be entitled
72 An act relating to optometry; amending s. 463.006,
73 F.S.; requiring an applicant for licensure as an
74 optometrist to submit proof to the Department of
75 Health that she or he meets certain requirements;
76 removing a requirement that the department examine an
77 applicant who meets specified requirements for
78 licensure and certification; requiring the Board of
79 Optometry to approve a licensure examination that
80 meets certain requirements; clarifying that the board
81 may offer a practical examination in addition to a
82 written examination under certain circumstances;
83 providing that an applicant must pass the licensure
84 examination within a specified timeframe as a
85 condition of licensure as an optometrist and
86 certification to administer and prescribe ocular
87 pharmaceutical agents; amending s. 463.0057, F.S.;
88 conforming a cross-reference; providing an effective
89 date.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR JACK LATVALA

16th District

COMMITTEES:
Appropriations, *Chair*
Appropriations Subcommittee on the
Environment and Natural Resources
Commerce and Tourism
Environmental Preservation and Conservation
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission,
Alternating Chair

November 7, 2017

The Honorable Dana Young
316 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Young,

Per our conversation, I respectfully request you place Senate Bill 520, relating to Optometrists, on your Health Policy agenda at your earliest convenience.

Should you have any questions or concerns regarding this legislation, please do not hesitate to contact me personally.

Sincerely,

A handwritten signature in black ink that reads "Jack Latvala".

Jack Latvala
Senator, 16th District

cc: Sandra Stovall, Staff Director

REPLY TO:

- 26133 U.S. Highway 19 North, Suite 201, Clearwater, Florida 33763 (727) 793-2797 FAX: (888) 263-7847
- 412 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5016

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

12/5/17

Meeting Date

520

Bill Number (if applicable)

510350

Amendment Barcode (if applicable)

Topic OPTOMETRY LICENSURE

Name DAVID RAMBA

Job Title RAMBA LAW GROUP

Address 120 S. MONROE ST.

Street

Phone 850-727-7087

TALLAHASSEE

City

FL

State

32311

Zip

Email

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

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

Representing FLORIDA OPTOMETRIC ASSOC.

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

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

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

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.)

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

BILL: CS/SB 520

INTRODUCER: Health Policy Committee and Senator Latvala and others

SUBJECT: Optometrists

DATE: December 5, 2017 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	Fav/CS
2.	_____	_____	AP	_____
3.	_____	_____	RC	_____

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 520 eliminates the requirement in current law that any person desiring an optometry license in Florida must file an application for licensure/certification and then must take and successfully pass the licensure exam. Under the bill, an applicant may submit an application and proof of having successfully passed the licensure examination within 3 years before the date of the application or after the submission of the application. This process applies to new licensees to the practice of optometry as well as to persons who are licensed to practice optometry in another state and desire licensure in Florida.

The bill also requires the Board of Optometry (board) to approve the licensure examination and clarifies that the board may, by rule, offer a practical examination in addition to a written examination.

The bill takes effect July 1, 2018.

II. Present Situation:

The Practice of Optometry

The Department of Health (DOH) is responsible for the regulation of optometrists in Florida for the preservation of the health, safety, and welfare of the public. The Board of Optometry was

established to ensure that every person engaged in the practice of optometry meets minimum requirements for safe practice.¹

Optometry is the diagnosis of conditions of the human eye and its appendages.² The practice of optometry includes the employment of any objective or subjective means or methods to assist in the diagnosis of conditions of the human eyes and its appendages, including:

- The administration of ocular pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and
- The prescribing and use of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including ocular pharmaceutical agents,³ for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.⁴

Licensed optometrists who are not certified, may use only topical anesthetics for the sole purpose of glaucoma examinations, but are otherwise prohibited from administering or prescribing ocular pharmaceutical agents.⁵ A licensed optometrist is required to post in his or her practice location a sign which states, “I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe ocular pharmaceutical agents.”⁶

All optometrists initially licensed after July 1, 1993,⁷ are now required to be certified; and may administer and prescribe ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques.⁸

Licensure and Certification

Pursuant to ch. 456, F.S., the general provisions applicable to all professions regulated by the DOH, in the Division of Medical Quality Assurance, the DOH must provide for the development, preparation, administration, scoring, score reporting, and evaluation of all examinations, in consultation with the appropriate board. For each examination developed by the DOH or a contract vendor, the board must specify by rule:

- The general areas to be covered by each examination;
- The relative weight to be assigned in grading each area tested; and

¹ Section 463.001, F.S., and The Department of Health, *Florida Board of Optometry*, available at: <http://floridasoptometry.gov/>, (last visited Nov. 8, 2017).

² Section 463.002(10), F.S. “Appendages” means the eyelids, the eyebrows, the conjunctiva, and the lacrimal apparatus.

³ “Ocular pharmaceutical agent” means a pharmaceutical agent that is administered topically or orally for the diagnosis or treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. See s. 463.002(5), F.S.

⁴ Section 463.002(7), F.S.

⁵ See s. 463.0055(1)(a), F.S.

⁶ Section 463.002(3), F.S.

⁷ Section 463.002(3), F.S. During the 1986 Legislation, ch 463, F.S., was amended to require that anyone applying for an optometrist license after July 1, 1993, become a Certified Optometrist. The amendment required all applicants after that date to meet additional education and examination requirements. See also the Department of Health, Board of Optometry, *Licensing and Registration*, available at <http://floridasoptometry.gov/licensing/>, (last visited Nov. 8, 2017).

⁸ Sections 463.002(4) and 463.0055, F.S.

- The score necessary to achieve a passing grade.⁹

However, neither the board, nor the DOH, may administer a state-developed written examination if a national examination has been certified by the DOH.¹⁰ The board may administer a state-developed practical or clinical examination, if required by the applicable practice act, if all costs are paid by the candidate. If a national practical or clinical examination is available, and certified by the DOH, the board may administer the national examination.¹¹

Currently any person desiring to be a certified optometrist in Florida must apply to the DOH to take the licensure and certification examination(s).¹² The requirements for certification as an optometrist are:

- Submission of a completed application form;
- Submission of an application and examination fee;
- Be at least 18 years of age;
- Graduation from a school or college of optometry approved by the board;
- Provide proof of at least 110 hours of transcript quality course work and clinical training in general and ocular pharmacology;
- Have completed at least 1 year of supervised experience in differential diagnosis of eye disease or disorders as part of the optometric training or in a clinical setting as part of the optometric experience;
- Successfully pass all four parts of the Florida Licensure Examination, consisting of:
 - Part I – the Applied Basic Science (ABS) portion of the examination developed by the National Board of Examiners in Optometry (NBEO);
 - Part II – the Patient Assessment and Management (PAM) portion of the examination developed by the NBEO which includes an embedded Treatment and Management of Ocular Disease examination;
 - Part III – the Clinical Skills (CSE) portion of the examination developed by the NBEO; and
 - Part IV – a written examination on applicable Florida laws and rules governing the practice of optometry, and
- If the applicant is, or has ever been, licensed in another state, he or she must also submit a licensure verification from each state.¹³

An applicant who fails to achieve a passing score on Part I, Part II, Part III or Part IV of the licensure examination may retake any part. Reexamination is limited to an 18-month period from the date of the original failure. The board may grant an extension of 1 additional year to allow an additional retake based on a medical disability substantiated by documentation from the applicant's physician.¹⁴

⁹ Section 456.017(1)(a) and (b), F.S.

¹⁰ Section 456.017(1)(c)2., F.S.

¹¹ Section 456.017, F.S.

¹² Section 463.006(1), F.S.

¹³ The Department of Health, Board of Optometry, *Licensure Requirements*, available at: <http://floridasoptometry.gov/licensing/certified-optometrist/>, (last visited November 8, 2017).

¹⁴ Rule 64B13-4.002, F.A.C.

Florida schools of optometry, and several out of state colleges, include the 4-part examination in the school curriculum and spread the four parts over the course of 4 years of education and training required by the program.¹⁵

Prior to April 14, 2017, the DOH, Board of Optometry, had by rule¹⁶ accepted licensure applicants' passing scores on Part I, Part II, Part III and Part IV of the licensure examination that had been obtained within the 7 year period immediately preceding licensure application. This practice was challenged in 2016¹⁷ at the Division of Administrative hearing and the Administrative Law Judge found that the petitioners had demonstrated that the rule's look-back period for test scores was an invalid exercise of delegated authority in violation of section 120.52(8)(b) and (c); ". . . and that should this result be onerous, the answer [was] a legislative change."¹⁸ As a result of this decision graduating students applying for licensure in Florida were required to retake examinations they had previously taken and passed while in school or college; and all out-of-state applicants were required to retake the examination.¹⁹

Renewal of Licensure and Certification

A licensed optometrist must renew his or her license every 2 years. In order to do so the licensee must pay a renewal fee not to exceed \$300, and demonstrate his or her professional competence by completing 30 hours of continuing education during the preceding 2-year period before license renewal. Certified optometrists must also complete 30-hour continuing education during the preceding 2 years, but their hours must include 6 or more hours of approved transcript-quality coursework in ocular and systemic pharmacology and the diagnosis, treatment, and management of ocular and systemic conditions and diseases.²⁰

III. Effect of Proposed Changes:

CS/SB 520 amends s. 463.006, F.S., to eliminate the requirement that applicants for licensure must take, and successfully pass, the licensure examinations after an application for licensure/certification is submitted. The bill permits an applicant for licensure/certification to submit an application for licensure that includes proof of specific items, and to also submit proof that he or she has successfully passed all parts of the licensure/certification examination within 3 years prior to the date of application or after submission of the application. This allows graduates from a board approved, accredited school or college and some out-of-state practitioners, from taking the licensure/certification examination a second time if the applicant successfully passed the examination within the prior 3 years.

The bill requires the board to approve the licensure examination that meets certain requirements; and clarifies that the board may offer a practical examination in addition to a written examination.

¹⁵ See Department of Health, *Senate Bill 520 Analysis* (Oct, 12, 2017) (on file with the Senate Committee on Health Policy).

¹⁶ Rule 64B13-4.001, F.A.C.

¹⁷ See Department of Administrative Hearings, *Final Order, Yontz & Johnson, v. DOH*, Case No. 16-6663RX (April 14, 2017), available at <https://www.doah.state.fl.us/ROS/2016/16006663.pdf> (last visited Dec. 5, 2017).

¹⁸ Id. at page 42.

¹⁹ *Supra* note 15.

²⁰ Section 463.007, F.S.

The bill also amends s. 463.0057, F.S., to make a conforming cross-reference change.

The bill takes effect July 1, 2018.

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:

New licensees to the optometry profession, as well as some optometrists licensed in other states, seeking licensure/certification in Florida, may avoid the cost of retaking the required examinations if they successfully passed the examinations within 3 years prior to submitting an application. The estimated cost of the examination, not including travel and overnight accommodations to North Carolina, the only location Part III is given, is approximately \$2,500.²¹

C. Government Sector Impact:

The DOH might incur additional expenses in the development, preparation, administration, scoring, score reporting and evaluation of the examinations if the board elects to offer its own practical examination.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

²¹ *Supra* note 15.

VIII. Statutes Affected:

This bill substantially amends section 463.006, 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 December 5, 2017:

The original bill amended s. 463.006, F.S., to authorize an optometry student, attending a board approved, accredited school of optometry, to submit his or her application for licensure and certification during the 24 months preceding his or her graduation. The CS removes this language and permits a graduate from a board approved, accredited school or college, and certain out-of-state optometrists seeking licensure in Florida, to submit an application for licensure and proof that the applicant has passed all parts of the licensure examination within 3 years before the date of application or after the application submission. The CS also requires the board to approve the licensure examination.

- B. **Amendments:**

None.

By Senator Latvala

16-00380A-18

2018520__

1 A bill to be entitled
2 An act relating to optometrists; amending s. 463.006,
3 F.S.; revising the requirements that applicants must
4 meet in order to qualify to take optometric licensure
5 and certification examinations; clarifying
6 interpretation of the authority of the Board of
7 Optometry to offer a practical examination in addition
8 to a written examination; specifying that applicants
9 must graduate from an accredited school or college of
10 optometry in order to obtain a license and practice as
11 optometrists; providing an effective date.

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

14
15 Section 1. Section 463.006, Florida Statutes, is amended to
16 read:

17 463.006 Licensure and certification by examination.—

18 (1) Any person desiring to be a licensed practitioner
19 pursuant to this chapter must ~~shall~~ apply to the department to
20 take the licensure and certification examinations. The
21 department shall examine each applicant who the board determines
22 has:

23 (a) Completed the application forms as required by the
24 board, remitted an application fee for certification not to
25 exceed \$250, remitted an examination fee for certification not
26 to exceed \$250, and remitted an examination fee for licensure
27 not to exceed \$325, all as set by the board.

28 (b) Submitted proof satisfactory to the department that she
29 or he:

16-00380A-18

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30 1. Is at least 18 years of age.

31 2. Has graduated from an accredited school or college of
32 optometry approved by rule of the board, or is attending such a
33 school or college and expects to graduate within 24 months
34 following the date of application.

35 3. Is of good moral character.

36 4. Has successfully completed at least 110 hours of
37 transcript-quality coursework and clinical training in general
38 and ocular pharmacology as determined by the board, at an
39 institution that:

40 a. Has facilities for both didactic and clinical
41 instructions in pharmacology; and

42 b. Is accredited by a regional or professional accrediting
43 organization that is recognized and approved by the Commission
44 on Recognition of Postsecondary Accreditation or the United
45 States Department of Education.

46 5. Has completed at least 1 year of supervised experience
47 in differential diagnosis of eye disease or disorders as part of
48 the optometric training or in a clinical setting as part of the
49 optometric experience.

50 (2) The examination shall consist of the appropriate
51 subjects and include, ~~including~~ applicable state laws and rules
52 and general and ocular pharmacology with emphasis on the use and
53 side effects of ocular pharmaceutical agents. The board may by
54 rule substitute a national examination as part or all of the
55 examination and, notwithstanding any provision of chapter 456 to
56 the contrary, may by rule offer a practical examination in
57 addition to a ~~the~~ written examination.

58 (3) Each applicant who successfully passes the examination

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59 and otherwise meets the requirements of this chapter, provided
60 that such applicant has graduated from an accredited school or
61 college of optometry approved by rule of the board, is entitled
62 to be licensed as a practitioner and to be certified to
63 administer and prescribe ocular pharmaceutical agents in the
64 diagnosis and treatment of ocular conditions.

65 Section 2. This act shall take effect upon becoming a law.



The Florida Senate

Committee Agenda Request

To: Senator Dana D. Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: November 7, 2017

I respectfully request that **Senate Bill #622**, relating to Health Care Facility Regulation, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in cursive script that reads "Denise Grimsley".

Senator Denise Grimsley
Senate District 26

cc: Sandra Stovall, Staff Director
Celia Georgiades, Committee Administrative Assistant

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: SB 622

INTRODUCER: Senator Grimsley

SUBJECT: Health Care Facility Regulation

DATE: December 4, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Favorable
2.			AHS	
3.			AP	
4.			RC	

I. Summary:

SB 622 amends numerous provisions related to the regulation of health care facilities by the Agency for Health Care Administration (AHCA or agency). The bill’s provisions include, but are not limited to:

- Eliminating obsolete language and terms such as mobile surgical facility and provisions related to specialty definitions for rural hospitals.
- Eliminating the requirement that health care facility risk managers be licensed by the state.
- Amending various statutes related to home health agencies, nurse registries, assisted living facilities (ALF), and general licensing requirements.
- Exempting certain hospitals from volume requirements needed to provide Level I adult cardiovascular services (ACS).
- Specifying training that staff must have in hospitals providing ACS if the experience was not obtained in a hospital with a surgical center.
- Repealing the subscriber assistance program.
- Repealing state licensure of clinical laboratories in favor of deferring to federal requirements.
- Eliminating both statewide and district Ombudsman Committees.

II. Present Situation:

The AHCA is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, ALFs, and home health agencies. In total, the agency licenses, certifies, regulates or provides exemptions for more than 42,000 providers.¹

¹ See the Agency for Health Care Administration, *Division of Health Quality Assurance*, available at: <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited Nov. 29, 2017).

Generally applicable provisions of health care provider licensure are addressed in the Health Care Licensing Procedures Act in part II of ch. 408, F.S. Additional chapters or sections in the Florida Statutes provide specific licensure or regulatory requirements pertaining to health care providers in this state.²

Due to the many diverse issues within the bill, pertinent background is provided within the effect of proposed changes for the reader's convenience.

III. Effect of Proposed Changes:

SB 622 amends numerous statutes related to the AHCA.

Public Health Trust Facilities

Section 2 creates s. 154.13, F.S., to specify that any designated facility owned or operated by a public health trust and located within the boundaries of a municipality is under the exclusive jurisdiction of the county creating the public health trust and not within the municipality's jurisdiction. The Public Health Trust of Miami-Dade County is the only public health trust which owns/operates health care providers. Jackson Health System consists of three hospitals: Jackson Memorial, Jackson North Medical Center and Jackson South Community Hospital. These are the only hospitals owned by a public health trust, Public Health Trust of Miami-Dade County. According to the license information there is also a nursing home, Jackson Memorial Perdue Medical Center and five hospital-based clinical labs.³

Birth Centers

Section 16 amends s. 383.313, F.S., to require that all birthing centers that perform laboratory tests on their patients be federally certified by the Federal Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments and federal rules adopted thereunder. Currently, birthing centers are exempt from the requirement to be licensed as a clinical laboratory under part I of ch. 483, F.S.,⁴ if the birth center has no more than five physicians and the tests are conducted exclusively for the diagnosis and treatment of clients of the birth center.

Section 18 repeals s. 383.335, F.S., which provides obsolete exemptions to certain rules related to birth centers. Currently no providers meet these exemptions.⁵

Mobile Surgical Facilities

Sections 22, 23, 24, 27, 28, 60, and 123 amend ss. 395.001, 395.002, 395.003, 395.0161, 395.0163, 408.036, and 766.118, F.S., respectively, to repeal obsolete provisions related to mobile surgical facilities. No license has been issued for a mobile surgical facility and none are anticipated. The Florida Department of Corrections operates one hospital: Reception and

² See s. 408.802, F.S., for the health care provider types and applicable licensure statutes.

³ Agency for Health Care Administration, *Senate Bill 622 Analysis* (Nov. 15, 2017) (on file with the Senate Committee on Health Policy.)

⁴ Part I of ch. 483, F.S., is repealed in this bill.

⁵ Supra note 3

Medical Center Hospital in Lake Butler. The hospital does not offer surgical services directly to its inmates, but contracts with U.S. Medical Group, Inc., via its licensed ASC, Modular Freestanding Surgery Center. This Ambulatory Surgical Center has been licensed since September, 24, 2002, and is stationary on the premises of the correctional facility. A separate license type is not needed in order to meet the surgical needs of the inmate population.⁶

Alternate-Site Testing

Section 26 creates s. 395.0091, F.S., to define the term “alternate-site testing” to mean any laboratory testing done under the administrative control of a hospital, but performed out the of physical or administrative confines of the hospital’s central laboratory. This section also requires the AHCA, in consultation with the Board of Clinical Laboratory Personnel, to adopt rules for criteria for alternate-site testing. The bill establishes minimum criteria the rules must address and requires alternate-site testing locations to register when the associated hospital applies to renew its license. This change will keep the requirements in place for alternate-site testing after the repeal of provisions related to clinical laboratory state licensure.⁷

Deregulation of Risk Managers

Current law requires every hospital, ambulatory surgical center, and HMO providing direct services to employ a state licensed health care risk manager to oversee the facility’s risk management program. No other state requires licensure of risk managers. Other Florida licensed facilities such as nursing homes are not required to employ a licensed risk manager and can employ anyone meeting the facility’s qualifications for their risk manager positions.

The health care risk manager licensure requirements have multiple pathways, including being licensed as a health care professional such as a nurse, respiratory therapist, physical therapist or emergency medical technician. Physician assistants and other professions licensed by the Florida Department of Health may not qualify unless they also meet another pathway. There are no licensure examinations, no continuing education requirements, and no method for the agency to determine a licensee’s continued competency in health care risk management. Licensees are required to renew their license biennially. As there are no requalification requirements to renew a license, the process involves verification of contact information, employment, if applicable, and background screening status. Professional certification is available through the American Society for Healthcare Risk Management, but is not required for licensure.

The agency currently licenses 2,458 health care risk managers, of which only 602 (24.5 percent) report working in a licensed capacity for at least one hospital or ambulatory surgical center. A licensed health care risk manager may also appoint an unlicensed delegate to assist with risk management functions. On-the-job training is a common pathway to licensure. On average for the past 5 years, approximately 174 initial applications are received and 181 licensees fail to renew each year. Roughly 50 of the 1,200 applications (initial and renewal) reviewed each year are withdrawn from consideration because the applicant does not submit all of the required documentation.⁸

⁶ Supra note 3

⁷ Supra note 3

⁸ Supra note 3

Sections 29, 34, 93, and 116 amend ss. 395.0197, 395.10973, 458.307, and 641.55, F.S., respectively and **sections 32, 33, 35, and 36** repeal ss. 395.10971, 395.10972, 395.10974, and 395.10975, F.S., respectively, to eliminate the requirement that health care facility risk managers be licensed by the state. The bill continues to require risk managers and that risk managers demonstrate competence in specified areas, as determined by each health care facility. The bill eliminates all provisions related to licensure of risk managers by the AHCA, but continues to require the AHCA to develop a model risk management program for health care facilities that will satisfy the requirements of s. 395.0197, F.S.

Complaint Investigation Procedures

Section 30 repeals s. 395.1046, F.S., relating to the complaint investigation procedures for alleged violation of the emergency access to care provisions found in s. 395.1041, F.S. The state's emergency access to care provisions are similar to the federal Emergency Medical Treatment and Labor Act, commonly known as EMTALA.⁹ The agency enforces the emergency access to care requirements through the uniform complaint investigation procedure used for all license types and these complaints are given top priority. Section 395.1046, F.S., duplicates the complaint investigation procedures found in the general licensing provisions in part II of ch. 408, F.S. Also, s. 395.1046, F.S., provides confidentiality protections and a public records exemption for the results in the investigation report, which the agency proposes is an unnecessary level of confidentiality.¹⁰

AHCA Rules for Certain Healthcare Services

Section 31 amends s. 395.1055, F.S., to require the agency to adopt rules to ensure that all hospitals providing organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. The licensure requirement must include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards. The bill also requires the AHCA to mandate level 2 background screening for personnel of distinct part nursing units of hospitals.

Repealing Obsolete Provisions Relating to Rural Hospitals

Section 37 amends s. 395.602, F.S., relating to rural hospitals, to remove the definitions of "emergency care hospital," "essential access community hospital," "inactive rural hospital bed," and "rural primary care hospital." These definitions relate to obsolete rural hospital programs that are no longer available or applicable to rural hospitals. Hospitals are authorized to make changes to their bed inventory at will so there is no longer a need to maintain an inventory of inactive rural hospital beds for CON purposes.¹¹ Additionally, this section amends the definition

⁹ EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272. Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the emergency department of a hospital and request examination or treatment for an emergency medical condition, regardless of ability to pay. The statute further provides that, if a hospital finds that such an individual has an emergency medical condition, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility. See the CMS.gov website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html> (last visited Dec. 1, 2017).

¹⁰ Supra note 3

¹¹ Supra note 3

of “rural hospital” to limit the number of beds to 175 that a hospital classified as a sole community hospital under 42 C.F.R. s. 412.92 may have in order to be considered a rural hospital. Current law classifies a sole community hospital as a rural hospital regardless of the number of beds.¹²

Section 38 amends s. 395.603, F.S., to remove provisions relating to the deactivation of general hospital beds in order to seek licensure for programs that are now obsolete.

Section 39 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.

Section 40 repeals s. 395.605, F.S., relating to licensing emergency care hospitals which is now an obsolete program.

Hospital Annual Assessments

Sections 41 and 64 amend ss. 395.701 and 408.20, F.S., relating to hospital assessments on inpatient and outpatient services. Current law excludes hospitals operated by the agency or the DOC. The bill expands the exclusion to any hospital operated by a state agency, to specifically exclude hospitals operated by the Department of Children and Families.¹³

Nursing Homes

Section 43 amends s. 400.0625, F.S., to strike language allowing nursing homes to accept clinical laboratory tests performed by a clinical laboratory prior to admission in lieu of routine examinations and any clinical laboratory tests ordered by a physician as required upon admission. This section also conforms provisions to the repeal of part I of ch. 483, F.S.

Section 44 amends s. 400.191, F.S., to require the AHCA to post nursing home survey and deficiency information that is older than 30 months in its nursing home guide.

Home Health Agencies

Home health agencies are health care providers that provide skilled services (by nurses, therapists, and social workers) and/or unskilled services (by home health aides, certified nursing assistants, homemaker, and companions) to patients in their homes. A home health agency may also provide staffing to health care facilities on a temporary basis.¹⁴

Section 45 amends s. 400.464, F.S., to require that any license issued for a home health agency on or after July 1, 2018, must specify the services that the home health agency is authorized to perform. Any advertising or provision of services by the home health agency that the home health agency is not licensed to perform constitutes unlicensed activity. The bill eliminates a 10-day grace period for the cessation of unlicensed activity after receiving notification of such

¹² Currently, no rural hospital has over 100 beds. See Florida Health Finder list of rural hospitals, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx>, (last visited on Dec. 1, 2017).

¹³ Supra note 3.

¹⁴ Home Health Agencies, AHCA webpage, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Home_Care/HHA/index.shtml, (last visited on Nov. 29, 2017).

from the AHCA and ties penalties for unlicensed activity to s. 408.812, F.S.¹⁵ The bill also authorizes a voluntary process for applying for a certificate of exemption from licensure for a person providing home health services who is exempt from licensure as a home health agency. The agency may charge a fee of \$100 or the actual cost of processing this certificate. The certificate of exemption is valid for up to 2 years.

Section 46 amends s. 400.471, F.S., to require application for a change of ownership or for the addition of skilled services. Applicants for license renewal no longer need to provide volume data. Under the bill, evidence of contingency funding refers to the general licensing provisions in part II of ch. 408, F.S., to eliminate an inconsistency between the two chapters. Under current law, a home health agency that is not Medicare or Medicaid certified and does not provide skilled care is exempt from providing proof of accreditation. This bill provides the exemption only if the home health agency does not provide skilled care. The bill further clarifies that the accrediting organization must be recognized by the agency, the survey must demonstrate compliance with Florida laws pertaining to home health agencies, and must be continuously maintained.

Sections 46 and 47 amend ss. 400.471 and 400.474, F.S., respectively, to clarify that a licensed home health agency must provide the services specified in the written agreement with the patient except in emergency situations that are beyond the provider's control that make it impossible to provide the services.

Section 48 amends s. 400.476, F.S., to require a home health agency that provides skilled nursing care to have a director of nursing. Current law exempts a home health agency from this requirement if it is Medicare or Medicaid certified or provides only physical, occupational, or speech therapy. This exemption is repealed.

Section 49 amends s. 400.484, F.S., renaming deficiencies as violations with respect to providing care by home health agencies and tying these violations to the general licensing provisions for health care facilities in part II of ch. 408, F.S.

Nurse Registries

As of October 1, 2017, there were 593 nurse registries licensed by the agency responsible for securing health-care-related contracts for private duty (in home) or health care facility staffing services by independently contracted caregivers within Florida.

In accordance with s. 400.506(5)(a), F.S., the continued operation of an unlicensed nurse registry for more than 10 days after agency notification is considered a second degree misdemeanor. Each day of continued non-compliance is considered a separate offense, with each offense carrying the potential for imprisonment of up to 60 days. In addition to the criminal actions, s. 400.506(5)(b), F.S., authorizes the agency to impose a \$500 fine for each day of continued non-compliance. While it does not make unlicensed activity a criminal offense, the Health Care Licensing Procedures Act of Chapter 408, Part II, F.S., prevails over s. 400.506, F.S., and

¹⁵ Section 408.812, F.S., prohibits unlicensed activity and provides penalties for violations including fines of up to \$1,000 a day, injunctive relief, and potential application of licensure violations as if the operator were licensed.

authorizes the agency to impose a \$1000.00 per day fine for each day of continued operation after agency notification.

Agency records show that 37 complaints alleging nurse registry unlicensed activity were filed between January 1, 2012, and present. Upon investigation, 11 of the complaints were substantiated. Of the 11 substantiated complaints, the agency imposed an administrative fine of \$46,000 for one unlicensed nurse registry who failed to discontinue operations after notification.

Nurse registries are not eligible for participation in the Medicare program and are only authorized to participate in Florida Medicaid through the Long Term Care Waiver program. Current s. 400.506, F.S., specifically prohibits licensed nurse registries who bill Florida Medicaid or the Medicare program from giving remuneration to certain named parties who are involved in the discharge of patients from health care facilities such as hospitals and nursing homes from which the registry receives referrals. Likewise they are prohibited from giving remuneration to physicians, physicians' office staff members, and immediate family members of physicians if the nurse registry received a referral from the physician or his or her office within the previous 12 months.¹⁶

Section 51 amends s. 400.506, F.S., to eliminate a 10-day grace period for the cessation of unlicensed activity after receiving notification of such from the AHCA and ties penalties for unlicensed activity to s. 408.812, F.S.¹⁷ In addition, the bill removes the prohibitions on a nurse registry providing remuneration to a case manager, discharge planner, facility based staff member, third party vendor, physician, member of the physician's office staff, or an immediate family member of a physician for referrals. Current law exempts nurse registries from this prohibition if they do not bill Medicare or Medicaid or share a controlling interest with any entity that bills Medicare or Medicaid. In addition to s. 400.506, F.S., s. 817.505(1)(a), F.S., makes it unlawful for any health care provider or health care facility, including nurse registries, to "offer or pay a commission, benefit, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement whatsoever, to induce the referral of a patient or patronage to or from a health care provider or health care facility."¹⁸

Hospices

Section 52 amends s. 400.606, F.S., to eliminate the requirement that applicants for hospice licensure that are existing health care providers submit a profit-loss statement and the most recent licensure inspection report. The requirement to provide a profit-loss statement is duplicative of general health care licensing statutes that require uniform proof of financial ability to operate and the requirement to provide an inspection report is unnecessary since all inspection reports are available to the public online.¹⁹

Home Medical Equipment Providers

Section 53 amends s. 400.925, F.S., to make technical clarifying changes to the definition of home medical equipment.

¹⁶ Supra note 3

¹⁷ Supra note 3

¹⁸ Supra note 3

¹⁹ Supra note 3

Section 54 amends s. 400.931, F.S., to require a licensed home medical equipment provider to notify the AHCA of a change in the general manager within the timeframes established in part II of ch. 408, F.S., which is 21 days, rather than the 45-day timeframe provided in this section of law.

Health Care Service Pools

Section 56 amends s. 400.980, F.S., to require changes of information contained on the original registration application to be submitted to the agency within the timeframes established in part II of ch. 408, F.S., rather than 14 days prior to the change as required in this section of law.

Health Care Clinic Exemptions

Section 58 amends s. 400.9935, F.S., to make certificates of exemption from licensure valid for up to 2 years. Currently, such exemptions are valid indefinitely. This change will improve the integrity of the exemption process.²⁰

Adult Cardiovascular Services

Hospitals are regulated by the AHCA under ch. 395, F.S., and the general licensure provisions of part II of ch. 408, F.S. Hospitals are subject to the certificate of need (CON) provisions in part I of ch. 408, F.S. A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.²¹

Adult cardiovascular services (ACS), including percutaneous coronary intervention (PCI), were previously regulated through the CON program.²² However, in 2004, the Legislature established a licensure process for adult interventional cardiology services (the predecessor terminology for ACS), dependent upon rulemaking, in lieu of the CON procedure.²³ Among other things, that law required the rules to establish two hospital program licensure levels: a Level I program authorizing the performance of adult primary PCI for emergency patients without onsite cardiac surgery, and a Level II program authorizing the performance of PCI with onsite cardiac surgery.²⁴ Additionally the rules must require compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient-selection criteria to ensure quality and safety.²⁵ Current law requires that a hospital seeking a Level I program must demonstrate that it has, in the most recent 12-month period, provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or discharged

²⁰ Supra note 3

²¹ Section 408.032(3), F.S.

²² See s. 408.036(3)(m) and (n), F.S., allowing for an exemption from the full review process for certain adult open-heart services and PCI services.

²³ Chapter 2004-383, s. 7, Laws of Fla.

²⁴ Level I and Level II ACS programs may also perform adult diagnostic cardiac catheterization in accordance with Rule 59A-3.2085(13), F.A.C. Adult diagnostic cardiac catheterization involves the insertion of a catheter into one or more heart chambers for the purpose of diagnosing cardiovascular diseases.

²⁵ See s. 408.0361(3), F.S.

at least 300 patients with the principal diagnosis of ischemic heart disease and has a transfer agreement with a Level II hospital within 60 minutes transfer time.

The AHCA adopted rules for Level I ACS²⁶ and Level II ACS.²⁷ Staffing rules for both levels require the nursing and technical catheterization laboratory staff to meet the following:

- Be experienced in handling acutely ill patients requiring intervention or balloon pump;
- Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II ACS program;²⁸
- Be skilled in all aspects of interventional cardiology equipment; and
- Participate in a 24-hour-per-day, 365 day-per-year call schedule;

One of the authoritative sources referenced in the AHCA's rulemaking is The American College of Cardiology/American Heart Association Task Force on Practice Guidelines' report: ACC/AHA/SCAI 2005 Guideline Update for PCI.²⁹ Table 15 in that report provides criteria for the performance of primary PCI at hospitals without onsite cardiac surgery. It states:

The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center.

In 2014, the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., issued the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup.³⁰ That report acknowledged advances and best practices in PCI performed in hospitals without onsite surgery. Table IV in that report addresses personnel requirements for PCI programs without onsite surgery. It recommends the program have experienced nursing and technical laboratory staff with training in interventional laboratories. The report does not reference a requirement that the training or experience should occur in a dedicated interventional laboratory at a surgical center.

²⁶ Rule 59A-3.2085(16), F.A.C.

²⁷ Rule 59A-3.2085(17), F.A.C.

²⁸ The standard in the CON exemption in s. 408.036(3)(n), F.S., for providing PCI in a hospital without an approved adult open-heart-surgery program required previous experience in dedicated interventional laboratories or surgical centers.

²⁹ Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. *ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)*. the Society for Cardiovascular Angiography and Interventions (2005), available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwizrYy2zubKAhUBfSYKHafZCiAQFggvMAI&url=http%3A%2Fwww.scai.org%2Fasset.axd%3Fid%3Da1d96b40-b6c7-42e7-9b71-1090e581b58c%26t%3D634128854999430000&usq=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw (last visited Nov. 29, 2017).

³⁰ Gregory J. Dehmer, et.al, available at <http://circ.ahajournals.org/content/129/24/2610.full.pdf+html> (last visited Nov. 29, 2017).

As of October 31, 2017, there are 56 Florida hospitals providing Level I ACS services and 79 Florida hospitals providing Level II ACS services.³¹

Section 61 amends s. 408.0361, F.S., to exempt a hospital located more than 100 road miles from the closest Level II ACS from the requirement to meet ischemic heart disease diagnosis volume requirements if the hospital demonstrates that it has, for the most recent 12-month period as reported to the agency, provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations or that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease. This change would allow Lower Keys Medical Center to become a Level I provider.³²

The bill also requires AHCA licensure rules for hospitals providing ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring PCI in dedicated cardiac interventional laboratories or surgical centers. Currently, pursuant to AHCA rules, the experience must have been acquired in a hospital with a surgical center. The bill states that, if a staff member's previous experience was in a dedicated cardiac interventional laboratory at a hospital that did not have an approved adult open-heart-surgery program, the laboratory must meet the following criteria in order for the staff member's experience to qualify. The laboratory must have:

- Had an annual volume of 500 or more PCI procedures;
- Achieved a demonstrated success rate of 95 percent or higher for PCI;
- Experienced a complication rate of less than 5 percent for PCI; and
- Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

Subscriber Assistance Program

The subscriber assistance panel (SAP) was created in 1985 to assist members of managed care entities whose grievances or appeals were not satisfactorily resolved by the managed care entity upon exhaustion of the managed care entity's internal grievance and appeal process. Under the federal Patient Protection and Affordable Care Act (PPACA),³³ managed care entities were given an option to either comply with the state's external review requirement or opt-out and participate in the federal external review program. The majority of health plans in Florida elected to use the federal program and the SAP program experienced a significant decrease in the number of cases being reviewed by the panel.³⁴

³¹ See The AHCA FloridaHealthFinder.gov available at <http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx>, (last visited Nov. 29, 2017).

³² Id.

³³ Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law No. 111-152 (Mar. 30, 2010).

³⁴ According to the agency, between FY 2011-2012 and FY 2012-2013, when the majority of plans opted to use the federal external review program, the number of cases received by the SAP dropped from 415 to 213. The number of cases heard by the SAP dropped from 74 to 17. There has been an uptick in both number of cases received by the subscriber assistance program and the number of cases heard by the panel for FY 2014-2015 and FY 2015-2016 however FY 2016-2017 showed a decline in the number of cases received and heard from 350 to 253 and 53 to 28, respectively. The predominant outcome of the cases in FY 2016-2017 was a determination of non-jurisdiction (165), followed by submission of an incomplete application (24) and resolved prior to panel hearing (26). See the chart prepared by the agency for activity since FY 2009-2010 at supra note 1.

The SAP is currently available to members of managed care entities with coverage by: Statewide Medicaid Managed Care, Healthy Kids, Prepaid Health Clinics, or grandfathered policies³⁵ that have not elected to have all of their health insurance policies subject to an external review process by independent review organization(s). Medicaid recipients in managed care can file for an external review through a Medicaid Fair Hearing and members with grandfathered commercial policies may appeal through independent review organizations.³⁶

Repeal of the SAP eliminates this program as an external appeal option for members in Healthy Kids and Prepaid Health Clinics, although according to the agency, no Prepaid Health Clinic members have used the SAP. At this time, these members do not have another avenue in which to file an external appeal.³⁷

Section 65 of the bill repeals s. 408.7056, F.S., relating to the subscriber assistance program.

General Licensing Provisions

Section 67 amends s. 408.803, F.S., to add a definition of “relative.” This addition is to clarify the meaning of the term when used in the newly created s. 408.810(1), F.S., (see Section 70, below).

Section 68 amends s. 408.806, F.S., to authorize a licensee that holds a license for multiple providers licensed by the agency to request alignment of all license expiration dates. In order to accomplish this, the agency is authorized to issue a license for an abbreviated licensure period with a prorated licensure fee.

Section 69 amends s. 408.809, F.S., to apply background screening provisions to all controlling interests in a health care facility. Current law only requires background screening of controlling interests if the AHCA has reason to believe that such a person has been convicted of a prohibited offense. The bill also requires background screening for contractors with a licensee who work for 20 hours or more per week and have access to client funds, personal property, or living areas.

Section 70 amends s. 408.810, F.S., to exempt an applicant for a change of ownership from submitting proof of financial ability to operate if the provider has been licensed for at least 5 years and the change is the result of a corporate reorganization under which the controlling interest is unchanged or solely due to the death of a controlling interest, and the surviving controlling interest continue to hold at least 51 percent of the ownership.

The agency is authorized to adopt rules to address the circumstances under which a controlling interest, an administrator, an employee, a contractor, or a representative thereof who is not a relative of the patient or client may act as a legal representative, agent, health care surrogate,

³⁵ A grandfathered health plan is a plan that existed on March 23, 2010, the date that the PPACA was enacted, and that at least one person had been continuously covered for 1 year. Plans or policies may lose their “grandfathered” status if they make certain significant changes that reduce benefits or increase costs to consumers. See Healthcare.gov, *Grandfathered Health Plans*, <https://www.healthcare.gov/glossary/grandfathered-health-plan/> (last visited Nov. 28, 2017).

³⁶ Supra note 3.

³⁷ *Id.*

power of attorney, or guardian of a patient or client. According to the agency, licensure regulations are currently inconsistent in this area. Due to the vulnerability of persons receiving health or custodial care, allowing the paid caregiver to control finances or health care decisions of the patient can result in exploitation or abuse. In some cases, the facility has a surety bond, but this is not required for all provider types.³⁸

The bill also requires that the licensee must ensure that no person holds any ownership interest who has a disqualifying offense³⁹ or who holds any ownership interest in a provider that had a license revoke or application denied. This provision does not apply to shareholders in a publicly traded corporation.

Section 71 amends s. 408.812, F.S., relating to unlicensed activity to pronounce that unlicensed activity constitutes abuse and neglect, as defined in s. 415.102, F.S.⁴⁰ The bill removes the requirement that a person or entity must apply for a license after receiving notification from the agency that the person or entity is engaging in unlicensed activity. If a controlling interest or licensee has more than one provider and fails to license all providers that require licensure, the agency may impose a fine, regardless of correction, as one of the authorized sanctions.

Background Screening

Sections 74 and 87 amend ss. 409.907 and 435.04, F.S., respectively, to move certain disqualifying offenses from the Medicaid requirements into background screening standards. This move allows Medicaid applicants to apply for an exemption to a disqualifying offense in the same manner as other persons required to be screened under these provisions.⁴¹ The bill also provides more specificity as to which offenses are disqualifying.

Section 87 also amends s. 435.04, F.S., to disqualify persons from employment as a health care worker who have been arrested for and are awaiting final disposition of an offense related to domestic violence. This change conforms to the language used in subsection (2) disqualifying persons from employment for all other enumerated offenses.

Assisted Living Facilities

ALFs provide full-time living arrangements in the least restrictive and most home-like setting. Facilities can include individual apartments or rooms that a resident has alone or shares with another person. These facilities can also range in size from one resident to several hundred residents.

The basic services provided by an ALF include, but are not limited to:

- Housing, nutritional meals, and special diets;

³⁸ Supra note 1.

³⁹ Pursuant to s. 408.809, F.S.

⁴⁰ In summary, s. 415.102, F.S., defines “abuse” as any willful act or threatened act by a relative, caregiver, or household member which causes or is likely to cause significant impairment to a vulnerable adult’s physical, mental, or emotional health; and that abuse includes acts and omissions. “Neglect” is defined as the failure or omission on the part of the caregiver or vulnerable adult to provide the care, supervision, and services necessary to maintain the physical and mental health of the vulnerable adult. Refer to s. 415.102(16), F.S., for additional acts that constitute neglect.

⁴¹ Supra n. 3

- Personal care (help with bathing, dressing, eating, walking, physical transfer);
- Give medications (by a nurse employed at the facility or arranged by contract) or help residents give themselves medications;
- Supervise residents;
- Arrange for health care services;
- Provide or arrange for transportation to health care services;
- Health monitoring;
- Respite care;
- Social and leisure activities; and
- Mental Health services.

Section 78 amends s. 429.04, F.S., relating to exemptions from licensure to clarify and expand the exemptions to include facilities licensed by the Agency for Persons with Disabilities, mental health facilities, licensed hospitals, nursing homes, inpatient hospices, homes for special services,⁴² intermediate care facilities, or transitional living facilities. Additionally, the bill assigns the burden of providing documentation substantiating an exemption to the person or entity asserting an exemption in response to an agency investigation of unlicensed activity.

A current exemption includes any person who provides housing, meals, or one or more personal services on a 24-hour basis in the person's own home to not more than two adults who do not receive optional state supplementation. The bill specifies that in addition to owning or renting the home, the person who provides these services must have established the home as the person's permanent residence. If the person holds a homestead exemption at a different address, a presumption exists that the person has not established permanent residence as required by this section. Furthermore, the bill provides that the exemption does not apply to a person or entity who previously held licensure issued by the agency and such license was revoked or licensure renewal was denied by final order, or when the license was voluntarily relinquished during agency enforcement proceedings.

Section 79 amends s. 429.08, F.S., relating to unlicensed facilities to clarify and create a felony of the third degree penalty for renting or otherwise maintaining a building or property that operates or maintains an unlicensed ALF. This section now provides that any person who owns, operates, or maintains an unlicensed ALF after receiving notice from the agency that licensure is required and to cease such operation commits a felony of the third degree. Current law provides a 6-month window after a statutory or rule change takes place if the change placed the person in the position of violating this provision before the violation occurs. This 6-month timeframe is repealed in the bill.

Section 80 amends s. 429.176, F.S., to prohibit an ALF from operating for more than 120 consecutive days without an administrator who has completed the core educational requirements.

⁴² Homes for special services is defined in s. 400.801, F.S., as a site licensed by the agency prior to January 1, 2006, where specialized health care services are provided, including personal and custodial care, but not continuous nursing services.

Section 82 amends s. 429.24, F.S., to specify that new services added to a resident's contract for which the resident was not previously charged do not require a 30-day written notice of rate increase.

Section 83 amends s. 429.28, F.S., to specify that residents in an ALF have the right to "assistance with" obtaining access to adequate and appropriate health care. Current law provides the resident with the right to "access to adequate and appropriate health care." The bill further specifies that "adequate and appropriate health care" includes management of medications, assistance in making appointments for health care services, the provision of or arrangement of transportation to health care appointments, and the performance of health care services in accordance with s. 429.255, F.S.⁴³

Sections 83 and 85 amend ss. 429.28 and 429.34, F.S., to strike provisions from the "resident's bill of rights" section that are related to AHCA inspections of ALFs and move the provisions into the section related to AHCA right of entry and inspection powers.

Section 84 amends s. 429.294, F.S., to conform the requirement that ALFs provide copies of medical records to the provisions requiring nursing homes to provide such records. Current law requires ALFs to provide the records within 10 days while nursing homes have 30 days to provide the records.⁴⁴

Section 86 amends s. 429.52, F.S., to specify that an ALF administrator must complete staff training, including passing the competency test, within 90 days of the date of employment.

Clinical Laboratories

The CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).⁴⁵ Facilities that provide clinical laboratory services are required to be certified by the CMS CLIA laboratory certification program which operates in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Certain laboratories may qualify as a waived testing laboratory and receive a CLIA Certificate of Waiver.⁴⁶

Clinical laboratories in the state performing non-waived tests must also obtain a state license from the AHCA and comply with part I of ch. 483, F.S., relating to clinical laboratories, and the general licensing provisions in part II of ch. 408, F.S. This requirement also applies to a clinical laboratory operated by one or more practitioners such as physicians, chiropractors, podiatrists,

⁴³ Section 429.255, F.S., specifies the types of care that may be provided by various staff in an ALF, including nursing and medical staff, and includes provisions for emergency situations.

⁴⁴ See s. 400.145, F.S.

⁴⁵ CMS.gov, *Clinical Laboratory Improvement Amendments (CLIA)* (April 5, 2017) <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA> (last visited Nov. 29, 2017).

⁴⁶ Waived testing laboratories: employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, pose no reasonable risk of harm to the patient if the test is performed incorrectly, use tests that are cleared by the FDA for home use, and conduct testing that is considered non-technical requiring little or no difficulty. See Agency for Health Care Administration, Waived Laboratories:

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/waived_apps.shtml (last visited Nov. 29, 2017).

optometrists, or dentists, exclusively in connection with the diagnosis and treatment of their own patients.⁴⁷

As of July 1, 2017, the agency licenses 3,904 clinical laboratories and collects an average of \$1,540,000 per year in recurring licensure fees and an average of \$321,900 per year in recurring biennial assessments required by s. 408.033, F.S. In addition, the CLIA program certifies another 18,446 Florida based laboratories that only perform “waived” testing and therefore, are exempt from state licensure requirements.⁴⁸

Section 90 amends s. 456.054, F.S., to move anti-kickback language for clinical labs from s. 483.245, F.S., which is being repealed into the general provisions for healthcare practitioners.

Section 96 of the bill repeals part I of ch. 483, F.S., relating to the licensure and regulation of clinical laboratories by the agency. Part I includes ss. 483.011 - 483.26, F.S. Laboratories will continue to be certified by, or receive a certificate of waiver from the CMS under the CLIA. Included within the repeal is a requirement that lab results must be reported directly to the licensed practitioner or other authorized person who requested it, and the authorization for a laboratory to disclose the results without a patient’s consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a), F.S.

Section 98 amends s. 483.801, F.S., to exempt from licensure persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners who are licensed under Florida law as allopathic or osteopathic physicians, chiropractors, podiatrists, optometrists, or dentists and who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by a health care provider who is not a member of the same group.

Managed Care Ombudsman Committees

The Statewide Managed Care Ombudsman Committee (statewide committee) and the district managed care ombudsman committees (district committees) were established in 1996.⁴⁹ The statewide committee is created within the agency as a consumer protection and advocacy organization on behalf of managed care subscribers. The statewide committee has administrative authority over the district committees and consists of the chairpersons of the district committees.

A district committee is created in s. 641.65, F.S., in each district of the agency that has staff assigned for the regulation of managed care programs. Each district committee must have no fewer than nine members or more than 16 members, including at least four physicians, one licensed under chs. 458, 459, 460, and 461; one psychologist; one registered nurse; one clinical social worker; one attorney; and one consumer.⁵⁰

According to the agency, due to the very stringent committee composition requirements, the majority of districts could not form district committees. The first committee was established in

⁴⁷ Section 483.035(1), F.S.

⁴⁸ Supra note 3.

⁴⁹ Chapter 96-391, Laws of Fla.

⁵⁰ Section 641.65(2), F.S.

1999 and only three other districts were able to meet committee requirements. The last activity on record was in 2010 and there are currently no active committees.⁵¹

Sections 117-122 repeal ss. 641.60, 641.65, 641.67, 641.68, 641.70, and 641.75, F.S., to eliminate the state wide and district Managed Care Ombudsman Committees.

Miscellaneous Provisions

Section 62 amends s. 408.061, F.S., relating to data collection by the agency from health care facilities, to conform cross-references and to exclude hospitals operated by state agencies from the requirement to submit certain financial reports.

Section 88 amends s. 435.12, F.S., to allow a person who passed a level 2 screening after December 31, 2012, to extend the date for screening renewal until January 1, 2020, (rather than for 5 years as required in current law) unless the Florida Department of Law Enforcement (FDLE) begins participation in the nation retained print arrest notification program before that date. The bill also extends the retention of fingerprints by the FDLE until January 1, 2021, or the date the FDLE begins participation in the program.

Technical and Conforming Sections

The following sections makes technical changes to the Florida statutes to conform its provisions to other changes made by this bill:

Section 55 amends s. 400.933, F.S., to make a technical change specifying that it is the Department of Business and Professional Regulation that issues medical oxygen retail establishment permits and not the DOH.

Section 77 amends s. 492.02, F.S., to make technical grammatical changes to the section.

Sections 1, 3-15, 17, 19, 20-22, 25, 42,50, 57, 59, 63, 66, 72, 73, 75-76, 81, 89, 91-95, 97, 99-116, and 123-127.

These sections amend ss. 20.43, 220.1845, 376.30781, 376.86, 381.0031, 381.0034, 381.004, 381.0405, 383.14, 383.30, 383.301, 383.302, 383.305, 383.309, 383.33, 384.31, 385.211, 394.4787, 395.001, 395.009, 395.7015, 400.497, 400.9905, 408.033, 408.07, 408.802, 408.820, 409.905, 409.9116, 409.975, , 429.19, 456.001, 456.057, 456.076, 458.307, 458.345, 459.021, 483.294, 483.803, 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406, 627.64194, 627.6513, 627.6574, 641.185, 641.31, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 766.118, 766.202, 945.36, 1009.65, and 1011.52, F.S., respectively.

Effective Date

Section 128 establishes an effective date of July 1, 2018.

⁵¹ Supra note 3

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:

Repealing the licensure requirement for health care risk managers will save each risk manager the cost of the licensure fee, which is \$104.54 for initial applicants and \$52.78 for renewal applicants.⁵²

Repealing clinical laboratory licensure, will save each clinical laboratory that was required to be licensed and is accredited \$100 biennially. If not accredited the fee is between \$400 - \$3,919 biennially, depending upon the annual volume of non-waived tests performed.⁵³

C. Government Sector Impact:

Revenue of risk manager application fees will decrease by approximately \$64,866 per year and revenue from laboratory licensure application fees will decrease by \$1,540,000 per year.⁵⁴

VI. Technical Deficiencies:

The title of the bill does not include language stricken from s. 400.0625, F.S., on lines 1182-1186.

⁵² See the Application checklist available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml (last visited Nov. 29, 2017).

⁵³ See AHCA Clinical laboratory fees, available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml (last visited Nov. 29, 2017).

⁵⁴ Supra n. 3

The bill amends s. 408.0361, F.S., to mandate the establishment of rules to require nursing and technical staff in hospitals performing adult cardiovascular services to have specified experience. This change appears to apply to both hospitals providing Level I and Level II services, however, this is placed within a statutory paragraph only relating to a hospital seeking a Level I program license. As such, it is unclear whether the staff training requirement applies to both hospitals providing Level I and Level II services or only to hospitals providing Level I services. The bill may need to be amended to clearly indicate to which hospitals the requirement applies.

The bill amends s. 491.003, F.S., to make technical grammatical changes to the bill. Line 2941 eliminates parentheses around the phrase “mental dysfunctions or disorders (whether cognitive, affective, or behavioral).” This phrase is part of a list and as such, the list should also be amended to use semicolons rather than commas in order to adequately distinguish the individual parts of the list from the phrase within the deleted parentheses. Additionally, the parenthetical phrase is used on lines 2838-2839, 2847-2848, 2882, 2893-2894, and 2951-2952 and these instances have not been amended. The bill should be amended to be consistent in its usage throughout the section.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 20.43, 220.1845, 376.30781, 376.86, 381.0031, 381.0034, 381.004, 381.0405, 383.14, 383.30, 383.301, 383.302, 383.305, 383.309, 383.313, 383.33, 384.31, 385.211, 394.4787, 395.001, 395.002, 395.003, 395.009, 395.0161, 395.0163, 395.0197, 395.1055, 395.10973, 395.602, 395.603, 395.701, 395.7015, 400.0625, 400.191, 400.464, 400.471, 400.474, 400.476, 400.484, 400.497, 400.506, 400.606, 400.925, 400.931, 400.933, 400.980, 400.9905, 400.9935, 408.033, 408.036, 408.0361, 408.061, 408.07, 408.20, 408.7056, 408.802, 408.803, 408.806, 408.809, 408.810, 408.812, 408.820, 409.905, 409.907, 409.9116, 409.975, 429.02, 429.04, 429.08, 429.176, 429.19, 429.24, 429.28, 429.294, 429.34, 429.52, 435.04, 435.12, 456.001, 456.054, 456.057, 456.076, 458.307, 458.345, 459.021, 483.294, 483.801, 483.803, 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406, 627.64194, 627.6513, 627.6574, 641.185, 641.31, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 766.118, 766.202, 945.36, 1009.65, and 1011.52.

This bill creates the following sections of the Florida Statutes: 154.13 and 395.0091.

This bill repeals the following sections of the Florida Statutes: 383.335, 395.1046, 395.10971, 395.10972, 395.10974, 395.10975, 395.604, 395.605, 483.011, 483.021, 483.031, 483.035, 483.041, 483.051, 483.061, 483.091, 483.101, 483.111, 483.172, 483.181, 483.191, 483.201, 483.221, 483.23, 483.245, 483.26, 641.60, 641.65, 641.67, 641.68, 641.70, and 641.75.

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.

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

By Senator Grimsley

26-00620-18

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1 A bill to be entitled
2 An act relating to health care facility regulation;
3 creating s. 154.13, F.S.; providing that a designated
4 facility owned or operated by a public health trust
5 and located within the boundaries of a municipality is
6 under the exclusive jurisdiction of the county
7 creating the public health trust; amending ss.
8 381.0031, 381.004, 384.31, 395.009, 400.0625, and
9 409.905, F.S.; eliminating state licensure
10 requirements for clinical laboratories; requiring
11 clinical laboratories to be federally certified;
12 amending s. 383.313, F.S.; requiring a birth center to
13 be federally certified and meet specified requirements
14 to perform certain laboratory tests; repealing s.
15 383.335, F.S., relating to partial exemptions from
16 licensure requirements for certain facilities that
17 provide obstetrical and gynecological surgical
18 services; amending s. 395.002, F.S.; revising and
19 deleting definitions to remove the term "mobile
20 surgical facility"; conforming a cross-reference;
21 creating s. 395.0091, F.S.; requiring the Agency for
22 Health Care Administration, in consultation with the
23 Board of Clinical Laboratory Personnel, to adopt rules
24 establishing criteria for alternate-site laboratory
25 testing; requiring specifications to be included in
26 the criteria; defining the term "alternate-site
27 testing"; amending ss. 395.0161 and 395.0163, F.S.;
28 deleting licensure and inspection requirements for
29 mobile surgical facilities to conform to changes made

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30 by the act; amending s. 395.0197, F.S.; requiring the
31 manager of a hospital or ambulatory surgical center
32 internal risk management program to demonstrate
33 competence in specified administrative and health care
34 service areas; conforming provisions to changes made
35 by the act; repealing s. 395.1046, F.S., relating to
36 hospital complaint investigation procedures; amending
37 s. 395.1055, F.S.; requiring hospitals that provide
38 specified services to meet agency licensure
39 requirements; providing standards to be included in
40 licensure requirements; conforming a provision to
41 changes made by the act; requiring a level 2
42 background screening for personnel of distinct part
43 nursing units; repealing ss. 395.10971 and 395.10972,
44 F.S., relating to the purpose and the establishment of
45 the Health Care Risk Manager Advisory Council,
46 respectively; amending s. 395.10973, F.S.; removing
47 requirements relating to agency standards for health
48 care risk managers to conform provisions to changes
49 made by the act; repealing s. 395.10974, F.S.,
50 relating to licensure of health care risk managers,
51 qualifications, licensure, and fees; repealing s.
52 395.10975, F.S., relating to grounds for denial,
53 suspension, or revocation of a health care risk
54 manager's license and an administrative fine; amending
55 s. 395.602, F.S.; deleting definitions for the terms
56 "emergency care hospital", "essential access community
57 hospital," "inactive rural hospital bed", and "rural
58 primary care hospital"; amending s. 395.603, F.S.;

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59 deleting provisions relating to deactivation of
60 general hospital beds by certain rural and emergency
61 care hospitals; repealing s. 395.604, F.S., relating
62 to other rural hospital programs; repealing s.
63 395.605, F.S., relating to emergency care hospitals;
64 amending s. 395.701, F.S.; revising the definition of
65 the term "hospital" to exclude hospitals operated by a
66 state agency; amending s. 400.191, F.S.; removing the
67 30-month reporting timeframe for the Nursing Home
68 Guide; amending s. 400.464, F.S.; requiring that a
69 license issued to a home health agency on or after a
70 specified date specify the services the organization
71 is authorized to perform and whether the services
72 constitute skilled care; providing that the provision
73 or advertising of certain services constitutes
74 unlicensed activity under certain circumstances;
75 authorizing certain persons, entities or organizations
76 providing home health services to voluntarily apply
77 for a certificate of exemption from licensure by
78 providing certain information to the agency; providing
79 that the certificate is valid for a specified time and
80 is nontransferable; authorizing the agency to charge a
81 fee for the certificate; amending s. 400.471, F.S.;
82 revising home health agency licensure requirements;
83 providing requirements for proof of accreditation for
84 home health agencies applying for change of ownership
85 or the addition of skilled care services; removing a
86 provision prohibiting the agency from issuing a
87 license to a home health agency that fails to satisfy

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88 the requirements of a Medicare certification survey
89 from the agency; amending s. 400.474, F.S.; revising
90 conditions for the imposition of a fine against a home
91 health agency; amending s. 400.476, F.S.; requiring a
92 home health agency providing skilled nursing care to
93 have a director of nursing; amending s. 400.484, F.S.;
94 imposing administrative fines on home health agencies
95 for specified classes of violations; amending s.
96 400.497, F.S.; requiring the agency to adopt, publish,
97 and enforce rules establishing standards for
98 certificates of exemption; amending s. 400.506, F.S.;
99 specifying a criminal penalty for any person who owns,
100 operates, or maintains an unlicensed nurse registry
101 that fails to cease operation immediately and apply
102 for a license after notification from the agency;
103 revising provisions authorizing the agency to impose a
104 fine on a nurse registry that fails to cease operation
105 after agency notification; revising circumstances
106 under which the agency is authorized to deny, suspend,
107 or revoke a license or impose a fine on a nurse
108 registry; amending s. 400.606, F.S.; removing a
109 requirement that an existing licensed health care
110 provider's hospice licensure application be
111 accompanied by a copy of the most recent profit-loss
112 statement and licensure inspection report; amending s.
113 400.925, F.S.; revising the definition of the term
114 "home medical equipment"; amending s. 400.931, F.S.;
115 requiring a home medical equipment provider to notify
116 the agency of certain personnel changes within a

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117 specified timeframe; amending s. 400.933, F.S.;

118 requiring the agency to accept the submission of a

119 valid medical oxygen retail establishment permit

120 issued by the Department of Business and Professional

121 Regulation in lieu of an agency inspection for

122 licensure; amending s. 400.980, F.S.; revising the

123 timeframe within which a health care services pool

124 registrant must provide the agency with certain

125 changes of information; amending s. 400.9935, F.S.;

126 specifying that a voluntary certificate of exemption

127 may be valid for up to 2 years; amending s. 408.0361,

128 F.S.; providing an exception for a hospital to become

129 a Level I Adult Cardiovascular provider if certain

130 requirements are met; amending s. 408.061, F.S.;

131 excluding hospitals operated by state agencies from

132 certain financial reporting requirements; conforming a

133 cross-reference; amending s. 408.07, F.S.; deleting

134 the definition for the term "clinical laboratory";

135 amending s. 408.20, F.S.; exempting hospitals operated

136 by any state agency from assessments against the

137 Health Care Trust Fund to fund certain agency

138 activities; repealing s. 408.7056, F.S., relating to

139 the Subscriber Assistance Program; amending s.

140 408.803, F.S.; defining the term "relative" for

141 purposes of the Health Care Licensing Procedures Act;

142 amending s. 408.806, F.S.; authorizing licensees who

143 hold licenses for multiple providers to request that

144 the agency align related license expiration dates;

145 authorizing the agency to issue licenses for an

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146 abbreviated licensure period and to charge a prorated
147 licensure fee; amending s. 408.809, F.S.; expanding
148 the scope of persons subject to a level 2 background
149 screening to include any employee of a licensee who is
150 a controlling interest and certain part-time
151 contractors; amending s. 408.810, F.S.; providing that
152 an applicant for change of ownership licensure is
153 exempt from furnishing proof of financial ability to
154 operate if certain conditions are met; authorizing the
155 agency to adopt rules governing circumstances under
156 which a controlling interest may act in certain legal
157 capacities on behalf of a patient or client; requiring
158 a licensee to ensure that certain persons do not hold
159 an ownership interest if the licensee is not organized
160 as or owned by a publicly traded corporation; defining
161 the term "publicly traded corporation"; amending s.
162 408.812, F.S.; providing that certain unlicensed
163 activity by a provider constitutes abuse and neglect;
164 clarifying that the agency may impose a fine or
165 penalty, as prescribed in an authorizing statute, if
166 an unlicensed provider who has received notification
167 fails to cease operation; authorizing the agency to
168 revoke all licenses and impose a fine or penalties
169 upon a controlling interest or licensee who has an
170 interest in more than one provider and who fails to
171 license a provider rendering services that require
172 licensure in certain circumstances; amending s.
173 408.820, F.S.; deleting certain exemptions from part
174 II of ch. 408, F.S., for specified providers to

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175 conform provisions to changes made by the act;
176 amending s. 409.907, F.S.; removing the agency's
177 authority to consider certain factors in determining
178 whether to enter into, and in maintaining, a Medicaid
179 provider agreement; amending s. 429.02, F.S.; revising
180 definitions of the terms "assisted living facility"
181 and "personal services"; amending s. 429.04, F.S.;
182 providing additional exemptions from licensure as an
183 assisted living facility; requiring a person or entity
184 asserting the exemption to provide documentation that
185 substantiates the claim upon agency investigation of
186 unlicensed activity; amending s. 429.08, F.S.;
187 providing criminal penalties and fines for a person
188 who rents or otherwise maintains a building or
189 property use as an unlicensed assisted living
190 facility; providing criminal penalties and fines for a
191 person who owns, operates, or maintains an unlicensed
192 assisted living facility after receiving notice from
193 the agency; amending s. 429.176, F.S.; prohibiting an
194 assisted living facility from operating for more than
195 a specified time without an administrator who has
196 completed certain educational requirements; amending
197 s. 429.24, F.S.; providing that 30-day written notice
198 of rate increase for residency in an assisted living
199 facility is not required in certain situations;
200 amending s. 429.28, F.S.; revising the assisted living
201 facility resident bill of rights to include assistance
202 with obtaining access to adequate and appropriate
203 health care; defining the term "adequate and

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204 appropriate health care"; deleting a requirement that
205 the agency conduct at least one monitoring visit under
206 certain circumstances; deleting provisions authorizing
207 the agency to conduct periodic followup inspections
208 and complaint investigations under certain
209 circumstances; amending s. 429.294, F.S.; deleting the
210 specified timeframe within which an assisted living
211 facility must provide complete copies of a resident's
212 records in an investigation of resident's rights;
213 amending s. 429.34, F.S.; authorizing the agency to
214 inspect and investigate assisted living facilities as
215 necessary to determine compliance with certain laws;
216 removing a provision requiring the agency to inspect
217 each licensed assisted living facility at least
218 biennially; authorizing the agency to conduct
219 monitoring visits of each facility cited for prior
220 violations under certain circumstances; amending s.
221 429.52, F.S.; requiring an assisted living facility
222 administrator to complete required training and
223 education within a specified timeframe; amending s.
224 435.04, F.S.; providing that security background
225 investigations must ensure that a person has not been
226 arrested for, and is not awaiting final disposition
227 of, certain offenses; requiring that security
228 background investigations for purposes of
229 participation in the Medicaid program screen for
230 violations of federal or state law, rule, or
231 regulation governing any state Medicaid program, the
232 Medicare program, or any other publicly funded federal

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233 or state health care or health insurance program;
234 specifying offenses under federal law or any state law
235 that the security background investigations must
236 screen for; amending s. 435.12, F.S.; revising
237 fingerprinting requirements for purposes of a person's
238 inclusion in the care provider background screening
239 clearinghouse; amending s. 456.054, F.S.; prohibiting
240 any person or entity from paying or receiving a
241 kickback for referring patients to a clinical
242 laboratory; prohibiting a clinical laboratory from
243 providing personnel to perform certain functions or
244 duties in a health care practitioner's office or
245 dialysis facility; providing an exception; prohibiting
246 a clinical laboratory from leasing space in any part
247 of a health care practitioner's office or dialysis
248 facility; repealing part I of ch. 483, F.S., relating
249 to clinical laboratories; amending s. 483.294, F.S.;
250 removing a requirement that the agency inspect
251 multiphasic health testing centers at least once
252 annually; amending s. 483.801, F.S.; providing an
253 exemption from regulation for certain persons employed
254 by certain laboratories; amending s. 483.803, F.S.;
255 revising definitions of the terms "clinical
256 laboratory", and "clinical laboratory examination";
257 removing a cross-reference; amending s. 641.511, F.S.;
258 revising health maintenance organization subscriber
259 grievance reporting requirements; repealing s. 641.60,
260 F.S., relating to the Statewide Managed Care Ombudsman
261 Committee; repealing s. 641.65, F.S., relating to

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262 district managed care ombudsman committees; repealing
263 s. 641.67, F.S., relating to a district managed care
264 ombudsman committee, exemption from public records
265 requirements, and exceptions; repealing s. 641.68,
266 F.S., relating to a district managed care ombudsman
267 committee and exemption from public meeting
268 requirements; repealing s. 641.70, F.S., relating to
269 agency duties relating to the Statewide Managed Care
270 Ombudsman Committee and the district managed care
271 ombudsman committees; repealing s. 641.75, F.S.,
272 relating to immunity from liability and limitation on
273 testimony; amending s. 945.36, F.S.; authorizing law
274 enforcement personnel to conduct drug tests on certain
275 inmates and releasees; amending ss. 20.43, 220.1845,
276 376.30781, 376.86, 381.0034, 381.0405, 383.14, 383.30,
277 383.301, 383.302, 383.305, 383.309, 383.33, 385.211,
278 394.4787, 395.001, 395.003, 395.7015, 400.9905,
279 408.033, 408.036, 408.802, 409.9116, 409.975, 429.19,
280 456.001, 456.057, 456.076, 458.307, 458.345, 459.021,
281 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406,
282 627.64194, 627.6513, 627.6574, 641.185, 641.31,
283 641.312, 641.3154, 641.51, 641.515, 641.55, 766.118,
284 766.202, 1009.65, and 1011.52, F.S.; conforming
285 provisions to changes made by the act; providing an
286 effective date.

287

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

289

290 Section 1. Paragraph (g) of subsection (3) of section

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291 20.43, Florida Statutes, is amended to read:

292 20.43 Department of Health.—There is created a Department
293 of Health.

294 (3) The following divisions of the Department of Health are
295 established:

296 (g) Division of Medical Quality Assurance, which is
297 responsible for the following boards and professions established
298 within the division:

299 1. The Board of Acupuncture, created under chapter 457.

300 2. The Board of Medicine, created under chapter 458.

301 3. The Board of Osteopathic Medicine, created under chapter
302 459.

303 4. The Board of Chiropractic Medicine, created under
304 chapter 460.

305 5. The Board of Podiatric Medicine, created under chapter
306 461.

307 6. Naturopathy, as provided under chapter 462.

308 7. The Board of Optometry, created under chapter 463.

309 8. The Board of Nursing, created under part I of chapter
310 464.

311 9. Nursing assistants, as provided under part II of chapter
312 464.

313 10. The Board of Pharmacy, created under chapter 465.

314 11. The Board of Dentistry, created under chapter 466.

315 12. Midwifery, as provided under chapter 467.

316 13. The Board of Speech-Language Pathology and Audiology,
317 created under part I of chapter 468.

318 14. The Board of Nursing Home Administrators, created under
319 part II of chapter 468.

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- 320 15. The Board of Occupational Therapy, created under part
321 III of chapter 468.
- 322 16. Respiratory therapy, as provided under part V of
323 chapter 468.
- 324 17. Dietetics and nutrition practice, as provided under
325 part X of chapter 468.
- 326 18. The Board of Athletic Training, created under part XIII
327 of chapter 468.
- 328 19. The Board of Orthotists and Prosthetists, created under
329 part XIV of chapter 468.
- 330 20. Electrolysis, as provided under chapter 478.
- 331 21. The Board of Massage Therapy, created under chapter
332 480.
- 333 22. The Board of Clinical Laboratory Personnel, created
334 under part II ~~III~~ of chapter 483.
- 335 23. Medical physicists, as provided under part IV of
336 chapter 483.
- 337 24. The Board of Opticianry, created under part I of
338 chapter 484.
- 339 25. The Board of Hearing Aid Specialists, created under
340 part II of chapter 484.
- 341 26. The Board of Physical Therapy Practice, created under
342 chapter 486.
- 343 27. The Board of Psychology, created under chapter 490.
- 344 28. School psychologists, as provided under chapter 490.
- 345 29. The Board of Clinical Social Work, Marriage and Family
346 Therapy, and Mental Health Counseling, created under chapter
347 491.
- 348 30. Emergency medical technicians and paramedics, as

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349 provided under part III of chapter 401.

350 Section 2. Section 154.13, Florida Statutes, is created to
351 read:

352 154.13 Designated facilities; jurisdiction.—Any designated
353 facility owned or operated by a public health trust and located
354 within the boundaries of a municipality is under the exclusive
355 jurisdiction of the county creating the public health trust and
356 is not within the jurisdiction of the municipality.

357 Section 3. Paragraph (k) of subsection (2) of section
358 220.1845, Florida Statutes, is amended to read:

359 220.1845 Contaminated site rehabilitation tax credit.—

360 (2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.—

361 (k) In order to encourage the construction and operation of
362 a new health care facility as defined in s. 408.032 or s.
363 408.07, or a health care provider as defined in s. 408.07 ~~or s.~~
364 ~~408.7056~~, on a brownfield site, an applicant for a tax credit
365 may claim an additional 25 percent of the total site
366 rehabilitation costs, not to exceed \$500,000, if the applicant
367 meets the requirements of this paragraph. In order to receive
368 this additional tax credit, the applicant must provide
369 documentation indicating that the construction of the health
370 care facility or health care provider by the applicant on the
371 brownfield site has received a certificate of occupancy or a
372 license or certificate has been issued for the operation of the
373 health care facility or health care provider.

374 Section 4. Paragraph (f) of subsection (3) of section
375 376.30781, Florida Statutes, is amended to read:

376 376.30781 Tax credits for rehabilitation of drycleaning-
377 solvent-contaminated sites and brownfield sites in designated

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378 brownfield areas; application process; rulemaking authority;
379 revocation authority.—

380 (3) (f) In order to encourage the construction and operation
381 of a new health care facility or a health care provider, as
382 defined in s. 408.032 or, s. 408.07, ~~or s. 408.7056~~, on a
383 brownfield site, an applicant for a tax credit may claim an
384 additional 25 percent of the total site rehabilitation costs,
385 not to exceed \$500,000, if the applicant meets the requirements
386 of this paragraph. In order to receive this additional tax
387 credit, the applicant must provide documentation indicating that
388 the construction of the health care facility or health care
389 provider by the applicant on the brownfield site has received a
390 certificate of occupancy or a license or certificate has been
391 issued for the operation of the health care facility or health
392 care provider.

393 Section 5. Subsection (1) of section 376.86, Florida
394 Statutes, is amended to read:

395 376.86 Brownfield Areas Loan Guarantee Program.—

396 (1) The Brownfield Areas Loan Guarantee Council is created
397 to review and approve or deny, by a majority vote of its
398 membership, the situations and circumstances for participation
399 in partnerships by agreements with local governments, financial
400 institutions, and others associated with the redevelopment of
401 brownfield areas pursuant to the Brownfields Redevelopment Act
402 for a limited state guaranty of up to 5 years of loan guarantees
403 or loan loss reserves issued pursuant to law. The limited state
404 loan guaranty applies only to 50 percent of the primary lenders
405 loans for redevelopment projects in brownfield areas. If the
406 redevelopment project is for affordable housing, as defined in

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407 s. 420.0004, in a brownfield area, the limited state loan
 408 guaranty applies to 75 percent of the primary lender's loan. If
 409 the redevelopment project includes the construction and
 410 operation of a new health care facility or a health care
 411 provider, as defined in s. 408.032 or s. 408.07, ~~or s.~~
 412 ~~408.7056~~, on a brownfield site and the applicant has obtained
 413 documentation in accordance with s. 376.30781 indicating that
 414 the construction of the health care facility or health care
 415 provider by the applicant on the brownfield site has received a
 416 certificate of occupancy or a license or certificate has been
 417 issued for the operation of the health care facility or health
 418 care provider, the limited state loan guaranty applies to 75
 419 percent of the primary lender's loan. A limited state guaranty
 420 of private loans or a loan loss reserve is authorized for
 421 lenders licensed to operate in the state upon a determination by
 422 the council that such an arrangement would be in the public
 423 interest and the likelihood of the success of the loan is great.

424 Section 6. Subsection (2) of section 381.0031, Florida
 425 Statutes, is amended to read:

426 381.0031 Epidemiological research; report of diseases of
 427 public health significance to department.-

428 (2) Any practitioner licensed in this state to practice
 429 medicine, osteopathic medicine, chiropractic medicine,
 430 naturopathy, or veterinary medicine; any hospital licensed under
 431 part I of chapter 395; or any laboratory appropriately certified
 432 by the Centers for Medicare and Medicaid Services under the
 433 federal Clinical Laboratory Improvement Amendments and the
 434 federal rules adopted thereunder which licensed under chapter
 435 ~~483 that~~ diagnoses or suspects the existence of a disease of

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436 public health significance shall immediately report the fact to
437 the Department of Health.

438 Section 7. Subsection (3) of section 381.0034, Florida
439 Statutes, is amended to read:

440 381.0034 Requirement for instruction on HIV and AIDS.—

441 (3) The department shall require, as a condition of
442 granting a license under chapter 467 or part II ~~III~~ of chapter
443 483, that an applicant making initial application for licensure
444 complete an educational course acceptable to the department on
445 human immunodeficiency virus and acquired immune deficiency
446 syndrome. Upon submission of an affidavit showing good cause, an
447 applicant who has not taken a course at the time of licensure
448 shall be allowed 6 months to complete this requirement.

449 Section 8. Paragraph (c) of subsection (4) of section
450 381.004, Florida Statutes, is amended to read:

451 381.004 HIV testing.—

452 (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS;
453 REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM
454 REGISTRATION.—No county health department and no other person in
455 this state shall conduct or hold themselves out to the public as
456 conducting a testing program for acquired immune deficiency
457 syndrome or human immunodeficiency virus status without first
458 registering with the Department of Health, reregistering each
459 year, complying with all other applicable provisions of state
460 law, and meeting the following requirements:

461 (c) The program shall have all laboratory procedures
462 performed in a laboratory appropriately certified by the Centers
463 for Medicare and Medicaid Services under the federal Clinical
464 Laboratory Improvement Amendments and the federal rules adopted

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465 thereunder ~~licensed under the provisions of chapter 483.~~

466 Section 9. Paragraph (f) of subsection (4) of section
467 381.0405, Florida Statutes, is amended to read:

468 381.0405 Office of Rural Health.—

469 (4) COORDINATION.—The office shall:

470 (f) Assume responsibility for state coordination of the
471 Rural Hospital Transition Grant Program, ~~the Essential Access~~
472 ~~Community Hospital Program,~~ and other federal rural health care
473 programs.

474 Section 10. Paragraph (a) of subsection (2) of section
475 383.14, Florida Statutes, is amended to read:

476 383.14 Screening for metabolic disorders, other hereditary
477 and congenital disorders, and environmental risk factors.—

478 (2) RULES.—

479 (a) After consultation with the Genetics and Newborn
480 Screening Advisory Council, the department shall adopt and
481 enforce rules requiring that every newborn in this state shall:

482 1. Before becoming 1 week of age, be subjected to a test
483 for phenylketonuria;

484 2. Be tested for any condition included on the federal
485 Recommended Uniform Screening Panel which the council advises
486 the department should be included under the state's screening
487 program. After the council recommends that a condition be
488 included, the department shall submit a legislative budget
489 request to seek an appropriation to add testing of the condition
490 to the newborn screening program. The department shall expand
491 statewide screening of newborns to include screening for such
492 conditions within 18 months after the council renders such
493 advice, if a test approved by the United States Food and Drug

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494 Administration or a test offered by an alternative vendor ~~which~~
495 ~~is compatible with the clinical standards established under part~~
496 ~~I of chapter 483~~ is available. If such a test is not available
497 within 18 months after the council makes its recommendation, the
498 department shall implement such screening as soon as a test
499 offered by the United States Food and Drug Administration or by
500 an alternative vendor is available; and

501 3. At the appropriate age, be tested for such other
502 metabolic diseases and hereditary or congenital disorders as the
503 department may deem necessary from time to time.

504 Section 11. Section 383.30, Florida Statutes, is amended to
505 read:

506 383.30 Birth Center Licensure Act; short title.—Sections
507 383.30-383.332 ~~383.30-383.335~~ shall be known and may be cited as
508 the "Birth Center Licensure Act."

509 Section 12. Section 383.301, Florida Statutes, is amended
510 to read:

511 383.301 Licensure and regulation of birth centers;
512 legislative intent.—It is the intent of the Legislature to
513 provide for the protection of public health and safety in the
514 establishment, maintenance, and operation of birth centers by
515 providing for licensure of birth centers and for the
516 development, establishment, and enforcement of minimum standards
517 with respect to birth centers. The requirements of part II of
518 chapter 408 shall apply to the provision of services that
519 require licensure pursuant to ss. 383.30-383.332 ~~383.30-383.335~~
520 and part II of chapter 408 and to entities licensed by or
521 applying for such licensure from the Agency for Health Care
522 Administration pursuant to ss. 383.30-383.332 ~~383.30-383.335~~. A

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523 license issued by the agency is required in order to operate a
524 birth center in this state.

525 Section 13. Section 383.302, Florida Statutes, is amended
526 to read:

527 383.302 Definitions of terms used in ss. 383.30-383.332
528 ~~383.30-383.335~~.—As used in ss. 383.30-383.332 ~~383.30-383.335~~,
529 the term:

530 (1) "Agency" means the Agency for Health Care
531 Administration.

532 (2) "Birth center" means any facility, institution, or
533 place, which is not an ambulatory surgical center or a hospital
534 or in a hospital, in which births are planned to occur away from
535 the mother's usual residence following a normal, uncomplicated,
536 low-risk pregnancy.

537 (3) "Clinical staff" means individuals employed full time
538 or part time by a birth center who are licensed or certified to
539 provide care at childbirth.

540 (4) "Consultant" means a physician licensed pursuant to
541 chapter 458 or chapter 459 who agrees to provide advice and
542 services to a birth center and who either:

543 (a) Is certified or eligible for certification by the
544 American Board of Obstetrics and Gynecology, or

545 (b) Has hospital obstetrical privileges.

546 (5) "Governing body" means any individual, group,
547 corporation, or institution which is responsible for the overall
548 operation and maintenance of a birth center.

549 (6) "Governmental unit" means the state or any county,
550 municipality, or other political subdivision or any department,
551 division, board, or other agency of any of the foregoing.

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552 (7) "Licensed facility" means a facility licensed in
553 accordance with s. 383.305.

554 (8) "Low-risk pregnancy" means a pregnancy which is
555 expected to result in an uncomplicated birth, as determined
556 through risk criteria developed by rule of the department, and
557 which is accompanied by adequate prenatal care.

558 (9) "Person" means any individual, firm, partnership,
559 corporation, company, association, institution, or joint stock
560 association and means any legal successor of any of the
561 foregoing.

562 (10) "Premises" means those buildings, beds, and facilities
563 located at the main address of the licensee and all other
564 buildings, beds, and facilities for the provision of maternity
565 care located in such reasonable proximity to the main address of
566 the licensee as to appear to the public to be under the dominion
567 and control of the licensee.

568 Section 14. Subsection (1) of section 383.305, Florida
569 Statutes, is amended to read:

570 383.305 Licensure; fees.—

571 (1) In accordance with s. 408.805, an applicant or a
572 licensee shall pay a fee for each license application submitted
573 under ss. 383.30-383.332 ~~383.30-383.335~~ and part II of chapter
574 408. The amount of the fee shall be established by rule.

575 Section 15. Subsection (1) of section 383.309, Florida
576 Statutes, is amended to read:

577 383.309 Minimum standards for birth centers; rules and
578 enforcement.—

579 (1) The agency shall adopt and enforce rules to administer
580 ss. 383.30-383.332 ~~383.30-383.335~~ and part II of chapter 408,

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581 which rules shall include, but are not limited to, reasonable
582 and fair minimum standards for ensuring that:

583 (a) Sufficient numbers and qualified types of personnel and
584 occupational disciplines are available at all times to provide
585 necessary and adequate patient care and safety.

586 (b) Infection control, housekeeping, sanitary conditions,
587 disaster plan, and medical record procedures that will
588 adequately protect patient care and provide safety are
589 established and implemented.

590 (c) Licensed facilities are established, organized, and
591 operated consistent with established programmatic standards.

592 Section 16. Subsection (1) of section 383.313, Florida
593 Statutes, is amended to read:

594 383.313 Performance of laboratory and surgical services;
595 use of anesthetic and chemical agents.—

596 (1) LABORATORY SERVICES.—A birth center may collect
597 specimens for those tests that are requested under protocol. A
598 birth center must obtain and continuously maintain certification
599 by the Centers for Medicare and Medicaid Services under the
600 federal Clinical Laboratory Improvement Amendments and the
601 federal rules adopted thereunder in order to ~~may perform simple~~
602 laboratory tests specified, ~~as defined~~ by rule of the agency,
603 and which are appropriate to meet the needs of the patient ~~is~~
604 ~~exempt from the requirements of chapter 483, provided no more~~
605 ~~than five physicians are employed by the birth center and~~
606 ~~testing is conducted exclusively in connection with the~~
607 ~~diagnosis and treatment of clients of the birth center.~~

608 Section 17. Subsection (1) and paragraph (a) of subsection
609 (2) of section 383.33, Florida Statutes, are amended to read:

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610 383.33 Administrative penalties; moratorium on admissions.-

611 (1) In addition to the requirements of part II of chapter
612 408, the agency may impose an administrative fine not to exceed
613 \$500 per violation per day for the violation of any provision of
614 ss. 383.30-383.332 ~~383.30-383.335~~, part II of chapter 408, or
615 applicable rules.

616 (2) In determining the amount of the fine to be levied for
617 a violation, as provided in this section, the following factors
618 shall be considered:

619 (a) The severity of the violation, including the
620 probability that death or serious harm to the health or safety
621 of any person will result or has resulted; the severity of the
622 actual or potential harm; and the extent to which ~~the provisions~~
623 ~~of~~ ss. 383.30-383.332 ~~383.30-383.335~~, part II of chapter 408, or
624 applicable rules were violated.

625 Section 18. Section 383.335, Florida Statutes, is repealed.

626 Section 19. Section 384.31, Florida Statutes, is amended to
627 read:

628 384.31 Testing of pregnant women; duty of the attendant.-
629 Every person, including every physician licensed under chapter
630 458 or chapter 459 or midwife licensed under part I of chapter
631 464 or chapter 467, attending a pregnant woman for conditions
632 relating to pregnancy during the period of gestation and
633 delivery shall cause the woman to be tested for sexually
634 transmissible diseases, including HIV, as specified by
635 department rule. Testing shall be performed by a laboratory
636 appropriately certified by the Centers for Medicare and Medicaid
637 Services under the federal Clinical Laboratory Improvement
638 Amendments and the federal rules adopted thereunder ~~approved~~ for

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639 such purposes ~~under part I of chapter 483~~. The woman shall be
640 informed of the tests that will be conducted and of her right to
641 refuse testing. If a woman objects to testing, a written
642 statement of objection, signed by the woman, shall be placed in
643 the woman's medical record and no testing shall occur.

644 Section 20. Subsection (2) of section 385.211, Florida
645 Statutes, is amended to read:

646 385.211 Refractory and intractable epilepsy treatment and
647 research at recognized medical centers.—

648 (2) Notwithstanding chapter 893, medical centers recognized
649 pursuant to s. 381.925, or an academic medical research
650 institution legally affiliated with a licensed children's
651 specialty hospital as defined in s. 395.002(27) ~~s. 395.002(28)~~
652 that contracts with the Department of Health, may conduct
653 research on cannabidiol and low-THC cannabis. This research may
654 include, but is not limited to, the agricultural development,
655 production, clinical research, and use of liquid medical
656 derivatives of cannabidiol and low-THC cannabis for the
657 treatment for refractory or intractable epilepsy. The authority
658 for recognized medical centers to conduct this research is
659 derived from 21 C.F.R. parts 312 and 316. Current state or
660 privately obtained research funds may be used to support the
661 activities described in this section.

662 Section 21. Subsection (7) of section 394.4787, Florida
663 Statutes, is amended to read:

664 394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and
665 394.4789.—As used in this section and ss. 394.4786, 394.4788,
666 and 394.4789:

667 (7) "Specialty psychiatric hospital" means a hospital

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668 licensed by the agency pursuant to s. 395.002(27) ~~s. 395.002(28)~~
669 and part II of chapter 408 as a specialty psychiatric hospital.

670 Section 22. Section 395.001, Florida Statutes, is amended
671 to read:

672 395.001 Legislative intent.—It is the intent of the
673 Legislature to provide for the protection of public health and
674 safety in the establishment, construction, maintenance, and
675 operation of hospitals and, ambulatory surgical centers, ~~and~~
676 ~~mobile surgical facilities~~ by providing for licensure of same
677 and for the development, establishment, and enforcement of
678 minimum standards with respect thereto.

679 Section 23. Present subsections (22) through (33) of
680 section 395.002, Florida Statutes, are redesignated as
681 subsections (21) through (32), respectively, and subsections (3)
682 and (16) of that section and present subsections (21) and (23)
683 of that section are amended, to read:

684 395.002 Definitions.—As used in this chapter:

685 (3) "Ambulatory surgical center" ~~or "mobile surgical~~
686 ~~facility"~~ means a facility the primary purpose of which is to
687 provide elective surgical care, in which the patient is admitted
688 to and discharged from such facility within the same working day
689 and is not permitted to stay overnight, and which is not part of
690 a hospital. However, a facility existing for the primary purpose
691 of performing terminations of pregnancy, an office maintained by
692 a physician for the practice of medicine, or an office
693 maintained for the practice of dentistry may ~~shall~~ not be
694 construed to be an ambulatory surgical center, provided that any
695 facility or office which is certified or seeks certification as
696 a Medicare ambulatory surgical center shall be licensed as an

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697 ambulatory surgical center pursuant to s. 395.003. ~~Any structure~~
698 ~~or vehicle in which a physician maintains an office and~~
699 ~~practices surgery, and which can appear to the public to be a~~
700 ~~mobile office because the structure or vehicle operates at more~~
701 ~~than one address, shall be construed to be a mobile surgical~~
702 ~~facility.~~

703 (16) "Licensed facility" means a hospital or, ambulatory
704 surgical center, ~~or mobile surgical facility~~ licensed in
705 accordance with this chapter.

706 ~~(21) "Mobile surgical facility" is a mobile facility in~~
707 ~~which licensed health care professionals provide elective~~
708 ~~surgical care under contract with the Department of Corrections~~
709 ~~or a private correctional facility operating pursuant to chapter~~
710 ~~957 and in which inmate patients are admitted to and discharged~~
711 ~~from said facility within the same working day and are not~~
712 ~~permitted to stay overnight. However, mobile surgical facilities~~
713 ~~may only provide health care services to the inmate patients of~~
714 ~~the Department of Corrections, or inmate patients of a private~~
715 ~~correctional facility operating pursuant to chapter 957, and not~~
716 ~~to the general public.~~

717 (22) ~~(23)~~ "Premises" means those buildings, beds, and
718 equipment located at the address of the licensed facility and
719 all other buildings, beds, and equipment for the provision of
720 hospital or, ambulatory surgical, ~~or mobile surgical~~ care
721 located in such reasonable proximity to the address of the
722 licensed facility as to appear to the public to be under the
723 dominion and control of the licensee. For any licensee that is a
724 teaching hospital as defined in s. 408.07 ~~s. 408.07(45)~~,
725 reasonable proximity includes any buildings, beds, services,

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726 programs, and equipment under the dominion and control of the
727 licensee that are located at a site with a main address that is
728 within 1 mile of the main address of the licensed facility; and
729 all such buildings, beds, and equipment may, at the request of a
730 licensee or applicant, be included on the facility license as a
731 single premises.

732 Section 24. Paragraphs (a) and (b) of subsection (1) and
733 paragraph (b) of subsection (2) of section 395.003, Florida
734 Statutes, are amended to read:

735 395.003 Licensure; denial, suspension, and revocation.—

736 (1) (a) The requirements of part II of chapter 408 apply to
737 the provision of services that require licensure pursuant to ss.
738 395.001-395.1065 and part II of chapter 408 and to entities
739 licensed by or applying for such licensure from the Agency for
740 Health Care Administration pursuant to ss. 395.001-395.1065. A
741 license issued by the agency is required in order to operate a
742 hospital or ambulatory surgical center, ~~or mobile surgical~~
743 ~~facility~~ in this state.

744 (b)1. It is unlawful for a person to use or advertise to
745 the public, in any way or by any medium whatsoever, any facility
746 as a "hospital," or "ambulatory surgical center," ~~or "mobile~~
747 ~~surgical facility"~~ unless such facility has first secured a
748 license under ~~the provisions of~~ this part.

749 2. This part does not apply to veterinary hospitals or to
750 commercial business establishments using the word "hospital," or
751 "ambulatory surgical center," ~~or "mobile surgical facility"~~ as a
752 part of a trade name if no treatment of human beings is
753 performed on the premises of such establishments.

754 (2) (b) The agency shall, at the request of a licensee that

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755 is a teaching hospital as defined in s. 408.07 ~~s. 408.07(45)~~,
756 issue a single license to a licensee for facilities that have
757 been previously licensed as separate premises, provided such
758 separately licensed facilities, taken together, constitute the
759 same premises as defined in s. 395.002 ~~s. 395.002(23)~~. Such
760 license for the single premises shall include all of the beds,
761 services, and programs that were previously included on the
762 licenses for the separate premises. The granting of a single
763 license under this paragraph may ~~shall~~ not in any manner reduce
764 the number of beds, services, or programs operated by the
765 licensee.

766 Section 25. Subsection (1) of section 395.009, Florida
767 Statutes, is amended to read:

768 395.009 Minimum standards for clinical laboratory test
769 results and diagnostic X-ray results; prerequisite for issuance
770 or renewal of license.-

771 (1) As a requirement for issuance or renewal of its
772 license, each licensed facility shall require that all clinical
773 laboratory tests performed by or for the licensed facility be
774 performed by a clinical laboratory appropriately certified by
775 the Centers for Medicare and Medicaid Services under the federal
776 Clinical Laboratory Improvement Amendments and the federal rules
777 adopted thereunder ~~licensed under the provisions of chapter 483.~~

778 Section 26. Section 395.0091, Florida Statutes, is created
779 to read:

780 395.0091 Alternate-site testing.-The agency, in
781 consultation with the Board of Clinical Laboratory Personnel,
782 shall adopt by rule the criteria for alternate-site testing to
783 be performed under the supervision of a clinical laboratory

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784 director. At a minimum, the criteria must address hospital
785 internal needs assessment; a protocol for implementation,
786 including the identification of tests to be performed and who
787 will perform them; selection of the method of testing to be used
788 for alternate-site testing; minimum training and education
789 requirements for those who will perform alternate-site testing,
790 such as documented training, licensure, certification, or other
791 medical professional background not limited to laboratory
792 professionals; documented inservice training and initial and
793 ongoing competency validation; an appropriate internal and
794 external quality control protocol; an internal mechanism for the
795 central laboratory to identify and track alternate-site testing;
796 and recordkeeping requirements. Alternate-site testing locations
797 must register when the hospital applies to renew its license.
798 For purposes of this section, the term "alternate-site testing"
799 includes any laboratory testing done under the administrative
800 control of a hospital, but performed out of the physical or
801 administrative confines of the central laboratory.

802 Section 27. Paragraph (f) of subsection (1) of section
803 395.0161, Florida Statutes, is amended to read:

804 395.0161 Licensure inspection.—

805 (1) In addition to the requirement of s. 408.811, the
806 agency shall make or cause to be made such inspections and
807 investigations as it deems necessary, including:

808 ~~(f) Inspections of mobile surgical facilities at each time~~
809 ~~a facility establishes a new location, prior to the admission of~~
810 ~~patients. However, such inspections shall not be required when a~~
811 ~~mobile surgical facility is moved temporarily to a location~~
812 ~~where medical treatment will not be provided.~~

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813 Section 28. Subsection (3) of section 395.0163, Florida
814 Statutes, is amended to read:

815 395.0163 Construction inspections; plan submission and
816 approval; fees.—

817 ~~(3) In addition to the requirements of s. 408.811, the~~
818 ~~agency shall inspect a mobile surgical facility at initial~~
819 ~~licensure and at each time the facility establishes a new~~
820 ~~location, prior to admission of patients. However, such~~
821 ~~inspections shall not be required when a mobile surgical~~
822 ~~facility is moved temporarily to a location where medical~~
823 ~~treatment will not be provided.~~

824 Section 29. Subsection (2), paragraph (c) of subsection
825 (6), and subsections (16) and (17) of section 395.0197, Florida
826 Statutes, are amended to read:

827 395.0197 Internal risk management program.—

828 (2) The internal risk management program is the
829 responsibility of the governing board of the health care
830 facility. Each licensed facility shall hire a risk manager,
831 ~~licensed under s. 395.10974,~~ who is responsible for
832 implementation and oversight of the such facility's internal
833 risk management program and who demonstrates competence, through
834 education or experience, in all of the following areas:

835 (a) Applicable standards of health care risk management.

836 (b) Applicable federal, state, and local health and safety
837 laws and rules.

838 (c) General risk management administration.

839 (d) Patient care.

840 (e) Medical care.

841 (f) Personal and social care.

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842 (g) Accident prevention.
843 (h) Departmental organization and management.
844 (i) Community interrelationships.
845 (j) Medical terminology as required by this section. A risk
846 ~~manager must not be made responsible for more than four internal~~
847 ~~risk management programs in separate licensed facilities, unless~~
848 ~~the facilities are under one corporate ownership or the risk~~
849 ~~management programs are in rural hospitals.~~

850 (6) (c) The report submitted to the agency must ~~shall~~ also
851 contain the name ~~and license number~~ of the risk manager of the
852 licensed facility, a copy of its policy and procedures which
853 govern the measures taken by the facility and its risk manager
854 to reduce the risk of injuries and adverse incidents, and the
855 results of such measures. The annual report is confidential and
856 is not available to the public pursuant to s. 119.07(1) or any
857 other law providing access to public records. The annual report
858 is not discoverable or admissible in any civil or administrative
859 action, except in disciplinary proceedings by the agency or the
860 appropriate regulatory board. The annual report is not available
861 to the public as part of the record of investigation for and
862 prosecution in disciplinary proceedings made available to the
863 public by the agency or the appropriate regulatory board.
864 However, the agency or the appropriate regulatory board shall
865 make available, upon written request by a health care
866 professional against whom probable cause has been found, any
867 such records which form the basis of the determination of
868 probable cause.

869 (16) There shall be no monetary liability on the part of,
870 and no cause of action for damages shall arise against, any risk

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871 manager, ~~licensed under s. 395.10974,~~ for the implementation and
872 oversight of the internal risk management program in a facility
873 licensed under this chapter or chapter 390 as required by this
874 section, for any act or proceeding undertaken or performed
875 within the scope of the functions of such internal risk
876 management program if the risk manager acts without intentional
877 fraud.

878 (17) A privilege against civil liability is hereby granted
879 to any ~~licensed~~ risk manager or licensed facility with regard to
880 information furnished pursuant to this chapter, unless the
881 ~~licensed~~ risk manager or facility acted in bad faith or with
882 malice in providing such information.

883 Section 30. Section 395.1046, Florida Statutes, is
884 repealed.

885 Section 31. Subsections (2) and (3) of section 395.1055,
886 Florida Statutes, are amended, and paragraph (i) is added to
887 subsection (1), to read:

888 395.1055 Rules and enforcement.—

889 (1) The agency shall adopt rules pursuant to ss. 120.536(1)
890 and 120.54 to implement the provisions of this part, which shall
891 include reasonable and fair minimum standards for ensuring that:

892 (i) All hospitals providing organ transplantation, neonatal
893 intensive care services, inpatient psychiatric services,
894 inpatient substance abuse services, or comprehensive medical
895 rehabilitation meet the minimum licensure requirements adopted
896 by the agency. Such licensure requirements must include quality
897 of care, nurse staffing, physician staffing, physical plant,
898 equipment, emergency transportation, and data reporting
899 standards.

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900 (2) Separate standards may be provided for general and
901 specialty hospitals, ambulatory surgical centers, ~~mobile~~
902 ~~surgical facilities,~~ and statutory rural hospitals as defined in
903 s. 395.602.

904 (3) The agency shall adopt rules with respect to the care
905 and treatment of patients residing in distinct part nursing
906 units of hospitals which are certified for participation in
907 Title XVIII (Medicare) and Title XIX (Medicaid) of the Social
908 Security Act skilled nursing facility program. Such rules shall
909 take into account the types of patients treated in hospital
910 skilled nursing units, including typical patient acuity levels
911 and the average length of stay in such units, and shall be
912 limited to the appropriate portions of the Omnibus Budget
913 Reconciliation Act of 1987 (Pub. L. No. 100-203) (December 22,
914 1987), Title IV (Medicare, Medicaid, and Other Health-Related
915 Programs), Subtitle C (Nursing Home Reform), as amended. The
916 agency shall require level 2 background screening as specified
917 in s. 408.809(1)(e) pursuant to s. 408.809 and chapter 435 for
918 personnel of distinct part nursing units.

919 Section 32. Section 395.10971, Florida Statutes, is
920 repealed.

921 Section 33. Section 395.10972, Florida Statutes, is
922 repealed.

923 Section 34. Section 395.10973, Florida Statutes, is amended
924 to read:

925 395.10973 Powers and duties of the agency.—It is the
926 function of the agency to:

927 (1) Adopt rules pursuant to ss. 120.536(1) and 120.54 to
928 implement ~~the provisions of~~ this part and part II of chapter 408

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929 conferring duties upon it.

930 ~~(2) Develop, impose, and enforce specific standards within~~
931 ~~the scope of the general qualifications established by this part~~
932 ~~which must be met by individuals in order to receive licenses as~~
933 ~~health care risk managers. These standards shall be designed to~~
934 ~~ensure that health care risk managers are individuals of good~~
935 ~~character and otherwise suitable and, by training or experience~~
936 ~~in the field of health care risk management, qualified in~~
937 ~~accordance with the provisions of this part to serve as health~~
938 ~~care risk managers, within statutory requirements.~~

939 ~~(3) Develop a method for determining whether an individual~~
940 ~~meets the standards set forth in s. 395.10974.~~

941 ~~(4) Issue licenses to qualified individuals meeting the~~
942 ~~standards set forth in s. 395.10974.~~

943 ~~(5) Receive, investigate, and take appropriate action with~~
944 ~~respect to any charge or complaint filed with the agency to the~~
945 ~~effect that a certified health care risk manager has failed to~~
946 ~~comply with the requirements or standards adopted by rule by the~~
947 ~~agency or to comply with the provisions of this part.~~

948 ~~(6) Establish procedures for providing periodic reports on~~
949 ~~persons certified or disciplined by the agency under this part.~~

950 (2)~~(7)~~ Develop a model risk management program for health
951 care facilities which will satisfy the requirements of s.
952 395.0197.

953 (3)~~(8)~~ Enforce the special-occupancy provisions of the
954 Florida Building Code which apply to hospitals, intermediate
955 residential treatment facilities, and ambulatory surgical
956 centers in conducting any inspection authorized by this chapter
957 and part II of chapter 408.

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958 Section 35. Section 395.10974, Florida Statutes, is
 959 repealed.

960 Section 36. Section 395.10975, Florida Statutes, is
 961 repealed.

962 Section 37. Subsection (2) of section 395.602, Florida
 963 Statutes, is amended to read:

964 395.602 Rural hospitals.—

965 (2) DEFINITIONS.—As used in this part, the term:

966 (a) ~~“Emergency care hospital” means a medical facility~~
 967 ~~which provides:~~

968 1. ~~Emergency medical treatment; and~~

969 2. ~~Inpatient care to ill or injured persons prior to their~~
 970 ~~transportation to another hospital or provides inpatient medical~~
 971 ~~care to persons needing care for a period of up to 96 hours. The~~
 972 ~~96-hour limitation on inpatient care does not apply to respite,~~
 973 ~~skilled nursing, hospice, or other nonacute care patients.~~

974 (b) ~~“Essential access community hospital” means any~~
 975 ~~facility which:~~

976 1. ~~Has at least 100 beds;~~

977 2. ~~Is located more than 35 miles from any other essential~~
 978 ~~access community hospital, rural referral center, or urban~~
 979 ~~hospital meeting criteria for classification as a regional~~
 980 ~~referral center;~~

981 3. ~~Is part of a network that includes rural primary care~~
 982 ~~hospitals;~~

983 4. ~~Provides emergency and medical backup services to rural~~
 984 ~~primary care hospitals in its rural health network;~~

985 5. ~~Extends staff privileges to rural primary care hospital~~
 986 ~~physicians in its network; and~~

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987 ~~6. Accepts patients transferred from rural primary care~~
988 ~~hospitals in its network.~~

989 ~~(c) "Inactive rural hospital bed" means a licensed acute~~
990 ~~care hospital bed, as defined in s. 395.002(13), that is~~
991 ~~inactive in that it cannot be occupied by acute care inpatients.~~

992 (a) ~~(d)~~ "Rural area health education center" means an area
993 health education center (AHEC), as authorized by Pub. L. No. 94-
994 484, which provides services in a county with a population
995 density of up to ~~no greater than~~ 100 persons per square mile.

996 (b) ~~(e)~~ "Rural hospital" means an acute care hospital
997 licensed under this chapter, having 100 or fewer licensed beds
998 and an emergency room, which is:

999 1. The sole provider within a county with a population
1000 density of up to 100 persons per square mile;

1001 2. An acute care hospital, in a county with a population
1002 density of up to 100 persons per square mile, which is at least
1003 30 minutes of travel time, on normally traveled roads under
1004 normal traffic conditions, from any other acute care hospital
1005 within the same county;

1006 3. A hospital supported by a tax district or subdistrict
1007 whose boundaries encompass a population of up to 100 persons per
1008 square mile;

1009 4. A hospital classified as a sole community hospital under
1010 42 C.F.R. s. 412.92 which has up to 175, ~~regardless of the~~
1011 ~~number of~~ licensed beds;

1012 5. A hospital with a service area that has a population of
1013 up to 100 persons per square mile. As used in this subparagraph,
1014 the term "service area" means the fewest number of zip codes
1015 that account for 75 percent of the hospital's discharges for the

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1016 most recent 5-year period, based on information available from
1017 the hospital inpatient discharge database in the Florida Center
1018 for Health Information and Transparency at the agency; or

1019 6. A hospital designated as a critical access hospital, as
1020 defined in s. 408.07.

1021
1022 Population densities used in this paragraph must be based upon
1023 the most recently completed United States census. A hospital
1024 that received funds under s. 409.9116 for a quarter beginning no
1025 later than July 1, 2002, is deemed to have been and shall
1026 continue to be a rural hospital from that date through June 30,
1027 2021, if the hospital continues to have up to 100 licensed beds
1028 and an emergency room. An acute care hospital that has not
1029 previously been designated as a rural hospital and that meets
1030 the criteria of this paragraph shall be granted such designation
1031 upon application, including supporting documentation, to the
1032 agency. A hospital that was licensed as a rural hospital during
1033 the 2010-2011 or 2011-2012 fiscal year shall continue to be a
1034 rural hospital from the date of designation through June 30,
1035 2021, if the hospital continues to have up to 100 licensed beds
1036 and an emergency room.

1037 ~~(f) "Rural primary care hospital" means any facility~~
1038 ~~meeting the criteria in paragraph (c) or s. 395.605 which~~
1039 ~~provides:~~

1040 ~~1. Twenty-four-hour emergency medical care;~~
1041 ~~2. Temporary inpatient care for periods of 72 hours or less~~
1042 ~~to patients requiring stabilization before discharge or transfer~~
1043 ~~to another hospital. The 72-hour limitation does not apply to~~
1044 ~~respite, skilled nursing, hospice, or other nonacute care~~

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1045 ~~patients; and~~

1046 ~~3. Has no more than six licensed acute care inpatient beds.~~

1047 (c)~~(g)~~ "Swing-bed" means a bed which can be used
 1048 interchangeably as either a hospital, skilled nursing facility
 1049 (SNF), or intermediate care facility (ICF) bed pursuant to 42
 1050 C.F.R. parts 405, 435, 440, 442, and 447.

1051 Section 38. Section 395.603, Florida Statutes, is amended
 1052 to read:

1053 395.603 ~~Deactivation of general hospital beds; Rural~~
 1054 ~~hospital impact statement.-~~

1055 ~~(1) The agency shall establish, by rule, a process by which~~
 1056 ~~a rural hospital, as defined in s. 395.602, that seeks licensure~~
 1057 ~~as a rural primary care hospital or as an emergency care~~
 1058 ~~hospital, or becomes a certified rural health clinic as defined~~
 1059 ~~in Pub. L. No. 95-210, or becomes a primary care program such as~~
 1060 ~~a county health department, community health center, or other~~
 1061 ~~similar outpatient program that provides preventive and curative~~
 1062 ~~services, may deactivate general hospital beds. Rural primary~~
 1063 ~~care hospitals and emergency care hospitals shall maintain the~~
 1064 ~~number of actively licensed general hospital beds necessary for~~
 1065 ~~the facility to be certified for Medicare reimbursement.~~
 1066 ~~Hospitals that discontinue inpatient care to become rural health~~
 1067 ~~care clinics or primary care programs shall deactivate all~~
 1068 ~~licensed general hospital beds. All hospitals, clinics, and~~
 1069 ~~programs with inactive beds shall provide 24-hour emergency~~
 1070 ~~medical care by staffing an emergency room. Providers with~~
 1071 ~~inactive beds shall be subject to the criteria in s. 395.1041.~~
 1072 ~~The agency shall specify in rule requirements for making 24-hour~~
 1073 ~~emergency care available. Inactive general hospital beds shall~~

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1074 ~~be included in the acute care bed inventory, maintained by the~~
1075 ~~agency for certificate of need purposes, for 10 years from the~~
1076 ~~date of deactivation of the beds. After 10 years have elapsed,~~
1077 ~~inactive beds shall be excluded from the inventory. The agency~~
1078 ~~shall, at the request of the licensee, reactivate the inactive~~
1079 ~~general beds upon a showing by the licensee that licensure~~
1080 ~~requirements for the inactive general beds are met.~~

1081 ~~(2)~~ In formulating and implementing policies and rules that
1082 may have significant impact on the ability of rural hospitals to
1083 continue to provide health care services in rural communities,
1084 the agency, the department, or the respective regulatory board
1085 adopting policies or rules regarding the licensure or
1086 certification of health care professionals shall provide a rural
1087 hospital impact statement. The rural hospital impact statement
1088 shall assess the proposed action in light of the following
1089 questions:

1090 (1) ~~(a)~~ Do the health personnel affected by the proposed
1091 action currently practice in rural hospitals or are they likely
1092 to in the near future?

1093 (2) ~~(b)~~ What are the current numbers of the affected health
1094 personnel in this state, their geographic distribution, and the
1095 number practicing in rural hospitals?

1096 (3) ~~(c)~~ What are the functions presently performed by the
1097 affected health personnel, and are such functions presently
1098 performed in rural hospitals?

1099 (4) ~~(d)~~ What impact will the proposed action have on the
1100 ability of rural hospitals to recruit the affected personnel to
1101 practice in their facilities?

1102 (5) ~~(e)~~ What impact will the proposed action have on the

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1103 limited financial resources of rural hospitals through increased
 1104 salaries and benefits necessary to recruit or retain such health
 1105 personnel?

1106 (6)~~(f)~~ Is there a less stringent requirement which could
 1107 apply to practice in rural hospitals?

1108 (7)~~(g)~~ Will this action create staffing shortages, which
 1109 could result in a loss to the public of health care services in
 1110 rural hospitals or result in closure of any rural hospitals?

1111 Section 39. Section 395.604, Florida Statutes, is repealed.

1112 Section 40. Section 395.605, Florida Statutes, is repealed.

1113 Section 41. Paragraph (c) of subsection (1) of section
 1114 395.701, Florida Statutes, is amended to read:

1115 395.701 Annual assessments on net operating revenues for
 1116 inpatient and outpatient services to fund public medical
 1117 assistance; administrative fines for failure to pay assessments
 1118 when due; exemption.—

1119 (1) For the purposes of this section, the term:

1120 (c) "Hospital" means a health care institution as defined
 1121 in s. 395.002(12), but does not include any hospital operated by
 1122 a state ~~the agency or the Department of Corrections.~~

1123 Section 42. Paragraph (b) of subsection (2) of section
 1124 395.7015, Florida Statutes, is amended to read:

1125 395.7015 Annual assessment on health care entities.—

1126 (2) There is imposed an annual assessment against certain
 1127 health care entities as described in this section:

1128 (b) For the purpose of this section, "health care entities"
 1129 include the following:

1130 1. Ambulatory surgical centers ~~and mobile surgical~~
 1131 ~~facilities licensed under s. 395.003. This subsection shall only~~

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1132 ~~apply to mobile surgical facilities operating under contracts~~
1133 ~~entered into on or after July 1, 1998.~~

1134 ~~2. Clinical laboratories licensed under s. 483.091,~~
1135 ~~excluding any hospital laboratory defined under s. 483.041(6),~~
1136 ~~any clinical laboratory operated by the state or a political~~
1137 ~~subdivision of the state, any clinical laboratory which~~
1138 ~~qualifies as an exempt organization under s. 501(c)(3) of the~~
1139 ~~Internal Revenue Code of 1986, as amended, and which receives 70~~
1140 ~~percent or more of its gross revenues from services to charity~~
1141 ~~patients or Medicaid patients, and any blood, plasma, or tissue~~
1142 ~~bank procuring, storing, or distributing blood, plasma, or~~
1143 ~~tissue either for future manufacture or research or distributed~~
1144 ~~on a nonprofit basis, and further excluding any clinical~~
1145 ~~laboratory which is wholly owned and operated by 6 or fewer~~
1146 ~~physicians who are licensed pursuant to chapter 458 or chapter~~
1147 ~~459 and who practice in the same group practice, and at which no~~
1148 ~~clinical laboratory work is performed for patients referred by~~
1149 ~~any health care provider who is not a member of the same group.~~

1150 ~~2.3.~~ Diagnostic-imaging centers that are freestanding
1151 outpatient facilities that provide specialized services for the
1152 identification or determination of a disease through examination
1153 and also provide sophisticated radiological services, and in
1154 which services are rendered by a physician licensed by the Board
1155 of Medicine under s. 458.311, s. 458.313, or s. 458.317, or by
1156 an osteopathic physician licensed by the Board of Osteopathic
1157 Medicine under s. 459.0055 or s. 459.0075. For purposes of this
1158 paragraph, "sophisticated radiological services" means the
1159 following: magnetic resonance imaging; nuclear medicine;
1160 angiography; arteriography; computed tomography; positron

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1161 emission tomography; digital vascular imaging; bronchography;
1162 lymphangiography; splenography; ultrasound, excluding ultrasound
1163 providers that are part of a private physician's office practice
1164 or when ultrasound is provided by two or more physicians
1165 licensed under chapter 458 or chapter 459 who are members of the
1166 same professional association and who practice in the same
1167 medical specialties; and such other sophisticated radiological
1168 services, excluding mammography, as adopted in rule by the
1169 board.

1170 Section 43. Subsection (1) of section 400.0625, Florida
1171 Statutes, is amended to read:

1172 400.0625 Minimum standards for clinical laboratory test
1173 results and diagnostic X-ray results.—

1174 (1) Each nursing home, as a requirement for issuance or
1175 renewal of its license, shall require that all clinical
1176 laboratory tests performed for the nursing home be performed by
1177 a ~~clinical~~ laboratory appropriately certified by the Centers for
1178 Medicare and Medicaid Services under the federal Clinical
1179 Laboratory Improvement Amendments and the federal rules adopted
1180 thereunder ~~licensed under the provisions of chapter 483~~, except
1181 for such self-testing procedures as are approved by the agency
1182 by rule. ~~Results of clinical laboratory tests performed prior to~~
1183 ~~admission which meet the minimum standards provided in s.~~
1184 ~~483.181(3) shall be accepted in lieu of routine examinations~~
1185 ~~required upon admission and clinical laboratory tests which may~~
1186 ~~be ordered by a physician for residents of the nursing home.~~

1187 Section 44. Paragraph (a) of subsection (2) of section
1188 400.191, Florida Statutes, is amended to read:

1189 400.191 Availability, distribution, and posting of reports

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1190 and records.—

1191 (2) The agency shall publish the Nursing Home Guide
1192 quarterly in electronic form to assist consumers and their
1193 families in comparing and evaluating nursing home facilities.

1194 (a) The agency shall provide an Internet site which shall
1195 include at least the following information either directly or
1196 indirectly through a link to another established site or sites
1197 of the agency's choosing:

1198 1. A section entitled "Have you considered programs that
1199 provide alternatives to nursing home care?" which shall be the
1200 first section of the Nursing Home Guide and which shall
1201 prominently display information about available alternatives to
1202 nursing homes and how to obtain additional information regarding
1203 these alternatives. The Nursing Home Guide shall explain that
1204 this state offers alternative programs that permit qualified
1205 elderly persons to stay in their homes instead of being placed
1206 in nursing homes and shall encourage interested persons to call
1207 the Comprehensive Assessment Review and Evaluation for Long-Term
1208 Care Services (CARES) Program to inquire if they qualify. The
1209 Nursing Home Guide shall list available home and community-based
1210 programs which shall clearly state the services that are
1211 provided and indicate whether nursing home services are included
1212 if needed.

1213 2. A list by name and address of all nursing home
1214 facilities in this state, including any prior name by which a
1215 facility was known during the previous 24-month period.

1216 3. Whether such nursing home facilities are proprietary or
1217 nonproprietary.

1218 4. The current owner of the facility's license and the year

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1219 that that entity became the owner of the license.

1220 5. The name of the owner or owners of each facility and
1221 whether the facility is affiliated with a company or other
1222 organization owning or managing more than one nursing facility
1223 in this state.

1224 6. The total number of beds in each facility and the most
1225 recently available occupancy levels.

1226 7. The number of private and semiprivate rooms in each
1227 facility.

1228 8. The religious affiliation, if any, of each facility.

1229 9. The languages spoken by the administrator and staff of
1230 each facility.

1231 10. Whether or not each facility accepts Medicare or
1232 Medicaid recipients or insurance, health maintenance
1233 organization, Veterans Administration, CHAMPUS program, or
1234 workers' compensation coverage.

1235 11. Recreational and other programs available at each
1236 facility.

1237 12. Special care units or programs offered at each
1238 facility.

1239 13. Whether the facility is a part of a retirement
1240 community that offers other services pursuant to part III of
1241 this chapter or part I or part III of chapter 429.

1242 14. Survey and deficiency information, including all
1243 federal and state recertification, licensure, revisit, and
1244 complaint survey information, for each facility ~~for the past 30~~
1245 ~~months~~. For noncertified nursing homes, state survey and
1246 deficiency information, including licensure, revisit, and
1247 complaint survey information ~~for the past 30 months~~ shall be

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1248 provided.

1249 Section 45. Subsection (1) and paragraphs (b), (e), and (f)
1250 of subsection (4) of section 400.464, Florida Statutes, are
1251 amended, and subsection (6) is added to that section, to read:

1252 400.464 Home health agencies to be licensed; expiration of
1253 license; exemptions; unlawful acts; penalties.—

1254 (1) The requirements of part II of chapter 408 apply to the
1255 provision of services that require licensure pursuant to this
1256 part and part II of chapter 408 and entities licensed or
1257 registered by or applying for such licensure or registration
1258 from the Agency for Health Care Administration pursuant to this
1259 part. A license issued by the agency is required in order to
1260 operate a home health agency in this state. A license issued on
1261 or after July 1, 2018, must specify the home health services the
1262 organization is authorized to perform and indicate whether such
1263 specified services are considered skilled care. The provision or
1264 advertising of services that require licensure pursuant to this
1265 part without such services being specified on the face of the
1266 license issued on or after July 1, 2018, constitutes unlicensed
1267 activity as prohibited under s. 408.812.

1268 (4) (b) The operation or maintenance of an unlicensed home
1269 health agency or the performance of any home health services in
1270 violation of this part is declared a nuisance, inimical to the
1271 public health, welfare, and safety. The agency or any state
1272 attorney may, in addition to other remedies provided in this
1273 part, bring an action for an injunction to restrain such
1274 violation, or to enjoin the future operation or maintenance of
1275 the home health agency or the provision of home health services
1276 in violation of this part or part II of chapter 408, until

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1277 compliance with this part or the rules adopted under this part
1278 has been demonstrated to the satisfaction of the agency.

1279 (e) Any person who owns, operates, or maintains an
1280 unlicensed home health agency and who, ~~within 10 working days~~
1281 after receiving notification from the agency, fails to cease
1282 operation and apply for a license under this part commits a
1283 misdemeanor of the second degree, punishable as provided in s.
1284 775.082 or s. 775.083. Each day of continued operation is a
1285 separate offense.

1286 (f) Any home health agency that fails to cease operation
1287 after agency notification may be fined in accordance with s.
1288 408.812 \$500 for each day of noncompliance.

1289 (6) Any person, entity, or organization providing home
1290 health services which is exempt from licensure under subsection
1291 (5) may voluntarily apply for a certificate of exemption from
1292 licensure under its exempt status with the agency on a form that
1293 specifies its name or names and addresses, a statement of the
1294 reasons why it is exempt from licensure as a home health agency,
1295 and other information deemed necessary by the agency. A
1296 certificate of exemption is valid for a period of not more than
1297 2 years and is not transferable. The agency may charge an
1298 applicant \$100 for a certificate of exemption or charge the
1299 actual cost of processing the certificate.

1300 Section 46. Subsections (6) through (9) of section 400.471,
1301 Florida Statutes, are redesignated as subsections (5) through
1302 (8), respectively, and present subsections (2), (6), and (9) of
1303 that section are amended, to read:

1304 400.471 Application for license; fee.—

1305 (2) In addition to the requirements of part II of chapter

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1306 408, the initial applicant, the applicant for a change of
1307 ownership, and the applicant for the addition of skilled care
1308 services must file with the application satisfactory proof that
1309 the home health agency is in compliance with this part and
1310 applicable rules, including:

1311 (a) A listing of services to be provided, either directly
1312 by the applicant or through contractual arrangements with
1313 existing providers.

1314 (b) The number and discipline of professional staff to be
1315 employed.

1316 ~~(c) Completion of questions concerning volume data on the~~
1317 ~~renewal application as determined by rule.~~

1318 (c) ~~(d)~~ A business plan, signed by the applicant, which
1319 details the home health agency's methods to obtain patients and
1320 its plan to recruit and maintain staff.

1321 (d) ~~(e)~~ Evidence of contingency funding as required under s.
1322 408.8065 ~~equal to 1 month's average operating expenses during~~
1323 ~~the first year of operation.~~

1324 (e) ~~(f)~~ A balance sheet, income and expense statement, and
1325 statement of cash flows for the first 2 years of operation which
1326 provide evidence of having sufficient assets, credit, and
1327 projected revenues to cover liabilities and expenses. The
1328 applicant has demonstrated financial ability to operate if the
1329 applicant's assets, credit, and projected revenues meet or
1330 exceed projected liabilities and expenses. An applicant may not
1331 project an operating margin of 15 percent or greater for any
1332 month in the first year of operation. All documents required
1333 under this paragraph must be prepared in accordance with
1334 generally accepted accounting principles and compiled and signed

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1335 by a certified public accountant.

1336 ~~(f)(g)~~ All other ownership interests in health care
1337 entities for each controlling interest, as defined in part II of
1338 chapter 408.

1339 ~~(g)(h)~~ In the case of an application for initial licensure,
1340 an application for a change of ownership, or an application for
1341 the addition of skilled care services, documentation of
1342 accreditation, or an application for accreditation, from an
1343 accrediting organization that is recognized by the agency as
1344 having standards comparable to those required by this part and
1345 part II of chapter 408. A home health agency that ~~is not~~
1346 ~~Medicare or Medicaid certified and~~ does not provide skilled care
1347 is exempt from this paragraph. Notwithstanding s. 408.806, an
1348 initial applicant ~~that has applied for accreditation~~ must
1349 provide proof of accreditation that is not conditional or
1350 provisional and a survey demonstrating compliance with the
1351 requirements of this part, part II of chapter 408, and
1352 applicable rules from an accrediting organization that is
1353 recognized by the agency as having standards comparable to those
1354 required by this part and part II of chapter 408 within 120 days
1355 after the date of the agency's receipt of the application for
1356 licensure ~~or the application shall be withdrawn from further~~
1357 ~~consideration~~. Such accreditation must be continuously
1358 maintained by the home health agency to maintain licensure. The
1359 agency shall accept, in lieu of its own periodic licensure
1360 survey, the submission of the survey of an accrediting
1361 organization that is recognized by the agency if the
1362 accreditation of the licensed home health agency is not
1363 provisional and if the licensed home health agency authorizes

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1364 releases of, and the agency receives the report of, the
1365 accrediting organization.

1366 ~~(6) The agency may not issue a license designated as~~
1367 ~~certified to a home health agency that fails to satisfy the~~
1368 ~~requirements of a Medicare certification survey from the agency.~~

1369 (8)~~(9)~~ The agency may not issue a renewal license for a
1370 home health agency in any county having at least one licensed
1371 home health agency and that has more than one home health agency
1372 per 5,000 persons, as indicated by the most recent population
1373 estimates published by the Legislature's Office of Economic and
1374 Demographic Research, if the applicant or any controlling
1375 interest has been administratively sanctioned by the agency
1376 during the 2 years prior to the submission of the licensure
1377 renewal application for one or more of the following acts:

1378 (a) An intentional or negligent act that materially affects
1379 the health or safety of a client of the provider;

1380 (b) Knowingly providing home health services in an
1381 unlicensed assisted living facility or unlicensed adult family-
1382 care home, unless the home health agency or employee reports the
1383 unlicensed facility or home to the agency within 72 hours after
1384 providing the services;

1385 (c) Preparing or maintaining fraudulent patient records,
1386 such as, but not limited to, charting ahead, recording vital
1387 signs or symptoms which were not personally obtained or observed
1388 by the home health agency's staff at the time indicated,
1389 borrowing patients or patient records from other home health
1390 agencies to pass a survey or inspection, or falsifying
1391 signatures;

1392 (d) Failing to provide at least one service directly to a

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1393 patient for a period of 60 days;

1394 (e) Demonstrating a pattern of falsifying documents
1395 relating to the training of home health aides or certified
1396 nursing assistants or demonstrating a pattern of falsifying
1397 health statements for staff who provide direct care to patients.
1398 A pattern may be demonstrated by a showing of at least three
1399 fraudulent entries or documents;

1400 (f) Demonstrating a pattern of billing any payor for
1401 services not provided. A pattern may be demonstrated by a
1402 showing of at least three billings for services not provided
1403 within a 12-month period;

1404 (g) Demonstrating a pattern of failing to provide a service
1405 specified in the home health agency's written agreement with a
1406 patient or the patient's legal representative, or the plan of
1407 care for that patient, except ~~unless a reduction in service is~~
1408 ~~mandated by Medicare, Medicaid, or a state program~~ or as
1409 provided in s. 400.492(3). A pattern may be demonstrated by a
1410 showing of at least three incidents, regardless of the patient
1411 or service, in which the home health agency did not provide a
1412 service specified in a written agreement or plan of care during
1413 a 3-month period;

1414 (h) Giving remuneration to a case manager, discharge
1415 planner, facility-based staff member, or third-party vendor who
1416 is involved in the discharge planning process of a facility
1417 licensed under chapter 395, chapter 429, or this chapter from
1418 whom the home health agency receives referrals or gives
1419 remuneration as prohibited in s. 400.474(6)(a);

1420 (i) Giving cash, or its equivalent, to a Medicare or
1421 Medicaid beneficiary;

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1422 (j) Demonstrating a pattern of billing the Medicaid program
1423 for services to Medicaid recipients which are medically
1424 unnecessary as determined by a final order. A pattern may be
1425 demonstrated by a showing of at least two such medically
1426 unnecessary services within one Medicaid program integrity audit
1427 period;

1428 (k) Providing services to residents in an assisted living
1429 facility for which the home health agency does not receive fair
1430 market value remuneration; or

1431 (l) Providing staffing to an assisted living facility for
1432 which the home health agency does not receive fair market value
1433 remuneration.

1434 Section 47. Subsection (5) of section 400.474, Florida
1435 Statutes, is amended to read:

1436 400.474 Administrative penalties.—

1437 (5) The agency shall impose a fine of \$5,000 against a home
1438 health agency that demonstrates a pattern of failing to provide
1439 a service specified in the home health agency's written
1440 agreement with a patient or the patient's legal representative,
1441 or the plan of care for that patient, except ~~unless a reduction~~
1442 ~~in service is mandated by Medicare, Medicaid, or a state program~~
1443 ~~or~~ as provided in s. 400.492(3). A pattern may be demonstrated
1444 by a showing of at least three incidences, regardless of the
1445 patient or service, where the home health agency did not provide
1446 a service specified in a written agreement or plan of care
1447 during a 3-month period. The agency shall impose the fine for
1448 each occurrence. The agency may also impose additional
1449 administrative fines under s. 400.484 for the direct or indirect
1450 harm to a patient, or deny, revoke, or suspend the license of

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1451 the home health agency for a pattern of failing to provide a
1452 service specified in the home health agency's written agreement
1453 with a patient or the plan of care for that patient.

1454 Section 48. Paragraph (c) of subsection (2) of section
1455 400.476, Florida Statutes, is amended to read:

1456 400.476 Staffing requirements; notifications; limitations
1457 on staffing services.—

1458 (2) DIRECTOR OF NURSING.—

1459 (c) A home health agency that provides skilled nursing care
1460 must ~~is not Medicare or Medicaid certified and does not provide~~
1461 ~~skilled care or provides only physical, occupational, or speech~~
1462 ~~therapy is not required to have a director of nursing and is~~
1463 ~~exempt from paragraph (b).~~

1464 Section 49. Section 400.484, Florida Statutes, is amended
1465 to read:

1466 400.484 Right of inspection; violations ~~deficiencies~~;
1467 fines.—

1468 (1) In addition to the requirements of s. 408.811, the
1469 agency may make such inspections and investigations as are
1470 necessary in order to determine the state of compliance with
1471 this part, part II of chapter 408, and applicable rules.

1472 (2) The agency shall impose fines for various classes of
1473 violations ~~deficiencies~~ in accordance with the following
1474 schedule:

1475 (a) Class I violations are as provided in s. 408.813 A
1476 ~~class I deficiency is any act, omission, or practice that~~
1477 ~~results in a patient's death, disablement, or permanent injury,~~
1478 ~~or places a patient at imminent risk of death, disablement, or~~
1479 ~~permanent injury.~~ Upon finding a class I violation ~~deficiency~~,

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1480 the agency shall impose an administrative fine in the amount of
1481 \$15,000 for each occurrence and each day that the violation
1482 ~~deficiency~~ exists.

1483 (b) Class II violations are as provided in s. 408.813 A
1484 ~~class II deficiency is any act, omission, or practice that has a~~
1485 ~~direct adverse effect on the health, safety, or security of a~~
1486 ~~patient.~~ Upon finding a class II violation ~~deficiency~~, the
1487 agency shall impose an administrative fine in the amount of
1488 \$5,000 for each occurrence and each day that the violation
1489 ~~deficiency~~ exists.

1490 (c) Class III violations are as provided in s. 408.813 A
1491 ~~class III deficiency is any act, omission, or practice that has~~
1492 ~~an indirect, adverse effect on the health, safety, or security~~
1493 ~~of a patient.~~ Upon finding an uncorrected or repeated class III
1494 violation ~~deficiency~~, the agency shall impose an administrative
1495 fine not to exceed \$1,000 for each occurrence and each day that
1496 the uncorrected or repeated violation ~~deficiency~~ exists.

1497 (d) Class IV violations are as provided in s. 408.813 A
1498 ~~class IV deficiency is any act, omission, or practice related to~~
1499 ~~required reports, forms, or documents which does not have the~~
1500 ~~potential of negatively affecting patients.~~ These violations are
1501 of a type that the agency determines do not threaten the health,
1502 safety, or security of patients. Upon finding an uncorrected or
1503 repeated class IV violation ~~deficiency~~, the agency shall impose
1504 an administrative fine not to exceed \$500 for each occurrence
1505 and each day that the uncorrected or repeated violation
1506 ~~deficiency~~ exists.

1507 (3) In addition to any other penalties imposed pursuant to
1508 this section or part, the agency may assess costs related to an

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1509 investigation that results in a successful prosecution,
1510 excluding costs associated with an attorney's time.

1511 Section 50. Subsection (4) of section 400.497, Florida
1512 Statutes, is amended to read:

1513 400.497 Rules establishing minimum standards.—The agency
1514 shall adopt, publish, and enforce rules to implement part II of
1515 chapter 408 and this part, including, as applicable, ss. 400.506
1516 and 400.509, which must provide reasonable and fair minimum
1517 standards relating to:

1518 (4) Licensure application and renewal and certificates of
1519 exemption.

1520 Section 51. Subsection (5) and paragraph (a) of subsection
1521 (15) of section 400.506, Florida Statutes, are amended to read:

1522 400.506 Licensure of nurse registries; requirements;
1523 penalties.—

1524 (5) (a) In addition to the requirements of s. 408.812, any
1525 person who owns, operates, or maintains an unlicensed nurse
1526 registry and who, ~~within 10 working days~~ after receiving
1527 notification from the agency, fails to cease operation and apply
1528 for a license under this part commits a misdemeanor of the
1529 second degree, punishable as provided in s. 775.082 or s.
1530 775.083. Each day of continued operation is a separate offense.

1531 (b) If a nurse registry fails to cease operation after
1532 agency notification, the agency may impose a fine pursuant to s.
1533 408.812 ~~of \$500 for each day of noncompliance~~.

1534 (15) (a) The agency may deny, suspend, or revoke the license
1535 of a nurse registry and shall impose a fine of \$5,000 against a
1536 nurse registry that:

1537 1. Provides services to residents in an assisted living

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1538 facility for which the nurse registry does not receive fair
1539 market value remuneration.

1540 2. Provides staffing to an assisted living facility for
1541 which the nurse registry does not receive fair market value
1542 remuneration.

1543 3. Fails to provide the agency, upon request, with copies
1544 of all contracts with assisted living facilities which were
1545 executed within the last 5 years.

1546 ~~4. Gives remuneration to a case manager, discharge planner,~~
1547 ~~facility-based staff member, or third-party vendor who is~~
1548 ~~involved in the discharge planning process of a facility~~
1549 ~~licensed under chapter 395 or this chapter and from whom the~~
1550 ~~nurse registry receives referrals. A nurse registry is exempt~~
1551 ~~from this subparagraph if it does not bill the Florida Medicaid~~
1552 ~~program or the Medicare program or share a controlling interest~~
1553 ~~with any entity licensed, registered, or certified under part II~~
1554 ~~of chapter 408 that bills the Florida Medicaid program or the~~
1555 ~~Medicare program.~~

1556 ~~5. Gives remuneration to a physician, a member of the~~
1557 ~~physician's office staff, or an immediate family member of the~~
1558 ~~physician, and the nurse registry received a patient referral in~~
1559 ~~the last 12 months from that physician or the physician's office~~
1560 ~~staff. A nurse registry is exempt from this subparagraph if it~~
1561 ~~does not bill the Florida Medicaid program or the Medicare~~
1562 ~~program or share a controlling interest with any entity~~
1563 ~~licensed, registered, or certified under part II of chapter 408~~
1564 ~~that bills the Florida Medicaid program or the Medicare program.~~

1565 Section 52. Subsection (1) of section 400.606, Florida
1566 Statutes, is amended to read:

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1567 400.606 License; application; renewal; conditional license
1568 or permit; certificate of need.—

1569 (1) In addition to the requirements of part II of chapter
1570 408, the initial application and change of ownership application
1571 must be accompanied by a plan for the delivery of home,
1572 residential, and homelike inpatient hospice services to
1573 terminally ill persons and their families. Such plan must
1574 contain, but need not be limited to:

1575 (a) The estimated average number of terminally ill persons
1576 to be served monthly.

1577 (b) The geographic area in which hospice services will be
1578 available.

1579 (c) A listing of services which are or will be provided,
1580 either directly by the applicant or through contractual
1581 arrangements with existing providers.

1582 (d) Provisions for the implementation of hospice home care
1583 within 3 months after licensure.

1584 (e) Provisions for the implementation of hospice homelike
1585 inpatient care within 12 months after licensure.

1586 (f) The number and disciplines of professional staff to be
1587 employed.

1588 (g) The name and qualifications of any existing or
1589 potential contractee.

1590 (h) A plan for attracting and training volunteers.

1591
1592 ~~If the applicant is an existing licensed health care provider,~~
1593 ~~the application must be accompanied by a copy of the most recent~~
1594 ~~profit-loss statement and, if applicable, the most recent~~
1595 ~~licensure inspection report.~~

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1596 Section 53. Subsection (6) of section 400.925, Florida
 1597 Statutes, is amended to read:

1598 400.925 Definitions.—As used in this part, the term:

1599 (6) "Home medical equipment" includes any product as
 1600 defined by the Food and Drug Administration's Federal Food,
 1601 Drug, and Cosmetic Act, any products reimbursed under the
 1602 Medicare Part B Durable Medical Equipment benefits, or any
 1603 products reimbursed under the Florida Medicaid durable medical
 1604 equipment program. Home medical equipment includes:

1605 (a) Oxygen and related respiratory equipment; ~~manual,~~
 1606 ~~motorized, or customized wheelchairs and related seating and~~
 1607 ~~positioning, but does not include prosthetics or orthotics or~~
 1608 ~~any splints, braces, or aids custom fabricated by a licensed~~
 1609 ~~health care practitioner;~~

1610 (b) Motorized scooters;

1611 (c) Personal transfer systems; ~~and~~

1612 (d) Specialty beds, for use by a person with a medical
 1613 need; and

1614 (e) Manual, motorized, or customized wheelchairs and
 1615 related seating and positioning, but does not include
 1616 prosthetics or orthotics or any splints, braces, or aids custom
 1617 fabricated by a licensed health care practitioner.

1618 Section 54. Subsection (4) of section 400.931, Florida
 1619 Statutes, is amended to read:

1620 400.931 Application for license; fee.—

1621 (4) When a change of the general manager of a home medical
 1622 equipment provider occurs, the licensee must notify the agency
 1623 of the change within the timeframes established in part II of
 1624 chapter 408 and applicable rules ~~45 days.~~

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1625 Section 55. Subsection (2) of section 400.933, Florida
1626 Statutes, is amended to read:

1627 400.933 Licensure inspections and investigations.—

1628 (2) The agency shall accept, in lieu of its own periodic
1629 inspections for licensure, submission of the following:

1630 (a) The survey or inspection of an accrediting
1631 organization, provided the accreditation of the licensed home
1632 medical equipment provider is not provisional and provided the
1633 licensed home medical equipment provider authorizes release of,
1634 and the agency receives the report of, the accrediting
1635 organization; or

1636 (b) A copy of a valid medical oxygen retail establishment
1637 permit issued by the Department of Business and Professional
1638 Regulation Health, pursuant to chapter 499.

1639 Section 56. Subsection (2) of section 400.980, Florida
1640 Statutes, is amended to read:

1641 400.980 Health care services pools.—

1642 (2) The requirements of part II of chapter 408 apply to the
1643 provision of services that require licensure or registration
1644 pursuant to this part and part II of chapter 408 and to entities
1645 registered by or applying for such registration from the agency
1646 pursuant to this part. Registration or a license issued by the
1647 agency is required for the operation of a health care services
1648 pool in this state. In accordance with s. 408.805, an applicant
1649 or licensee shall pay a fee for each license application
1650 submitted using this part, part II of chapter 408, and
1651 applicable rules. The agency shall adopt rules and provide forms
1652 required for such registration and shall impose a registration
1653 fee in an amount sufficient to cover the cost of administering

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1654 this part and part II of chapter 408. In addition to the
1655 requirements in part II of chapter 408, the registrant must
1656 provide the agency with any change of information contained on
1657 the original registration application within the timeframes
1658 established in this part, part II of chapter 408, and applicable
1659 rules ~~14 days prior to the change.~~

1660 Section 57. Paragraphs (a) through (d) of subsection (4) of
1661 section 400.9905, Florida Statutes, are amended to read:

1662 400.9905 Definitions.—

1663 (4) "Clinic" means an entity where health care services are
1664 provided to individuals and which tenders charges for
1665 reimbursement for such services, including a mobile clinic and a
1666 portable equipment provider. As used in this part, the term does
1667 not include and the licensure requirements of this part do not
1668 apply to:

1669 (a) Entities licensed or registered by the state under
1670 chapter 395; entities licensed or registered by the state and
1671 providing only health care services within the scope of services
1672 authorized under their respective licenses under ss. 383.30-
1673 383.332 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397,
1674 this chapter except part X, chapter 429, chapter 463, chapter
1675 465, chapter 466, chapter 478, ~~part I of chapter 483~~, chapter
1676 484, or chapter 651; end-stage renal disease providers
1677 authorized under 42 C.F.R. part 405, subpart U; providers
1678 certified under 42 C.F.R. part 485, subpart B or subpart H; or
1679 any entity that provides neonatal or pediatric hospital-based
1680 health care services or other health care services by licensed
1681 practitioners solely within a hospital licensed under chapter
1682 395.

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1683 (b) Entities that own, directly or indirectly, entities
1684 licensed or registered by the state pursuant to chapter 395;
1685 entities that own, directly or indirectly, entities licensed or
1686 registered by the state and providing only health care services
1687 within the scope of services authorized pursuant to their
1688 respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~,
1689 chapter 390, chapter 394, chapter 397, this chapter except part
1690 X, chapter 429, chapter 463, chapter 465, chapter 466, chapter
1691 478, ~~part I of chapter 483~~, chapter 484, or chapter 651; end-
1692 stage renal disease providers authorized under 42 C.F.R. part
1693 405, subpart U; providers certified under 42 C.F.R. part 485,
1694 subpart B or subpart H; or any entity that provides neonatal or
1695 pediatric hospital-based health care services by licensed
1696 practitioners solely within a hospital licensed under chapter
1697 395.

1698 (c) Entities that are owned, directly or indirectly, by an
1699 entity licensed or registered by the state pursuant to chapter
1700 395; entities that are owned, directly or indirectly, by an
1701 entity licensed or registered by the state and providing only
1702 health care services within the scope of services authorized
1703 pursuant to their respective licenses under ss. 383.30-383.332
1704 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397, this
1705 chapter except part X, chapter 429, chapter 463, chapter 465,
1706 chapter 466, chapter 478, ~~part I of chapter 483~~, chapter 484, or
1707 chapter 651; end-stage renal disease providers authorized under
1708 42 C.F.R. part 405, subpart U; providers certified under 42
1709 C.F.R. part 485, subpart B or subpart H; or any entity that
1710 provides neonatal or pediatric hospital-based health care
1711 services by licensed practitioners solely within a hospital

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1712 under chapter 395.

1713 (d) Entities that are under common ownership, directly or
 1714 indirectly, with an entity licensed or registered by the state
 1715 pursuant to chapter 395; entities that are under common
 1716 ownership, directly or indirectly, with an entity licensed or
 1717 registered by the state and providing only health care services
 1718 within the scope of services authorized pursuant to their
 1719 respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~,
 1720 chapter 390, chapter 394, chapter 397, this chapter except part
 1721 X, chapter 429, chapter 463, chapter 465, chapter 466, chapter
 1722 478, ~~part I of chapter 483~~, chapter 484, or chapter 651; end-
 1723 stage renal disease providers authorized under 42 C.F.R. part
 1724 405, subpart U; providers certified under 42 C.F.R. part 485,
 1725 subpart B or subpart H; or any entity that provides neonatal or
 1726 pediatric hospital-based health care services by licensed
 1727 practitioners solely within a hospital licensed under chapter
 1728 395.

1729
 1730 Notwithstanding this subsection, an entity shall be deemed a
 1731 clinic and must be licensed under this part in order to receive
 1732 reimbursement under the Florida Motor Vehicle No-Fault Law, ss.
 1733 627.730-627.7405, unless exempted under s. 627.736(5)(h).

1734 Section 58. Subsection (6) of section 400.9935, Florida
 1735 Statutes, is amended to read:

1736 400.9935 Clinic responsibilities.—

1737 (6) Any person or entity providing health care services
 1738 which is not a clinic, as defined under s. 400.9905, may
 1739 voluntarily apply for a certificate of exemption from licensure
 1740 under its exempt status with the agency on a form that sets

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1741 forth its name or names and addresses, a statement of the
1742 reasons why it cannot be defined as a clinic, and other
1743 information deemed necessary by the agency. An exemption may be
1744 valid for up to 2 years and is not transferable. The agency may
1745 charge an applicant for a certificate of exemption in an amount
1746 equal to \$100 or the actual cost of processing the certificate,
1747 whichever is less. An entity seeking a certificate of exemption
1748 must publish and maintain a schedule of charges for the medical
1749 services offered to patients. The schedule must include the
1750 prices charged to an uninsured person paying for such services
1751 by cash, check, credit card, or debit card. The schedule must be
1752 posted in a conspicuous place in the reception area of the
1753 entity and must include, but is not limited to, the 50 services
1754 most frequently provided by the entity. The schedule may group
1755 services by three price levels, listing services in each price
1756 level. The posting must be at least 15 square feet in size. As a
1757 condition precedent to receiving a certificate of exemption, an
1758 applicant must provide to the agency documentation of compliance
1759 with these requirements.

1760 Section 59. Paragraph (a) of subsection (2) of section
1761 408.033, Florida Statutes, is amended to read:

1762 408.033 Local and state health planning.—

1763 (2) FUNDING.—

1764 (a) The Legislature intends that the cost of local health
1765 councils be borne by assessments on selected health care
1766 facilities subject to facility licensure by the Agency for
1767 Health Care Administration, including abortion clinics, assisted
1768 living facilities, ambulatory surgical centers, birth birthing
1769 centers, ~~clinical laboratories except community nonprofit blood~~

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1770 ~~banks and clinical laboratories operated by practitioners for~~
1771 ~~exclusive use regulated under s. 483.035,~~ home health agencies,
1772 hospices, hospitals, intermediate care facilities for the
1773 developmentally disabled, nursing homes, health care clinics,
1774 and multiphasic testing centers and by assessments on
1775 organizations subject to certification by the agency pursuant to
1776 chapter 641, part III, including health maintenance
1777 organizations and prepaid health clinics. Fees assessed may be
1778 collected prospectively at the time of licensure renewal and
1779 prorated for the licensure period.

1780 Section 60. Paragraphs (f) through (t) of subsection (3) of
1781 section 408.036, Florida Statutes, are redesignated as
1782 paragraphs (e) through (s), respectively, and present paragraphs
1783 (e) and (p) of that subsection are amended, to read:

1784 408.036 Projects subject to review; exemptions.—

1785 (3) EXEMPTIONS.—Upon request, the following projects are
1786 subject to exemption from the provisions of subsection (1):

1787 ~~(e) For mobile surgical facilities and related health care~~
1788 ~~services provided under contract with the Department of~~
1789 ~~Corrections or a private correctional facility operating~~
1790 ~~pursuant to chapter 957.~~

1791 (o) ~~(p)~~ For replacement of a licensed nursing home on the
1792 same site, or within 5 miles of the same site if within the same
1793 subdistrict, if the number of licensed beds does not increase
1794 except as permitted under paragraph (e) ~~(f)~~.

1795 Section 61. Paragraph (b) of subsection (3) of section
1796 408.0361, Florida Statutes, is amended to read:

1797 408.0361 Cardiovascular services and burn unit licensure.—

1798 (3) In establishing rules for adult cardiovascular

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1799 services, the agency shall include provisions that allow for:

1800 (b)1. For a hospital seeking a Level I program,
1801 demonstration that, for the most recent 12-month period as
1802 reported to the agency, it has provided a minimum of 300 adult
1803 inpatient and outpatient diagnostic cardiac catheterizations or,
1804 for the most recent 12-month period, has discharged or
1805 transferred at least 300 patients ~~inpatients~~ with the principal
1806 diagnosis of ischemic heart disease and that it has a
1807 formalized, written transfer agreement with a hospital that has
1808 a Level II program, including written transport protocols to
1809 ensure safe and efficient transfer of a patient within 60
1810 minutes.

1811 2.a. A hospital located more than 100 road miles from the
1812 closest Level II adult cardiovascular services program does not
1813 need to meet the diagnostic cardiac catheterization volume and
1814 ischemic heart disease diagnosis volume requirements in
1815 subparagraph 1., if the hospital demonstrates that it has, for
1816 the most recent 12-month period as reported to the agency,
1817 provided a minimum of 100 adult inpatient and outpatient
1818 diagnostic cardiac catheterizations or that, for the most recent
1819 12-month period, it has discharged or transferred at least 300
1820 patients with the principal diagnosis of ischemic heart disease.

1821 b. ~~However,~~ A hospital located more than 100 road miles
1822 from the closest Level II adult cardiovascular services program
1823 does not need to meet the 60-minute transfer time protocol
1824 requirement in subparagraph 1., if the hospital demonstrates
1825 that it has a formalized, written transfer agreement with a
1826 hospital that has a Level II program. The agreement must include
1827 written transport protocols to ensure the safe and efficient

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1828 transfer of a patient, taking into consideration the patient's
1829 clinical and physical characteristics, road and weather
1830 conditions, and viability of ground and air ambulance service to
1831 transfer the patient.

1832 3. At a minimum, the rules for adult cardiovascular
1833 services must require nursing and technical staff to have
1834 demonstrated experience in handling acutely ill patients
1835 requiring intervention, based on the staff member's previous
1836 experience in dedicated cardiac interventional laboratories or
1837 surgical centers. If a staff member's previous experience is in
1838 a dedicated cardiac interventional laboratory at a hospital that
1839 does not have an approved adult open-heart-surgery program, the
1840 staff member's previous experience qualifies only if, at the
1841 time the staff member acquired his or her experience, the
1842 dedicated cardiac interventional laboratory:

1843 a. Had an annual volume of 500 or more percutaneous cardiac
1844 intervention procedures;

1845 b. Achieved a demonstrated success rate of 95 percent or
1846 greater for percutaneous cardiac intervention procedures;

1847 c. Experienced a complication rate of less than 5 percent
1848 for percutaneous cardiac intervention procedures; and

1849 d. Performed diverse cardiac procedures, including, but not
1850 limited to, balloon angioplasty and stenting, rotational
1851 atherectomy, cutting balloon atheroma remodeling, and procedures
1852 relating to left ventricular support capability.

1853 Section 62. Subsection (4) of section 408.061, Florida
1854 Statutes, is amended to read:

1855 408.061 Data collection; uniform systems of financial
1856 reporting; information relating to physician charges;

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1857 confidential information; immunity.—

1858 (4) Within 120 days after the end of its fiscal year, each
 1859 health care facility, excluding continuing care facilities,
 1860 hospitals operated by state agencies, and nursing homes as those
 1861 terms are defined in s. 408.07 ~~s. 408.07(14) and (37)~~, shall
 1862 file with the agency, on forms adopted by the agency and based
 1863 on the uniform system of financial reporting, its actual
 1864 financial experience for that fiscal year, including
 1865 expenditures, revenues, and statistical measures. Such data may
 1866 be based on internal financial reports which are certified to be
 1867 complete and accurate by the provider. However, hospitals'
 1868 actual financial experience shall be their audited actual
 1869 experience. Every nursing home shall submit to the agency, in a
 1870 format designated by the agency, a statistical profile of the
 1871 nursing home residents. The agency, in conjunction with the
 1872 Department of Elderly Affairs and the Department of Health,
 1873 shall review these statistical profiles and develop
 1874 recommendations for the types of residents who might more
 1875 appropriately be placed in their homes or other noninstitutional
 1876 settings.

1877 Section 63. Subsection (11) of section 408.07, Florida
 1878 Statutes, is amended to read:

1879 408.07 Definitions.—As used in this chapter, with the
 1880 exception of ss. 408.031-408.045, the term:

1881 ~~(11) "Clinical laboratory" means a facility licensed under~~
 1882 ~~s. 483.091, excluding: any hospital laboratory defined under s.~~
 1883 ~~483.041(6); any clinical laboratory operated by the state or a~~
 1884 ~~political subdivision of the state; any blood or tissue bank~~
 1885 ~~where the majority of revenues are received from the sale of~~

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1886 ~~blood or tissue and where blood, plasma, or tissue is procured~~
1887 ~~from volunteer donors and donated, processed, stored, or~~
1888 ~~distributed on a nonprofit basis; and any clinical laboratory~~
1889 ~~which is wholly owned and operated by physicians who are~~
1890 ~~licensed pursuant to chapter 458 or chapter 459 and who practice~~
1891 ~~in the same group practice, and at which no clinical laboratory~~
1892 ~~work is performed for patients referred by any health care~~
1893 ~~provider who is not a member of that same group practice.~~

1894 Section 64. Subsection (4) of section 408.20, Florida
1895 Statutes, is amended to read:

1896 408.20 Assessments; Health Care Trust Fund.—

1897 (4) Hospitals operated by a state agency ~~the Department of~~
1898 ~~Children and Families, the Department of Health, or the~~
1899 ~~Department of Corrections~~ are exempt from the assessments
1900 required under this section.

1901 Section 65. Section 408.7056, Florida Statutes, is
1902 repealed.

1903 Section 66. Subsections (10), (11), and (27) of section
1904 408.802, Florida Statutes, are amended to read:

1905 408.802 Applicability.—The provisions of this part apply to
1906 the provision of services that require licensure as defined in
1907 this part and to the following entities licensed, registered, or
1908 certified by the agency, as described in chapters 112, 383, 390,
1909 394, 395, 400, 429, 440, 483, and 765:

1910 ~~(10) Mobile surgical facilities, as provided under part I~~
1911 ~~of chapter 395.~~

1912 ~~(11) Health care risk managers, as provided under part I of~~
1913 ~~chapter 395.~~

1914 ~~(27) Clinical laboratories, as provided under part I of~~

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1915 ~~chapter 483.~~

1916 Section 67. Subsections (12) and (13) of section 408.803,
1917 Florida Statutes, are redesignated as subsections (13) and (14),
1918 respectively, and a new subsection (12) is added to that
1919 section, to read:

1920 408.803 Definitions.—As used in this part, the term:

1921 (12) "Relative" means an individual who is the father,
1922 mother, stepfather, stepmother, son, daughter, brother, sister,
1923 grandmother, grandfather, great-grandmother, great-grandfather,
1924 grandson, granddaughter, uncle, aunt, first cousin, nephew,
1925 niece, husband, wife, father-in-law, mother-in-law, son-in-law,
1926 daughter-in-law, brother-in-law, sister-in-law, stepson,
1927 stepdaughter, stepbrother, stepsister, half-brother, or half-
1928 sister of a patient or client.

1929 Section 68. Paragraph (c) of subsection (7) of section
1930 408.806, Florida Statutes, is amended, and subsection (9) is
1931 added to that section, to read:

1932 408.806 License application process.—

1933 (7) (c) If an inspection is required by the authorizing
1934 statute for a license application other than an initial
1935 application, the inspection must be unannounced. This paragraph
1936 does not apply to inspections required pursuant to ss. 383.324,
1937 395.0161(4) and, 429.67(6), ~~and 483.061(2).~~

1938 (9) A licensee that holds a license for multiple providers
1939 licensed by the agency may request that all related license
1940 expiration dates be aligned. Upon such request, the agency may
1941 issue a license for an abbreviated licensure period with a
1942 prorated licensure fee.

1943 Section 69. Paragraphs (d) and (e) of subsection (1) of

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1944 section 408.809, Florida Statutes, are amended to read:

1945 408.809 Background screening; prohibited offenses.—

1946 (1) Level 2 background screening pursuant to chapter 435
1947 must be conducted through the agency on each of the following
1948 persons, who are considered employees for the purposes of
1949 conducting screening under chapter 435:

1950 (d) Any person who is a controlling interest ~~if the agency~~
1951 ~~has reason to believe that such person has been convicted of any~~
1952 ~~offense prohibited by s. 435.04. For each controlling interest~~
1953 ~~who has been convicted of any such offense, the licensee shall~~
1954 ~~submit to the agency a description and explanation of the~~
1955 ~~conviction at the time of license application.~~

1956 (e) Any person, as required by authorizing statutes,
1957 seeking employment with a licensee or provider who is expected
1958 to, or whose responsibilities may require him or her to, provide
1959 personal care or services directly to clients or have access to
1960 client funds, personal property, or living areas; and any
1961 person, as required by authorizing statutes, contracting with a
1962 licensee or provider whose responsibilities require him or her
1963 to provide personal care or personal services directly to
1964 clients, or contracting with a licensee or provider to work 20
1965 hours a week or more who will have access to client funds,
1966 personal property, or living areas. Evidence of contractor
1967 screening may be retained by the contractor's employer or the
1968 licensee.

1969 Section 70. Subsection (8) of section 408.810, Florida
1970 Statutes, is amended, and subsections (11), (12), and (13) are
1971 added to that section, to read:

1972 408.810 Minimum licensure requirements.—In addition to the

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1973 licensure requirements specified in this part, authorizing
1974 statutes, and applicable rules, each applicant and licensee must
1975 comply with the requirements of this section in order to obtain
1976 and maintain a license.

1977 (8) Upon application for initial licensure or change of
1978 ownership licensure, the applicant shall furnish satisfactory
1979 proof of the applicant's financial ability to operate in
1980 accordance with the requirements of this part, authorizing
1981 statutes, and applicable rules. The agency shall establish
1982 standards for this purpose, including information concerning the
1983 applicant's controlling interests. The agency shall also
1984 establish documentation requirements, to be completed by each
1985 applicant, that show anticipated provider revenues and
1986 expenditures, the basis for financing the anticipated cash-flow
1987 requirements of the provider, and an applicant's access to
1988 contingency financing. A current certificate of authority,
1989 pursuant to chapter 651, may be provided as proof of financial
1990 ability to operate. The agency may require a licensee to provide
1991 proof of financial ability to operate at any time if there is
1992 evidence of financial instability, including, but not limited
1993 to, unpaid expenses necessary for the basic operations of the
1994 provider. An applicant applying for change of ownership
1995 licensure is exempt from furnishing proof of financial ability
1996 to operate if the provider has been licensed for at least 5
1997 years, and:

1998 (a) The ownership change is a result of a corporate
1999 reorganization under which the controlling interest is unchanged
2000 and the applicant submits organizational charts that represent
2001 the current and proposed structure of the reorganized

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2002 corporation; or

2003 (b) The ownership change is due solely to the death of a
2004 person holding a controlling interest, and the surviving
2005 controlling interests continue to hold at least 51 percent of
2006 ownership after the change of ownership.

2007 (11) The agency may adopt rules that govern the
2008 circumstances under which a controlling interest, an
2009 administrator, an employee, or a contractor, or a representative
2010 thereof, who is not a relative of the client may act as an agent
2011 of the client in authorizing consent for medical treatment,
2012 assignment or benefits, and release of information. Such rules
2013 may include requirements related to disclosure, bonding,
2014 restrictions, and client protections.

2015 (12) The licensee shall ensure that no person holds any
2016 ownership interest, either directly or indirectly, regardless of
2017 ownership structure, who:

2018 (a) Has a disqualifying offense pursuant to s. 408.809; or

2019 (b) Holds or has held any ownership interest, either
2020 directly or indirectly, regardless of ownership structure, in a
2021 provider that had a license revoked or an application denied
2022 pursuant to s. 408.815.

2023 (13) If the licensee is a publicly traded corporation or is
2024 wholly owned, directly or indirectly, by a publicly traded
2025 corporation, subsection (12) does not apply to those persons
2026 whose sole relationship with the corporation is as a shareholder
2027 of publicly traded shares. As used in this subsection, a
2028 "publicly traded corporation" is a corporation that issues
2029 securities traded on an exchange registered with the United
2030 States Securities and Exchange Commission as a national

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2031 securities exchange.

2032 Section 71. Section 408.812, Florida Statutes, is amended
2033 to read:

2034 408.812 Unlicensed activity.—

2035 (1) A person or entity may not offer or advertise services
2036 that require licensure as defined by this part, authorizing
2037 statutes, or applicable rules to the public without obtaining a
2038 valid license from the agency. A licenseholder may not advertise
2039 or hold out to the public that he or she holds a license for
2040 other than that for which he or she actually holds the license.

2041 (2) The operation or maintenance of an unlicensed provider
2042 or the performance of any services that require licensure
2043 without proper licensure is a violation of this part and
2044 authorizing statutes. Unlicensed activity constitutes harm that
2045 materially affects the health, safety, and welfare of clients,
2046 and constitutes abuse and neglect, as defined in s. 415.102. The
2047 agency or any state attorney may, in addition to other remedies
2048 provided in this part, bring an action for an injunction to
2049 restrain such violation, or to enjoin the future operation or
2050 maintenance of the unlicensed provider or the performance of any
2051 services in violation of this part and authorizing statutes,
2052 until compliance with this part, authorizing statutes, and
2053 agency rules has been demonstrated to the satisfaction of the
2054 agency.

2055 (3) It is unlawful for any person or entity to own,
2056 operate, or maintain an unlicensed provider. If after receiving
2057 notification from the agency, such person or entity fails to
2058 cease operation ~~and apply for a license under this part and~~
2059 ~~authorizing statutes,~~ the person or entity is ~~shall be~~ subject

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2060 to penalties as prescribed by authorizing statutes and
2061 applicable rules. Each day of ~~continued~~ operation is a separate
2062 offense.

2063 (4) Any person or entity that fails to cease operation
2064 after agency notification may be fined \$1,000 for each day of
2065 noncompliance.

2066 (5) When a controlling interest or licensee has an interest
2067 in more than one provider and fails to license a provider
2068 rendering services that require licensure, the agency may revoke
2069 all licenses, ~~and~~ impose actions under s. 408.814, and
2070 regardless of correction, impose a fine of \$1,000 per day,
2071 unless otherwise specified by authorizing statutes, against each
2072 licensee until such time as the appropriate license is obtained
2073 or the unlicensed activity ceases ~~for the unlicensed operation.~~

2074 (6) In addition to granting injunctive relief pursuant to
2075 subsection (2), if the agency determines that a person or entity
2076 is operating or maintaining a provider without obtaining a
2077 license and determines that a condition exists that poses a
2078 threat to the health, safety, or welfare of a client of the
2079 provider, the person or entity is subject to the same actions
2080 and fines imposed against a licensee as specified in this part,
2081 authorizing statutes, and agency rules.

2082 (7) Any person aware of the operation of an unlicensed
2083 provider must report that provider to the agency.

2084 Section 72. Subsections (10), (11) and (26) of section
2085 408.820, Florida Statutes, are amended, and subsections (12)
2086 through (25) and (27) and (28) are redesignated as subsections
2087 (10) through (23) and (24) and (25), respectively, to read:

2088 408.820 Exemptions.—Except as prescribed in authorizing

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2089 statutes, the following exemptions shall apply to specified
2090 requirements of this part:

2091 ~~(10) Mobile surgical facilities, as provided under part I~~
2092 ~~of chapter 395, are exempt from s. 408.810(7) (10).~~

2093 ~~(11) Health care risk managers, as provided under part I of~~
2094 ~~chapter 395, are exempt from ss. 408.806(7), 408.810(4) (10),~~
2095 ~~and 408.811.~~

2096 ~~(26) Clinical laboratories, as provided under part I of~~
2097 ~~chapter 483, are exempt from s. 408.810(5) (10).~~

2098 Section 73. Subsection (7) of section 409.905, Florida
2099 Statutes, is amended to read:

2100 409.905 Mandatory Medicaid services.—The agency may make
2101 payments for the following services, which are required of the
2102 state by Title XIX of the Social Security Act, furnished by
2103 Medicaid providers to recipients who are determined to be
2104 eligible on the dates on which the services were provided. Any
2105 service under this section shall be provided only when medically
2106 necessary and in accordance with state and federal law.

2107 Mandatory services rendered by providers in mobile units to
2108 Medicaid recipients may be restricted by the agency. Nothing in
2109 this section shall be construed to prevent or limit the agency
2110 from adjusting fees, reimbursement rates, lengths of stay,
2111 number of visits, number of services, or any other adjustments
2112 necessary to comply with the availability of moneys and any
2113 limitations or directions provided for in the General
2114 Appropriations Act or chapter 216.

2115 (7) INDEPENDENT LABORATORY SERVICES.—The agency shall pay
2116 for medically necessary diagnostic laboratory procedures ordered
2117 by a licensed physician or other licensed practitioner of the

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2118 healing arts which are provided for a recipient in a laboratory
2119 that meets the requirements for Medicare participation and is
2120 appropriately certified by the Centers for Medicare and Medicaid
2121 Services under the federal Clinical Laboratory Improvement
2122 Amendments and the federal rules adopted thereunder ~~licensed~~
2123 ~~under chapter 483, if required.~~

2124 Section 74. Subsection (10) of section 409.907, Florida
2125 Statutes, is amended to read:

2126 409.907 Medicaid provider agreements.—The agency may make
2127 payments for medical assistance and related services rendered to
2128 Medicaid recipients only to an individual or entity who has a
2129 provider agreement in effect with the agency, who is performing
2130 services or supplying goods in accordance with federal, state,
2131 and local law, and who agrees that no person shall, on the
2132 grounds of handicap, race, color, or national origin, or for any
2133 other reason, be subjected to discrimination under any program
2134 or activity for which the provider receives payment from the
2135 agency.

2136 (10) The agency may consider whether the provider, or any
2137 officer, director, agent, managing employee, or affiliated
2138 person, or any partner or shareholder having an ownership
2139 interest equal to 5 percent or greater in the provider if the
2140 provider is a corporation, partnership, or other business
2141 entity, has:

2142 (a) Made a false representation or omission of any material
2143 fact in making the application, including the submission of an
2144 application that conceals the controlling or ownership interest
2145 of any officer, director, agent, managing employee, affiliated
2146 person, or partner or shareholder who may not be eligible to

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2147 participate;

2148 (b) Been or is currently excluded, suspended, terminated
2149 from, or has involuntarily withdrawn from participation in,
2150 Florida's Medicaid program or any other state's Medicaid
2151 program, or from participation in any other governmental or
2152 private health care or health insurance program;

2153 ~~(c) Been convicted of a criminal offense relating to the~~
2154 ~~delivery of any goods or services under Medicaid or Medicare or~~
2155 ~~any other public or private health care or health insurance~~
2156 ~~program including the performance of management or~~
2157 ~~administrative services relating to the delivery of goods or~~
2158 ~~services under any such program;~~

2159 ~~(d) Been convicted under federal or state law of a criminal~~
2160 ~~offense related to the neglect or abuse of a patient in~~
2161 ~~connection with the delivery of any health care goods or~~
2162 ~~services;~~

2163 ~~(e) Been convicted under federal or state law of a criminal~~
2164 ~~offense relating to the unlawful manufacture, distribution,~~
2165 ~~prescription, or dispensing of a controlled substance;~~

2166 ~~(f) Been convicted of any criminal offense relating to~~
2167 ~~fraud, theft, embezzlement, breach of fiduciary responsibility,~~
2168 ~~or other financial misconduct;~~

2169 ~~(g) Been convicted under federal or state law of a crime~~
2170 ~~punishable by imprisonment of a year or more which involves~~
2171 ~~moral turpitude;~~

2172 ~~(h) Been convicted in connection with the interference or~~
2173 ~~obstruction of any investigation into any criminal offense~~
2174 ~~listed in this subsection;~~

2175 ~~(i) Been found to have violated federal or state laws,~~

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2176 ~~rules, or regulations governing Florida's Medicaid program or~~
2177 ~~any other state's Medicaid program, the Medicare program, or any~~
2178 ~~other publicly funded federal or state health care or health~~
2179 ~~insurance program, and been sanctioned accordingly;~~

2180 (c) ~~(j)~~ Been previously found by a licensing, certifying, or
2181 professional standards board or agency to have violated the
2182 standards or conditions relating to licensure or certification
2183 or the quality of services provided; or

2184 (d) ~~(k)~~ Failed to pay any fine or overpayment properly
2185 assessed under the Medicaid program in which no appeal is
2186 pending or after resolution of the proceeding by stipulation or
2187 agreement, unless the agency has issued a specific letter of
2188 forgiveness or has approved a repayment schedule to which the
2189 provider agrees to adhere.

2190 Section 75. Subsection (6) of section 409.9116, Florida
2191 Statutes, is amended to read:

2192 409.9116 Disproportionate share/financial assistance
2193 program for rural hospitals.—In addition to the payments made
2194 under s. 409.911, the Agency for Health Care Administration
2195 shall administer a federally matched disproportionate share
2196 program and a state-funded financial assistance program for
2197 statutory rural hospitals. The agency shall make
2198 disproportionate share payments to statutory rural hospitals
2199 that qualify for such payments and financial assistance payments
2200 to statutory rural hospitals that do not qualify for
2201 disproportionate share payments. The disproportionate share
2202 program payments shall be limited by and conform with federal
2203 requirements. Funds shall be distributed quarterly in each
2204 fiscal year for which an appropriation is made. Notwithstanding

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2205 the provisions of s. 409.915, counties are exempt from
 2206 contributing toward the cost of this special reimbursement for
 2207 hospitals serving a disproportionate share of low-income
 2208 patients.

2209 (6) This section applies only to hospitals that were
 2210 defined as statutory rural hospitals, or their successor-in-
 2211 interest hospital, prior to January 1, 2001. Any additional
 2212 hospital that is defined as a statutory rural hospital, or its
 2213 successor-in-interest hospital, on or after January 1, 2001, is
 2214 not eligible for programs under this section unless additional
 2215 funds are appropriated each fiscal year specifically to the
 2216 rural hospital disproportionate share and financial assistance
 2217 programs in an amount necessary to prevent any hospital, or its
 2218 successor-in-interest hospital, eligible for the programs prior
 2219 to January 1, 2001, from incurring a reduction in payments
 2220 because of the eligibility of an additional hospital to
 2221 participate in the programs. A hospital, or its successor-in-
 2222 interest hospital, which received funds pursuant to this section
 2223 before January 1, 2001, and which qualifies under s.
 2224 395.602(2)(b) ~~s. 395.602(2)(e)~~, shall be included in the
 2225 programs under this section and is not required to seek
 2226 additional appropriations under this subsection.

2227 Section 76. Paragraphs (a) and (b) of subsection (1) of
 2228 section 409.975, Florida Statutes, are amended to read:

2229 409.975 Managed care plan accountability.—In addition to
 2230 the requirements of s. 409.967, plans and providers
 2231 participating in the managed medical assistance program shall
 2232 comply with the requirements of this section.

2233 (1) PROVIDER NETWORKS.—Managed care plans must develop and

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2234 maintain provider networks that meet the medical needs of their
2235 enrollees in accordance with standards established pursuant to
2236 s. 409.967(2)(c). Except as provided in this section, managed
2237 care plans may limit the providers in their networks based on
2238 credentials, quality indicators, and price.

2239 (a) Plans must include all providers in the region that are
2240 classified by the agency as essential Medicaid providers, unless
2241 the agency approves, in writing, an alternative arrangement for
2242 securing the types of services offered by the essential
2243 providers. Providers are essential for serving Medicaid
2244 enrollees if they offer services that are not available from any
2245 other provider within a reasonable access standard, or if they
2246 provided a substantial share of the total units of a particular
2247 service used by Medicaid patients within the region during the
2248 last 3 years and the combined capacity of other service
2249 providers in the region is insufficient to meet the total needs
2250 of the Medicaid patients. The agency may not classify physicians
2251 and other practitioners as essential providers. The agency, at a
2252 minimum, shall determine which providers in the following
2253 categories are essential Medicaid providers:

- 2254 1. Federally qualified health centers.
- 2255 2. Statutory teaching hospitals as defined in s. 408.07(44)
2256 ~~s. 408.07(45)~~.
- 2257 3. Hospitals that are trauma centers as defined in s.
2258 395.4001(14).
- 2259 4. Hospitals located at least 25 miles from any other
2260 hospital with similar services.

2261
2262 Managed care plans that have not contracted with all essential

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2263 providers in the region as of the first date of recipient
2264 enrollment, or with whom an essential provider has terminated
2265 its contract, must negotiate in good faith with such essential
2266 providers for 1 year or until an agreement is reached, whichever
2267 is first. Payments for services rendered by a nonparticipating
2268 essential provider shall be made at the applicable Medicaid rate
2269 as of the first day of the contract between the agency and the
2270 plan. A rate schedule for all essential providers shall be
2271 attached to the contract between the agency and the plan. After
2272 1 year, managed care plans that are unable to contract with
2273 essential providers shall notify the agency and propose an
2274 alternative arrangement for securing the essential services for
2275 Medicaid enrollees. The arrangement must rely on contracts with
2276 other participating providers, regardless of whether those
2277 providers are located within the same region as the
2278 nonparticipating essential service provider. If the alternative
2279 arrangement is approved by the agency, payments to
2280 nonparticipating essential providers after the date of the
2281 agency's approval shall equal 90 percent of the applicable
2282 Medicaid rate. Except for payment for emergency services, if the
2283 alternative arrangement is not approved by the agency, payment
2284 to nonparticipating essential providers shall equal 110 percent
2285 of the applicable Medicaid rate.

2286 (b) Certain providers are statewide resources and essential
2287 providers for all managed care plans in all regions. All managed
2288 care plans must include these essential providers in their
2289 networks. Statewide essential providers include:

- 2290 1. Faculty plans of Florida medical schools.
- 2291 2. Regional perinatal intensive care centers as defined in

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2292 s. 383.16(2).

2293 3. Hospitals licensed as specialty children's hospitals as
2294 defined in s. 395.002(27) ~~s. 395.002(28)~~.

2295 4. Accredited and integrated systems serving medically
2296 complex children which comprise separately licensed, but
2297 commonly owned, health care providers delivering at least the
2298 following services: medical group home, in-home and outpatient
2299 nursing care and therapies, pharmacy services, durable medical
2300 equipment, and Prescribed Pediatric Extended Care.

2301
2302 Managed care plans that have not contracted with all statewide
2303 essential providers in all regions as of the first date of
2304 recipient enrollment must continue to negotiate in good faith.
2305 Payments to physicians on the faculty of nonparticipating
2306 Florida medical schools shall be made at the applicable Medicaid
2307 rate. Payments for services rendered by regional perinatal
2308 intensive care centers shall be made at the applicable Medicaid
2309 rate as of the first day of the contract between the agency and
2310 the plan. Except for payments for emergency services, payments
2311 to nonparticipating specialty children's hospitals shall equal
2312 the highest rate established by contract between that provider
2313 and any other Medicaid managed care plan.

2314 Section 77. Subsections (5) and (17) of section 429.02,
2315 Florida Statutes, are amended to read:

2316 429.02 Definitions.—When used in this part, the term:

2317 (5) "Assisted living facility" means any building or
2318 buildings, section or distinct part of a building, private home,
2319 boarding home, home for the aged, or other residential facility,
2320 regardless of whether operated for profit ~~or not~~, which

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2321 ~~undertakes~~ through its ownership or management provides ~~to~~
2322 ~~provide~~ housing, meals, and one or more personal services for a
2323 period exceeding 24 hours to one or more adults who are not
2324 relatives of the owner or administrator.

2325 (17) "Personal services" means direct physical assistance
2326 with or supervision of the activities of daily living, ~~and~~ the
2327 self-administration of medication, ~~or~~ ~~and~~ other similar services
2328 which the department may define by rule. The term may ~~"Personal~~
2329 ~~services"~~ shall not be construed to mean the provision of
2330 medical, nursing, dental, or mental health services.

2331 Section 78. Paragraphs (b) and (d) of subsection (2) of
2332 section 429.04, Florida Statutes, are amended, and subsection
2333 (3) is added that section, to read:

2334 429.04 Facilities to be licensed; exemptions.—

2335 (2) The following are exempt from licensure under this
2336 part:

2337 (b) Any facility or part of a facility licensed by the
2338 Agency for Persons with Disabilities under chapter 393, a mental
2339 health facility licensed under ~~or~~ chapter 394, a hospital
2340 licensed under chapter 395, a nursing home licensed under part
2341 II of chapter 400, an inpatient hospice licensed under part IV
2342 of chapter 400, a home for special services licensed under part
2343 V of chapter 400, an intermediate care facility licensed under
2344 part VIII of chapter 400, or a transitional living facility
2345 licensed under part XI of chapter 400.

2346 (d) Any person who provides housing, meals, and one or more
2347 personal services on a 24-hour basis in the person's own home to
2348 not more than two adults who do not receive optional state
2349 supplementation. The person who provides the housing, meals, and

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2350 personal services must own or rent the home and must have
 2351 established the home as his or her permanent residence. For
 2352 purposes of this paragraph, any person holding a homestead
 2353 exemption at an address other than that at which the person
 2354 asserts this exemption is presumed to not have established
 2355 permanent residence ~~reside therein~~. This exemption does not
 2356 apply to a person or entity that previously held a license
 2357 issued by the agency which was revoked or for which renewal was
 2358 denied by final order of the agency, or when the person or
 2359 entity voluntarily relinquished the license during agency
 2360 enforcement proceedings.

2361 (3) Upon agency investigation of unlicensed activity, any
 2362 person or entity that claims that it is exempt under this
 2363 section must provide documentation substantiating entitlement to
 2364 the exemption.

2365 Section 79. Paragraphs (b) and (d) of subsection (1) of
 2366 section 429.08, Florida Statutes, are amended to read:

2367 429.08 Unlicensed facilities; referral of person for
 2368 residency to unlicensed facility; penalties.—

2369 (1) (b) ~~Except as provided under paragraph (d),~~ Any person
 2370 who owns, rents, or otherwise maintains a building or property
 2371 used as ~~operates, or maintains~~ an unlicensed assisted living
 2372 facility commits a felony of the third degree, punishable as
 2373 provided in s. 775.082, s. 775.083, or s. 775.084. Each day of
 2374 continued operation is a separate offense.

2375 (d) In addition to the requirements of s. 408.812, any
 2376 person who owns, operates, or maintains an unlicensed assisted
 2377 living facility after receiving notice from the agency ~~due to a~~
 2378 ~~change in this part or a modification in rule within 6 months~~

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2379 ~~after the effective date of such change and who, within 10~~
2380 ~~working days after receiving notification from the agency, fails~~
2381 ~~to cease operation or apply for a license under this part~~
2382 commits a felony of the third degree, punishable as provided in
2383 s. 775.082, s. 775.083, or s. 775.084. Each day of continued
2384 operation is a separate offense.

2385 Section 80. Section 429.176, Florida Statutes, is amended
2386 to read:

2387 429.176 Notice of change of administrator.—If, during the
2388 period for which a license is issued, the owner changes
2389 administrators, the owner must notify the agency of the change
2390 within 10 days and provide documentation within 90 days that the
2391 new administrator has completed the applicable core educational
2392 requirements under s. 429.52. A facility may not be operated for
2393 more than 120 consecutive days without an administrator who has
2394 completed the core educational requirements.

2395 Section 81. Subsection (7) of section 429.19, Florida
2396 Statutes, is amended to read:

2397 429.19 Violations; imposition of administrative fines;
2398 grounds.—

2399 (7) In addition to any administrative fines imposed, the
2400 agency may assess a survey fee, equal to the lesser of one half
2401 of the facility's biennial license and bed fee or \$500, to cover
2402 the cost of conducting initial complaint investigations that
2403 result in the finding of a violation that was the subject of the
2404 complaint or monitoring visits conducted ~~under s. 429.28(3)(c)~~
2405 to verify the correction of the violations.

2406 Section 82. Subsection (2) of section 429.24, Florida
2407 Statutes, is amended to read:

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2408 429.24 Contracts.—

2409 (2) Each contract must contain express provisions
2410 specifically setting forth the services and accommodations to be
2411 provided by the facility; the rates or charges; provision for at
2412 least 30 days' written notice of a rate increase; the rights,
2413 duties, and obligations of the residents, other than those
2414 specified in s. 429.28; and other matters that the parties deem
2415 appropriate. A new service or accommodation added to, or
2416 implemented in, a resident's contract for which the resident was
2417 not previously charged does not require a 30-day written notice
2418 of a rate increase. Whenever money is deposited or advanced by a
2419 resident in a contract as security for performance of the
2420 contract agreement or as advance rent for other than the next
2421 immediate rental period:

2422 (a) Such funds shall be deposited in a banking institution
2423 in this state that is located, if possible, in the same
2424 community in which the facility is located; shall be kept
2425 separate from the funds and property of the facility; may not be
2426 represented as part of the assets of the facility on financial
2427 statements; and shall be used, or otherwise expended, only for
2428 the account of the resident.

2429 (b) The licensee shall, within 30 days of receipt of
2430 advance rent or a security deposit, notify the resident or
2431 residents in writing of the manner in which the licensee is
2432 holding the advance rent or security deposit and state the name
2433 and address of the depository where the moneys are being held.
2434 The licensee shall notify residents of the facility's policy on
2435 advance deposits.

2436 Section 83. Paragraphs (e) and (j) of subsection (1) and

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2437 paragraphs (c), (d), and (e) of subsection (3) of section
2438 429.28, Florida Statutes, are amended to read:

2439 429.28 Resident bill of rights.—

2440 (1) No resident of a facility shall be deprived of any
2441 civil or legal rights, benefits, or privileges guaranteed by
2442 law, the Constitution of the State of Florida, or the
2443 Constitution of the United States as a resident of a facility.
2444 Every resident of a facility shall have the right to:

2445 (e) Freedom to participate in and benefit from community
2446 services and activities and to pursue ~~achieve~~ the highest
2447 possible level of independence, autonomy, and interaction within
2448 the community.

2449 (j) Assistance with obtaining access to adequate and
2450 appropriate health care. For purposes of this paragraph, the
2451 term "adequate and appropriate health care" means the management
2452 of medications, assistance in making appointments for health
2453 care services, the provision of or arrangement of transportation
2454 to health care appointments, and the performance of health care
2455 services in accordance with s. 429.255 which are consistent with
2456 established and recognized standards within the community.

2457 ~~(3)(c) During any calendar year in which no survey is~~
2458 ~~conducted, the agency shall conduct at least one monitoring~~
2459 ~~visit of each facility cited in the previous year for a class I~~
2460 ~~or class II violation, or more than three uncorrected class III~~
2461 ~~violations.~~

2462 ~~(d) The agency may conduct periodic followup inspections as~~
2463 ~~necessary to monitor the compliance of facilities with a history~~
2464 ~~of any class I, class II, or class III violations that threaten~~
2465 ~~the health, safety, or security of residents.~~

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2466 ~~(c) The agency may conduct complaint investigations as~~
2467 ~~warranted to investigate any allegations of noncompliance with~~
2468 ~~requirements required under this part or rules adopted under~~
2469 ~~this part.~~

2470 Section 84. Subsection (1) of section 429.294, Florida
2471 Statutes, is amended to read:

2472 429.294 Availability of facility records for investigation
2473 of resident's rights violations and defenses; penalty.—

2474 (1) Failure to provide complete copies of a resident's
2475 records, including, but not limited to, all medical records and
2476 the resident's chart, within the control or possession of the
2477 facility ~~within 10 days,~~ in accordance with ~~the provisions of s.~~
2478 400.145, shall constitute evidence of failure of that party to
2479 comply with good faith discovery requirements and shall waive
2480 the good faith certificate and presuit notice requirements under
2481 this part by the requesting party.

2482 Section 85. Subsection (2) of section 429.34, Florida
2483 Statutes, is amended to read:

2484 429.34 Right of entry and inspection.—

2485 (2) (a) In addition to the requirements of s. 408.811, the
2486 agency may inspect and investigate facilities as necessary to
2487 determine compliance with this part, part II of chapter 408, and
2488 rules adopted thereunder. ~~The agency shall inspect each licensed~~
2489 ~~assisted living facility at least once every 24 months to~~
2490 ~~determine compliance with this chapter and related rules. If an~~
2491 ~~assisted living facility is cited for a class I violation or~~
2492 ~~three or more class II violations arising from separate surveys~~
2493 ~~within a 60-day period or due to unrelated circumstances during~~
2494 ~~the same survey, the agency must conduct an additional licensure~~

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2495 inspection within 6 months.

2496 (b) During any calendar year in which a survey is not
2497 conducted, the agency may conduct monitoring visits of each
2498 facility cited in the previous year for a class I or class II
2499 violation or for more than three uncorrected class III
2500 violations.

2501 Section 86. Subsection (4) of section 429.52, Florida
2502 Statutes, is amended to read:

2503 429.52 Staff training and educational programs; core
2504 educational requirement.—

2505 (4) Effective January 1, 2004, a new facility administrator
2506 must complete the required training and education, including the
2507 competency test, within 90 days of the date of employment ~~a~~
2508 ~~reasonable time after being employed as an administrator, as~~
2509 ~~determined by the department.~~ Failure to do so is a violation of
2510 this part and subjects the violator to an administrative fine as
2511 prescribed in s. 429.19. Administrators licensed in accordance
2512 with part II of chapter 468 are exempt from this requirement.
2513 Other licensed professionals may be exempted, as determined by
2514 the department by rule.

2515 Section 87. Subsection (3) of section 435.04, Florida
2516 Statutes, is amended, and subsection (4) is added to that
2517 section, to read:

2518 435.04 Level 2 screening standards.—

2519 (3) The security background investigations under this
2520 section must ensure that no person subject to this section has
2521 been arrested for and is awaiting final disposition of, been
2522 found guilty of, regardless of adjudication, or entered a plea
2523 of nolo contendere or guilty to, any offense that constitutes

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2524 domestic violence as defined in s. 741.28, whether such act was
2525 committed in this state or in another jurisdiction.

2526 (4) For the purpose of screening applicability to
2527 participate in the Medicaid program, the security background
2528 investigations under this section must ensure that a person
2529 subject to screening under this section has not been arrested
2530 for and is not awaiting final disposition of; has not been found
2531 guilty of, regardless of adjudication, or entered a plea of nolo
2532 contendere or guilty to; and has not been adjudicated delinquent
2533 and the record sealed or expunged for, any of the following
2534 offenses:

2535 (a) Violation of a federal law or a law in any state which
2536 creates a criminal offense relating to:

2537 1. The delivery of any goods or services under Medicaid or
2538 Medicare or any other public or private health care or health
2539 insurance program, including the performance of management or
2540 administrative services relating to the delivery of goods or
2541 services under any such program;

2542 2. Neglect or abuse of a patient in connection with the
2543 delivery of any health care good or service;

2544 3. Unlawful manufacture, distribution, prescription, or
2545 dispensing of a controlled substance;

2546 4. Fraud, theft, embezzlement, breach of fiduciary
2547 responsibility, or other financial misconduct; or

2548 5. Moral turpitude, if punishable by imprisonment of a year
2549 or more.

2550 6. Interference with or obstruction of an investigation
2551 into any criminal offense identified in this subsection.

2552 (b) Violation of the following state laws or laws of

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2553 another jurisdiction:

2554 1. Section 817.569, criminal use of a public record or
2555 information contained in a public record;

2556 2. Section 838.016, unlawful compensation or reward for
2557 official behavior;

2558 3. Section 838.021, corruption by threat against a public
2559 servant;

2560 4. Section 838.022, official misconduct;

2561 5. Section 838.22, bid tampering;

2562 6. Section 839.13, falsifying records;

2563 7. Section 839.26, misuse of confidential information; or

2564 (c) Violation of a federal or state law, rule, or
2565 regulation governing the Florida Medicaid program or any other
2566 state Medicaid program, the Medicare program, or any other
2567 publicly funded federal or state health care or health insurance
2568 program.

2569 Section 88. Paragraph (a) of subsection (2) of section
2570 435.12, Florida Statutes, is amended to read:

2571 435.12 Care Provider Background Screening Clearinghouse.—

2572 (2) (a) To ensure that the information in the clearinghouse
2573 is current, the fingerprints of an employee required to be
2574 screened by a specified agency and included in the clearinghouse
2575 must be:

2576 1. Retained by the Department of Law Enforcement pursuant
2577 to s. 943.05(2)(g) and (h) and (3), and the Department of Law
2578 Enforcement must report the results of searching those
2579 fingerprints against state incoming arrest fingerprint
2580 submissions to the Agency for Health Care Administration for
2581 inclusion in the clearinghouse.

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2582 2. Retained by the Federal Bureau of Investigation in the
2583 national retained print arrest notification program as soon as
2584 the Department of Law Enforcement begins participation in such
2585 program. Arrest prints will be searched against retained prints
2586 at the Federal Bureau of Investigation and notification of
2587 arrests will be forwarded to the Florida Department of Law
2588 Enforcement and reported to the Agency for Health Care
2589 Administration for inclusion in the clearinghouse.

2590 3. Resubmitted for a Federal Bureau of Investigation
2591 national criminal history check every 5 years until such time as
2592 the fingerprints are retained by the Federal Bureau of
2593 Investigation.

2594 4. Subject to retention on a 5-year renewal basis with fees
2595 collected at the time of initial submission or resubmission of
2596 fingerprints.

2597 a. A person who passed a level 2 screening under s. 435.04
2598 after December 31, 2012, by a specified agency may extend the
2599 screening renewal period until January 1, 2020, unless the
2600 Department of Law Enforcement begins participation in the
2601 national retained print arrest notification program before that
2602 date.

2603 b. The retention of fingerprints by the Department of Law
2604 Enforcement pursuant to s. 943.05(2)(g) and (h) and (3) is
2605 extended until the earlier of January 1, 2021, or the date that
2606 the Department of Law Enforcement begins participation in the
2607 national retained print arrest notification program.

2608 5. Submitted with a photograph of the person taken at the
2609 time the fingerprints are submitted.

2610 Section 89. Subsection (4) of section 456.001, Florida

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2611 Statutes, is amended to read:

2612 456.001 Definitions.—As used in this chapter, the term:

2613 (4) "Health care practitioner" means any person licensed
2614 under chapter 457; chapter 458; chapter 459; chapter 460;
2615 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;
2616 chapter 466; chapter 467; part I, part II, part III, part V,
2617 part X, part XIII, or part XIV of chapter 468; chapter 478;
2618 chapter 480; part II or part III ~~or part IV~~ of chapter 483;
2619 chapter 484; chapter 486; chapter 490; or chapter 491.

2620 Section 90. Subsection (3) of section 456.054, Florida
2621 Statutes, is redesignated as subsection (4), and a new
2622 subsection (3) is added to that section, to read:

2623 456.054 Kickbacks prohibited.—

2624 (3) (a) It is unlawful for any person or any entity to pay
2625 or receive, directly or indirectly, a commission, bonus,
2626 kickback, or rebate from, or to engage in any form of a split-
2627 fee arrangement with, a dialysis facility, health care
2628 practitioner, surgeon, person, or entity for referring patients
2629 to a clinical laboratory as defined in s. 483.803.

2630 (b) It is unlawful for any clinical laboratory to:

2631 1. Provide personnel to perform any functions or duties in
2632 a health care practitioner's office or dialysis facility for any
2633 purpose, including for the collection or handling of specimens,
2634 directly or indirectly through an employee, contractor,
2635 independent staffing company, lease agreement, or otherwise,
2636 unless the laboratory and the practitioner's office, or dialysis
2637 facility, are wholly owned and operated by the same entity.

2638 2. Lease space within any part of a health care
2639 practitioner's office or dialysis facility for any purpose,

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2640 including for the purpose of establishing a collection station
 2641 where materials or specimens are collected or drawn from
 2642 patients.

2643 Section 91. Paragraphs (h) and (i) of subsection (2) of
 2644 section 456.057, Florida Statutes, are amended to read:

2645 456.057 Ownership and control of patient records; report or
 2646 copies of records to be furnished; disclosure of information.—

2647 (2) As used in this section, the terms "records owner,"
 2648 "health care practitioner," and "health care practitioner's
 2649 employer" do not include any of the following persons or
 2650 entities; furthermore, the following persons or entities are not
 2651 authorized to acquire or own medical records, but are authorized
 2652 under the confidentiality and disclosure requirements of this
 2653 section to maintain those documents required by the part or
 2654 chapter under which they are licensed or regulated:

2655 (h) Clinical laboratory personnel licensed under part II
 2656 ~~III~~ of chapter 483.

2657 (i) Medical physicists licensed under part III ~~IV~~ of
 2658 chapter 483.

2659 Section 92. Paragraph (j) of subsection (1) of section
 2660 456.076, Florida Statutes, is amended to read:

2661 456.076 Impaired practitioner programs.—

2662 (1) As used in this section, the term:

2663 (j) "Practitioner" means a person licensed, registered,
 2664 certified, or regulated by the department under part III of
 2665 chapter 401; chapter 457; chapter 458; chapter 459; chapter 460;
 2666 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;
 2667 chapter 466; chapter 467; part I, part II, part III, part V,
 2668 part X, part XIII, or part XIV of chapter 468; chapter 478;

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2669 chapter 480; part II or part III ~~or part IV~~ of chapter 483;
2670 chapter 484; chapter 486; chapter 490; or chapter 491; or an
2671 applicant for a license, registration, or certification under
2672 the same laws.

2673 Section 93. Subsection (2) of section 458.307, Florida
2674 Statutes, is amended to read:

2675 458.307 Board of Medicine.—

2676 (2) Twelve members of the board must be licensed physicians
2677 in good standing in this state who are residents of the state
2678 and who have been engaged in the active practice or teaching of
2679 medicine for at least 4 years immediately preceding their
2680 appointment. One of the physicians must be on the full-time
2681 faculty of a medical school in this state, and one of the
2682 physicians must be in private practice and on the full-time
2683 staff of a statutory teaching hospital in this state as defined
2684 in s. 408.07. At least one of the physicians must be a graduate
2685 of a foreign medical school. The remaining three members must be
2686 residents of the state who are not, and never have been,
2687 licensed health care practitioners. One member must be a health
2688 care risk manager ~~licensed under s. 395.10974~~. At least one
2689 member of the board must be 60 years of age or older.

2690 Section 94. Subsection (1) of section 458.345, Florida
2691 Statutes, is amended to read:

2692 458.345 Registration of resident physicians, interns, and
2693 fellows; list of hospital employees; prescribing of medicinal
2694 drugs; penalty.—

2695 (1) Any person desiring to practice as a resident
2696 physician, assistant resident physician, house physician,
2697 intern, or fellow in fellowship training which leads to

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2698 subspecialty board certification in this state, or any person
2699 desiring to practice as a resident physician, assistant resident
2700 physician, house physician, intern, or fellow in fellowship
2701 training in a teaching hospital in this state as defined in s.
2702 408.07 ~~s. 408.07(45)~~ or s. 395.805(2), who does not hold a
2703 valid, active license issued under this chapter shall apply to
2704 the department to be registered and shall remit a fee not to
2705 exceed \$300 as set by the board. The department shall register
2706 any applicant the board certifies has met the following
2707 requirements:

2708 (a) Is at least 21 years of age.

2709 (b) Has not committed any act or offense within or without
2710 the state which would constitute the basis for refusal to
2711 certify an application for licensure pursuant to s. 458.331.

2712 (c) Is a graduate of a medical school or college as
2713 specified in s. 458.311(1)(f).

2714 Section 95. Subsection (1) of s. 459.021, Florida Statutes,
2715 is amended to read:

2716 459.021 Registration of resident physicians, interns, and
2717 fellows; list of hospital employees; penalty.—

2718 (1) Any person who holds a degree of Doctor of Osteopathic
2719 Medicine from a college of osteopathic medicine recognized and
2720 approved by the American Osteopathic Association who desires to
2721 practice as a resident physician, intern, or fellow in
2722 fellowship training which leads to subspecialty board
2723 certification in this state, or any person desiring to practice
2724 as a resident physician, intern, or fellow in fellowship
2725 training in a teaching hospital in this state as defined in s.
2726 408.07 ~~s. 408.07(45)~~ or s. 395.805(2), who does not hold an

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2727 active license issued under this chapter shall apply to the
2728 department to be registered, on an application provided by the
2729 department, before commencing such a training program and shall
2730 remit a fee not to exceed \$300 as set by the board.

2731 Section 96. Part I of chapter 483, Florida Statutes,
2732 consisting of sections 483.011, 483.021, 483.031, 483.035,
2733 483.041, 483.051, 483.061, 483.091, 483.101, 483.111, 483.172,
2734 483.181, 483.191, 483.201, 483.221, 483.23, 483.245, and 483.26,
2735 is repealed.

2736 Section 97. Section 483.294, Florida Statutes, is amended
2737 to read:

2738 483.294 Inspection of centers.—In accordance with s.
2739 408.811, the agency shall, ~~at least once annually,~~ inspect the
2740 premises and operations of all centers subject to licensure
2741 under this part.

2742 Section 98. Subsections (3) and (5) of section 483.801,
2743 Florida Statutes, are amended, and subsection (6) is added to
2744 that section, to read:

2745 483.801 Exemptions.—This part applies to all clinical
2746 laboratories and clinical laboratory personnel within this
2747 state, except:

2748 (3) Persons engaged in testing performed by laboratories
2749 that are wholly owned and operated by one or more practitioners
2750 licensed under chapter 458, chapter 459, chapter 460, chapter
2751 461, chapter 462, chapter 463, or chapter 466 who practice in
2752 the same group practice, and in which no clinical laboratory
2753 work is performed for patients referred by any health care
2754 provider who is not a member of that group practice regulated
2755 under s. 483.035(1) or exempt from regulation under s.

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2756 483.031(2).

2757 (5) Advanced registered nurse practitioners licensed under
2758 part I of chapter 464 who perform provider-performed microscopy
2759 procedures (PPMP) in a an-exclusive-use laboratory setting
2760 pursuant to subsection (3).

2761 (6) Persons performing laboratory testing within a
2762 physician office practice for patients referred by a health care
2763 provider who is a member of the same physician office practice,
2764 if the laboratory or entity operating the laboratory within a
2765 physician office practice is under common ownership, directly or
2766 indirectly, with an entity licensed pursuant to chapter 395.

2767 Section 99. Subsections (2), (3), and (4) of section
2768 483.803, Florida Statutes, are amended to read:

2769 483.803 Definitions.—As used in this part, the term:

2770 (2) "Clinical laboratory" means the physical location in
2771 which one or more of the following services are performed to
2772 provide information or materials for use in the diagnosis,
2773 prevention, or treatment of a disease or the identification or
2774 assessment of a medical or physical condition:

2775 (a) Clinical laboratory services, which entail the
2776 examination of fluids or other materials taken from the human
2777 body.

2778 (b) Anatomic laboratory services, which entail the
2779 examination of tissue taken from the human body.

2780 (c) Cytology laboratory services, which entail the
2781 examination of cells from individual tissues or fluid taken from
2782 the human body ~~a clinical laboratory as defined in s. 483.041.~~

2783 (3) "Clinical laboratory examination" means a procedure
2784 performed to deliver the services identified in subsection (2),

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2785 including the oversight or interpretation of such services
2786 ~~clinical laboratory examination as defined in s. 483.041.~~

2787 (4) "Clinical laboratory personnel" includes a clinical
2788 laboratory director, supervisor, technologist, blood gas
2789 analyst, or technician who performs or is responsible for
2790 laboratory test procedures, but the term does not include
2791 trainees, persons who perform screening for blood banks or
2792 plasmapheresis centers, phlebotomists, or persons employed by a
2793 clinical laboratory to perform manual pretesting duties or
2794 clerical, personnel, or other administrative responsibilities,
2795 ~~or persons engaged in testing performed by laboratories~~
2796 ~~regulated under s. 483.035(1) or exempt from regulation under s.~~
2797 ~~483.031(2).~~

2798 Section 100. Section 483.813, Florida Statutes, is amended
2799 to read:

2800 483.813 Clinical laboratory personnel license.—A person may
2801 not conduct a clinical laboratory examination or report the
2802 results of such examination unless such person is licensed under
2803 this part to perform such procedures. However, this provision
2804 does not apply to any practitioner of the healing arts
2805 authorized to practice in this state ~~or to persons engaged in~~
2806 ~~testing performed by laboratories regulated under s. 483.035(1)~~
2807 ~~or exempt from regulation under s. 483.031(2).~~ The department
2808 may grant a temporary license to any candidate it deems properly
2809 qualified, for a period not to exceed 1 year.

2810 Section 101. Subsection (2) of section 483.823, Florida
2811 Statutes, is amended to read:

2812 483.823 Qualifications of clinical laboratory personnel.—
2813 (2) Personnel qualifications may require appropriate

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2814 education, training, or experience or the passing of an
2815 examination in appropriate subjects or any combination of these,
2816 but a ~~ne~~ practitioner of the healing arts licensed to practice
2817 in this state is not required to obtain any license ~~under this~~
2818 ~~part~~ or to pay any fee under this part ~~hereunder except the fee~~
2819 ~~required for clinical laboratory licensure.~~

2820 Section 102. Paragraph (c) of subsection (7), and
2821 subsections (8) and (9) of section 491.003, Florida Statutes,
2822 are amended to read:

2823 491.003 Definitions.—As used in this chapter:

2824 (7) The “practice of clinical social work” is defined as
2825 the use of scientific and applied knowledge, theories, and
2826 methods for the purpose of describing, preventing, evaluating,
2827 and treating individual, couple, marital, family, or group
2828 behavior, based on the person-in-situation perspective of
2829 psychosocial development, normal and abnormal behavior,
2830 psychopathology, unconscious motivation, interpersonal
2831 relationships, environmental stress, differential assessment,
2832 differential planning, and data gathering. The purpose of such
2833 services is the prevention and treatment of undesired behavior
2834 and enhancement of mental health. The practice of clinical
2835 social work includes methods of a psychological nature used to
2836 evaluate, assess, diagnose, treat, and prevent emotional and
2837 mental disorders and dysfunctions (whether cognitive, affective,
2838 or behavioral), sexual dysfunction, behavioral disorders,
2839 alcoholism, and substance abuse. The practice of clinical social
2840 work includes, but is not limited to, psychotherapy,
2841 hypnotherapy, and sex therapy. The practice of clinical social
2842 work also includes counseling, behavior modification,

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2843 consultation, client-centered advocacy, crisis intervention, and
2844 the provision of needed information and education to clients,
2845 when using methods of a psychological nature to evaluate,
2846 assess, diagnose, treat, and prevent emotional and mental
2847 disorders and dysfunctions (whether cognitive, affective, or
2848 behavioral), sexual dysfunction, behavioral disorders,
2849 alcoholism, or substance abuse. The practice of clinical social
2850 work may also include clinical research into more effective
2851 psychotherapeutic modalities for the treatment and prevention of
2852 such conditions.

2853 (c) The terms "diagnose" and "treat," as used in this
2854 chapter, when considered in isolation or in conjunction with ~~any~~
2855 ~~provision of~~ the rules of the board, may ~~shall~~ not be construed
2856 to permit the performance of any act which clinical social
2857 workers are not educated and trained to perform, including, but
2858 not limited to, admitting persons to hospitals for treatment of
2859 the foregoing conditions, treating persons in hospitals without
2860 medical supervision, prescribing medicinal drugs as defined in
2861 chapter 465, authorizing clinical laboratory procedures ~~pursuant~~
2862 ~~to chapter 483~~, or radiological procedures, or use of
2863 electroconvulsive therapy. In addition, this definition ~~shall~~
2864 may not be construed to permit any person licensed,
2865 provisionally licensed, registered, or certified pursuant to
2866 this chapter to describe or label any test, report, or procedure
2867 as "psychological," except to relate specifically to the
2868 definition of practice authorized in this subsection.

2869 (8) The term "practice of marriage and family therapy"
2870 means ~~is defined as~~ the use of scientific and applied marriage
2871 and family theories, methods, and procedures for the purpose of

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2872 describing, evaluating, and modifying marital, family, and
2873 individual behavior, within the context of marital and family
2874 systems, including the context of marital formation and
2875 dissolution, and is based on marriage and family systems theory,
2876 marriage and family development, human development, normal and
2877 abnormal behavior, psychopathology, human sexuality,
2878 psychotherapeutic and marriage and family therapy theories and
2879 techniques. The practice of marriage and family therapy includes
2880 methods of a psychological nature used to evaluate, assess,
2881 diagnose, treat, and prevent emotional and mental disorders or
2882 dysfunctions (whether cognitive, affective, or behavioral),
2883 sexual dysfunction, behavioral disorders, alcoholism, and
2884 substance abuse. The practice of marriage and family therapy
2885 includes, but is not limited to, marriage and family therapy,
2886 psychotherapy, including behavioral family therapy,
2887 hypnotherapy, and sex therapy. The practice of marriage and
2888 family therapy also includes counseling, behavior modification,
2889 consultation, client-centered advocacy, crisis intervention, and
2890 the provision of needed information and education to clients,
2891 when using methods of a psychological nature to evaluate,
2892 assess, diagnose, treat, and prevent emotional and mental
2893 disorders and dysfunctions (whether cognitive, affective, or
2894 behavioral), sexual dysfunction, behavioral disorders,
2895 alcoholism, or substance abuse. The practice of marriage and
2896 family therapy may also include clinical research into more
2897 effective psychotherapeutic modalities for the treatment and
2898 prevention of such conditions.

2899 (a) Marriage and family therapy may be rendered to
2900 individuals, including individuals affected by termination of

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2901 marriage, to couples, whether married or unmarried, to families,
2902 or to groups.

2903 (b) The use of specific methods, techniques, or modalities
2904 within the practice of marriage and family therapy is restricted
2905 to marriage and family therapists appropriately trained in the
2906 use of such methods, techniques, or modalities.

2907 (c) The terms "diagnose" and "treat," as used in this
2908 chapter, when considered in isolation or in conjunction with ~~any~~
2909 ~~provision of~~ the rules of the board, may ~~shall~~ not be construed
2910 to permit the performance of any act that ~~which~~ marriage and
2911 family therapists are not educated and trained to perform,
2912 including, but not limited to, admitting persons to hospitals
2913 for treatment of the foregoing conditions, treating persons in
2914 hospitals without medical supervision, prescribing medicinal
2915 drugs as defined in chapter 465, authorizing clinical laboratory
2916 procedures ~~pursuant to chapter 483,~~ or radiological procedures,
2917 or the use of electroconvulsive therapy. In addition, this
2918 definition may ~~shall~~ not be construed to permit any person
2919 licensed, provisionally licensed, registered, or certified
2920 pursuant to this chapter to describe or label any test, report,
2921 or procedure as "psychological," except to relate specifically
2922 to the definition of practice authorized in this subsection.

2923 (d) The definition of "marriage and family therapy"
2924 contained in this subsection includes all services offered
2925 directly to the general public or through organizations, whether
2926 public or private, and applies whether payment is requested or
2927 received for services rendered.

2928 (9) The term "practice of mental health counseling" means
2929 ~~is defined as~~ the use of scientific and applied behavioral

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2930 science theories, methods, and techniques for the purpose of
2931 describing, preventing, and treating undesired behavior and
2932 enhancing mental health and human development and is based on
2933 the person-in-situation perspectives derived from research and
2934 theory in personality, family, group, and organizational
2935 dynamics and development, career planning, cultural diversity,
2936 human growth and development, human sexuality, normal and
2937 abnormal behavior, psychopathology, psychotherapy, and
2938 rehabilitation. The practice of mental health counseling
2939 includes methods of a psychological nature used to evaluate,
2940 assess, diagnose, and treat emotional and mental dysfunctions or
2941 disorders, (whether cognitive, affective, or behavioral),
2942 ~~behavioral disorders,~~ interpersonal relationships, sexual
2943 dysfunction, alcoholism, and substance abuse. The practice of
2944 mental health counseling includes, but is not limited to,
2945 psychotherapy, hypnotherapy, and sex therapy. The practice of
2946 mental health counseling also includes counseling, behavior
2947 modification, consultation, client-centered advocacy, crisis
2948 intervention, and the provision of needed information and
2949 education to clients, when using methods of a psychological
2950 nature to evaluate, assess, diagnose, treat, and prevent
2951 emotional and mental disorders and dysfunctions (whether
2952 cognitive, affective, or behavioral), behavioral disorders,
2953 sexual dysfunction, alcoholism, or substance abuse. The practice
2954 of mental health counseling may also include clinical research
2955 into more effective psychotherapeutic modalities for the
2956 treatment and prevention of such conditions.

2957 (a) Mental health counseling may be rendered to
2958 individuals, including individuals affected by the termination

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2959 of marriage, and to couples, families, groups, organizations,
2960 and communities.

2961 (b) The use of specific methods, techniques, or modalities
2962 within the practice of mental health counseling is restricted to
2963 mental health counselors appropriately trained in the use of
2964 such methods, techniques, or modalities.

2965 (c) The terms "diagnose" and "treat," as used in this
2966 chapter, when considered in isolation or in conjunction with any
2967 provision of the rules of the board, may ~~shall~~ not be construed
2968 to permit the performance of any act that ~~which~~ mental health
2969 counselors are not educated and trained to perform, including,
2970 but not limited to, admitting persons to hospitals for treatment
2971 of the foregoing conditions, treating persons in hospitals
2972 without medical supervision, prescribing medicinal drugs as
2973 defined in chapter 465, authorizing clinical laboratory
2974 procedures ~~pursuant to chapter 483,~~ or radiological procedures,
2975 or the use of electroconvulsive therapy. In addition, this
2976 definition may ~~shall~~ not be construed to permit any person
2977 licensed, provisionally licensed, registered, or certified
2978 pursuant to this chapter to describe or label any test, report,
2979 or procedure as "psychological," except to relate specifically
2980 to the definition of practice authorized in this subsection.

2981 (d) The definition of "mental health counseling" contained
2982 in this subsection includes all services offered directly to the
2983 general public or through organizations, whether public or
2984 private, and applies whether payment is requested or received
2985 for services rendered.

2986 Section 103. Paragraph (h) of subsection (4) of section
2987 627.351, Florida Statutes, is amended to read:

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2988 627.351 Insurance risk apportionment plans.—

2989 (4) MEDICAL MALPRACTICE RISK APPORTIONMENT.—

2990 (h) As used in this subsection:

2991 1. "Health care provider" means hospitals licensed under

2992 chapter 395; physicians licensed under chapter 458; osteopathic

2993 physicians licensed under chapter 459; podiatric physicians

2994 licensed under chapter 461; dentists licensed under chapter 466;

2995 chiropractic physicians licensed under chapter 460; naturopaths

2996 licensed under chapter 462; nurses licensed under part I of

2997 chapter 464; midwives licensed under chapter 467; ~~clinical~~

2998 ~~laboratories registered under chapter 483;~~ physician assistants

2999 licensed under chapter 458 or chapter 459; physical therapists

3000 and physical therapist assistants licensed under chapter 486;

3001 health maintenance organizations certificated under part I of

3002 chapter 641; ambulatory surgical centers licensed under chapter

3003 395; other medical facilities as defined in subparagraph 2.;

3004 blood banks, plasma centers, industrial clinics, and renal

3005 dialysis facilities; or professional associations, partnerships,

3006 corporations, joint ventures, or other associations for

3007 professional activity by health care providers.

3008 2. "Other medical facility" means a facility the primary

3009 purpose of which is to provide human medical diagnostic services

3010 or a facility providing nonsurgical human medical treatment, to

3011 which facility the patient is admitted and from which facility

3012 the patient is discharged within the same working day, and which

3013 facility is not part of a hospital. However, a facility existing

3014 for the primary purpose of performing terminations of pregnancy

3015 or an office maintained by a physician or dentist for the

3016 practice of medicine may ~~shall~~ not be construed to be an "other

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3017 medical facility.”

3018 3. “Health care facility” means any hospital licensed under
3019 chapter 395, health maintenance organization certificated under
3020 part I of chapter 641, ambulatory surgical center licensed under
3021 chapter 395, or other medical facility as defined in
3022 subparagraph 2.

3023 Section 104. Paragraph (h) of subsection (1) of section
3024 627.602, Florida Statutes, is amended to read:

3025 627.602 Scope, format of policy.—

3026 (1) Each health insurance policy delivered or issued for
3027 delivery to any person in this state must comply with all
3028 applicable provisions of this code and all of the following
3029 requirements:

3030 (h) Section 641.312 and the provisions of the Employee
3031 Retirement Income Security Act of 1974, as implemented by 29
3032 C.F.R. s. 2560.503-1, relating to internal grievances. This
3033 paragraph does not apply ~~to a health insurance policy that is~~
3034 ~~subject to the Subscriber Assistance Program under s. 408.7056~~
3035 ~~or~~ to the types of benefits or coverages provided under s.
3036 627.6513(1)-(14) issued in any market.

3037 Section 105. Subsection (1) of section 627.6406, Florida
3038 Statutes, is amended to read:

3039 627.6406 Maternity care.—

3040 (1) Any policy of health insurance which ~~that~~ provides
3041 coverage for maternity care must also cover the services of
3042 certified nurse-midwives and midwives licensed pursuant to
3043 chapter 467, and the services of birth centers licensed under
3044 ss. 383.30-383.332 ~~383.30-383.335~~.

3045 Section 106. Paragraphs (b) and (e) of subsection (1) of

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section 627.64194, Florida Statutes, are amended to read:
 627.64194 Coverage requirements for services provided by nonparticipating providers; payment collection limitations.—
 (1) As used in this section, the term:
 (b) "Facility" means a licensed facility as defined in s. 395.002(16) and an urgent care center as defined in s. 395.002 ~~s. 395.002(30)~~.
 (e) "Nonparticipating provider" means a provider who is not a preferred provider as defined in s. 627.6471 or a provider who is not an exclusive provider as defined in s. 627.6472. For purposes of covered emergency services under this section, a facility licensed under chapter 395 or an urgent care center defined in s. 395.002 ~~s. 395.002(30)~~ is a nonparticipating provider if the facility has not contracted with an insurer to provide emergency services to its insureds at a specified rate.
 Section 107. Section 627.6513, Florida Statutes, is amended to read:
 627.6513 Scope.—Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances, apply to all group health insurance policies issued under this part. This section does not apply to ~~a group health insurance policy that is subject to the Subscriber Assistance Program in s. 408.7056 or to:~~
 (1) Coverage only for accident insurance, or disability income insurance, or any combination thereof.
 (2) Coverage issued as a supplement to liability insurance.
 (3) Liability insurance, including general liability insurance and automobile liability insurance.

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- 3075 (4) Workers' compensation or similar insurance.
- 3076 (5) Automobile medical payment insurance.
- 3077 (6) Credit-only insurance.
- 3078 (7) Coverage for onsite medical clinics, including prepaid
3079 health clinics under part II of chapter 641.
- 3080 (8) Other similar insurance coverage, specified in rules
3081 adopted by the commission, under which benefits for medical care
3082 are secondary or incidental to other insurance benefits. To the
3083 extent possible, such rules must be consistent with regulations
3084 adopted by the United States Department of Health and Human
3085 Services.
- 3086 (9) Limited scope dental or vision benefits, if offered
3087 separately.
- 3088 (10) Benefits for long-term care, nursing home care, home
3089 health care, or community-based care, or any combination
3090 thereof, if offered separately.
- 3091 (11) Other similar, limited benefits, if offered
3092 separately, as specified in rules adopted by the commission.
- 3093 (12) Coverage only for a specified disease or illness, if
3094 offered as independent, noncoordinated benefits.
- 3095 (13) Hospital indemnity or other fixed indemnity insurance,
3096 if offered as independent, noncoordinated benefits.
- 3097 (14) Benefits provided through a Medicare supplemental
3098 health insurance policy, as defined under s. 1882(g)(1) of the
3099 Social Security Act, coverage supplemental to the coverage
3100 provided under 10 U.S.C. chapter 55, and similar supplemental
3101 coverage provided to coverage under a group health plan, which
3102 are offered as a separate insurance policy and as independent,
3103 noncoordinated benefits.

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3104 Section 108. Subsection (1) of section 627.6574, Florida
3105 Statutes, is amended to read:

3106 627.6574 Maternity care.—

3107 (1) Any group, blanket, or franchise policy of health
3108 insurance which ~~that~~ provides coverage for maternity care must
3109 also cover the services of certified nurse-midwives and midwives
3110 licensed pursuant to chapter 467, and the services of birth
3111 centers licensed under ss. 383.30-383.332 ~~383.30-383.335~~.

3112 Section 109. Paragraph (j) of subsection (1) of section
3113 641.185, Florida Statutes, is amended to read:

3114 641.185 Health maintenance organization subscriber
3115 protections.—

3116 (1) With respect to the provisions of this part and part
3117 III, the principles expressed in the following statements ~~shall~~
3118 serve as standards to be followed by the commission, the office,
3119 the department, and the Agency for Health Care Administration in
3120 exercising their powers and duties, in exercising administrative
3121 discretion, in administrative interpretations of the law, in
3122 enforcing its provisions, and in adopting rules:

3123 ~~(j) A health maintenance organization should receive timely~~
3124 ~~and, if necessary, urgent review by an independent state~~
3125 ~~external review organization for unresolved grievances and~~
3126 ~~appeals pursuant to s. 408.7056.~~

3127 Section 110. Paragraph (a) of subsection (18) of section
3128 641.31, Florida Statutes, is amended to read:

3129 641.31 Health maintenance contracts.—

3130 (18) (a) Health maintenance contracts that provide coverage,
3131 benefits, or services for maternity care must provide, as an
3132 option to the subscriber, the services of nurse-midwives and

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3133 midwives licensed pursuant to chapter 467, and the services of
3134 birth centers licensed pursuant to ss. 383.30-383.332 ~~383.30-~~
3135 ~~383.335~~, if such services are available within the service area.

3136 Section 111. Section 641.312, Florida Statutes, is amended
3137 to read:

3138 641.312 Scope.—The Office of Insurance Regulation may adopt
3139 rules to administer ~~the provisions of~~ the National Association
3140 of Insurance Commissioners' Uniform Health Carrier External
3141 Review Model Act, issued by the National Association of
3142 Insurance Commissioners and dated April 2010. This section does
3143 not apply to ~~a health maintenance contract that is subject to~~
3144 ~~the Subscriber Assistance Program under s. 408.7056 or to the~~
3145 types of benefits or coverages provided under s. 627.6513(1)-
3146 (14) issued in any market.

3147 Section 112. Subsection (4) of section 641.3154, Florida
3148 Statutes, is amended to read:

3149 641.3154 Organization liability; provider billing
3150 prohibited.—

3151 (4) A provider or any representative of a provider,
3152 regardless of whether the provider is under contract with the
3153 health maintenance organization, may not collect or attempt to
3154 collect money from, maintain any action at law against, or
3155 report to a credit agency a subscriber of an organization for
3156 payment of services for which the organization is liable, if the
3157 provider in good faith knows or should know that the
3158 organization is liable. This prohibition applies during the
3159 pendency of any claim for payment made by the provider to the
3160 organization for payment of the services and any legal
3161 proceedings or dispute resolution process to determine whether

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3162 the organization is liable for the services if the provider is
3163 informed that such proceedings are taking place. It is presumed
3164 that a provider does not know and should not know that an
3165 organization is liable unless:

3166 (a) The provider is informed by the organization that it
3167 accepts liability;

3168 (b) A court of competent jurisdiction determines that the
3169 organization is liable; or

3170 ~~(c) The office or agency makes a final determination that~~
3171 ~~the organization is required to pay for such services subsequent~~
3172 ~~to a recommendation made by the Subscriber Assistance Panel~~
3173 ~~pursuant to s. 408.7056; or~~

3174 (c) ~~(d)~~ The agency issues a final order that the
3175 organization is required to pay for such services subsequent to
3176 a recommendation made by a resolution organization pursuant to
3177 s. 408.7057.

3178 Section 113. Paragraph (c) of subsection (5) of section
3179 641.51, Florida Statutes, is amended to read:

3180 641.51 Quality assurance program; second medical opinion
3181 requirement.—

3182 (5) (c) For second opinions provided by contract physicians
3183 the organization is prohibited from charging a fee to the
3184 subscriber in an amount in excess of the subscriber fees
3185 established by contract for referral contract physicians. The
3186 organization shall pay the amount of all charges, which are
3187 usual, reasonable, and customary in the community, for second
3188 opinion services performed by a physician not under contract
3189 with the organization, but may require the subscriber to be
3190 responsible for up to 40 percent of such amount. The

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3191 organization may require that any tests deemed necessary by a
3192 noncontract physician shall be conducted by the organization.
3193 The organization may deny reimbursement rights granted under
3194 this section in the event the subscriber seeks in excess of
3195 three such referrals per year if such subsequent referral costs
3196 are deemed by the organization to be evidence that the
3197 subscriber has unreasonably overutilized the second opinion
3198 privilege. A subscriber ~~thus~~ denied reimbursement under this
3199 section has ~~shall have~~ recourse to grievance procedures as
3200 specified in ss. ~~408.7056~~, 641.495~~7~~, and 641.511. The
3201 organization's physician's professional judgment concerning the
3202 treatment of a subscriber derived after review of a second
3203 opinion is ~~shall be~~ controlling as to the treatment obligations
3204 of the health maintenance organization. Treatment not authorized
3205 by the health maintenance organization is ~~shall be~~ at the
3206 subscriber's expense.

3207 Section 114. Subsection (1), paragraph (e) of subsection
3208 (3), paragraph (d) of subsection (4), paragraphs (g) and (h) of
3209 subsection (6), and subsections (7) through (12) of section
3210 641.511, Florida Statutes, are amended to read:

3211 641.511 Subscriber grievance reporting and resolution
3212 requirements.—

3213 (1) Every organization must have a grievance procedure
3214 available to its subscribers for the purpose of addressing
3215 complaints and grievances. Every organization must notify its
3216 subscribers that a subscriber must submit a grievance within 1
3217 year after the date of occurrence of the action that initiated
3218 the grievance, ~~and may submit the grievance for review to the~~
3219 ~~Subscriber Assistance Program panel as provided in s. 408.7056~~

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3220 ~~after receiving a final disposition of the grievance through the~~
3221 ~~organization's grievance process.~~ An organization shall maintain
3222 records of all grievances and shall report annually to the
3223 agency the total number of grievances handled, a categorization
3224 of the cases underlying the grievances, and the final
3225 disposition of the grievances.

3226 (3) Each organization's grievance procedure, as required
3227 under subsection (1), must include, at a minimum:

3228 (e) A notice that a subscriber may voluntarily pursue
3229 binding arbitration in accordance with the terms of the contract
3230 if offered by the organization, after completing the
3231 organization's grievance procedure ~~and as an alternative to the~~
3232 ~~Subscriber Assistance Program.~~ Such notice shall include an
3233 explanation that the subscriber may incur some costs if the
3234 subscriber pursues binding arbitration, depending upon the terms
3235 of the subscriber's contract.

3236 (4) ~~(d) In any case when the review process does not resolve~~
3237 ~~a difference of opinion between the organization and the~~
3238 ~~subscriber or the provider acting on behalf of the subscriber,~~
3239 ~~the subscriber or the provider acting on behalf of the~~
3240 ~~subscriber may submit a written grievance to the Subscriber~~
3241 ~~Assistance Program.~~

3242 (6) ~~(g) In any case when the expedited review process does~~
3243 ~~not resolve a difference of opinion between the organization and~~
3244 ~~the subscriber or the provider acting on behalf of the~~
3245 ~~subscriber, the subscriber or the provider acting on behalf of~~
3246 ~~the subscriber may submit a written grievance to the Subscriber~~
3247 ~~Assistance Program.~~

3248 (g) ~~(h)~~ An organization shall not provide an expedited

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3249 retrospective review of an adverse determination.

3250 ~~(7) Each organization shall send to the agency a copy of~~
3251 ~~its quarterly grievance reports submitted to the office pursuant~~
3252 ~~to s. 408.7056(12).~~

3253 ~~(7)(8)~~ The agency shall investigate all reports of
3254 unresolved quality of care grievances received from:

3255 ~~(a) annual and quarterly grievance reports submitted by the~~
3256 ~~organization to the office.~~

3257 ~~(b) Review requests of subscribers whose grievances remain~~
3258 ~~unresolved after the subscriber has followed the full grievance~~
3259 ~~procedure of the organization.~~

3260 ~~(9)(a) The agency shall advise subscribers with grievances~~
3261 ~~to follow their organization's formal grievance process for~~
3262 ~~resolution prior to review by the Subscriber Assistance Program.~~
3263 ~~The subscriber may, however, submit a copy of the grievance to~~
3264 ~~the agency at any time during the process.~~

3265 ~~(b) Requiring completion of the organization's grievance~~
3266 ~~process before the Subscriber Assistance Program panel's review~~
3267 ~~does not preclude the agency from investigating any complaint or~~
3268 ~~grievance before the organization makes its final determination.~~

3269 ~~(10) Each organization must notify the subscriber in a~~
3270 ~~final decision letter that the subscriber may request review of~~
3271 ~~the organization's decision concerning the grievance by the~~
3272 ~~Subscriber Assistance Program, as provided in s. 408.7056, if~~
3273 ~~the grievance is not resolved to the satisfaction of the~~
3274 ~~subscriber. The final decision letter must inform the subscriber~~
3275 ~~that the request for review must be made within 365 days after~~
3276 ~~receipt of the final decision letter, must explain how to~~
3277 ~~initiate such a review, and must include the addresses and toll-~~

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3278 ~~free telephone numbers of the agency and the Subscriber~~
3279 ~~Assistance Program.~~

3280 (8)~~(11)~~ Each organization, as part of its contract with any
3281 provider, must require the provider to post a consumer
3282 assistance notice prominently displayed in the reception area of
3283 the provider and clearly noticeable by all patients. The
3284 consumer assistance notice must state the addresses and toll-
3285 free telephone numbers of the Agency for Health Care
3286 Administration,~~the Subscriber Assistance Program,~~ and the
3287 Department of Financial Services. The consumer assistance notice
3288 must also clearly state that the address and toll-free telephone
3289 number of the organization's grievance department shall be
3290 provided upon request. The agency may adopt rules to implement
3291 this section.

3292 (9)~~(12)~~ The agency may impose administrative sanction, in
3293 accordance with s. 641.52, against an organization for
3294 noncompliance with this section.

3295 Section 115. Subsection (1) of section 641.515, Florida
3296 Statutes, is amended to read:

3297 641.515 Investigation by the agency.—

3298 (1) The agency shall investigate further any quality of
3299 care issue contained in recommendations and reports submitted
3300 pursuant to s. ss. 408.7056~~and~~ 641.511. The agency shall also
3301 investigate further any information that indicates that the
3302 organization does not meet accreditation standards or the
3303 standards of the review organization performing the external
3304 quality assurance assessment pursuant to reports submitted under
3305 s. 641.512. Every organization shall submit its books and
3306 records and take other appropriate action as may be necessary to

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3307 facilitate an examination. The agency shall have access to the
3308 organization's medical records of individuals and records of
3309 employed and contracted physicians, with the consent of the
3310 subscriber or by court order, as necessary to administer ~~carry~~
3311 ~~out the provisions of~~ this part.

3312 Section 116. Subsection (2) of section 641.55, Florida
3313 Statutes, is amended to read:

3314 641.55 Internal risk management program.—

3315 (2) The risk management program shall be the responsibility
3316 of the governing authority or board of the organization. Every
3317 organization which has an annual premium volume of \$10 million
3318 or more and which directly provides health care in a building
3319 owned or leased by the organization shall hire a risk manager,
3320 ~~certified under ss. 395.10971-395.10975, who is~~ shall be
3321 responsible for implementation of the organization's risk
3322 management program required by this section. A part-time risk
3323 manager may ~~shall~~ not be responsible for risk management
3324 programs in more than four organizations or facilities. Every
3325 organization that ~~which~~ does not directly provide health care in
3326 a building owned or leased by the organization and every
3327 organization with an annual premium volume of less than \$10
3328 million shall designate an officer or employee of the
3329 organization to serve as the risk manager.

3330
3331 The gross data compiled under this section or s. 395.0197 shall
3332 be furnished by the agency upon request to organizations to be
3333 utilized for risk management purposes. The agency shall adopt
3334 rules necessary to administer ~~carry out the provisions of~~ this
3335 section.

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3336 Section 117. Section 641.60, Florida Statutes, is repealed.
3337 Section 118. Section 641.65, Florida Statutes, is repealed.
3338 Section 119. Section 641.67, Florida Statutes, is repealed.
3339 Section 120. Section 641.68, Florida Statutes, is repealed.
3340 Section 121. Section 641.70, Florida Statutes, is repealed.
3341 Section 122. Section 641.75, Florida Statutes, is repealed.
3342 Section 123. Paragraph (b) of subsection (6) of section
3343 766.118, Florida Statutes, is amended to read:
3344 766.118 Determination of noneconomic damages.—
3345 (6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF A
3346 PRACTITIONER PROVIDING SERVICES AND CARE TO A MEDICAID
3347 RECIPIENT.—Notwithstanding subsections (2), (3), and (5), with
3348 respect to a cause of action for personal injury or wrongful
3349 death arising from medical negligence of a practitioner
3350 committed in the course of providing medical services and
3351 medical care to a Medicaid recipient, regardless of the number
3352 of such practitioner defendants providing the services and care,
3353 noneconomic damages may not exceed \$300,000 per claimant, unless
3354 the claimant pleads and proves, by clear and convincing
3355 evidence, that the practitioner acted in a wrongful manner. A
3356 practitioner providing medical services and medical care to a
3357 Medicaid recipient is not liable for more than \$200,000 in
3358 noneconomic damages, regardless of the number of claimants,
3359 unless the claimant pleads and proves, by clear and convincing
3360 evidence, that the practitioner acted in a wrongful manner. The
3361 fact that a claimant proves that a practitioner acted in a
3362 wrongful manner does not preclude the application of the
3363 limitation on noneconomic damages prescribed elsewhere in this
3364 section. For purposes of this subsection:

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3365 (b) The term "practitioner," in addition to the meaning
3366 prescribed in subsection (1), includes any hospital or
3367 ambulatory surgical center, ~~or mobile surgical facility~~ as
3368 defined and licensed under chapter 395.

3369 Section 124. Subsection (4) of section 766.202, Florida
3370 Statutes, is amended to read:

3371 766.202 Definitions; ss. 766.201-766.212.—As used in ss.
3372 766.201-766.212, the term:

3373 (4) "Health care provider" means any hospital or
3374 ambulatory surgical center, ~~or mobile surgical facility~~ as
3375 defined and licensed under chapter 395; a birth center licensed
3376 under chapter 383; any person licensed under chapter 458,
3377 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
3378 part I of chapter 464, chapter 466, chapter 467, part XIV of
3379 chapter 468, or chapter 486; ~~a clinical lab licensed under~~
3380 ~~chapter 483~~; a health maintenance organization certificated
3381 under part I of chapter 641; a blood bank; a plasma center; an
3382 industrial clinic; a renal dialysis facility; or a professional
3383 association partnership, corporation, joint venture, or other
3384 association for professional activity by health care providers.

3385 Section 125. Section 945.36, Florida Statutes, is amended
3386 to read:

3387 945.36 ~~Exemption from health testing regulations for Law~~
3388 ~~enforcement personnel~~ authorized to conduct ~~conducting~~ drug
3389 tests on inmates and releasees.—

3390 (1) Any law enforcement officer, state or county probation
3391 officer, employee of the Department of Corrections, or employee
3392 of a contracted community correctional center who is certified
3393 by the Department of Corrections pursuant to subsection (2) may

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3394 ~~administer, is exempt from part I of chapter 483, for the~~
3395 ~~limited purpose of administering~~ a urine screen drug test to:

- 3396 (a) Persons during incarceration;
- 3397 (b) Persons released as a condition of probation for either
3398 a felony or misdemeanor;
- 3399 (c) Persons released as a condition of community control;
- 3400 (d) Persons released as a condition of conditional release;
- 3401 (e) Persons released as a condition of parole;
- 3402 (f) Persons released as a condition of provisional release;
- 3403 (g) Persons released as a condition of pretrial release; or
- 3404 (h) Persons released as a condition of control release.

3405 (2) The Department of Corrections shall develop a procedure
3406 for certification of any law enforcement officer, state or
3407 county probation officer, employee of the Department of
3408 Corrections, or employee of a contracted community correctional
3409 center to perform a urine screen drug test on the persons
3410 specified in subsection (1).

3411 Section 126. Paragraph (b) of subsection (2) of section
3412 1009.65, Florida Statutes, is amended to read:

3413 1009.65 Medical Education Reimbursement and Loan Repayment
3414 Program.—

3415 (2) From the funds available, the Department of Health
3416 shall make payments to selected medical professionals as
3417 follows:

3418 (b) All payments are ~~shall be~~ contingent on continued proof
3419 of primary care practice in an area defined in s. 395.602(2)(b)
3420 ~~s. 395.602(2)(e)~~, or an underserved area designated by the
3421 Department of Health, provided the practitioner accepts Medicaid
3422 reimbursement if eligible for such reimbursement. Correctional

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3423 facilities, state hospitals, and other state institutions that
3424 employ medical personnel shall be designated by the Department
3425 of Health as underserved locations. Locations with high
3426 incidences of infant mortality, high morbidity, or low Medicaid
3427 participation by health care professionals may be designated as
3428 underserved.

3429 Section 127. Subsection (2) of section 1011.52, Florida
3430 Statutes, is amended to read:

3431 1011.52 Appropriation to first accredited medical school.-

3432 (2) In order for a medical school to qualify under ~~the~~
3433 ~~provisions of~~ this section and to be entitled to the benefits
3434 herein, such medical school:

3435 (a) Must be primarily operated and established to offer,
3436 afford, and render a medical education to residents of the state
3437 qualifying for admission to such institution;

3438 (b) Must be operated by a municipality or county of this
3439 state, or by a nonprofit organization heretofore or hereafter
3440 established exclusively for educational purposes;

3441 (c) Must, upon the formation and establishment of an
3442 accredited medical school, transmit and file with the Department
3443 of Education documentary proof evidencing the facts that such
3444 institution has been certified and approved by the council on
3445 medical education and hospitals of the American Medical
3446 Association and has adequately met the requirements of that
3447 council in regard to its administrative facilities,
3448 administrative plant, clinical facilities, curriculum, and all
3449 other such requirements as may be necessary to qualify with the
3450 council as a recognized, approved, and accredited medical
3451 school;

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3452 (d) Must certify to the Department of Education the name,
3453 address, and educational history of each student approved and
3454 accepted for enrollment in such institution for the ensuing
3455 school year; and

3456 (e) Must have in place an operating agreement with a
3457 government-owned hospital that is located in the same county as
3458 the medical school and that is a statutory teaching hospital as
3459 defined in s. 408.07(44) ~~s. 408.07(45)~~. The operating agreement
3460 must ~~shall~~ provide for the medical school to maintain the same
3461 level of affiliation with the hospital, including the level of
3462 services to indigent and charity care patients served by the
3463 hospital, which was in place in the prior fiscal year. Each
3464 year, documentation demonstrating that an operating agreement is
3465 in effect shall be submitted jointly to the Department of
3466 Education by the hospital and the medical school prior to the
3467 payment of moneys from the annual appropriation.

3468 Section 128. This act shall take effect July 1, 2018.



260700

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
12/05/2017	.	
	.	
	.	
	.	

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

Senate Amendment

Delete line 61
and insert:
s. 499.003, and includes cancer drugs. The term does not include
a substance listed in Schedule II, Schedule III, Schedule IV, or
Schedule V of s. 893.03.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on the
Environment and Natural Resources, *Chair*
Appropriations
Appropriations Subcommittee on Health and
Human Services
Education
Environmental Preservation and
Conservation
Health Policy
Rules

SENATOR LAUREN BOOK

Democratic Leader Pro Tempore
32nd District

November 17, 2017

Chair Dana Young
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Young,

I respectfully request that you place SB 710, relating to Prescription Drug Donation Program, on the agenda of the Committee on Health Policy at your earliest convenience.

Should you have any questions or concerns, please feel free to contact my office or me. Thank you in advance for your consideration.

Thank you,

A handwritten signature in cursive script that reads "Lauren Book".

Senator Lauren Book
Senate District 32

cc: Sandra Stovall, Staff Director
Celia Georgiades, Administrative Assistant

REPLY TO:

- 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
- 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

12/5/17
Meeting Date

710
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name DAVID RIMBALO CEO

Job Title POLARIS PLANNING SERVICES

Address 2900 NW 60TH ST.
Street

Phone 954-919-1818

FT LAUD FL 33309
City State Zip

Email DRIMBALO@POLARISRX.COM

Speaking: For Against Information

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

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.

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 710

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Prescription Drug Donation Program

DATE: December 5, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 710 changes the name of the Cancer Drug Donation Program (CDDP) to the Prescription Drug Donation Program. The bill expands the program from handling cancer only drugs to permitting the donation of any prescription drug, excluding non-controlled substance, that meets the applicable safety criteria. The bill also extends participation in the program to certain, licensed nursing home facilities with a closed drug delivery system.

The bill is effective July 1, 2018.

II. Present Situation:

State Prescription Drug Donation and Reuse Programs

State prescription drug donation and reuse programs have been in effect for two decades beginning with a pilot program in Georgia in 1997.¹ Such drug donation and reuse programs permit unused prescription or non-prescription drugs to be donated and re-dispensed to patients within certain federal guidelines. More than 38 states have passed laws authorizing such programs; however, many are not currently operational.² Georgia's program started with a

¹ National Conference of State Legislatures, *State Prescription Drug Return, Reuse and Recycling Laws* (March 31, 2017), <http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx> (last visited Nov. 28, 2017).

² *Supra* note 1.

prescription drug reuse program in long-term care facilities only and has since expanded to a collection and donation program that accepts prescription and non-prescription drugs.³

Pharmaceutical donation programs and reuse programs involve the voluntary collection of donated, unused prescription and non-prescription drugs from patients. States may vary in the number and types of sites that are considered to be eligible locations where patients or donors may deposit donations and in the types of drugs included in the program. Generally, the drugs are not controlled substances and pharmacies, charitable clinics, and hospitals are locations where such donations are accepted.

In Florida's Cancer Drug Donation Program,⁴ only Class II hospital pharmacies that elect or volunteer to participate in the program are eligible to accept donations of cancer drugs from designated individuals or entities.⁵

The statutory provisions of many of the pharmaceutical donation programs have several common requirements:

- No controlled substances are accepted as donations;
- No adulterated or misbranded medications are allowed;
- All pharmaceuticals must be checked by a pharmacist prior to being dispensed;
- Pharmaceuticals must not be expired and most pharmaceuticals must have at least 6 months or more before expiration;
- All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging; and,
- Liability protection is assured for both donors and recipients.⁶

State programs vary by which drugs and supplies will be accepted, participant eligibility requirements, and the dispensing fees for the donated drugs. Some programs, such as Florida's, are limited to cancer treatment drugs only. Twelve other states besides Florida - Colorado, Kentucky, Michigan, Minnesota, Montana, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin - have cancer drug only donation programs. Individuals may also be required to meet certain eligibility requirements beyond a cancer diagnosis to participate in the donation program such as proof of state residency (Minnesota), lack of access to other insurance coverage, or Medicaid ineligibility (Florida).

Most states permit the donation of any non-controlled substance to a designated medical facility, clinic, or pharmacy that has elected to participate in the program. Twenty states have operational repository programs, either cancer drug programs or broader collection programs, including states such as Iowa which has served over 70,000 patients and re-distributed \$15 million in donated supplies since 2007.⁷ The Iowa program is limited to residents with incomes at or below 200 percent of the federal poverty level (FPL) or \$49,200 for a family of four under the current

³ GA. CODE ANN. § 31-8-301-304 (2017).

⁴ Section 499.029, F.S.

⁵ See s. 465.019, F.S. Class II institutional pharmacies are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to the patients of that institution, for use on the premises of that institution.

⁶ *Supra* note 1.

⁷ *Supra* note 1.

guidelines, who are uninsured or underinsured, and are eligible to receive the donated medications and supplies.⁸ The Iowa program accepts donations from any organization or individual in the country with the medication provided in its sealed or original, tamper-resistant packaging. Any pharmacy or medical facility with authorization to dispense under Iowa administrative rules may then re-dispense the donated medication or supplies.⁹

Wyoming has also had a long-running Medication Donation Program. The state's program filled over 150,000 prescriptions since its inception in 2007 and provided more than \$2.4 million worth of donated prescriptions in 2016.¹⁰ Assistance under the program is time-limited and recipients must have incomes under 200 percent of the FPL, be without prescription insurance or Medicaid coverage. A dispensing site may also charge a recipient up to \$10 per prescription to cover dispensing fees. Controlled substances are not covered in the program.¹¹

Florida Cancer Drug Donation Program

The Florida Cancer Drug Donation Program (CDDP) was created by the 2006 Florida Legislature¹² and is administratively housed within the Department of Business and Professional Regulation (DBPR). The CDDP allows defined donors to donate cancer drugs and related supplies to participating facilities that may dispense the donations to eligible cancer patients. Eligible donors include patients, patient representatives, health care facilities, nursing home facilities, hospices, or hospitals with a closed drug delivery system; or pharmacies, drug manufacturers, medical device manufacturers, or suppliers or wholesalers of drugs or supplies.¹³

Eligible participating facilities which may collect donations are currently only those Florida hospital pharmacies with a Class II institutional pharmacy permit.¹⁴ These pharmacies participate on a voluntary basis and must agree to accept, inspect, and dispense the donated drugs to the eligible patients in accordance with the statute. The DBPR is required to establish and maintain a participant facility registry for the CDDP. The statute provides the content for the registry and a requirement for a website posting. Currently, 14 hospital pharmacies participate in the CDDP.¹⁵

Florida's recipient eligibility requirements limit participation to individuals who are:

- Florida residents who have been diagnosed with cancer; and
- Ineligible for the Medicaid program, or any other prescription drug program funded in whole or in part by the federal government, or do not have third party insurance unless the benefits have been exhausted or a certain cancer drug is not covered.¹⁶

⁸ Iowa Department of Public Health, *SafeNetRx Program*, <https://idph.iowa.gov/ohds/rural-health-primary-care/repository>, (last visited Nov. 28, 2017).

⁹ *Id.*

¹⁰ Wyoming Department of Health, *Wyoming Medication Donation Program*, <https://health.wyo.gov/healthcarefin/medicationdonation/> (last visited Nov. 28, 2017).

¹¹ *Id.*

¹² Chapter 2006-310, Laws of Fla. (creating s. 499.029, effective July 1, 2006). It was originally created within the Department of Health, but was part of a programmatic transfer by the 2010 Legislature to DBPR effective October 1, 2011.

¹³ Section 499.029(3)(c), F.S.

¹⁴ Section 499.029(2)(e), F.S.

¹⁵ Florida Department of Business and Professional Regulation, *Cancer Drug Donation Program Participation Report*, <http://www.myfloridalicense.com/dbpr/ddc/documents/ParticipatingHospital.pdf> (last visited Nov. 28, 2017).

¹⁶ Rule 61N-1.026(1), F.A.C.

Donated drugs may only be prescribed by a licensed practitioner and dispensed by a licensed pharmacist to an eligible patient.¹⁷ Dispensed drugs and supplies under the CDDP are not eligible for reimbursement by third parties, either public or private. However, the facility may charge the recipient of the donated drug a handling fee of no more than 300 percent of the Medicaid dispensing fee or no more than \$15, whichever is less, for each cancer drug that is dispensed.¹⁸

The DBPR, Division of Drugs, Devices, and Cosmetics maintains a list of available donated medications on its website, however no cancer medications are currently reported on the list.¹⁹ As of November 2017, the DBPR does not require the participating facilities to report the medications that are available for inclusion on the CDDP website or the number of donated drugs that have been administered.²⁰ Facilities are required to maintain their data for 3 years.²¹

The CDDP will only accept drugs if:

- The drug expires at least 6 months after the date of donation and the drug's tamper resistant packaging is intact;
- The drug is in its original, unopened, sealed, tamper-evident unit dose packaging with lot number and expiration date, if so packaged; and
- The drug is not a substance listed on Schedule II, III, IV, or V of s. 893.03, F.S.²²

Under the act, a donor or a participant in the program who acts with reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies is immune from civil or criminal liability or professional disciplinary action for any kind of injury, death, or loss relating to such activities.²³

Regulation of Pharmacy

The DBPR is the state's agency charged with the regulation and licensure of businesses and professionals.²⁴ Under the provisions of chapter 499, F.S., the DBPR's Division of Drugs, Devices, and Cosmetics safeguards the health, safety, and welfare of the state's citizens from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients and cosmetics. The Division oversees the CDDP; issuance and regulation of licensure and permits for drug manufacturers, wholesalers, and distributors; controlled substance reporting requirements for certain wholesale distributors; issuance and regulation of other permit and licenses; and the Drug Wholesale Distributor Advisory Council.²⁵

¹⁷ Section 499.029(5), F.S.

¹⁸ Section 409.029(7)(b), F.S. and Rule 61N-1.026(5), F.A.C.

¹⁹ Florida Department of Business and Professional Regulation, *Medication Supply Availability List*,

²⁰ E-Mail Correspondence from Colton Madill, Department of Business and Professional Regulation (Nov. 29, 2017) (on file with the Senate Committee on Health Policy).

²¹ Id.

²² Rule 61N-1.026(6), F.A.C.

²³ Section 409.029(11), F.S.

²⁴ Section 20.165, F.S.

²⁵ Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/dbpr/ddc/index.html> (last visited Nov. 29, 2017).

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 – 499.081, F.S. The chapter provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics. The Act provides definitions for what is considered a device, drug, and specifically, a prescription drug.²⁶

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in the Department of Health. Section 465(2)(b), F.S., provides requirements for institutional pharmacies. “Class II institutional pharmacies” are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacist from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy, any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.²⁷ The exception is that in a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for re-dispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer’s control number, and expiration date, if any. In the case of controlled substances, such drugs may only be returned as permitted under federal law.²⁸ A “closed drug delivery system” means a system in which control of the unit-dose medication is maintained by the facility rather than by the individual patient. A “unit dose system” means a system in which all the individually sealed unit doses are physically connected as a unit.²⁹

For nursing facility residents, s. 400.141(1)(d), F.S., requires a pharmacist, licensed in Florida, that is under contract with a nursing home, to repackage a resident’s bulk prescription medication which has been packaged by another pharmacist into a unit-dose system compatible with the system used by the nursing facility, if requested by the facility. In order to be eligible for the repacking service, the resident or the resident’s spouse’s prescription medication benefits must be covered through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program

²⁶ A “prescription drug” under s. 499.003(40) is defined as a “prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by, s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

²⁷ Rule 64B16-28.118(2), F.A.C.

²⁸ Rule 64B16-28-118(2), F.A.C.

²⁹ Rule 64B16-28-118(1), F.A.C.

as specified under 5 C.F.R. part 831, or a long-term care policy as defined under specified state law. A pharmacist who correctly repackages and relabels the medication and the nursing home who correctly administers the repackaged medication cannot be held liable in any civil or administrative action arising from the repackaging. The pharmacist may charge a reasonable fee for costs of the repackaging.

A nursing home typically has a Class I institutional permit. This permit authorizes the nursing home to have patient-specific medications that have already been dispensed to the resident. Prescription drugs may not be dispensed in a Class I pharmacy.³⁰

Federal Law and Regulations

The federal Controlled Substances Act (CSA) was enacted by Congress in 1970 and codified as 21 U.S.C. §801, et seq. The CSA regulates the manufacture and distribution of controlled substances in the United States. The federal Drug Enforcement Agency (DEA) is responsible for the enforcement of the CSA.

The CSA categorizes drugs into five “schedules” based on their potential for abuse and safety or dependence liability.³¹ The CSA provides for specific dispensing requirements for controlled substances, including written prescriptions, retention requirements, and refill restrictions, depending on the drug’s schedule.³² Prescriptions must also meet specific labeling and packaging requirements. For Schedule II, III, and IV drugs, the label must clearly contain a warning that it is a crime to transfer the drug to any person other than the patient.³³

The CSA does permit the delivery of controlled substances by an “ultimate user”³⁴ who has lawfully obtained the drug to a designated covered entity for disposal and destruction, such as through a prescription drug take back program.³⁵ An authorized covered entity is defined in federal law as:

- A specified law enforcement agency,
- A manufacturer, distributor, or reverse distributor of prescription medications;
- A retail pharmacy;

³⁰ Section 465.019(2)(a), F.S.

³¹ U.S. Department of Justice, Diversion Control Division, *Controlled Substance Security Manual*, https://www.deadiversion.usdoj.gov/pubs/manuals/sec/app_law.htm (last visited Nov. 28, 2017). Drugs classified as Schedule I are those that are considered to have no medical use in the United States and have a high abuse potential and examples of such drugs include heroin, LSD, and marijuana. Schedule II substances have a high abuse potential with severe psychological or physical dependency, but have accepted medical use. Examples of such drugs under Schedule II include opium, morphine, codeine, and oxycodone. Under Schedule III, these drugs have an abuse potential and dependency liability less than Schedule II with an accepted medical use. Schedule III drugs may also contain limited quantities of certain narcotic and non-narcotic drugs. Schedule IV drugs have an abuse potential and dependency liability less than those drugs in Schedule III and have an accepted medical use and include drugs like Valium, Xanax, and Darvon. The fifth and final schedule, Schedule V, have an abuse potential less than those listed in Schedule IV and have an accepted medical use and are often available without a prescription, including some for antitussive and antidiarrheal purposes.

³² 21 U.S.C. §829 and 21 CFR §§1306.21 and 1306.22.

³³ 21 U.S.C. §825.

³⁴ An “ultimate user” is defined under 21 U.S.C. 802(27), as the person who has lawfully obtained, and who possesses, a controlled substance for his own use or the use of a member of his household or for an animal owned by him or by a member of his household.

³⁵ 21 U.S.C. 822a.

- A registered narcotic treatment program;
- A hospital or clinic with an onsite pharmacy;
- An eligible long-term care facility; or
- Any other entity authorized by the DEA to dispose of prescription medications.³⁶

The last National Prescription Take Back Day sponsored by the DEA resulted in more than 912,305 pounds of expired, unused, and unwanted prescription drugs being returned at 5,300 sites on November 7, 2017.³⁷ The goal of the take-back program is to prevent the diversion of unwanted drugs to misuse and abuse and to also avoid the potential safety hazard of drugs flushed down the toilet.³⁸

III. Effect of Proposed Changes:

CS/SB 710 amends s. 499.029, F.S., changing the name of the Cancer Drug Donation Program to the Prescription Drug Donation Program. The bill amends any reference that currently limits donations to “cancer drugs,” replacing it with “prescription drugs” and extends participation of certain, licensed nursing home facilities with a closed drug delivery system.

The term “prescription drug” is defined in the bill as having the same meaning as provided in s. 499.003, F.S., and includes cancer drugs. This definition does not include a controlled substance which includes a substance listed in Schedules II through V of s. 893.03, F.S.

The bill also redefines the term “donor” and the term “participant facility” to include a nursing home facility licensed under part II of chapter 400 which has a closed drug delivery system. This will allow a nursing home to not only donate prescription drugs, but to receive donations and dispense applicable donations to eligible patients. Nursing homes operating with a Class I permit are currently prohibited from dispensing prescription drugs under state law. However, under s. 499.0029(13), F.S., it provides that if any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the sections that control the CDDP would control.

The bill provides an effective date of July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

³⁶ Id.

³⁷ Drug Enforcement Administration, *Drug Enforcement Administration collects record number of unused pills as part of its 14th Prescription Drug Take Back Day* (November 7, 2017), <https://www.dea.gov/divisions/hq/2017/hq110717.shtml> (last visited Nov. 28, 2017).

³⁸ Id.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Participation in the program is voluntary; however, for the private, eligible facilities that may elect to collect pharmaceutical donations there may be a cost involved in the collecting, storing, and re-dispensing of donations. For those patients on the receiving end of these donations, there may also be a cost savings to those same health care participating facilities as those patients may be receiving needed health care services on a more timely basis. Without such donations, those same patients could return as sicker, more costlier patients at a later date.

Hospitals and facilities participating in the program are permitted to recoup some costs through a small handling fee. Current state regulations permit a handling fee of up to 300 percent of the Medicaid dispensing fee or \$15, whichever is less for each cancer drug or supply dispensed.³⁹

C. Government Sector Impact:

The expansion of the program to include all prescription drugs and to allow nursing homes to participate will increase the workload on the DBPR staff to process application requests for the registry. The DBPR indicates that this workload increase can be handled within current resources.⁴⁰

Public facilities would face the same collecting, storing, and dispensing fiscal impacts if electing to participate in the expanded program and could potentially also achieve any savings through the participation of the uninsured or underinsured from their communities.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill redefines a “donor” and amends the definition of a “participant facility” to permit the participation of nursing home facilities licensed under part II of chapter 400 in the proposed

³⁹ Rule 61N-1.026(5), F.A.C.

⁴⁰ Department of Business and Professional Regulation, *House Bill 291 Analysis* (Nov. 3, 2017), p.4, (on file with the Senate Committee on Health Policy).

Prescription Drug Donation Program. A nursing home typically has a Class I institutional pharmacy permit issued under s. 465.019(2)(a), F.S. The permit does not authorize the pharmacy to dispense medicinal drugs, but to have patient-specific medications that have already been dispensed to their residents.

Under the bill, participating nursing home facilities would be authorized to collect and dispense donated prescription drugs. This change would be in conflict with the existing permit conditions for nursing home facilities. The current CDDP statute, however, does provide a conflict of laws provision providing that if there is any conflict between the provisions of this chapter or chapter 465, the provisions of this section control the operation of the CDDP.

VIII. Statutes Affected:

This bill substantially amends section 499.029 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 December 5, 2017:

The CS amends the term “prescription drug” to exclude the donation of drugs to the program which fall under Schedules II through V of s. 803.03, F.S.

- B. **Amendments:**

None.

By Senator Book

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1 A bill to be entitled
2 An act relating to the Prescription Drug Donation
3 Program; amending s. 499.029, F.S.; renaming the
4 Cancer Drug Donation Program as the Prescription Drug
5 Donation Program; authorizing the donation of
6 prescription drugs, including cancer drugs, and
7 supplies to eligible patients; revising definitions;
8 authorizing nursing home facilities to participate in
9 the program; providing an effective date.

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

12
13 Section 1. Section 499.029, Florida Statutes, is amended to
14 read:

15 499.029 Prescription ~~Cancer~~ Drug Donation Program.—

16 (1) This section may be cited as the "Prescription ~~Cancer~~
17 Drug Donation Program Act."

18 (2) There is created a Prescription ~~Cancer~~ Drug Donation
19 Program within the department for the purpose of authorizing and
20 facilitating the donation of prescription ~~cancer~~ drugs and
21 supplies to eligible patients.

22 (3) As used in this section:

23 (a) "Cancer drug" means a prescription drug that has been
24 approved under s. 505 of the Federal Food, Drug, and Cosmetic
25 Act and is used to treat cancer or its side effects or is used
26 to treat the side effects of a prescription drug used to treat
27 cancer or its side effects. The term "~~Cancer drug~~" does not
28 include a substance listed in Schedule II, Schedule III,
29 Schedule IV, or Schedule V of s. 893.03.

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30 (b) "Closed drug delivery system" means a system in which
31 the actual control of the unit-dose medication package is
32 maintained by the facility rather than by the individual
33 patient.

34 (c) "Donor" means a patient or patient representative who
35 donates prescription ~~cancer~~ drugs or supplies needed to
36 administer prescription ~~cancer~~ drugs that have been maintained
37 within a closed drug delivery system; health care facilities,
38 nursing home facilities ~~homes~~, hospices, or hospitals with
39 closed drug delivery systems; or pharmacies, drug manufacturers,
40 medical device manufacturers or suppliers, or wholesalers of
41 drugs or supplies, in accordance with this section. The term
42 ~~"Donor"~~ includes a physician licensed under chapter 458 or
43 chapter 459 who receives prescription ~~cancer~~ drugs or supplies
44 directly from a drug manufacturer, wholesale distributor, or
45 pharmacy.

46 (d) "Eligible patient" means a person who the department
47 determines is eligible to receive prescription ~~cancer~~ drugs from
48 the program.

49 (e) "Participant facility" means a hospital that operates a
50 class II institutional ~~hospital~~ pharmacy or a nursing home
51 facility licensed under part II of chapter 400 with a closed
52 drug delivery system that has elected to participate in the
53 program and that accepts donated prescription ~~cancer~~ drugs and
54 supplies under the rules adopted by the department for the
55 program.

56 (f) "Prescribing practitioner" means a physician licensed
57 under chapter 458 or chapter 459 or any other medical
58 professional with authority under state law to prescribe

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59 prescription drugs ~~cancer medication~~.

60 (g) "Prescription drug" has the same meaning as provided in
61 s. 499.003, and includes cancer drugs.

62 (h)~~(g)~~ "Program" means the Prescription Cancer Drug
63 Donation Program created by this section.

64 (i)~~(h)~~ "Supplies" means any supplies used in the
65 administration of a prescription ~~cancer~~ drug.

66 (4) Any donor may donate prescription ~~cancer~~ drugs or
67 supplies to a participant facility that elects to participate in
68 the program and meets criteria established by the department for
69 such participation. Prescription Cancer drugs or supplies may
70 not be donated to a specific ~~cancer~~ patient, and donated drugs
71 or supplies may not be resold by the program. Prescription
72 ~~Cancer~~ drugs billed to and paid for by Medicaid in long-term
73 care facilities that are eligible for return to stock under
74 federal Medicaid regulations shall be credited to Medicaid and
75 are not eligible for donation under the program. A participant
76 facility may provide dispensing and consulting services to
77 individuals who are not patients of the hospital or nursing home
78 facility.

79 (5) The prescription ~~cancer~~ drugs or supplies donated to
80 the program may be prescribed only by a prescribing practitioner
81 for use by an eligible patient and may be dispensed only by a
82 pharmacist.

83 (6) (a) A prescription ~~cancer~~ drug may only be accepted or
84 dispensed under the program if the drug is in its original,
85 unopened, sealed container, or in a tamper-evident unit-dose
86 packaging, except that a prescription ~~cancer~~ drug packaged in
87 single-unit doses may be accepted and dispensed if the outside

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88 packaging is opened but the single-unit-dose packaging is
89 unopened with tamper-resistant packaging intact.

90 (b) A prescription ~~cancer~~ drug may not be accepted or
91 dispensed under the program if the drug bears an expiration date
92 that is less than 6 months after the date the drug was donated
93 or if the drug appears to have been tampered with or mislabeled
94 as determined in paragraph (c).

95 (c) Prior to being dispensed to an eligible patient, the
96 prescription ~~cancer~~ drug or supplies donated under the program
97 shall be inspected by a pharmacist to determine that the drug
98 and supplies do not appear to have been tampered with or
99 mislabeled.

100 (d) A dispenser of donated prescription ~~cancer~~ drugs or
101 supplies may not submit a claim or otherwise seek reimbursement
102 from any public or private third-party payor for donated
103 prescription ~~cancer~~ drugs or supplies dispensed to any patient
104 under the program, and a public or private third-party payor is
105 not required to provide reimbursement to a dispenser for donated
106 prescription ~~cancer~~ drugs or supplies dispensed to any patient
107 under the program.

108 (7) (a) A donation of prescription ~~cancer~~ drugs or supplies
109 shall be made only at a participant facility. A participant
110 facility may decline to accept a donation. A participant
111 facility that accepts donated prescription ~~cancer~~ drugs or
112 supplies under the program shall comply with all applicable
113 provisions of state and federal law relating to the storage and
114 dispensing of the donated prescription ~~cancer~~ drugs or supplies.

115 (b) A participant facility that voluntarily takes part in
116 the program may charge a handling fee sufficient to cover the

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117 cost of preparation and dispensing of prescription ~~cancer~~ drugs
118 or supplies under the program. The fee shall be established in
119 rules adopted by the department.

120 (8) The department, upon the recommendation of the Board of
121 Pharmacy, shall adopt rules to carry out the provisions of this
122 section. ~~Initial rules under this section shall be adopted no~~
123 ~~later than 90 days after the effective date of this act.~~ The
124 rules shall include, but not be limited to:

125 (a) Eligibility criteria, including a method to determine
126 priority of eligible patients under the program.

127 (b) Standards and procedures for participant facilities
128 that accept, store, distribute, or dispense donated prescription
129 ~~cancer~~ drugs or supplies.

130 (c) Necessary forms for administration of the program,
131 including, but not limited to, forms for use by entities that
132 donate, accept, distribute, or dispense prescription ~~cancer~~
133 drugs or supplies under the program.

134 (d) The maximum handling fee that may be charged by a
135 participant facility that accepts and distributes or dispenses
136 donated prescription ~~cancer~~ drugs or supplies.

137 (e) Categories of prescription ~~cancer~~ drugs and supplies
138 that the program will accept for dispensing; however, the
139 department may exclude any drug based on its therapeutic
140 effectiveness or high potential for abuse or diversion.

141 (f) Maintenance and distribution of the participant
142 facility registry established in subsection (10).

143 (9) A person who is eligible to receive prescription ~~cancer~~
144 drugs or supplies under the state Medicaid program or under any
145 other prescription drug program funded in whole or in part by

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146 the state, by any other prescription drug program funded in
147 whole or in part by the Federal Government, or by any other
148 prescription drug program offered by a third-party insurer,
149 unless benefits have been exhausted, or a certain prescription
150 ~~cancer~~ drug or supply is not covered by the prescription drug
151 program, is ineligible to participate in the program created
152 under this section.

153 (10) The department shall establish and maintain a
154 participant facility registry for the program. The participant
155 facility registry shall include the participant facility's name,
156 address, and telephone number. The department shall make the
157 participant facility registry available on the department's
158 website to any donor wishing to donate prescription ~~cancer~~ drugs
159 or supplies to the program. The department's website shall also
160 contain links to prescription ~~cancer~~ drug manufacturers that
161 offer drug assistance programs or free medication.

162 (11) Any donor of prescription ~~cancer~~ drugs or supplies, or
163 any participant in the program, who exercises reasonable care in
164 donating, accepting, distributing, or dispensing prescription
165 ~~cancer~~ drugs or supplies under the program and the rules adopted
166 under this section shall be immune from civil or criminal
167 liability and from professional disciplinary action of any kind
168 for any injury, death, or loss to person or property relating to
169 such activities.

170 (12) A pharmaceutical manufacturer is not liable for any
171 claim or injury arising from the transfer of any prescription
172 ~~cancer~~ drug under this section, including, but not limited to,
173 liability for failure to transfer or communicate product or
174 consumer information regarding the transferred drug, as well as

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175 the expiration date of the transferred drug.

176 (13) If any conflict exists between the provisions in this
177 section and the provisions in this chapter or chapter 465, the
178 provisions in this section shall control the operation of the
179 Prescription ~~Cancer~~ Drug Donation Program.

180 Section 2. This act shall take effect July 1, 2018.

CourtSmart Tag Report

Room: KN 412

Case No.:

Type:

Caption: Senate Committee on Health Policy

Judge:

Started: 12/5/2017 10:05:01 AM

Ends: 12/5/2017 11:01:10 AM

Length: 00:56:10

10:05:06 AM Meeting called to order
10:05:15 AM AA calls the role
10:05:19 AM Quorum present
10:06:15 AM Tab 2 SB 408
10:06:34 AM Sen Flores explains the bill
10:06:58 AM Chair calls for questions
10:07:11 AM Sen Flores waives close on SB 408
10:07:24 AM SB 408 recorded favorably
10:07:40 AM Tab 4 SB 520 Sen Latvala
10:07:47 AM Sen Latvala explains the bill
10:08:10 AM BC 510350 Sen Latvala
10:09:21 AM Chair calls for questions
10:09:42 AM Dave Ramba, FI optometric association, waives in support
10:09:50 AM Sen Latvala waives close
10:09:55 AM Amen adopted
10:10:05 AM Chair calls for question on bill as amen
10:10:15 AM Sen Latvala waives close
10:10:33 AM CS SB 520 recorded favorably
10:10:40 AM Tab 6 SB 710 Sen Book
10:10:49 AM Sen Book explains
10:12:10 AM Chair calls for questions
10:12:33 AM Chair Young question
10:12:39 AM Sen Book response
10:13:04 AM BC 260700 Sen Book explains
10:13:31 AM AM adopted
10:13:50 AM David Rambro Pluris planning Services waives in support
10:14:04 AM Sen Book waives close on SB 710 as Amen
10:14:15 AM Roll Call Sb 710
10:14:25 AM CS SB 710 recorded favorably
10:15:41 AM Recording Paused
10:17:05 AM Recording Resumed
10:17:14 AM Tab 3 SB 488 Sen Grimsley
10:17:20 AM Sen Grimsley explains
10:20:17 AM BC 257094 Sen Grimsley explains
10:20:42 AM Chair calls for questions and appearance forms on the Amen
10:20:47 AM Sen Grimsley waives close
10:20:50 AM Amen adopted
10:20:56 AM Questions on bill as Amen
10:21:08 AM Vice Chair Passidomo question on the bill
10:21:41 AM Jim Millican, Lealman Fire District waives in support
10:22:48 AM Brett Jameyson, North Collier Fire fighters speaks in support
10:24:30 AM Chris Lyon, FI Association Special Dist, waives in support
10:25:43 AM Joege Aguilera, , North Collier Fire Control and Rescue District, speaks in favor
10:27:03 AM Eric Prutuman, Florida Fire Chiefs Association
10:27:12 AM John Stanfill waives in support
10:27:19 AM Lisa Hurley, Collier County Board of County Commissions waives in opposition
10:27:27 AM Daphne Sanvill, Broward Co. waives in opposition
10:27:37 AM Jim Tolley waives in support
10:28:21 AM Mac Kemp, Florida Council of EMS chiefs, speaks in opposition
10:31:50 AM Greg Dewitt, Bonita Springs fire Control, waives in favor
10:33:39 AM Sen Benacquisto comments
10:33:47 AM Chief Kemp response

10:34:30 AM Sen Hudson question
10:35:20 AM fire Chief response
10:35:36 AM Sen Hukill comments
10:35:47 AM Sen Passidomo comments
10:38:27 AM Sen Grimsley closes
10:38:37 AM CS SB 488 Roll call
10:38:50 AM CS SB 488 recorded favorably
10:39:08 AM Tab 1 SB 250 Sen Stuebe
10:39:13 AM Sen Steube explains
10:39:29 AM Sen Montford question
10:40:16 AM Sen Steube responds
10:41:19 AM Sen Montford follow up quesiton
10:41:26 AM Sen Steube responds
10:41:40 AM Sen Powell question
10:41:49 AM Sen Steube responds
10:43:31 AM Sesn Powell question
10:43:36 AM Sen Steube response
10:43:41 AM Sen Hukill question
10:43:47 AM Sen Steube response
10:44:50 AM BC 588182 Sen Steube
10:44:55 AM Sen Steube explains
10:46:08 AM Anita Berry, Johns Hopkins All Childrens Hospital, waives in support
10:46:17 AM Brian Jogerest, Miami Children's Health System, waives in support
10:46:35 AM Chris Nuland, Florida Chapter of Americal College of Surgeons, waives in support
10:47:08 AM David Shapiro, FI Society of Ambulatory Surgery Centers, speaks in favor
10:52:29 AM Sen Hudson question
10:53:44 AM Shapiro response
10:53:51 AM Sen Hudson follow up
10:54:12 AM William Height James Madison
10:54:27 AM Monica Corbett, Florida Hospital Association, waives in opposition
10:54:33 AM Sen Stuebe closes
10:54:54 AM CS SB 250 recorded favorably
10:55:07 AM Tab 5 SB 622 Sen Grimsley
10:55:12 AM Sen Grimsley explains
10:56:14 AM Toni Large, FI Orthopedic Association, waives in support
11:00:10 AM Chair Calls for questions
11:00:22 AM Sen Grimsley waives close
11:00:32 AM SB 622 recorded favorably
11:01:02 AM Meeting adjourned