

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Monday, March 27, 2017**TIME:** 4:00—6:00 p.m.**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 414 Grimsley (Similar H 863)	Hospice Services; Exempting certain hospice services in a not-for-profit retirement community from specified review and application requirements, etc. HP 03/27/2017 Fav/CS CF RC	Fav/CS Yeas 6 Nays 1
2	SB 474 Grimsley (Similar CS/H 539)	Hospice Care; Requiring the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, to adopt by rule certain outcome measures by a specified date; authorizing hospices, or providers operating under contract with a hospice, to provide palliative care to seriously ill persons and their family members; authorizing a hospice to assist in the disposal of certain prescribed controlled substances, etc. HP 03/27/2017 Fav/CS BI CF RC	Fav/CS Yeas 7 Nays 0
3	SB 588 Passidomo (Compare CS/CS/H 249)	Drug Overdoses; Requiring certain persons to report controlled substance overdoses; providing for a reporting agency in each county; providing immunity for persons who make such reports in good faith; requiring sharing of data with specified entities; prohibiting failure to make such reports, whether by omission or willfully, etc. HP 03/27/2017 Fav/CS CJ RC	Fav/CS Yeas 7 Nays 0

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Health Policy

Monday, March 27, 2017, 4:00—6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	SB 682 Stargel (Compare H 1059, S 916)	Medicaid Managed Care; Revising parameters relating to the establishment of the Medicaid program; revising exemptions from the mandatory enrollment of Medicaid recipients in statewide Medicaid managed care; revising eligibility criteria for the long-term care managed care program to conform to exemptions; revising parameters under which a long-term care managed care plan must contract with nursing homes and hospices, etc. HP 03/27/2017 Fav/CS AHS AP	Fav/CS Yeas 6 Nays 1
5	SB 694 Hutson (Similar CS/H 619)	Medicaid; Authorizing any state agency or department involved in providing health, social, or human services to make payments for medical assistance for certain persons diagnosed with Acquired Immune Deficiency Syndrome (AIDS); requiring that Medicaid recipients enrolled in certain home and community-based service Medicaid waivers be transitioned into the long-term care managed care program by January 1, 2018; requiring the agency to seek federal approval to terminate certain waiver programs once all eligible Medicaid recipients have transitioned into the long-term care managed care program, etc. HP 03/27/2017 Fav/CS AHS AP RC	Fav/CS Yeas 7 Nays 0
6	SB 916 Grimsley (Compare S 682)	Statewide Medicaid Managed Care Program; Deleting the fee-for-service option as a basis for the reimbursement of Medicaid provider service networks; requiring provider service networks to be prepaid plans; revising the number of eligible Medicaid health care plans the agency must procure for certain regions in the state, etc. HP 03/27/2017 Favorable AHS AP RC	Favorable Yeas 7 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Monday, March 27, 2017, 4:00—6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	SB 1124 Book (Similar CS/H 963)	Newborn Screenings; Requiring the Department of Health, upon the advice of the Genetics and Newborn Screening Advisory Council, to expand within a specified period the statewide screening of newborns to include any condition on the federal Recommended Uniform Screening Panel; requiring the council to determine whether a condition should be included in the state's screening program within a specified period after its addition to the federal panel, etc. HP 03/27/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
8	SB 1144 Montford (Identical H 1041, Compare S 1074)	Laboratory Screening; Clarifying that certain requirements related to the reporting of positive HIV test results to county health departments apply only to testing performed in a nonhealth care setting; authorizing, rather than requiring, that the Governor, in conjunction with the State Surgeon General, sponsor a public information initiative on lead-based paint hazards; revising requirements for the State Surgeon General's program for early identification of persons at risk of having elevated blood-lead levels, etc. HP 03/27/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
9	SB 1206 Montford (Identical H 1253)	Rights and Responsibilities of Patients; Requiring health care facilities and providers to authorize patients to bring in any person of the patients' choosing to specified areas of the facilities or providers' offices under certain circumstances, etc. HP 03/27/2017 Fav/CS JU RC	Fav/CS Yeas 7 Nays 0
10	SB 1324 Garcia (Similar H 1011)	Hair Restoration or Transplant; Prohibiting a person who is not licensed under ch. 458, F.S., or ch. 459, F.S., or certified under s. 464.012, F.S., from performing a hair restoration or transplant or making incisions for the purpose of performing a hair restoration or transplant, etc. HP 03/27/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Monday, March 27, 2017, 4:00—6:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
11	SB 1406 Powell (Similar CS/CS/H 785)	Stroke Centers; Directing the Agency for Health Care Administration to include hospitals that meet the criteria for acute stroke ready centers on a list of stroke centers; requiring the Department of Health to establish a statewide stroke registry, etc. HP 03/27/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
12	SB 1760 Grimsley (Similar H 1195, Compare CS/H 7, S 676)	Health Care Facility Regulation; Eliminating state licensure requirements for clinical laboratories; authorizing the Agency for Health Care Administration to adopt rules establishing criteria for alternate-site laboratory testing; requiring the manager of a hospital or ambulatory surgical center internal risk management program to demonstrate competence in certain administrative and health care service areas; repealing provisions relating to the purpose and establishment of the Health Care Risk Manager Advisory Council; repealing provisions relating to the Subscriber Assistance Program and Statewide Managed Care Ombudsman Committee; authorizing law enforcement personnel to conduct drug tests on certain inmates and releasees, etc. HP 03/27/2017 Favorable AHS AP RC	Favorable Yeas 7 Nays 0

Other Related Meeting Documents

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 414

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Hospice Services

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 414 creates a new exemption from the certificate of need process for the establishment of a hospice program that shares a controlling interest¹ with a not-for-profit retirement community that offers independent living, assisted living, and nursing home services at a teaching nursing home that has been designated as a teaching nursing home² for at least five years. The bill specifies that only one hospice program may be established per teaching nursing home under the exemption.

¹ Section. 408.803(7), F.S., defines “controlling interest” to mean the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5 percent or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5 percent or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

² Section 430.80, F.S., defines “teaching nursing home” to mean a nursing home facility licensed under ch. 400, F.S., which contains a minimum of 170 licensed nursing home beds; has access to a resident senior population of sufficient size to support education, training, and research relating to geriatric care; and has a contractual relationship with a federally funded accredited geriatric research center in this state or operates in its own right a geriatric research center.

II. Present Situation:

Florida's Certificate of Need (CON) Program

Overview

In Florida, a CON is a written statement issued by the Agency for Health Care Administration (AHCA) evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full, expedited and exempt.³ Unless a project is exempt from the CON program, it must undergo a full comparative review. Expedited review is primarily targeted towards nursing home projects.

Full CON Review Process

Currently, prior to establishing a hospice or a hospice inpatient facility, an applicant is required to follow AHCA requirements for a full CON review.⁴

Full CON review is a lengthy process that starts with the AHCA determining need for a specific facility type or service. Upon determining that a need exists, AHCA accepts applications for CON based on batching cycles. At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.⁵ A letter of intent must describe the proposal, specify the number of beds sought, if applicable, and identify the services to be provided and the location of the project.⁶ Applications for CON review must be submitted by the specified deadline for the particular batch cycle.⁷ The AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.⁸ The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.⁹

Within 60 days of receipt of the completed applications for that batch, the AHCA must issue a State Agency Action Report and Notice of Intent to grant a CON for a project in its entirety, to grant a CON for identifiable portions of a project, or to deny a CON for a project.¹⁰ The AHCA must then publish the decision, within 14 days, in the Florida Administrative Register.¹¹ If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent become a final order of the AHCA.¹²

³ Section 408.036, F.S.

⁴ Section 408.036(1)(d), F.S. However, s. 408.036(3)(a), F.S., establishes an exemption to this process for hospice services in a rural hospital.

⁵ Section 408.039(2)(a), F.S.

⁶ Section 408.039(2)(c), F.S.

⁷ Rule 59C-1.008(1)(g), F.A.C.

⁸ Section 408.039(3)(a), F.S.

⁹ Id.

¹⁰ Section 408.039(4)(b), F.S.

¹¹ Section 408.039(4)(c), F.S.

¹² Section 408.039(4)(d), F.S.

An applicant for CON review must submit a fee to the AHCA at the time of application submission. The minimum CON application filing fee is \$10,000.¹³ In addition to the base fee, an applicant must pay a fee of .15 percent of each dollar of the proposed expenditure; however, the total fee may not exceed \$50,000.¹⁴

Hospice Need Calculations

Need for a new hospice program is part of the applicant's review criteria pursuant to s. 408.035(1)(a), F.S. Need for a new hospice program can be identified through publication of the fixed need pool (pursuant to Rule 59C-1.0355(4), F.A.C.) or in the absence of numeric need the applicant must demonstrate that circumstances exist to justify approval of a new hospice program. Those circumstances must include documentation of a specific terminally ill population that is not being served or that a county/counties within the service area of a licensed hospice program are not being served.¹⁵

Exemptions from CON Review

Section 408.036(3), F.S., provides many exemptions to CON review. Exempted projects must only submit an application for exemption to the AHCA and pay a \$250 fee.

Teaching Nursing Homes

A teaching nursing home is a nursing home facility licensed under chapter 400 which contains a minimum of 170 licensed nursing home beds; has access to a resident senior population of sufficient size to support education, training, and research relating to geriatric care; and has a contractual relationship with a federally funded accredited geriatric research center in this state or operates in its own right a geriatric research center.¹⁶ The AHCA is required to develop a program for the designation of teaching nursing homes and to be designated, a nursing home must:

- Provide a comprehensive program of integrated senior services that include institutional services and community-based services;
- Participate in a nationally recognized accrediting program and hold a valid accreditation, such as the accreditation awarded by the Joint Commission, or, at the time of initial designation, possess a Gold Seal Award as conferred by the state on its licensed nursing home;
- Have been in business in this state for a minimum of 10 consecutive years;
- Demonstrate an active program in multidisciplinary education and research that relates to gerontology;
- Have a formalized contractual relationship with at least one accredited health profession education program located in this state;
- Have senior staff members who hold formal faculty appointments at universities, which must include at least one accredited health profession education program; and

¹³ Section 408.038, F.S.

¹⁴ Id.

¹⁵ AHCA, *Senate Bill 414 Analysis*, (January 23, 2017) (on file with the Senate Committee on Health Policy).

¹⁶ Section 403.80(1), F.S.

- Maintain insurance coverage pursuant to s. 400.141(1)(q), F.S., or proof of financial responsibility in a minimum amount of \$750,000. Such proof of financial responsibility may include:
 - Maintaining an escrow account consisting of cash or assets eligible for deposit; or
 - Obtaining and maintaining an unexpired, irrevocable, nontransferable and nonassignable letter of credit. The letter of credit shall be used to satisfy a final judgment indicating liability and awarding damages or a settlement agreement when such final judgment or settlement is a result of a liability claim against the facility.¹⁷

Additionally, a teaching nursing home must be primarily operated and established to offer, afford, and render a comprehensive multidisciplinary program of geriatric education and research to residents of the state and certify to the AHCA each school year the name, address, and educational history of each trainee approved and accepted for enrollment in the institution.¹⁸

Currently there are two nursing homes in the state designated as teaching nursing homes: Miami Jewish Health Systems (hospice service area 11, Miami-Dade County) and The Joseph L. Morse Health Center (hospice service area 9C, Palm Beach County).¹⁹ Of the two, the controlling interest of the Joseph L. Morse Health Center has an open CON application with the AHCA to provide hospice services. The application was preliminarily denied on February 17, 2017, and the denial was timely appealed on March 10, 2017.²⁰

III. Effect of Proposed Changes:

CS/SB 414 creates a new exemption from the CON process for the establishment of a hospice program that shares a controlling interest²¹ with a not-for-profit retirement community that offers independent living, assisted living, and nursing home services at a teaching nursing home that has been designated as a teaching nursing home²² for at least five years. The bill specifies that only one hospice program may be established per teaching nursing home under the exemption.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

¹⁷ Section 403.80(3)(a)-(g), F.S.

¹⁸ Section 430.80(6)(a) and (b), F.S.

¹⁹ Supra note 15.

²⁰ Id.

²¹ Section 408.803(7), F.S., defines “controlling interest” to mean the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5 percent or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5 percent or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

²² Section 430.80, F.S., defines “teaching nursing home” to mean a nursing home facility licensed under ch. 400, F.S., which contains a minimum of 170 licensed nursing home beds; has access to a resident senior population of sufficient size to support education, training, and research relating to geriatric care; and has a contractual relationship with a federally funded accredited geriatric research center in this state or operates in its own right a geriatric research center.

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 414 may have a positive fiscal impact on a non-profit retirement community that is able to provide hospice services under the new exemption without first obtaining a CON from the AHCA due to eliminating the requirement to pay fees associated with obtaining a CON and due to being able to provide hospice services in an area where the AHCA may or may not have determined a need for such services.

The bill may have a negative fiscal impact on existing hospices in a service area where this exemption is applied due to a loss of patients that begin using the new hospice.

C. Government Sector Impact:

The bill may have a negative fiscal impact of approximately \$35,000 to the AHCA due to loss of revenues from the CON application fees if both providers applied for the CON exemption.²³

VI. Technical Deficiencies:

None.

VII. Related Issues:

It is unclear what entities the bill is referring to with the term “not-for-profit retirement communities.” This term might need further clarification.²⁴

VIII. Statutes Affected:

This bill substantially amends section 408.036 of the Florida Statutes.

²³ Supra note 15.

²⁴ Supra note 15.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2017:

The CS narrows the applicability of the CON exemption created by the bill by:

- Requiring the not-for-profit retirement community to offer independent living, assisted living, and nursing home services at a teaching nursing home that has been designated as a teaching nursing home for at least 5 years; and
- Specifying that only one hospice program may be offered per teaching nursing home;

The CS also clarifies the language of the bill and makes technical corrections.

B. Amendments:

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment

Delete lines 17 - 21
and insert:
exceed one-half of its licensed beds, or for a hospice program established by an entity that shares a controlling interest, as defined in s. 408.803, with a not-for-profit retirement community that offers all of the following:
1. Independent living.



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2. Assisted living.

3. Nursing home services located on the same premises as a
nursing home facility designated by the agency as a teaching
nursing home for a minimum of 5 years in accordance with s.
430.80.

Only one hospice program per teaching nursing home may be
established under the exemption in this paragraph.

By Senator Grimsley

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A bill to be entitled

An act relating to hospice services; amending s. 408.036, F.S.; exempting certain hospice services in a not-for-profit retirement community from specified review and application requirements; providing an effective date.

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

Section 1. Paragraph (a) of subsection (3) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

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

(a) For hospice services or for swing beds in a rural hospital, as defined in s. 395.602, in a number that does not exceed one-half of its licensed beds, or for hospice services in a not-for-profit retirement community that shares a controlling interest, as defined in s. 408.803(7), with a teaching nursing home, as defined in s. 430.80, and designated for a minimum of 5 years.

Section 2. This act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: February 9, 2017

I respectfully request that **Senate Bill #414**, relating to Hospice 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

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/27/17
Meeting Date

SB414
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Tina Braungardt

Job Title Internal Management Consultant

Address 1309 Sardinia Ct

Phone 636-614-6063

Street

Davenport

City

State

Zip

Email tina.braungardt@vitas.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing VITAS Healthcare

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)

3/27/17

Meeting Date

SB 414

Bill Number (if applicable)

Topic

Amendment Barcode (if applicable)

Name

Job Title

Address

Street

Phone

City

State

Zip

Email

Speaking:

☐

For

☐

Against

☒

Information

Waive Speaking:

☐

In Support

☐

Against

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

Representing

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)

3/27/17
Meeting Date

SB 414
Bill Number (if applicable)

Topic Teaching Hospice

Amendment Barcode (if applicable)

Name Alan D Sadeurk, Ph.D.

Job Title Sr VP MorseLife Health System

Address 4847 Fred Gladstone Dr.
Street

Phone 561 687-5745

City

State

Zip

Email ASadeurk@MorseLife.org

Speaking: ☐ For ☐ Against ☒ Information

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

Representing MorseLife

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: CS/SB 474

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Hospice Care

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 474 amends and creates several sections of the Florida Statutes related to the provision of hospice care. The bill:

- Requires the Department of Elder Affairs (DOEA) and the Agency for Health Care Administration (AHCA) to adopt federal guidelines for hospice outcome measures by December 31, 2019, and to develop a system for reporting hospice outcomes to consumers;
- Creates new requirements for hospices that choose to assist in the disposal of prescribed controlled substances after in a patient's home after his or her death ; and
- Expands the ways a person may be authorized to receive a hospice patient's medical records both before the patient's death and afterwards.

II. Present Situation:

Hospice Care

Hospice care is a continuum of care for the terminally ill¹ patient and his or her family members.² Hospice care is provided by a hospice team which includes physicians, nurses, medical social workers, spiritual/pastoral counselors, home health aides, therapists, bereavement

¹ "Terminally ill" means that the patient has a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course. s. 400.601, F.S.

² Fla. Admin. Code R. 59C-1.0355.

counselors, and specially trained volunteers.³ Currently there are 45 licensed hospice providers in Florida.⁴ Hospices can be for-profit or non-profit and provide four levels of care:

- **Routine care** provides the patient with hospice services at home or in a home-like setting. The patient's family provides the primary care with the assistance of the hospice team.
- **Continuous care** provides the patient with skilled nursing services in his or her home during a crisis.
- **Inpatient care** is provided in a healthcare facility for symptoms of a crisis that cannot be managed in the patient's home. Inpatient care is provided on a temporary basis as determined by the patient's physician and the hospice team.
- **Respite care** is provided in a healthcare facility and is primarily to provide the patient's family members and caretakers with a period of relief.⁵

Disposal of Prescription Medication by a Hospice

While there is no statutory provision related to hospice care that addresses the disposal of prescribed controlled substances in a hospice patient's home, Rule 58A-2.005(3)(a)7 of the Florida Administrative Code, requires hospices to have policies and procedures in place for disposal of Schedule II Controlled Substances upon the patient's death. Similarly, federal Medicare standards require hospices to dispose of controlled drugs in accordance with state and federal law.⁶

Hospice Outcome Measures

Current Florida Requirements

Rule 58A-2.005(4) of the Florida Administrative Code, requires hospice providers to annually report outcome measures to the DOEA including:

- Facility demographic information;
- The effectiveness of the hospice's pain management program;⁷
- Patient and family satisfaction including:
 - Whether or not the patient received the right amount of medicine for pain; and
 - Would the patient recommend hospice services to others; and
- Aggregate patient data including:
 - Age;
 - Race;
 - Payor source;
 - Total number of patient days by location; and
 - The number of discharges by disposition.⁸

³ Florida Hospice and Palliative Care Association, *About Hospice* <http://www.floridahospices.org/hospice-palliative-care/about-hospice/> (last visited Mar. 23, 2017).

⁴ Agency for Health Care Administration, *Senate Bill 474 Analysis* (January 27, 2017) (on file with the Senate Committee on Health Policy).

⁵ Supra note 3

⁶ Supra note 4. See 21 CFR s. 1317, for the federal regulations controlling the disposal of controlled substances.

⁷ Section 400.60501, F.S., requires 50 percent of patients who report severe pain at the time of admission to a hospice must report a reduction in pain to a level of five or less (on a ten point scale) by the end of the fourth day of hospice care.

⁸ DOEA Form H-002, *Hospice Demographic and Outcome Measures Report* (August 2008) available at <http://elderaffairs.state.fl.us/english/hospice/DOEAformH002.xls> (last visited on Mar. 23, 2017).

Federal Requirements

As a condition of participation for Medicare and Medicaid certification, 42 C.F.R. 418.54(e), requires that, as a part of a comprehensive assessment of each patient, the hospice must collect data elements that allow for measurement of outcomes for each patient. The hospice is required to document and measure the data elements in the same way for each patient and the data elements must take into consideration all aspects of care related to hospice and palliation. Additionally, the data elements must be documented in a systematic and retrievable way for each patient and must be used in individual patient care planning, in coordination of services, and must be used for each hospice's quality assessment and performance improvement program.⁹

Hospice Patient Records

Currently, s. 400.611, F.S., restricts a hospice from releasing a patient's record, or any portion thereof, unless:

- The patient or legal guardian has given express written informed consent;
- A court of competent jurisdiction has ordered the record released; or
- A state or federal agency, acting under its statutory authority, requires the submission of aggregate statistical data.

Legal Guardians, Health Care Surrogacies, and Health Care Proxies.

A legal guardian is a person who is designated by a court pursuant to ch. 744, F.S., to act on the behalf of a ward's person or property. In most cases, in order to have a guardian appointed, a court must determine that the ward is incapacitated. Chapter 744, F.S., defines an incapacitated person as a person who has been judicially determined to lack the capacity to manage at least some of the property or to meet at least some of the essential health and safety requirements of the person.

Section 765.101, F.S., defines a health care surrogate as any competent adult expressly designated by a principal to make health care decisions and to receive health information. The principal may stipulate whether the authority of the surrogate to make health care decisions or to receive health information is exercisable immediately without the necessity for a determination of incapacity or only upon the principal's incapacity as provided in s. 765.204, F.S. In the case of the of a patient who is incapacitated and has not designated a health care surrogate, the authority to make health care decisions for a patient rests in the patient's proxy.

Section 765.101, F.S., defines a proxy as a competent adult who has not been expressly designated to make health care decisions for a particular incapacitated individual, but who, nevertheless, is authorized pursuant to s. 765.401, F.S., to make health care decisions for such individual and s. 765.401, F.S., lists in descending order of priority persons who may be considered the patient's proxy.¹⁰

⁹ The details of the quality assessment and performance improvement program requirements are in 42 C.F.R. 418.58.

¹⁰ Proxies may include, in descending order of priority: a judicially appointed guardian, the patient's spouse, an adult child of the patient, the patient's parent, an adult sibling of the patient (or majority of adult siblings if he or she has more than one), an adult relative of the patient who is close to the patient, a close friend of the patient, and a clinical social worker who meets specified criteria.

III. Effect of Proposed Changes:

Section 1 amends s. 400.60501, F.S., to require that the DOEA and the AHCA adopt outcome measures for quality and effectiveness of hospice care by December 31, 2019. The bill requires that the DOEA and the AHCA adopt national hospice outcome measures in 42 C.F.R. part 418 and develop a system for publicly reporting these measures identified as useful consumer information. The bill also eliminates a quality standard pertaining to reducing a patient's severe pain by the end of the fourth day after admission.

Section 2 creates s. 400.6096, F.S., to establish requirements for a hospice if the hospice chooses to assist with the disposal of prescribed controlled substances after the death of a patient in his or her home. The bill requires a hospice that assists in the disposal of prescribed controlled substances in a patient's home to establish clearly defined policies, procedures, and systems for acceptable disposal methods. Disposal procedures must be carried out in the home and hospice staff and volunteers are not permitted to remove controlled substances from the patient's home. The bill permits hospice physicians, nurses, and social workers to assist family members with the disposal of controlled substances in the patient's home after a patient's death pursuant to regulations in 21 C.F.R. s. 1317 (related to the disposal of controlled substances) and pursuant to the hospice's written policy, procedure, or system for disposal methods.

Section 3 amends s. 400.611, F.S., to expand the ways a person may be authorized to receive a hospice patient's record of care both before and after the patient's death. The bill:

- Increases the length of time a hospice must keep a patient's record from 5 to 6 years after termination of hospice services;
- Restricts a hospice from releasing a patient's interdisciplinary record of care unless the person requesting the record provides:
 - A patient authorization executed by the patient;
 - For incapacitated patients, a patient authorization executed before the patient's death by the patient's legal guardian, health care surrogate, health care proxy, or agent under power of attorney;
 - A court order appointing the person as the administrator, curator, executor, or personal representative of the patient's estate with authority to obtain the patient's medical records;
 - If a judicial appointment has not been made, a last will that is self-proved pursuant to s. 732.503, F.S., and designates the person to act as the patient's personal representative; or
 - A court order by a court of competent jurisdiction mandating the release of the records.¹¹

For the purposes of this section, the bill defines the term "patient authorization" as an unrevoked written statement by the patient or an oral statement by the patient, or, in the case of incapacitated patients, the patient's legal guardian, health care surrogate, health care proxy, or agent under power of attorney which has been reduced to writing in the patient's record of care and gives the patient's permission to release the record to the person.

¹¹ Currently a hospice may only provide records pursuant to the patient's consent, the patient's legal guardian's consent, or a court order.

The effective date of the bill is July 1, 2017.

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 474 may have a positive fiscal impact on persons who would be authorized under the bill to receive a hospice patient's records without the need to obtain a court order.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill amends s. 400.611, F.S., to allow a hospice to release a patient's record of care to a person if the person has a "patient authorization" executed after the patient becomes incapacitated but before the patient's death by the patient's acting legal guardian, health care surrogate, health care proxy, or agent under power of attorney. However, the definition provided in the bill for "patient authorization" only allows the patient him or herself to provide a written authorization and requires that the a "patient authorization" from a patient's representative (as listed above) be provided as an oral statement that is reduced to writing in the patient's record of care. The bill should be clarified to allow a patient's representative to provide a written authorization as well as an oral authorization for the release of the patient's record of care.

VII. Related Issues:

The bill amends s. 400.611, F.S., to allow a hospice patient's record of care to be released to a person providing a last will that is self-proved under s. 732.503, F.S., and which designates the person to act as the patient's personal representative. Although the language implies that such person should only receive the patient's record of care after the patient's death by stating that the

provision is effective if there is no court order appointing the person as the administrator, curator, executor, or personal representative of the patient's estate, as written, the language may technically allow the person to receive the patient's record prior to the patient's death.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.60501 and 400.611.

This bill creates section 400.6096 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

The CS amends SB 474 to:

- Remove all portions of the bill related to a hospice providing palliative care to seriously ill persons;
- Amend s. 400.611, F.S., to expand the ways a person may be authorized to receive a hospice patient's record of care while the patient is still alive and after the patient's death;
- Require that hospice staff adhere to 21 C.F.R. s. 1317, when assisting with the disposal of controlled substances; and
- Make other technical and clarifying changes.

- B. Amendments:

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 400.6005, Florida Statutes, is amended
to read:

400.6005 Legislative findings and intent.—The Legislature
finds that a terminally ill patient ~~individuals and their~~
~~families,~~ who is ~~are~~ no longer pursuing curative medical
treatment and the patient's family, should have the opportunity



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to select a support system that allows ~~permits~~ the patient to exercise maximum independence and dignity during the final days of life. The Legislature also finds that a seriously ill patient and the patient's family should have the opportunity to select a support system that provides palliative care and supportive care and allows the patient to exercise maximum independence while receiving such care. The Legislature finds that hospice care provides a cost-effective and less intrusive form of medical care while meeting the social, psychological, and spiritual needs of terminally ill and seriously ill patients and their families. The intent of this part is to provide for the development, establishment, and enforcement of basic standards to ensure the safe and adequate care of persons receiving hospice services.

Section 2. Section 400.601, Florida Statutes, is amended to read:

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

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

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

(3) "Hospice" means a centrally administered corporation or a limited liability company that provides a continuum of palliative care and supportive care for a ~~the terminally ill~~ patient and his or her family.

(4) "Hospice care team" means an interdisciplinary team of qualified professionals and volunteers who, in consultation with a ~~the~~ patient, the patient's family, and the patient's primary or attending physician, collectively assess, coordinate, and provide the appropriate palliative care and supportive care to



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hospice patients and their families.

(5) "Hospice program" means a program offered by a hospice which provides a continuum of palliative care and supportive care for a patient and his or her family.

(6)~~(5)~~ "Hospice residential unit" means a homelike living facility, other than a facility licensed under other parts of this chapter, under chapter 395, or under chapter 429, which ~~that~~ is operated by a hospice for the benefit of its patients and is considered by a patient who lives there to be his or her primary residence.

(7)~~(6)~~ "Hospice services" means items and services furnished to a terminally ill patient and family by a hospice, or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility.

(8)~~(7)~~ "Palliative care" means services or interventions furnished to a seriously ill patient and family which are not curative but are provided for the reduction or abatement of pain and human suffering.

(9)~~(8)~~ "Patient" means the terminally or seriously ill individual receiving ~~hospice~~ services from a hospice.

(10)~~(9)~~ "Plan of care" means a written assessment by the hospice of each patient's and family's needs and preferences, and the services to be provided by the hospice to meet those needs.

(11) "Seriously ill" means that the person has a life-



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threatening medical condition that may be irreversible and may continue indefinitely, and such condition may be managed through palliative care.

(12)(10) "Terminally ill" means that the patient has a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course.

Section 3. Section 400.60501, Florida Statutes, is amended to read:

400.60501 Outcome measures; adoption of federal quality measures; public reporting ~~national initiatives; annual report.~~

(1) No later than December 31, 2019 ~~2007~~, the department ~~of Elderly Affairs~~, in conjunction with the agency ~~for Health Care Administration~~, shall ~~develop~~ adopt the national hospice outcome measures in 42 C.F.R. part 418 to determine the quality and effectiveness of hospice care for hospices licensed in the state. ~~At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0-to-10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.~~

(2) ~~For hospices licensed in the state,~~ The department ~~of Elderly Affairs~~, in conjunction with the agency ~~for Health Care Administration~~, shall:

(a) Make available to the public the national hospice outcome measures in a format that is comprehensible by a layperson and that allows a consumer to compare such measures of one or more hospices. ~~Consider and adopt national initiatives, such as those developed by the national hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.~~



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(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

Section 4. Section 400.609, Florida Statutes, is amended to read:

400.609 Hospice services.—Each hospice shall provide a continuum of hospice services which affords ~~afford~~ the terminally ill patient and the family of the patient a range of service delivery which can be tailored to specific needs and preferences of the terminally ill patient and family at any point ~~in time~~ throughout the length of care ~~for the terminally ill patient~~ and during the bereavement period. These services must be available 24 hours a day, 7 days a week, and must include:

(1) SERVICES.—

(a) The hospice care team shall directly provide the following core services: nursing services, social work services, pastoral or counseling services, dietary counseling, and bereavement counseling services. Physician services may be provided by the hospice directly or through contract. A hospice may also use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances.

(b) Each hospice must also provide or arrange for such additional services as are needed to meet the palliative and support needs of the patient and family. These services may include, but are not limited to, physical therapy, occupational therapy, speech therapy, massage therapy, home health aide services, infusion therapy, provision of medical supplies and



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127 durable medical equipment, day care, homemaker and chore
128 services, and funeral services.

129 (2) HOSPICE HOME CARE.—Hospice care and services provided
130 in a private home shall be the primary form of care. The goal of
131 hospice home care shall be to provide adequate training and
132 support to encourage self-sufficiency and allow patients and
133 families to maintain the patient comfortably at home for as long
134 as possible. The services of the hospice home care program shall
135 be of the highest quality and shall be provided by the hospice
136 care team.

137 (3) HOSPICE RESIDENTIAL CARE.—Hospice care and services, to
138 the extent practicable and compatible with the needs and
139 preferences of the patient, may be provided by the hospice care
140 team to a patient living in an assisted living facility, adult
141 family-care home, nursing home, hospice residential unit or
142 facility, or other nondomestic place of permanent or temporary
143 residence. A resident or patient living in an assisted living
144 facility, adult family-care home, nursing home, or other
145 facility subject to state licensing who has been admitted to a
146 hospice program shall be considered a hospice patient, and the
147 hospice program shall be responsible for coordinating and
148 ensuring the delivery of hospice care and services to such
149 person pursuant to the standards and requirements of this part
150 and rules adopted under this part.

151 (4) HOSPICE INPATIENT CARE.—The inpatient component of care
152 is a short-term adjunct to hospice home care and hospice
153 residential care and shall be used only for pain control,
154 symptom management, or respite care. The total number of
155 inpatient days for all hospice patients in any 12-month period



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may not exceed 20 percent of the total number of hospice days for all the hospice patients of the licensed hospice. Hospice inpatient care shall be under the direct administration of the hospice, whether the inpatient facility is a freestanding hospice facility or part of a facility licensed pursuant to chapter 395 or part II of this chapter. The facility or rooms within a facility used for the hospice inpatient component of care shall be arranged, administered, and managed in such a manner as to provide privacy, dignity, comfort, warmth, and safety for the terminally ill patient and the family. Every possible accommodation must be made to create as homelike an atmosphere as practicable. To facilitate overnight family visitation within the facility, rooms must be limited to no more than double occupancy; and, whenever possible, both occupants must be hospice patients. There must be a continuum of care and a continuity of caregivers between the hospice home program and the inpatient aspect of care to the extent practicable and compatible with the preferences of the patient and his or her family. Fees charged for hospice inpatient care, whether provided directly by the hospice or through contract, must be made available upon request to the Agency for Health Care Administration. The hours for daily operation and the location of the place where the services are provided must be determined, to the extent practicable, by the accessibility of such services to the patients and families served by the hospice.

(5) BEREAVEMENT COUNSELING.—The hospice bereavement program must be a comprehensive program, under professional supervision, that provides a continuum of formal and informal supportive services to the family for a minimum of 1 year after the



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patient's death. This subsection does not constitute an additional exemption from chapter 490 or chapter 491.

Section 5. Section 400.6093, Florida Statutes, is created to read:

400.6093 Community palliative care services.—A hospice may provide palliative care to a seriously ill patient and his or her family members. Such palliative care may be provided to manage the side effects of treatment for a progressive disease or medical or surgical condition. Such care may also be provided directly by the hospice or by other providers under contract with the hospice. This section does not preclude the provision of palliative care to seriously ill patients or their family members by any other health care provider or health care facility otherwise authorized to provide such care. This section does not mandate or prescribe additional Medicaid coverage.

Section 6. Subsections (1) and (2) of section 400.6095, Florida Statutes, are amended to read:

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

(1) Each hospice shall make its services available to all terminally ill patients ~~persons~~ and their families without regard to age, gender, national origin, sexual orientation, disability, diagnosis, cost of therapy, ability to pay, or life circumstances. A hospice may ~~shall~~ not impose any value or belief system on its patients or their families and shall respect the values and belief systems of its patients and their families.

(2) Admission of a terminally ill patient to a hospice program shall be made upon a diagnosis and prognosis of terminal



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illness by a physician licensed pursuant to chapter 458 or chapter 459 and must ~~shall~~ be dependent on the expressed request and informed consent of the patient.

Section 7. Section 400.6096, Florida Statutes, is created to read:

400.6096 Disposal of prescribed controlled substances following the death of a patient in the home.—

(1) A hospice physician, nurse, or social worker is authorized to assist in the disposal of a controlled substance prescribed to a patient at the time of the patient's death pursuant to the disposal regulations in 21 C.F.R. s. 1317.

(2) A hospice that assists in the disposal of a prescribed controlled substance found in the patient's home at the time of the patient's death must establish a written policy, procedure, or system for acceptable disposal methods.

(3) A hospice physician, nurse, or social worker, upon the patient's death and with the permission of a family member or a caregiver of the patient, may assist in the disposal of an unused controlled substance prescribed to the patient, pursuant to the written policy, procedure, or system established under subsection (2).

(4) The prescribed controlled substance disposal procedure must be carried out in the patient's home. Hospice staff and volunteers are not authorized to remove a prescribed controlled substance from the patient's home.

Section 8. Section 400.611, Florida Statutes, is amended to read:

400.611 Interdisciplinary records of care; confidentiality; release of records.—



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(1) A hospice shall maintain an up-to-date, interdisciplinary record of care being given and patient and family status ~~shall be kept~~. Records shall contain pertinent past and current medical, nursing, social, and other therapeutic information and such other information that is necessary for the safe and adequate care of the patient. Notations regarding all aspects of care for the patient and family shall be made in the record. When services are terminated, the record shall show the date and reason for termination.

(2) Patient records shall be retained for a period of ~~5~~ 6 years after termination of hospice services, unless otherwise provided by law. In the case of a patient who is a minor, the ~~5~~ 6-year period shall begin on the date the patient reaches or would have reached the age of majority.

(3) The interdisciplinary record of patient ~~records of care and billing records~~ are confidential.

(4) A hospice may not release a patient's interdisciplinary record or any portion thereof, unless the person requesting the information provides to the hospice:

(a) A patient authorization executed by the patient; ~~or legal guardian has given express written informed consent;~~

(b) If the patient is incapacitated, a patient authorization executed before the patient's death by the patient's then acting legal guardian, health care surrogate, health care proxy, or agent under power of attorney;

(c) A court order appointing the person as the administrator, curator, executor, or personal representative of the patient's estate with authority to obtain the patient's medical records;



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(d) If a judicial appointment has not been made pursuant to paragraph (c), a last will that is self-proved under s. 732.503 and designates the person to act as the patient's personal representative; or

(e) An order by a court of competent jurisdiction to release the interdisciplinary record to the person ~~has so ordered; or~~

~~(c) A state or federal agency, acting under its statutory authority, requires submission of aggregate statistical data. Any information obtained from patient records by a state agency pursuant to its statutory authority is confidential and exempt from the provisions of s. 119.07(1).~~

(5) For purposes of this section, the term "patient authorization" means an unrevoked written statement by the patient, or an oral statement made by the patient which has been reduced to writing in the patient's interdisciplinary record of care, or, in the case of an incapacitated patient, by the patient's then acting legal guardian, health care surrogate, agent under a power of attorney, or health care proxy giving the patient's permission to release the interdisciplinary record to a person requesting the record.

(6) A hospice must release requested aggregate patient statistical data to a state or federal agency acting under its statutory authority. Any information obtained from patient records by a state agency pursuant to its statutory authority is confidential and exempt from s. 119.07(1).

Section 9. This act shall take effect July 1, 2017.

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



479570

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled

An act relating to hospice care; amending s. 400.6005,
F.S.; revising legislative findings and intent;
amending s. 400.601, F.S.; redefining the term
"hospice"; defining the terms "hospice program" and
"seriously ill"; amending s. 400.60501, F.S.;
requiring the Department of Elderly Affairs, in
conjunction with the Agency for Health Care
Administration, to adopt national hospice outcome
measures by a specified date and to make such measures
available to the public; amending s. 400.609;
clarifying provisions relating to hospice services;
creating s. 400.6093, F.S.; authorizing hospices, or
providers operating under contract with a hospice, to
provide palliative care to seriously ill persons and
their family members; providing construction; amending
s. 400.6095, F.S.; making technical changes; creating
s. 400.6096, F.S.; authorizing certain hospice
personnel to assist in the disposal of certain
prescribed controlled substances; requiring a hospice
that chooses to assist in the disposal of certain
prescribed controlled substances to establish
policies, procedures, and systems for the disposal;
authorizing a hospice physician, nurse, or social
worker to assist in the disposals of certain
prescribed controlled substances; providing



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requirements for such disposals; amending s. 400.611,
F.S.; requiring a hospice to maintain an up-to-date
interdisciplinary record of care; revising the patient
records retention period; providing for the
confidentiality of the interdisciplinary record of
patient care; specifying to whom and under what
conditions a hospice may release a patient's
interdisciplinary record of care; defining a term;
requiring a hospice to release patient statistical
data to certain agencies; specifying that information
from patient records is confidential and exempt from
certain provisions; providing an effective date.



174398

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment to Amendment (479570) (with title amendment)

Delete lines 5 - 216
and insert:

Section 1. Section 400.60501, Florida Statutes, is amended to read:

400.60501 Outcome measures; adoption of federal quality measures; public reporting ~~national initiatives~~; annual report.—

(1) No later than December 31, 2019 ~~2007~~, the department of



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~~Elderly Affairs, in conjunction with the agency for Health Care Administration, shall adopt the national hospice develop outcome measures in 42 C.F.R. part 418 to determine the quality and effectiveness of hospice care for hospices licensed in the state. At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0 to 10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.~~

~~(2) For hospices licensed in the state, The department of Elderly Affairs, in conjunction with the agency for Health Care Administration, shall:~~

~~(a) Make available to the public the national hospice outcome measures in a format that is comprehensible by a layperson and that allows a consumer to compare such measures of one or more hospices Consider and adopt national initiatives, such as those developed by the national hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.~~

~~(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.~~

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

And the title is amended as follows:

Delete lines 305 - 320
and insert:

An act relating to hospice care; amending s.
400.60501, F.S.; requiring the Department of Elderly
Affairs, in conjunction with the Agency for Health



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40 Care Administration, to adopt national hospice outcome
41 measures by a specified date and to make such measures
42 available to the public; creating

By Senator Grimsley

26-00254A-17

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A bill to be entitled

An act relating to hospice care; amending s. 400.6005, F.S.; revising legislative findings and intent; amending s. 400.601, F.S.; redefining the term "hospice"; defining the terms "hospice program" and "seriously ill"; amending s. 400.60501, F.S.; requiring the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, to adopt by rule certain outcome measures by a specified date; requiring the department, in conjunction with the agency, to adopt national hospice outcome measures and develop a system for publicly reporting the measures; creating s. 400.6093, F.S.; authorizing hospices, or providers operating under contract with a hospice, to provide palliative care to seriously ill persons and their family members; providing construction; amending s. 400.6095, F.S.; making technical changes; creating s. 400.6096, F.S.; authorizing a hospice to assist in the disposal of certain prescribed controlled substances; requiring a hospice that chooses to assist in the disposals of certain prescribed controlled substances to establish policies, procedures, and systems for the disposals; authorizing a hospice physician, nurse, or social worker to assist in the disposals of certain prescribed controlled substances; providing requirements for such disposals; providing an effective date.

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

Section 1. Section 400.6005, Florida Statutes, is amended

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

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to read:

400.6005 Legislative findings and intent.—The Legislature finds that ~~a terminally ill patient individuals and their families, who is are~~ no longer pursuing curative medical treatment, and the patient's family should have the opportunity to select a support system that ~~allows~~ permits the patient to exercise maximum independence and dignity during the final days of life. The Legislature also finds that a seriously ill person and the person's family should have the opportunity to select a support system that provides palliative care and supportive care and allows the person to exercise maximum independence while receiving such care. The Legislature finds that hospice care provides a cost-effective and less intrusive form of medical care while meeting the social, psychological, and spiritual needs of ~~terminally ill~~ patients and their families and seriously ill persons and their families. The intent of this part is to provide for the development, establishment, and enforcement of basic standards to ensure the safe and adequate care of persons receiving hospice services.

Section 2. Section 400.601, Florida Statutes, is amended to read:

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

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

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

(3) "Hospice" means a centrally administered corporation or a limited liability company that provides a continuum of palliative care and supportive care for ~~a the~~ terminally ill patient and his or her family or a seriously ill person and his

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

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62 or her family.

63 (4) "Hospice care team" means an interdisciplinary team of
64 qualified professionals and volunteers who, in consultation with
65 a the patient, the patient's family, and the patient's primary
66 or attending physician, collectively assess, coordinate, and
67 provide the appropriate palliative care and supportive care to
68 hospice patients and their families.

69 (5) "Hospice program" means a program offered by a hospice
70 which provides a continuum of palliative care and supportive
71 care for a patient and his or her family or a seriously ill
72 person and his or her family.

73 (6)(5) "Hospice residential unit" means a homelike living
74 facility, other than a facility licensed under other parts of
75 this chapter, under chapter 395, or under chapter 429, which
76 that is operated by a hospice for the benefit of its patients
77 and is considered by a patient who lives there to be his or her
78 primary residence.

79 (7)(6) "Hospice services" means items and services
80 furnished to a patient and family by a hospice, or by others
81 under arrangements with such a program, in a place of temporary
82 or permanent residence used as the patient's home for the
83 purpose of maintaining the patient at home; or, if the patient
84 needs short-term institutionalization, the services shall be
85 furnished in cooperation with those contracted institutions or
86 in the hospice inpatient facility.

87 (8)(7) "Palliative care" means services or interventions
88 that which are not curative but are provided for the reduction
89 or abatement of pain and human suffering.

90 (9)(8) "Patient" means the terminally ill individual

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91 receiving hospice services.

92 (10)(9) "Plan of care" means a written assessment by the
93 hospice of each patient's and family's needs and preferences,
94 and the services to be provided by the hospice to meet those
95 needs.

96 (11) "Seriously ill" means that the person has a persistent
97 medical condition that materially and adversely affects the
98 person's quality of life; that is burdensome in its symptoms,
99 pain, or caregiver stress; and that may be managed through
100 palliative care.

101 (12)(10) "Terminally ill" means that the patient has a
102 medical prognosis that his or her life expectancy is 1 year or
103 less if the illness runs its normal course.

104 Section 3. Section 400.60501, Florida Statutes, is amended
105 to read:

106 400.60501 Outcome measures; adoption of federal quality
107 measures; public reporting national initiatives; annual report.-

108 (1) No later than December 31, 2019 ~~2007~~, the department of
109 ~~Elderly Affairs~~, in conjunction with the agency ~~for Health Care~~
110 ~~Administration~~, shall adopt ~~develop~~ outcome measures to
111 determine the quality and effectiveness of hospice care for
112 hospices licensed in the state. ~~At a minimum, these outcome~~
113 ~~measures shall include a requirement that 50 percent of patients~~
114 ~~who report severe pain on a 0 to 10 scale must report a~~
115 ~~reduction to 5 or less by the end of the 4th day of care on the~~
116 ~~hospice program.~~

117 (2) For hospices licensed in the state, the department of
118 ~~Elderly Affairs~~, in conjunction with the agency ~~for Health Care~~
119 ~~Administration~~, shall:

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(a) ~~Consider and Adopt national initiatives, such as those developed by the national hospice outcome measures found in 42 C.F.R. part 418 and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.~~

(b) Develop a system for publicly reporting these national hospice outcome measures identified as useful consumer information.

(c) ~~(b)~~ Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

Section 4. Section 400.6093, Florida Statutes, is created to read:

400.6093 Community palliative care services.—
Notwithstanding any other provision of law, a hospice may provide palliative care to a seriously ill person and his or her family members. Such care may be provided directly by the hospice or by other providers under contract with the hospice. This section does not preclude the provision of palliative care to seriously ill persons by any other health care provider or health care facility that is otherwise authorized to provide such care. This section does not mandate or prescribe additional Medicaid coverage.

Section 5. Subsections (1) and (2) of section 400.6095, Florida Statutes, are amended to read:

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

(1) Each hospice shall make its services available to all patients ~~terminally ill persons~~ and their families without

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regard to age, gender, national origin, sexual orientation, disability, diagnosis, cost of therapy, ability to pay, or life circumstances. A hospice ~~may~~ shall not impose any value or belief system on its patients or their families and shall respect the values and belief systems of its patients and their families.

(2) Admission of a patient with a terminal illness to a hospice program shall be made upon a diagnosis and prognosis of terminal illness by a physician licensed pursuant to chapter 458 or chapter 459 and must ~~shall~~ be dependent on the expressed request and informed consent of the patient.

Section 6. Section 400.6096, Florida Statutes, is created to read:

400.6096 Disposal of prescribed controlled substances
following the death of a patient in the home.—

(1) A hospice that assists in the disposal of a prescribed controlled substance in the patient's home under this section must establish clearly defined policies, procedures, and systems for acceptable disposal methods.

(2) A hospice physician, nurse, or social worker, upon the patient's death and with the permission of a family member or a caregiver of the patient, is authorized to assist in the disposal in the patient's home of an unused controlled substance prescribed to the decedent pursuant to the procedures established under subsection (1).

(3) Established disposal procedures must be carried out in the patient's home. Hospice staff and volunteers are not authorized to remove a prescribed controlled substance from the patient's home.

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178 (4) Disposal of a prescribed controlled substance in the
179 patient's home is optional for a hospice. The authorization
180 provided in subsection (2) does not require a hospice to
181 establish policies, procedures, or systems for acceptable
182 disposal methods of a prescribed controlled substance in the
183 patient's home.

184 Section 7. This act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: February 14, 2017

I respectfully request that **Senate Bill #474**, relating to Hospice Care, 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

THE FLORIDA SENATE
APPEARANCE RECORD

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

27 MAR 17

Meeting Date

474

Bill Number (if applicable)

Topic

HOSPICE CARE

Amendment Barcode (if applicable)

Name

MICHAEL MCQUONE (MICK-CUE-ONE)

Job Title

ASSOCIATE DIRECTOR FOR HEALTH

Address

201 W. PARK AVENUE

Phone

850-284-9130

Street

TALLAHASSEE

FL

32301

Email

mmcquone@flacch.org.

City

State

Zip

Speaking:

☐

For

☐

Against

☒

Information

Waive Speaking:

☐

In Support

☐

Against

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

Representing

FLORIDA CONFERENCE OF CATHOLIC BISHOPS

Appearing at request of Chair:

☐

Yes

☒

No

Lobbyist registered with Legislature:

☒

Yes

☐

No

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)

3/27/17
Meeting Date

58474
Bill Number (if applicable)

Topic _____

Name Tina Braungardt

Job Title Internal Management Consultant

Address 1309 Sardinia Ct
Street
Davenport FL
City State Zip

Phone 636-614-6063

Email tina.braungardt@vitas.com

→ Amendment Barcode (if applicable)
*Supporting the amendment to the strike all amendment

Speaking: ☒ For ☐ Against ☐ Information

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

Representing VITAS Healthcare

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)

3,27,2017

Meeting Date

474

Bill Number (if applicable)

Topic An Act Relating to Hospice

Name Paul Ledford

Job Title President + CEO

Address 2000 Apalachee Parkway Ste 200

Street

Tallahassee

City

FL

State

32309

Zip

Phone

850.878.2632

Email

paul@florida2hospices.org

Amendment Barcode (if applicable)

* Supporting the Amendment to the Strike-all Amendment

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Hospice and Palliative Care Organization

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)

3/27/2017
Meeting Date

SB474
Bill Number (if applicable)

Topic Hospice

Name Dr. Stephen Leedy

Job Title Hospice and Palliative Care Physician

Address 146 8th Avenue Northeast
Street
St. Petersburg FL 33701
City State Zip

Phone 727-412-3245

Email LeedyS@mac.com

Amendment Barcode (if applicable)

* Supporting The
Amendment to the
Strike-all amendment

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Hospice and Palliative Care

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)

3-27-17

Meeting Date

474

Bill Number (if applicable)

Topic

Hospice care (SB 474)

Amendment Barcode (if applicable)

Name

Diane Gowski MD

Job Title

State director of Florida Guilds of the Catholic Medical Association (CMA)

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Phone

727-480-7874

Street

Clearwater FL 33756

Email

dianetg@aol.com

City

State

Zip

Speaking:

☐ For

☒ Against

☐ Information

Waive Speaking:

☐ In Support

☒ Against

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

(Against SB 474 & its amendment)

Representing

FL Guilds of Catholic Medical Association

Appearing at request of Chair:

☐ Yes

☒ No

Lobbyist registered with Legislature:

☐ Yes

☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/27/2017
Meeting Date

SB474
Bill Number (if applicable)

Topic Hospice care

Amendment Barcode (if applicable)

Name Heather Yaumans

Job Title Senior Dir, Government Relations

Address 2619 Centennial Blvd, 100 Phone (850) 251-2111
Street

Tallahassee FL 32317 Email heather.yaumans@
City State Zip cancer.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing American Cancer Society - Cancer Action Network

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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 588

INTRODUCER: Health Policy Committee and Senator Passidomo

SUBJECT: Drug Overdoses

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 588 permits the voluntary reporting of a suspected or actual overdose of a controlled substance to the Department of Health (DOH) by basic and advanced life support service providers that treat and release, or transport, a person in response to an emergency call.

The bill defines overdose as a condition, including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of any controlled substance which requires medical attention, assistance, or treatment, or clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition.

If a report is made, it must contain the date and time of the overdose, the address of where the patient was picked up or where the overdose took place, whether an emergency opioid antagonist was administered, and whether the overdose was fatal or non-fatal. Additionally, a report must include the gender and approximate age of the patient and the suspected controlled substances involved only if permitted by the reporting mechanism. Reporters must use best efforts to make the report within 120 hours.

The DOH must make the data received available to law enforcement, public health, fire rescue, and EMS agencies in each county within 120 hours after receipt. Quarterly, the DOH must provide summarized reports to the Statewide Drug Policy Advisory Council, the Department of

Children and Families (DCF), and the Florida Fusion Center, which may be used to maximize the utilization of funding programs for licensed basic and advanced life support service providers, and to disseminate available federal, state and, private funds for local substance abuse treatment services.

The bill makes a reporter exempt from civil or criminal liability for reporting, if the report is made in good faith. It also specifies that the failure to make a report is not grounds for licensure discipline against a basic or advanced life support service.

The bill has an effective date of October 1, 2017.

II. Present Situation:

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.¹ Substance abuse disorders occur when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.² Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance abuse disorder.³ Brain imaging studies of persons with substance abuse disorders show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.⁴

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, a diagnosis of substance abuse disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria.⁵ The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.⁶

Opioid Abuse and Overdose

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.⁷ Drug overdose is now the leading cause of injury-related death in the United

¹ World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/, (last visited Mar. 23, 2017).

² Substance Abuse and Mental Health Services Administration, *Substance Use Disorders*, (last updated Oct. 27, 2015) available at <http://www.samhsa.gov/disorders/substance-use>, (last visited Mar. 23, 2017).

³ National Institute on Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction*, (last updated July 2014), available at <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction>, (last visited Mar. 23, 2017).

⁴ *Id.*

⁵ *Supra* note 2.

⁶ *Supra* note 2.

⁷ World Health Organization, *Information Sheet on Opioid Overdose* (November 2014), available at http://www.who.int/substance_abuse/information-sheet/en/, (last visited Mar. 23, 2017).

States.⁸ In 2015, Florida ranked fourth in the nation with 3,228 deaths from drug overdoses,⁹ and the presence of at least one opioid in a person's body caused 2,530 of those deaths.¹⁰ Statewide, in 2015, heroin caused 733 deaths, fentanyl caused 705, oxycodone caused 565, and hydrocodone caused 236; deaths caused by heroin and fentanyl increased more than 75 percent statewide when compared with 2014.¹¹

Drug overdose deaths doubled in Florida from 1999 to 2012.¹² Over the same time period, drug overdose deaths occurred at a rate 13.2 deaths per 100,000 persons.¹³ The crackdown on “pill mills” dispensing prescription opioid drugs, such as oxycodone and hydrocodone, reduced the rate of death attributable to prescription drugs,¹⁴ but may have generated a shift to heroin use, contributing to the rise in heroin addiction.¹⁵

Emergency Response to Overdose

Opioid overdose can occur when an individual deliberately misuses a prescription opioid or an illicit drug such as heroin.¹⁶ It can also occur when a patient takes an opioid as directed, but the prescriber miscalculated the opioid dose, an error was made by the dispensing pharmacist, or the patient misunderstood the directions for use.¹⁷ Opioid overdose is life threatening and requires immediate emergency attention.¹⁸

To treat an opioid overdose, emergency personnel or a physician may administer an opioid antagonist such as Narcan® or Nalaxone. An opioid antagonist is a drug that blocks the effects of exogenously administered opioids. Opioid antagonists are used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally.¹⁹ This occurs because opioid antagonists create a stronger bond with opioid receptors than opioids. This forces the opioids from the opioid receptors and allows the transmission of signals for respiration to resume.²⁰

⁸ Trust for America's Health, *The Facts Hurt: A State-by-State Injury Prevention Policy Report 2015*, available at <http://healthyamericans.org/reports/injuryprevention15/>, (last visited Mar. 23, 2017).

⁹ Centers for Disease Control and Prevention, *Drug Overdose Death Data* (Dec. 16, 2016), available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>, (last visited Mar. 23, 2017).

¹⁰ Florida Department of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners-2015 Annual Report* (Sept. 2016), available at <https://www.fdle.state.fl.us/cms/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2015-Annual-Drug-Report.aspx>, (last visited on Mar. 23, 2017).

¹¹ *Id.* at pg. 3.

¹² Department of Health, *Special Emphasis Report: Drug Poisoning (Overdose) Deaths (1999-2012)*, available <http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/documents/CDC-Special-Emphasis-Drug-poisoning-overdose-1999-2012-B-Poston-FINAL.pdf>, (last visited on Mar. 21, 2017).

¹³ *Id.*

¹⁴ *Supra* note 10.

¹⁵ World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/, (last visited Mar. 23, 2017).

¹⁶ Substance Abuse and Mental Health Services Administration, *Opioid Overdose Prevention Toolkit* (Rev. 2016), available at <http://store.samhsa.gov/shin/content/SMA16-4742/SMA16-4742.pdf>, (last visited Mar. 23, 2017).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Harm Reduction Coalition, “*Understanding Naloxone*,” available at <http://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/>, (last visited Mar. 23, 2017).

²⁰ Harm Reduction Coalition, *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, (2012), available at <http://harmreduction.org/our-work/overdose-prevention/> (last visited Mar. 23, 2017).

From 2004 through 2009, emergency department visits nationally involving the nonmedical use of pharmaceuticals increased 98.4 percent, from 627,291 visits to 1,244,679 visits.²¹ In 2009, almost one million emergency room visits nationally involved illicit drugs, either alone or in combination with other drugs.²²

From 2008 to 2011, about half of all emergency department visits nationally for both unintentional and self-inflicted drug poisoning involved drugs in the categories of analgesics,²³ antipyretics,²⁴ and antirheumatics²⁵ or sedatives, hypnotics, tranquilizers, and other psychotropic agents.²⁶

Opiates or related narcotics, including heroin and methadone, accounted for 14 percent of emergency department visits nationally for unintentional drug poisoning from 2008 to 2011.²⁷ In Florida, there were approximately 21,700 opioid-related emergency department visits in 2014.²⁸

Privacy Rights of Individuals Receiving Substance Abuse Treatment

Florida Protections

Section 397.501, F.S., establishes statutory rights for individuals receiving substance abuse services, including the right to dignity, non-discriminatory services, quality services, confidentiality, counsel and habeas corpus. In particular it prohibits service providers from disclosing records containing the identity, diagnosis, prognosis, and services provided to any individual without written consent of the individual, with certain exceptions.²⁹ The law makes service providers who violate these rights liable for damages, unless acting in good faith, reasonably, and without negligence.

Federal Protections of Personal Health Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002.³⁰ The rules address the use and disclosure of an

²¹ National Institute on Drug Abuse, *Drug-Related Hospital Emergency Room Visits* (May, 2011), available at <https://www.drugabuse.gov/publications/drugfacts/drug-related-hospital-emergency-room-visits>, (last visited Mar. 23, 2017).

²² Id.

²³ Analgesics are drugs that produce insensibility to pain.

²⁴ Antipyretics are drugs that reduce fever.

²⁵ Anti-rheumatics are drugs that alleviate or prevent inflammation or pain in muscles, joints, or fibrous tissue.

²⁶ Albert, M. et al., *Emergency Department Visits for Drug Poisoning: United States, 2008–2011*, NCHS Data Brief No. 196, April 2015, available at <https://www.cdc.gov/nchs/data/databriefs/db196.htm>, (last visited Mar. 23, 2017).

²⁷ Id.

²⁸ Weiss, A.J., et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009–2014*, HCUP Statistical Brief No. 219, January 2017, available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>, (last visited Mar. 23, 2017).

²⁹ Disclosure is permitted to: health service providers in cases of medical emergency if the information is necessary to provide services to the individual; DCF for the purposes of scientific research; comply with state-mandated child abuse and neglect reporting; comply with a valid court order; report crimes that occur on program premises or against staff; federal, state or local governments for audit purposes; or third party payors providing financial assistance or reimbursement.

³⁰ United States Department of Health and Human Services, *The Privacy Rule*, available at <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/>, (last visited on Mar. 23, 2017).

individual's personal health information and create standards for information security. Only certain entities, "covered entities," are subject to HIPAA's provisions. Covered entities are obligated to meet HIPAA's requirements to ensure privacy and confidentiality of personal health information. These "covered entities" include:³¹

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.

Additionally, federal law restricts the disclosure of alcohol and drug patient records maintained by federally assisted alcohol and drug abuse programs, which identify a patient as an alcohol or drug abuser.³² Disclosure of patient-identifying information is permitted in certain cases and patients may consent in writing to the disclosure of such information.³³

Statewide Drug Policy Advisory Council

The Legislature created the Office of Drug Control and the Drug Policy Advisory Council³⁴ in the Executive Office of the Governor in 1999. In 2011, the Legislature replaced it with the Statewide Drug Policy Advisory Council (the Council)³⁵ under the Florida Department of Health (DOH). The Council, among other things, submits annual reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives with recommendations concerning developing and implementing a state drug control strategy.³⁶

The Council's 2016 Report concluded that a key problem in combating drug overdoses in Florida is that there is "no sustainable process to compile massive amounts of data and information, perform analysis, and develop an evidence-based call to action."³⁷ To improve data collection and surveillance, the Council recommends that DOH collaborate with other agencies, organizations, and institutions to create a comprehensive statewide strategy addressing the fentanyl and heroin overdoses in the state.³⁸

³¹United States Department of Health and Human Services, *For Covered Entities and Business Associates* <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/> (last visited on Mar. 23, 2017).

³² 42 CFR Part 2 (2016).

³³ Disclosure is allowed to comply with state-mandated child abuse and neglect reporting; to report the cause of death; to comply with a valid court order; in cases of medical emergency; to report crimes that occur on program premises or against staff; to entities having administrative control; to qualified service organizations and to outside auditors, evaluators, central registries, and researchers.

³⁴ Section 397.332, F.S., created by s. 3, ch. 99-187, Laws of Fla.

³⁵ Section 397.333, F.S., created by s. 8, ch. 2011-51, Laws of Fla.

³⁶ Section 397.333(3), F.S.

³⁷ Florida Department of Health, *Statewide Drug Policy Advisory Council 2016 Annual Report* (Dec. 1, 2016), p. 4, available at <http://www.floridahealth.gov/provider-and-partner-resources/dpac/DPAC-Annual-Report-2016-FINAL.pdf>, (last visited Mar. 23, 2017).

³⁸ *Id.* at 14.

DOH Data Systems

Florida Injury Surveillance Data System

DOH's Injury Surveillance Data System is a passive data reporting mechanism that utilizes data resources from other agencies and systems, including:

- Vital records (death certificates);
- Hospital discharge data;
- Emergency department discharge data;
- Motor vehicle crash records;
- Behavioral Risk Factor Surveillance System;
- Youth Risk Behavior Surveillance System;
- Child Death Review;
- Uniform Crime Reporting System; and
- Emergency medical services.³⁹

The Injury Surveillance Data System is used to monitor the frequency of fatal and non-fatal injuries, determine the risk factors for these injuries, evaluate the completeness, timeliness, and quality of data sources, provide information to Florida's injury prevention community for program planning and evaluation, and provide a foundation for injury prevention strategies.⁴⁰ One of the injury mechanisms it receives information on is poisoning, which includes drug overdoses;⁴¹ however it is not currently set up to actively receive data regarding overdoses, or any other injury mechanism.⁴²

Emergency Medical Services Tracking and Reporting System (EMSTARS)

The DOH maintains⁴³ the Emergency Medical Services Tracking and Reporting System (EMSTARS) to collect data on pre-hospital emergency care from EMS providers.⁴⁴ This system allows for the collection and analysis of incident level data from EMS agencies for benchmarking and quality improvement initiatives.⁴⁵ Participation in the EMSTARS system, and the transmission of electronic incident level data from EMS Providers⁴⁶ to DOH, is voluntary.⁴⁷ However, the complete provision of incident level data, and full participation in the EMSTARS

³⁹ Department of Health, *Florida Injury Surveillance Data System*, available at <http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/index.html>, (last visited Mar. 23, 2017).

⁴⁰ Id.

⁴¹ Department of Health, *External Cause of Injury Intent and Mechanism Classifications and Descriptions* (Sept. 8, 2008), available at <http://www.floridahealth.gov/statistics-and-data/florida-injury-surveillance-system/documents/icd-code-explanations.pdf>, (last visited Mar. 13, 2017).

⁴² Department of Health, *House Bill 249 Analysis* (similar to SB 588), p. 6, (Jan. 17, 2017) (on file with Senate Committee on Health Policy).

⁴³ In 2004, the DOH signed a memorandum of understanding to participate in a national project that would standardize data collection for EMS agencies nationwide. The National Emergency Medical Services Information System is the national repository used to aggregate and analyze prehospital data from all participating states.

⁴⁴ Florida Department Of Health, *The Basic Facts: Prehospital EMS Tracking and Reporting System*, p. 1, available at http://www.floridaemstars.com/docs/EMSTARSFactSheet_102314.pdf, (last visited Mar. 23, 2017).

⁴⁵ Id.

⁴⁶ There are 147 participating EMS agencies. Florida Department of Health, *Florida EMS Agencies Participating in EMSTARS*, available at <http://www.floridaemstars.com/docs/partagencies.pdf>, (last visited Mar. 23, 2017).

⁴⁷ *Supra*, note 44.

Program, fulfills EMS Provider prehospital reporting requirements.⁴⁸ The data collected by EMSTARS includes:

- All NHTSA “national” data elements for demographic data and EMS event data;
- Other selected elements identified by participants and other stakeholders;
- Demographic elements for the provider agency, its personnel, and patients;
- Incident and unit times;
- Situation and scene information;
- Patient care information including vital signs, injury assessment, trauma score, and intervention and procedural information; and
- Outcome and disposition information.⁴⁹

Additionally, EMSTARS collects minimal data elements for overdoses if EMS administers an emergency opioid antagonist.⁵⁰ There are currently two versions of EMSTARS in use by EMS providers permitted by Rule 64J-1.014, F.A.C., versions 1.4.1 and 3.0. The more recent version allows EMS providers to capture the additional information about the patient, including his or her gender, as well as alcohol and drug use indicators.⁵¹

The electronic patient care records submitted by licensed EMS agencies to EMSTARS are confidential and exempt pursuant to s. 401.30(4), F.S.

Washington/ Baltimore High Intensity Drug Trafficking Overdose Detection Mapping Application Program (HIDTA)

The Washington/ Baltimore High Intensity Drug Trafficking Area (HIDTA) is a federal grant program administered by the White House Office of National Drug Control Policy, provides resources to assist federal, state, local and tribal agencies coordinate activities that address drug trafficking.⁵² HIDTA created an app, known as the Overdose Detection Mapping Application Program, which allows EMS agencies to report overdose incidents, which will then be transmitted to the app in real time with an electronic map showing the location, date, time, and incident type. It does not allow EMS agencies to report on the patient’s age or gender or suspected controlled substance involved in the overdose.

Emergency Medical Technicians and Paramedics

An emergency medical technician (EMT) a person who is certified by DOH to perform basic life support.⁵³ A paramedic is a person who is certified by DOH to perform basic and advanced life

⁴⁸ See Rule 64J-1.014(1), F.A.C.

⁴⁹ Id.

⁵⁰ *Supra*, note 42.

⁵¹ Florida Department of Health, Bureau of Emergency Medical Oversight, *Emergency Medical Services Tracking and Reporting System, Version 2, EMS Data Standards*, (Oct. 2015), available at <http://www.floridaemstars.com/docs/flemstarsdatastandardsvers3.pdf> (last visited Mar. 23, 2017).

⁵² Washington/Baltimore High Intensity Drug Trafficking Area, available at <http://www.hidta.org/>, (last visited Mar. 23, 2017).

⁵³ Sections 401.23(11), F.S.; s. 401.23(7), F.S., defines “basic life support” as, the assessment or treatment through the use of techniques described in the Emergency Medical Technician Basic National Standard Curriculum or the National EMS Education Standards of the U.S. Department of Transportation.

support.⁵⁴ EMTs and paramedics are regulated by DOH, under ch. 401, Part III, F.S. EMTs and paramedics care for sick or injured patients in an emergency medical setting and often work closely with police and firefighters during an emergency situation.⁵⁵ Some of the typical duties of an EMT or paramedic are:

- Responding to 911 calls for emergency medical assistance;
- Assessing a patient's condition and determining a course of treatment;
- Helping transfer patients to the emergency department of a healthcare facility and report their observations and treatment to the staff; and
- Creating a patient care report, documenting the medical care given to the patient.⁵⁶

Currently, there are 35,315 certified EMTs and 29,731 certified paramedics in Florida.⁵⁷

III. Effect of Proposed Changes:

Legislative Findings, Intent, and Goals

CS/SB 588 makes the following legislative findings:

- Substance abuse and drug overdose are a major health problems that affect the lives of many people, and multiple service systems, leading to profoundly disturbing consequences;
- These overdoses are a crisis and stress financial, health care, and public safety resources; and
- A central database that could quickly help address this problem does not currently exist.

The bill sets out the intent of the Legislature to:

- Require the collaboration of local, regional, and state agencies; service systems; and program offices to address the needs of the public;
- Establish a comprehensive system addressing the problems associated with drug overdoses;
- Reduce duplicative requirements across local, county, state, and health care agencies;
- Maximize the efficiency of financial, public education, health professional, and public safety resources so that these resources may be concentrated on areas and groups in need on the performance of professional functions; and
- Maximize the utilize funding programs for the dissemination of available federal, state, and private funds through contractual agreements with community based organizations or units of state or local government that deliver local substance abuse services.

The goals of the Legislature for the bill are identified as:

- Discouraging substance abuse and overdoses by quickly identifying the type of drug involved, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities; and

⁵⁴ Section 401.23(17), F.S.; s. 401.23(1), F.S., defines “advanced life support” as, the assessment or treatment by a qualified person through the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards.

⁵⁵ U.S. Bureau of Labor Statistics, EMTs and Paramedics, available at <http://www.bls.gov/ooh/Healthcare/EMTs-and-paramedics.htm#tab-2>, (last visited Mar. 23, 2017).

⁵⁶ Id.

⁵⁷ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan: Fiscal Year 2015-2016*, available at <http://mqawebteam.com/annualreports/1516/#12>, (last visited Mar. 23, 2017).

- Providing a central data point so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short and long term solutions while protecting and respecting the rights of individuals.

Overdose Reporting

The bill creates s. 401.253, F.S., which permits EMTs and paramedics, who provide basic and advanced life support services on an emergency call to report to the DOH a suspected or actual controlled substances overdose. The bill defines “overdose” as a condition which includes, but is not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death from the consumption or use of a controlled substance that requires medical attention, assistance, or treatment, and a clinical suspicion of a drug overdose such as respiratory depression, unconsciousness, or an altered mental state which is not explained by another condition.

An EMT or paramedic who treats and releases an individual, or treats and or transports an individual to a medical facility, in response to an emergency call for a suspected or actual overdose of a controlled substance, may voluntarily report. If they report, they must use best efforts to do so within 120 hours. The report must contain:

- The date and time of the overdose;
- The address of where the patient was picked up or where the overdose took place;
- Whether an emergency opioid antagonist was administered; and
- Whether the overdose was fatal or non-fatal.

Additionally, the report must include the approximate age and gender of the patient and the suspected controlled substances involved in the overdose only if permitted by its reporting mechanisms.

The bill requires reporters to use EMSTARS, the Washington/Baltimore High Intensity Drug Trafficking Overdose Detection Mapping Application Program, or other program identified by the DOH in rule.

Anyone who files a report in good faith is not subject to civil or criminal liability for making the report. The bill also specifies that the failure to make a report is not grounds for licensure discipline against a basic or advanced life support service.

Use of Report

The bill encourages reporting to the DOH within 120 hours. Within 120 hours of receiving the data, the DOH must make it available to law enforcement, public health, fire rescue, and EMS agencies in each county.

Additionally, the DOH must report quarterly to the Council, the DCF, and the Florida Fusion Center,⁵⁸ summarizing the data received. The Council, the DCF, and the DOH may use the

⁵⁸ The Fusion Center, housed within the Florida Department of Law Enforcement, is a collaborative effort of state and federal agencies working with local partners to share resources, expertise, and/or information to better identify, detect, prevent, apprehend and respond to criminal and terrorist activity utilizing an all crimes/all hazards approach. Florida Department of

reports to maximize the utilization of funding programs for basic and advanced life support service providers, and to disseminate available federal, state and, private funds for local substance abuse treatment services.

The bill has an effective date of October 1, 2017.

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:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The information collected by the DOH, and being made available to law enforcement, public health, fire rescue and emergency medical services agencies in each county may require a separate bill for a public records exception to protect the information from being obtained by other third parties.

VIII. Statutes Affected:

This bill creates section 401.253 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

The CS:

- Deletes mandatory reporting requirements for certain health care professionals, institutions, and their employees;
- Limits reporting to basic and advanced life support services who respond to an emergency call for a suspected or actual overdose;
- Makes reporting voluntary, and encourages reporting within 120 hours;
- Specifies the data elements to be reported;
- Deletes criminal penalties for failure to report;
- Provides that the failure to report is not grounds for licensure discipline;
- Reassigns the responsibility for receiving the reported data to the DOH rather than the county's chief law enforcement officer;
- Authorizes the DOH to identify the reporting system in rule; and
- Requires the DOH to disseminate raw data received within 120 hours to specified entities and a summary report quarterly.

- B. **Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. (1) The Legislature finds that substance abuse
and drug overdose are major health problems that affect the
lives of many people and multiple service systems and that lead
to such profoundly disturbing consequences as permanent injury
or death. Heroin, opiates, illegal drugs, and accidental
overdoses are a crisis and stress the financial, health care,



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and public safety resources because there are no central databases that can quickly help address this problem. Quick data collection will allow all agencies to focus on specific age groups, areas, criminal behavior, and needed public education and prevention with the maximum utilization of resources. Further, it is the intent of the Legislature to require the collaboration of local, regional, and state agencies, service systems, and program offices to address the needs of the public; to establish a comprehensive system addressing the problems associated with drug overdoses; and to reduce duplicative requirements across local, county, state, and health care agencies.

(2) It is the goal of the Legislature in this act to:

(a) Discourage substance abuse and accidental or intentional overdoses by quickly identifying the type of drug involved, whether prescription or illegal, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities.

(b) Provide a central data point so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short- and long-term solutions while protecting and respecting the rights of individuals.

(3) It is the intent of the Legislature in this act to maximize:

(a) The efficiency of financial, public education, health professional, and public safety resources so that these resources may be concentrated on areas and groups in need.



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(b) The utilization of funding programs for the dissemination of available federal, state, and private funds through contractual agreements with licensed basic life support service providers, advanced life support service providers, community-based organizations, or units of state or local government that deliver local substance abuse services in accordance with the intent of this act and s. 397.321(4), Florida Statutes.

Section 2. Section 401.253, Florida Statutes, is created to read:

401.253 Reporting of controlled substance overdoses.—

(1)(a) A basic life support service or advanced life support service that treats and releases, or transports to a medical facility, a person in response to an emergency call for a suspected or actual overdose of a controlled substance may report such incidents to the department. Such reports must be made using the Emergency Medical Services Tracking and Reporting System, or other appropriate method with secure access, including, but not limited to, the Washington/Baltimore High Intensity Drug Trafficking Area's Overdose Detection Mapping Application Program or other program identified by the department in rule. If a basic life support service or advanced life support service reports such incidents, it shall use best efforts to make the report to the department within 120 hours.

(b) The data collected by the department shall be made available within 120 hours to law enforcement, public health, fire rescue, and emergency medical service agencies in each county.

(c) For purposes of this section, the term "overdose" means



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a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of any controlled substance which requires medical attention, assistance, or treatment, or clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition.

(2)(a) A report of an overdose of a controlled substance under this section must include:

1. The date and time of overdose.
2. The approximate address of where the person was picked up or where the overdose took place.
3. Whether an emergency opioid antagonist, as defined in s. 381.887, was administered.
4. Whether the overdose was fatal or nonfatal.

(b) A report of an overdose of a controlled substance under this section must also include, if the reporting mechanism permits:

1. The gender and approximate age of the person receiving attention or treatment.
2. The suspected controlled substance involved in the overdose.

(3) A basic life support service or advanced life support service that reports information to or from the department pursuant to this section in good faith is not subject to civil or criminal liability for making the report.

(4) Failure to report an overdose under this section is not grounds for disciplinary action or penalties pursuant to s.



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401.411(1)(a).

(5) The department shall produce a quarterly report to the Statewide Drug Policy Advisory Council, the Department of Children and Families, and the Florida Fusion Center summarizing the raw data received pursuant to this section. Such reports shall also be made immediately available to the county-level agencies described in paragraph (1)(b). The Statewide Drug Policy Advisory Council, the Department of Children and Families, and the department may use these reports to maximize the utilization of funding programs for licensed basic life support service providers or advanced life support service providers, and for the dissemination of available federal, state, and private funds for local substance abuse services in accordance with s. 397.321(4).

Section 3. This act shall take effect October 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled

An act relating to drug overdoses; providing legislative findings and intent; creating s. 401.253, F.S.; authorizing certain entities to report controlled substance overdoses to the Department of Health; defining the term "overdose"; providing requirements for such reports; providing immunity for persons who make reports in good faith; providing that a failure to report is not a basis for licensure



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127 discipline; requiring the department to produce a
128 quarterly report and share the data with specified
129 entities; providing for use of such data; providing an
130 effective date.

By Senator Passidomo

28-00724-17

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A bill to be entitled

An act relating to drug overdoses; providing legislative findings and intent; creating s. 893.22, F.S.; requiring certain persons to report controlled substance overdoses; providing for a reporting agency in each county; defining the term "overdose"; providing requirements for such reports; providing immunity for persons who make such reports in good faith; requiring sharing of data with specified entities; providing for use of such data; requiring maintenance of records for a specified period; prohibiting failure to make such reports, whether by omission or willfully; providing criminal penalties; providing an effective date.

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

Section 1. (1) The Legislature finds that substance abuse and drug overdose is a major health problem that affects the lives of many people, multiple service systems, and leads to such profoundly disturbing consequences as permanent injury or death. Heroin, opiate, illegal drug, and accidental overdoses are a crisis and stress the financial, health care, and public safety resources because there exist no central databases that can quickly help address this problem. Quick data collection will allow all agencies to focus on specific age groups, areas, criminal behavior, and needed public education and prevention with the maximum utilization of resources. Further, it is the intent of the Legislature to require the collaboration of local, regional, and state agencies, service systems, and program offices to achieve the goals of chapter 893, Florida Statutes, and address the needs of the public; to establish a

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comprehensive system addressing the problems associated with drug overdoses; and to reduce duplicative requirements across local, county, state, and health care agencies. This act is designed to address the crisis of drug overdoses.

(2) It is the goal of the Legislature in this act to:

(a) Discourage substance abuse and accidental or intentional overdoses by quickly identifying the type of drug involved, whether prescription or illegal, the age of the individual involved, and the areas where drug overdoses pose a potential risk to the public, schools, workplaces, and communities.

(b) Provide a central data point in each county so that data can be shared between the health care community and municipal, county, and state agencies to quickly identify needs and provide short and long term solutions while protecting and respecting the rights of individuals.

(3) It is the intent of the Legislature in this act to maximize:

(a) The efficiency of financial, public education, health professional, and public safety resources so that these resources may be concentrated on areas and groups in need on the performance of professional functions necessary to carry out the intent of chapter 893, Florida Statutes.

(b) The utilization of funding programs for the dissemination of available federal, state, and private funds through contractual agreements with community-based organizations or units of state or local government that deliver local substance abuse services in accordance with s. 397.321(4), Florida Statutes.

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Section 2. Section 893.22, Florida Statutes, is created to read:

893.22 Mandatory reporting of controlled substance overdoses.-

(1)(a) A physician, nurse, paramedic, emergency medical technician, or health care worker, or employee thereof, and any employee of a hospital, sanatorium, or other institution or provider who knowingly attends or treats or who is requested to attend or treat an overdose of a controlled substance listed in s. 893.03 shall report, within 24 hours, such attention or treatment, or request therefor, to the sheriff or chief law enforcement officer in the county in which such attention or treatment is administered or request therefor received.

(b) The sheriff or chief law enforcement officer in each county may, in his or her discretion, designate or partner with a public organization or other agency, such as the medical examiner, to receive, store, and manage the reports and other data described in this section.

(c) For purposes of this section, the term "overdose" means a condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of any substance listed in 893.03 that requires medical attention, assistance or treatment, and clinical suspicion for drug overdose, such as respiratory depression, unconsciousness, or altered mental status, without other conditions to explain the clinical condition.

(2) A person who reports an overdose of a controlled substance under this section shall include in the report:

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(a) The date of overdose.

(b) The approximate age of the person receiving attention or treatment.

(c) The suspected kind and quantity of controlled substances involved in the overdose.

(d) The approximate address of where the person was picked up, where the overdose took place, or where the person resides.

(3) A person who makes a report under this section in good faith is not subject to civil or criminal liability for making the report.

(4) The sheriff or chief law enforcement officer in each county, or other organization or agency as designated by such officer pursuant to subsection (1), shall share the general data, excluding any data relating to a criminal charge, with health care professionals and the county health department. Each county health department shall make a semiannual report to the Statewide Drug Policy Advisory Council in accordance with a schedule set by the council summarizing the data for that county. The council may use the reports to maximize the utilization of funding programs for the dissemination of available federal, state, and private funds for local substance abuse services in accordance with s. 397.321(4).

(5) The sheriff or chief law enforcement officer in each county, or other organization or agency designated pursuant to subsection (1), shall maintain the records described in this section. Such records shall be kept and made available for a period of not less than 5 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement

28-00724-17

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120 officers are not required to obtain a subpoena, court order, or
121 search warrant in order to obtain access to copies of such
122 records.

123 (6) A person who:

124 (a) Fails by omission to report the treatment of a drug
125 overdose of a substance listed in s. 893.03 within 24 hours
126 after discovery as required in this section commits a
127 misdemeanor of the second degree, punishable as provided in s.
128 775.082 or s. 775.083.

129 (b) Willfully refuses to report the treatment of a drug
130 overdose of a substance listed in s. 893.03 within 24 hours
131 after discovery as required in this section commits a
132 misdemeanor of the first degree, punishable as provided in s.
133 775.082 or s. 775.083.

134 Section 3. This act shall take effect October 1, 2017.



The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 15, 2017

I respectfully request that **Senate Bill #588**, relating to Drug Overdoses, be placed on the:

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

A handwritten signature in black ink, appearing to read "K. Passidomo", with a long horizontal line extending to the right.

Senator Kathleen Passidomo
Florida Senate, District 28

THE FLORIDA SENATE
APPEARANCE RECORD

3-27-17

Meeting Date

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

SB
588

Bill Number (if applicable)

Topic Drug Overdoses

Amendment Barcode (if applicable)

Name Jill Gran

Job Title Policy Director

Address 2868 Mahan Dr

Phone 850-878-2196

Street

Tallahassee FL

32308

City

State

Zip

Email jill@myflha.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Behavioral Health Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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 682

INTRODUCER: Health Policy Committee and Senator Stargel

SUBJECT: Medicaid Managed Care

DATE: March 29, 2017

REVISED: 3/29/2017

	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 682 exempts from the Long-Term Care component (LTC) of the Statewide Medicaid Managed Care (SMMC) program those Medicaid recipients who have resided in a nursing facility for 60 or more consecutive days, with certain exceptions. The bill also exempts those recipients in the LTC component who are receiving hospice care while residing in a nursing facility. These recipients would receive long-term care services through fee-for-service Medicaid providers and other medical services through the managed medical assistance component (MMA) of the SMMC program. This section of the bill is effective October 1, 2018.

The bill provides that a nursing home resident would not be exempt from the LTC component if the resident has been identified as a candidate for home and community-based services (HCBS) by specified individuals. The agency must confirm whether an individual has been identified as a candidate for HCBS before determining that a person is exempt from the LTC component. The bill provides notice provisions should the nursing resident later be identified as a candidate for HCBS services. The additional exceptions apply to a Medicaid recipient who is aged 18 or older and eligible for Medicaid by reason of a disability or a person who has priority enrollment for home and community-based services.

Effective July 1, 2017, the bill requires the Agency for Health Care Administration (AHCA) to impose fines and authorizes other sanctions for willful violations with the prompt pay provisions of ss. 641.315, 641.3155, 641.513, and 409.982(5), F.S.

Managed care plans must also contract with all nursing homes and hospices that meet credentialing and re-credentialing requirements as specified in the plan's contract with the AHCA for the first 12 months following a procurement in any regions where a plan is awarded a contract and that region was not previously served by that plan during the most recent procurement period. If a plan excludes a nursing home or hospice for the remainder of the contract period, the AHCA must require the plan to submit the performance and quality criteria that was used to exclude the provider and to demonstrate how the provider failed to meet the plan's criteria.

Obsolete language is removed from the bill relating to the submission of the original SMMC waiver.

The AHCA has not provided a revised fiscal analysis reflecting the changes in CS/SB 682.

Except as otherwise provided, the bill is effective upon becoming law.

II. Present Situation:

Florida Medicaid

The Medicaid program is a partnership between the federal and state governments to provide medical care to low income children and disabled persons. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid serves as the safety net to Florida's healthcare delivery system. Medicaid currently is the second largest expenditure in Florida's budget behind education with estimated expenditures for the 2016-2017 state fiscal year of \$25.8 billion¹ and covers 20 percent of all Floridians. Over 4 million Floridians are currently enrolled in Medicaid, including:

- 47 percent of Florida's children;
- 63 percent of Florida's births; and
- 61 percent of Florida's nursing home days.²

However, Florida Medicaid does not cover all low-income Floridians. The maximum income limits for programs are illustrated below as a percentage of the federal poverty level (FPL).

¹ Office of Economic and Demographic Research, Social Services Estimating Conference, Medicaid Caseload and Expenditures (February 17, February 27, and March 9, 2017) Executive Summary, <http://edr.state.fl.us/Content/conferences/medicaid/execsummary.pdf> (last visited Mar. 21, 2017).

² Agency for Health Care Admin., Senate Health and Human Services Appropriations Committee Presentation, *Agency for Health Care Administration - Florida Medicaid* (January 11, 2017), slide 2, http://www.flsenate.gov/PublishedContent/Committees/2016-2018/AHS/MeetingRecords/MeetingPacket_3554.pdf (last visited Mar. 17, 2017).

Florida's Current Medicaid and CHIP Eligibility Levels in Florida ³ (With Income Disregards and Modified Adjusted Gross Income)						
Children's Medicaid			CHIP (Kidcare)	Pregnant Women	Parents	Childless Adults
Age 0-1	Age 1-5	Age 6-18	Ages 0-18			
206% FPL	140% FPL	133% FPL	210% FPL	191% FPL	31% FPL	0% FPL

Florida Medicaid is administered by the AHCA and is financed with federal and state funds. The Department of Children and Families (DCF) determines Medicaid eligibility and transmits that information to the AHCA. As the single state agency, the AHCA has the lead responsibility for the overall program.⁴

The structures of state Medicaid programs vary from state to state, and each state's share of expenditures also varies and is largely determined by the federal government. Federal law and regulations set the minimum amount, scope, and duration of services offered in the program, among other requirements. State Medicaid benefits are provided in statute under s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons).

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. While self-attestation is permitted for a number of data elements on the application, most components are matched through the Federal Data Services Hub.⁵ Applicants must also agree to cooperate with Child Support Enforcement during the application process.⁶

Minimum eligibility coverage thresholds are established in federal law for certain population groups, such as children, as well as minimum benefits and maximum cost sharing. The minimum benefits include items such as physician services, hospital services, home health services, and family planning.⁷ States can add benefits, pending federal approval. Florida has added benefits, including prescription drugs, adult dental services, and dialysis.⁸ For children under age 21, the benefits must include the Early and Periodic Screening, Diagnostic and Treatment services, which are those health care and diagnostic services and treatment and measures that may be needed to correct or ameliorate defects or physical and mental illnesses and conditions discovered by screening services, consistent with federal law.⁹

Waivers to the state plan may be requested and negotiated by the state through the federal Centers for Medicare and Medicaid Services (CMS) by the AHCA. Florida has several such Medicaid waivers, including one which implemented the SMMC program. Current federal law requires the state to obtain a waiver to implement managed care. Through these waivers, the

³ U.S. Centers for Medicare and Medicaid Services, Medicaid.gov, *Florida*, <http://www.medicaid.gov/medicaid-chip-program-information/by-state/florida.html> (last visited Mar. 17, 2017).

⁴ See s. 409.963, F.S.

⁵ Florida Dep't of Children and Families, *Family-Related Medicaid Programs Fact Sheet*, p. 4 (April 2016) <http://www.dcf.state.fl.us/programs/access/docs/Family-RelatedMedicaidFactSheet.pdf> (last visited Mar. 21, 2017).

⁶ Id.

⁷ Section 409.905, F.S.

⁸ Section 409.906, F.S.

⁹ See Section 1905 9(r) of the Social Security Act.

states have limited flexibility to design their Medicaid programs; however, even within waiver authorities, federal regulations prescribe requirements for benefits, delivery systems, cost sharing limitations, and population coverages.

Statewide Medicaid Managed Care (SMMC)

The SMMC program is designed for the AHCA to issue invitations to negotiate and competitively procure contracts with managed care plans in 11 regions of the state to provide comprehensive Medicaid coverage for most of the state's enrollees in the Medicaid program. The SMMC has two components: Managed medical assistance (MMA) and long-term care managed care (LTC). The MMA waiver expires on June 30, 2017, and the LTC waiver was recently extended through December 27, 2021.¹⁰

Part IV of ch. 409, F.S., was created in 2011 by ch. 2011-134, L.O.F., and governs the SMMC program. The LTC component began enrolling in August 2013, and completed its statewide roll-out in March 2014. The MMA component began enrolling Medicaid recipients in May 2014, and finished its roll-out in August 2014.

Services are delivered through six managed care plans which vary based on the recipient's region; however, each region has at least two plans. Plans are paid on a capitated basis meaning that a LTC plan must pay for all covered services under the contract regardless of whether the capitated rate covers the cost of services for that recipient. For nursing facilities and hospices, the plans are required to pay those designated providers a rate set by the AHCA.

Of those recipients enrolled in the LTC waiver, more than half or 47,465 recipients are receiving home and community based services (HCBS) as of February 1, 2017. The remaining enrollees are receiving nursing facility services.¹¹

Statewide Medicaid Managed Care - February 1, 2017			
Component	Enrollment Start Date	Budget¹²	Enrollment¹³ (as of Feb. 2017)
Long-Term Care Plan	August 2013	\$3.97 billion	94,844
<i>Home & Community Based Services</i>			47,465 ¹⁴
Managed Medical Assistance	May 2014	\$14.4 billion	3,237,296

¹⁰ The current Managed Medical Assistance waiver is approved as an 1115 waiver and was last approved for the time period of July 31, 2014 through June 30, 2017. The Long-Term Care Managed Care waiver is approved as a section 1915(b) and section 1915(c) combination waiver and was most recently approved through December 27, 2021 by the federal Centers for Medicare and Medicaid Services.

¹¹ Agency for Health Care Admin., *Senate Bill 682 Analysis* (Feb. 13, 2017), pg. 2, (on file with the Senate Committee on Health Policy).

¹² Agency for Health Care Admin., *Statewide Medicaid Managed Care (Presentation to House Health and Human Services Committee - Jan. 10, 2017)*, slide 2, http://ahca.myflorida.com/medicaid/recent_presentations/House_Health_Human_Services_Med_101_2017-01-10.pdf (last visited Mar. 1, 2017).

¹³ Agency for Health Care Admin., *SMMC MMA Enrollment by County by Plan* (as of February 1, 2017), http://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Mar. 1, 2017).

¹⁴ Agency for Health Care Admin., *Senate Bill 682 Analysis* (Feb. 13, 2017), pg. 2, (on file with Senate Committee on Health Policy).

The LTC program provides services in two settings: nursing facilities or HCBS such as a recipient's home, an assisted living facility, or an adult family care home. Nursing facility services are an entitlement program for eligible enrollees and no waitlist exists; however, HCBS are delivered through waivers and are dependent on the availability of annual funding in the General Appropriations Act (GAA).

Enrollment in the HCBS portion of LTC is managed based on a priority system and wait list. For the 2016-2017 waiver year, the state is approved for 62,500 unduplicated recipients in the HCBS portion of the program.¹⁵ In order to be eligible for the program, a recipient must be both clinically eligible as required under s. 409.979, F.S., and financially eligible for Medicaid.

Eligibility and Enrollment

The AHCA is the single state agency for Medicaid; however, through an interagency agreement with the Department of Elderly Affairs (DOEA), the DOEA is Florida's federally mandated pre-admission screening program for nursing home applicants through its Long-Term Care Services (CARES) program, including for LTC.¹⁶ The CARES program has 18 field offices across the state which are staffed with physicians, nurses, and other health care professionals who evaluate the level of care an individual may or may not need. The frailty-based assessment results in a priority score for an individual, who is then placed on the wait list based on his or her priority score.

To receive nursing facility care, an individual must also be determined to meet the requirements of s. 409.985(3), F.S. This subsection requires:

The CARES program shall determine if an individual requires nursing facility care and, if the individual requires such care, assign the individual to a level of care as described in s. 409.983(4), F.S. When determining the need for nursing facility care, consideration shall be given to the nature of the services prescribed and which level of nursing or other health care personnel meets the qualifications necessary to provide such services and the availability to and access by the individual of community or alternative resources. For the purposes of the long-term care managed care program, the term "nursing facility care" means the individual:

(a) Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and care required to be performed on a daily basis by, or under the direct supervision of, a registered nurse or other health care professional and requires services that are sufficiently medically complex to require supervision, assessment,

¹⁵ Letter from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services to Beth Kidder, Interim Deputy Secretary for Medicaid, Agency for Health Care Administration (December 19, 2016), http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/LTC_Approval_Letter_2016-12-19.pdf (last visited Mar. 1, 2017).

¹⁶ Florida Dep't of Elder Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, <http://elderaffairs.state.fl.us/doea/cares.php> (last visited Mar. 1, 2017).

planning, or intervention by a registered nurse because of a mental or physical incapacitation by the individual;

(b) Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment and requires services on a daily or intermittent basis that are to be performed under the supervision of licensed nursing or other health professionals because the individual is incapacitated mentally or physically; or

(c) Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and care and the constant availability of medical and nursing treatment and requires limited services that are to be performed under the supervision of licensed nursing or other health professionals because the individual is mildly incapacitated mentally or physically.

Individuals are released from the wait list periodically, based on the availability of funding and their priority scores. The Legislature has specifically directed funding in the past several years through the GAA to serve elders off the waitlist who have a priority score of 4 or higher.¹⁷ Individuals who are more frail or have a more immediate need for services receive a higher rank on the waitlist. Those who have resided in a nursing facility for more than 60 days receive priority enrollment into the HCBS portion of the program. Exemptions from the wait list also exist under s. 409.979(3)(f), F.S. Those exempted individuals include:

- Persons who are 18, 19, or 20 years of age who have a chronic, debilitating disease or condition of one or more physiological or organ systems which generally make the individual dependent upon 24-hour-per-day medical, nursing, or health supervision, or intervention;
- Nursing facility residents who request to transition into the community and who have resided in a Florida-licensed skilled nursing facility for at least 60-consecutive days; or
- Persons referred by the DCF pursuant to the Adult Protective Services, ss. 415.101-415.113, F.S., as high risk and who are placed in an assisted living facility temporarily funded by the DCF.

Before being released from the waitlist, however, individuals must meet the following eligibility requirements to enroll in the program:¹⁸

- Be age 65 years or older or age 18 and eligible for Medicaid by reason of a disability; and
- Be determined by the CARES preadmission screening program to require nursing facility care as defined in s. 409.985(3), F.S.

Some individuals who are enrolled in waiver programs or other coverages may enroll in the LTC program, but are not required to, and those are:

- Developmental Disabilities waiver program;
- Traumatic Brain and Spinal Cord Injury waiver;

¹⁷ See Ch. Law 2016-66, line item 232; Ch. Law 2015-232, line item 226; and Ch. Law 2014-51, line item 242. In state fiscal year 2013-14, the GAA provided funding during first year of the LTC program for those on the wait list with priority scores of 5 or higher. (Ch. Law 2013-40, line item 414).

¹⁸ See s. 409.979, F.S.

- Project AIDS Care (PAC) waiver;
- Adult Cystic Fibrosis waiver;
- Program of All-Inclusive Care for the Elderly (PACE);
- Familial Dysautonomia waiver;
- Model waiver; or
- Other creditable coverage excluding Medicare.¹⁹

Individuals, both those who are enrolled in LTC and those on the wait list, must be re-screened at least annually or whenever there is a significant change in circumstances, such as change in caregivers or medical condition.²⁰

Delivery System and Benefits

The AHCA conducted a competitive procurement to select LTC plans in each of the 11 regions in 2012. Contracts were awarded to health maintenance organizations (HMOs) and provider service networks (PSNs). Six non-specialty plans are currently contracted, including one PSN that is available in all 11 regions and one HMO that is in 10 regions. Recipients receive choice counseling services to assist them in selecting the plan that will best meet their needs.

Each plan under LTC is required to provide a minimum level of services. These services include:

- Adult companion care;
- Adult day health care;
- Assisted living;
- Assistive care services;
- Attendant care;
- Behavioral management;
- Care coordination and case management;
- Caregiver training;
- Home accessibility training;
- Home-delivered meals;
- Homemaker;
- Hospice;
- Intermittent and skilled nursing;
- Medical equipment and supplies;
- Medication administration;
- Medicaid management;
- Nursing facility;
- Nutritional assessment/risk reduction;
- Personal care;
- Personal emergency response system;
- Respite care;

¹⁹ See s. 409.972, F.S.

²⁰ Application for §1915(c) Home and Community-Based Services Waiver (Effective July 1, 2013), pp. 45-46, http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/LTC_1915c_Application.pdf (last visited Mar. 1, 2017).

- Therapies; and
- Non-emergency transportation.²¹

An LTC plan may elect to offer expanded benefits to its enrollees. Some of the approved expanded benefits within LTC include:

- Cellular phone service;
- Dental services;
- Emergency financial assistance;
- Hearing evaluation;
- Mobile personal emergency response system;
- Non-medical transportation;
- Over-the-counter medication and supplies;
- Support to transition out of a nursing facility;
- Vision services; and
- Wellness grocery discount.²²

LTC enrollees who are not eligible for Medicare also receive their medical services through an MMA plan. Some plans participate in both components in the same regions, and a recipient may choose the same managed care plan for both components, known as a comprehensive plan.

The AHCA's contract with the LTC plans include a statutorily required incentive payment adjustment to encourage increased utilization of HCBS services and a matching reduction in nursing facility placements. The incentive adjustment must be modified in each successive rate period in accordance with s. 409.983, F.S., as follows:

- (5) The agency shall make an incentive adjustment in payment rates to encourage the increased utilization of home and community-based services and commensurate reduction of institutional placement. The incentive adjustment shall be modified in each successive rate period during the first contract period, as follows:
- (a) A 2-percentage point shift in the first rating-setting period;
 - (b) A 2-percentage point shift in the second rate-setting period, as compared to the utilization mix at the end of the first rate-setting period; or
 - (c) A 3-percentage point shift in the third rate-setting period, and in each successive rate setting period during the first contract period, as compared to the utilization mix at the end of the immediately preceding rate-setting period.

The incentive adjustment shall continue in subsequent contract periods, at a rate of three percentage points per contract year as compared to the utilization mix at the end of the immediately preceding rate-setting period, until no more than 35 percent of the plan's enrollees' are placed in institutional settings. The agency shall annually report to the Legislature the actual change in the utilization mix of home and community-based services

²¹ See s. 409.98, F.S.

²² Agency for Health Care Administration, MMA - Model Contract - Attachment I - Scope of Services (effective date Feb. 1, 2017) pp. 4-6, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2017-02-01/02-01-17_MODEL_Attachment_I-Scope_of_Services.pdf (last visited Feb. 1, 2017).

compared to institutional placements and provide a recommendation for utilization mix requirements for future contracts.

During the first year of the LTC program, the AHCA reports a 12.1 percent decrease in the number of Medicaid recipients residing in a nursing facility.²³

Reprocurement of the SMMC Contracts

The AHCA has started the process for the re-procurement of the managed care contracts for the SMMC program. The contracts were initially procured in 2012 and became effective in 2013 as 5-year contracts. An invitation to negotiate (ITN) will be released in the summer of 2017.²⁴ The AHCA posted a request to receive non-binding Letters of Intent to Bid on its website with a deadline of February 13, 2017. The AHCA received 41 total responses from interested providers and plans for the ITN.²⁵ The databook will be posted to AHCA's website on March 30, 2017, and a public meeting to review the databook with the AHCA's contracted actuary is scheduled for April 12, 2017.

American with Disabilities Act

In June of 2009, the United States Supreme Court held that public entities must provide community-based services to persons with disabilities when such services would be appropriate; when affected persons are not opposed to such treatments; and when such services can be reasonably accommodated. To not provide the opportunity for persons with disabilities to receive services in the community constitutes discrimination in violation of Title II of the Americans with Disabilities Act (ADA).²⁶

The *Olmstead* decision is further supported through federal regulation which states:

No qualified individual with a disability shall, on the basis of disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subject to discrimination by any public entity.²⁷

The Department of Justice's (DOJ) Civil Rights Division has conducted more than 40 *Olmstead* review cases in 25 states from 2009 to 2012, including cases in Florida.²⁸ Intervention from the DOJ may come through two different forms: A statement of interest where the DOJ intervenes in

²³ Agency for Health Care Adm., *Senate Bill 682 Analysis* (Feb. 13, 2017) (on file with Senate Committee on Health Policy).

²⁴ Agency for Health Care Administration, *AHCA Announces Start of Re-Procurement Process for Statewide Medicaid Managed Care Program* (Feb. 3, 2017)

http://ahca.myflorida.com/Executive/Communications/Press_Releases/pdf/ReprocurementPressRelease.pdf (last visited: Mar. 21, 2017).

²⁵ Agency for Health Care Administration, *Statewide Medicaid Managed Care Program Non-Binding Letters of Intent Received by 2/13/2017, in response to Intent to Bid Posted 2/3/2017*,

http://ahca.myflorida.com/mc/statewide_mc/pdf/Intent_to_Bid_Responses.pdf (last visited Mar. 21, 2017).

²⁶ *Olmstead v. L.C.*, 527 U.S. 581(1999);138 F.3d 893, affirm in part, vacated, and remanded.

²⁷ 28 CFR section 35.130(a) (2016).

²⁸ MaryBeth Musumeci and Henry Claypool, KFF.org, *Olmstead's Role in Community Integration for People with Disabilities under Medicaid: 15 Years after the Supreme Court's Olmstead's Decision* (June 18, 2014) <http://kff.org/report-section/olmsteads-role-in-community-integration-for-people-with-disabilities-under-medicaid-issue-brief> (last visited Mar. 3, 2017).

an existing lawsuit, but is not a party, or secondly, the DOJ investigates allegations and issues a letter of findings and a settlement agreement. A DOJ investigation or intervention may also result in litigation to enforce a mandate.²⁹

In July 2013, the federal DOJ filed a lawsuit against the State of Florida alleging that the state had failed to move nearly 200 disabled children from nursing homes and institutional care to less restrictive environments in violation of the ADA.³⁰ The complaint included other allegations relating to the state's policies, procedures, reimbursement levels, method of service denials, and network capacity issues in its programs for children with significant medical needs.

A previous December 2011, investigation by the DOJ is detailed in the complaint, including notice that the parties met on several occasions to attempt resolution of the issues.³¹ The DOJ complaint sought a declaratory judgement that the state had violated Title II of the ADA, to award compensatory damages, and any other relief as the court may find appropriate.³² The case has been consolidated with a private lawsuit against the state alleging similar issues, that the state's practices and policies have unnecessarily placed children with disabilities in nursing facilities or placed them at risk of placement in nursing facilities.³³ Litigation may also be brought by individuals to enforce a mandate.

The state has disputed the allegations in the DOJ complaint and argued that with the implementation of managed care and other policy changes in Medicaid, these issues are moot. The court has rejected these arguments thus far. Florida has most recently sought partial summary judgement to remove monetary damages as a legal remedy.³⁴

Guidance from the federal CMS stresses that all waiver programs for long-term care support programs, such as LTC, "must be delivered in the most integrated fashion, in the most integrated setting, and in a way that offers the greatest opportunities for active community and workforce participation."³⁵ Consistency with the *Olmstead* decision is found in every "essential element" of the guidance document.

The CMS guidance document also indicates that states will be expected to incorporate all services into the managed care plan capitation payment and that any exemptions will require comprehensive justification of how the goals of integration, efficiency and improved health and

²⁹ *Id.*

³⁰ *U.S. v. Florida*, No. 12-CV-60460, (SD. Fla., filed July 22, 2013).

³¹ *U.S. v. Florida*, No. 12-CV-60460, (SD. Fla., filed July 22, 2013), 21.

³² *Id.* at 23.

³³ U.S. Dep't of Justice, *Americans with Disabilities Act - Olmstead Enforcement*, https://www.ada.gov/olmstead/olmstead_cases_list2.htm#fla (last visited Mar. 3, 2017); see *A.R. v. Dudek*, No. 12-CV 60460 (S.D. Fla. 2012).

³⁴ U.S. Dep't of Justice, *Americans with Disabilities Act - Olmstead Enforcement*, https://www.ada.gov/olmstead/olmstead_cases_list2.htm#fla (last visited Mar. 3, 2017).

³⁵ Centers for Medicare and Medicaid Services, *Guidance to States Using 1115 Demonstrations or 1915(b) Waivers for Managed Long Term Services and Supports Programs* (5/20/13), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Downloads/1115-and-1915b-MLTSS-guidance.pdf>, p. 8, (last visited Mar. 3, 2017).

quality of life will be achieved.³⁶ Exclusion of any services will require routine re-assessment to ensure no violations of any federal laws, including the ADA or *Olmstead* requirements.³⁷

Prompt Payment of Claims

Florida's prompt pay laws govern payment claims submitted to insurers and HMOs, including Medicaid managed care plans in accordance with ss. 641.315, 641.3155, and 641.513, F.S.³⁸ These provisions establish HMO provider contract requirements, prompt payment guidelines for provider payments, and requirements for the provision of emergency services and care for HMO enrollees. An HMO or insurer has 12 months after payment is made to a provider to make a claim for overpayment against the provider, if the provider is licensed under ch. 458, F.S., or ch. 459, F.S., (physicians), ch. 460, F.S., (chiropractors), ch. 461, F.S. (podiatrists), or ch. 466, F.S., (dentists). For all other types of providers, an insurer or HMO has up to 30 months after such payment to make a claim for overpayment, and a 40-day timeline for providers to pay, deny, or contest the claim for overpayment.³⁹ The law provides a process and timeline for providers to pay, deny, or contest the claim. Further, the law prohibits an insurer or HMO from retroactively denying a claim because of the ineligibility of an insured or subscriber more than one year after the date the claim is paid. The statutes do not include any provisions for the imposition of fines for non-compliance; however, the AHCA enforces these standards through the imposition of liquidated damages or sanctions, including fines.⁴⁰

III. Effect of Proposed Changes:

Section 1 amends s. 400.141, F.S., effective October 1, 2018, to add a requirement for nursing home facilities to confirm for the AHCA whether a nursing home facility resident who is a Medicaid recipient, or whose Medicaid eligibility is pending, is a candidate for home and community-based services (HCBS) under s. 409.965(3)(c), not later than the resident's 50th consecutive day of residency in the nursing home facility. The nursing home facility's notice to the AHCA is to assist in the identification of nursing home residents who may be eligible for both HCBS and the LTC component.

Section 2 amends s. 409.964, F.S., to remove obsolete dates relating to the submission of state plan amendments or waivers by a date certain, all of which have passed.

Section 3 amends s. 409.965, F.S., to create a new exemption from mandatory enrollment in the LTC program. Effective October 1, 2018, the bill exempts persons who are assigned into level of care 1 under s. 409.983(4), F.S., and have resided in a nursing facility for 60 or more consecutive days. The exemption shall become effective on the first day of the first month after the person

³⁶ *Id.* at 12.

³⁷ *Id.*

³⁸ The prompt pay provisions apply to HMO contracts and major medical policies offered by individual and group insurers licensed under ch. 624, F.S., including preferred provider policies and an exclusive provider organization, and individual and group contracts that only provide direct payments to dentists.

³⁹ Section 641.3155, F.S., provide exceptions to this time limit in cases relating to fraud.

⁴⁰ Agency for Health Care Administration, *Senate Bill 682 Analysis* (Feb. 2, 2017), p. 6, (on file with the Senate Committee on Health Policy).

meets the criteria for the exemption. An exemption under this section has no bearing on an individual's eligibility for the MMA program.

An exemption from mandatory participation in LTC program is also created for recipients receiving hospice care while residing in a nursing facility. The exemption shall become effective on the first day of the first month after the person meets the criteria for the exemption. An exemption under this section has no bearing on an individual's eligibility for the MMA program.

The effect of these exemptions is that nursing homes and hospices will be paid on a fee-for-service basis from the AHCA for these Medicaid recipients rather than receiving payment from the managed care plans.

Notwithstanding the exemptions provided above, the agency shall authorize the enrollment or continued enrollment of a Medicaid recipient in or into the LTC program who:

- Is eligible for the LTC program under s. 409.979, F.S., is 18 years of age or older, and is eligible for Medicaid by reason of disability;
- A person who is given priority enrollment for HCBS under s. 409.979(3)(f), F.S., or
- A person who has been identified as a candidate for HCBS by the nursing facility administrator and any long-term care plan case manager assigned to the resident.

The identification of the resident as a candidate for HCBS must be made in consultation with:

- The resident or the resident's legal representative or designee;
- The resident's personal physician or, if the resident does not have a personal physician, the facility's medical director; and
- A registered nurse who has participated in developing, maintaining, or reviewing the individual's resident care plan⁴¹ as defined in s. 400.021, F.S.

Before determining that a nursing home resident is exempt from the long-term care managed care program, the agency is required to confirm whether the person has been identified as a candidate for HCBS services. If a nursing facility resident who has been identified as exempt is later identified as a candidate for HCBS, the nursing facility administrator must promptly notify the AHCA to ensure candidates are transitioned smoothly between programs, if appropriate.

Section 4 amends s. 409.967, F.S., relating to managed care plan accountability, to direct the AHCA to impose fines, and to authorize the imposition of other sanctions on a plan that willfully fails to comply with the managed care plan accountability provisions of ss. 641.315 (provider contracts), 641.3155 (prompt payment of claims), 641.513 (requirements for providing emergency services and care), and the added cross-referenced provision, s. 409.928(5), F.S., (long-term care managed care plan accountability provisions).

⁴¹ A resident care plan is a written plan which must be reviewed not less than quarterly by a registered nurse, with participation by other staff and the resident or his or her legal representative, which includes, a comprehensive assessment of the needs of an individual resident; the type and frequency of services required to provide the necessary care for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being; a listing of services provided; and an explanation of goals.

Section 5 amends s. 409.979, F.S., relating to the pre-requisite criteria for eligibility for enrollees in the LTC program. The bill clarifies that only those Medicaid recipients who are not exempt under s. 409.965, F.S., and who meet all of the criteria under this section may be eligible to receive long-term care services by participating in the LTC program. The amended language aligns the eligibility with the modifications made in Section 2 of the bill.

Section 6 amends s. 409.982, F.S., relating to provider networks of a long-term care managed care plan. The bill requires the managed care plans to offer a network contract to all nursing homes and hospices for the first 12 months of a contract period in a region if that region was not served by that plan after the most recent procurement, i.e., under the prior contract period. The nursing homes and hospices must meet the credentialing and recredentialing requirements specified in the plan's contract with the agency.

After the 12-month period, the plan may exclude any nursing home or hospice for failure to meet quality or performance standards; however, the plan must provide 30 days' written notice before the effective date to all affected recipients. If the plan excludes providers from its network or fails to renew a provider's contract, the AHCA must require a report from that plan which shows the quality or performance indicators used to exclude the provider and demonstrates how the provider failed to meet the plan's criteria.

Section 7 provides that except as otherwise provided in this act, and except for this section, which shall take effect upon becoming a law, this act shall take effect July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

The *Olmstead* decision requires the state to deliver services "in the most integrated setting appropriate to meet the needs of qualified individuals with disabilities." The requirement applies whether the state delivers those services using a managed care delivery system or fee-for-service process. However, as noted earlier, the federal CMS has also released guidance statements since that 1999 decision about the exclusion of services from managed care and how the agency will review those actions. Such action by states will receive strict scrutiny from federal CMS and require justification that services are still being rendered in the most integrated manner.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/SB 682 changes how services are delivered for the LTC component when the new contracts are effective under the invitation to negotiate which will be conducted this summer. Changes in the delivery of benefits may impact private providers that are currently providing services to recipients in the program now; however, that may have occurred regardless with any changeover in managed care contracts. There is no guarantee that the same providers will receive contracts in the same areas of the state.

The revisions to the prompt-pay section of the bill may impact the private sector to a larger degree if it results in providers and facilities receiving payment for services on a more expedient basis. The AHCA indicates that the statutes already permit the imposition of sanctions for noncompliance with the prompt pay requirements and that sanctions have been applied. A more aggressive enforcement effort may have been lacking due to the inability to determine from the available claims data that the prompt pay provision has been violated.

Requiring managed care plans to contract with all nursing facilities and hospices that meet credentialing requirements in an awarded region for 12 months following any new procurement for the LTC program may require the plans to contract with providers that they previously non-renewed or terminated 4-5 years ago. The AHCA indicates that this number of non-renewed or terminated providers is low.

C. Government Sector Impact:

A revised bill analysis and fiscal impact statement reflecting the changes in CS/SB 682 have not been received by publication date of this analysis.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The CS/SB 682 includes a requirement for the long-term care managed care plans to offer a contract to all nursing homes and hospices in a region which meet the recredentialing or credentialing requirements of the plan's contract with the AHCA if that the region was not served by that plan after the most recent procurement. This language may be confusing as to which procurement process is the baseline for determining which nursing and hospices must be offered a contract and in which regions the mandatory contracting would be applicable. It may be better to reference those providers who did not have contracts immediately prior to the most recently concluded procurement process.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.964, 409.965, 409.967, 409.979, and 409.982.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

The CS:

- Requires a nursing home to be prepared to confirm for the AHCA whether a nursing home resident, who is a Medicaid recipient or whose Medicaid eligibility is pending, is a candidate for HCBS, by the resident's 50th consecutive day of residency in the nursing home facility;
- Establishes the effective date for those exempted from the LTC managed care program;
- Provides that a nursing facility resident is not exempt from the LTC managed care program if the resident has been identified as a candidate for HCBS by the nursing facility administrator and any LTC case manager assigned to the resident;
- Establishes an identification and evaluation process for nursing facility residents for HCBS;
- Requires confirmation from the AHCA as to whether the person has been identified as a candidate for HCBS before a determination can be made that an individual is exempt from the LTC managed care program;
- Requires nursing facility administrators to promptly notify the AHCA of any exempt nursing home residents who have later been identified as candidates for HCBS; and
- Requires a plan to contract with all credentialed nursing homes and hospices if a new region is awarded under a new procurement cycle.

B. Amendments:

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Stargel) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Effective October 1, 2018, paragraph (v) is
added to subsection (1) of section 400.141, Florida Statutes, to
read:

400.141 Administration and management of nursing home
facilities.—

(1) Every licensed facility shall comply with all



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applicable standards and rules of the agency and shall:

(v) Be prepared to confirm for the agency whether a nursing home facility resident who is a Medicaid recipient, or whose Medicaid eligibility is pending, is a candidate for home and community-based services under s. 409.965(3)(c), no later than the resident's 50th consecutive day of residency in the nursing home facility.

Section 2. Section 409.964, Florida Statutes, is amended to read:

409.964 Managed care program; state plan; waivers.—The Medicaid program is established as a statewide, integrated managed care program for all covered services, including long-term care services as specified under this part. The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the program. Before seeking a waiver, the agency shall provide public notice and the opportunity for public comment and include public feedback in the waiver application. The agency shall hold one public meeting in each of the regions described in s. 409.966(2), and the time period for public comment for each region shall end no sooner than 30 days after the completion of the public meeting in that region. ~~The agency shall submit any state plan amendments, new waiver requests, or requests for extensions or expansions for existing waivers, needed to implement the managed care program by August 1, 2011.~~

Section 3. Effective October 1, 2018, section 409.965, Florida Statutes, is amended to read:

409.965 Mandatory enrollment.—All Medicaid recipients shall receive covered services through the statewide managed care



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program, except as provided by this part pursuant to an approved federal waiver.

(1) The following Medicaid recipients are exempt from participation in the statewide managed care program:

(a)~~(1)~~ Women who are eligible only for family planning services.

(b)~~(2)~~ Women who are eligible only for breast and cervical cancer services.

(c)~~(3)~~ Persons who are eligible for emergency Medicaid for aliens.

(2) (a) Persons who are assigned into level of care 1 under s. 409.983(4) and have resided in a nursing facility for 60 or more consecutive days are exempt from participation in the long-term care managed care program. For a person who becomes exempt under this paragraph while enrolled in the long-term care managed care program, the exemption shall take effect on the first day of the first month after the person meets the criteria for the exemption. This paragraph does not affect a person's eligibility for the Medicaid managed medical assistance program.

(b) Persons receiving hospice care while residing in a nursing facility are exempt from participation in the long-term care managed care program. For a person who becomes exempt under this paragraph while enrolled in the long-term care managed care program, the exemption takes effect on the first day of the first month after the person meets the criteria for the exemption. This paragraph does not affect a person's eligibility for the Medicaid managed medical assistance program.

(3) Notwithstanding subsection (2):

(a) A Medicaid recipient who is otherwise eligible for the



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long-term care managed care program, who is 18 years of age or older, and who is eligible for Medicaid by reason of a disability is not exempt from the long-term care managed care program under subsection (2).

(b) A person who is afforded priority enrollment for home and community-based services under s. 409.979(3)(f) is not exempt from the long-term care managed care program under subsection (2).

(c) A nursing facility resident is not exempt from the long-term care managed care program under paragraph (2)(a) if the resident has been identified as a candidate for home and community-based services by the nursing facility administrator and any long-term care plan case manager assigned to the resident. Such identification must be made in consultation with the following persons:

1. The resident or the resident's legal representative or designee;

2. The resident's personal physician or, if the resident does not have a personal physician, the facility's medical director; and

3. A registered nurse who has participated in developing, maintaining, or reviewing the individual's resident care plan as defined in s. 400.021.

(d) Before determining that a person is exempt from the long-term care managed care program under paragraph (2)(a), the agency shall confirm whether the person has been identified as a candidate for home and community-based services under paragraph (c). If a nursing facility resident who has been determined exempt is later identified as a candidate for home and



716712

community-based services, the nursing facility administrator shall promptly notify the agency.

Section 4. Paragraph (j) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(j) *Prompt payment.*—Managed care plans shall comply with ss. 641.315, 641.3155, and 641.513, and the agency shall impose fines, and may impose other sanctions, on a plan that willfully fails to comply with those sections or s. 409.982(5).

Section 5. Subsection (1) of section 409.979, Florida Statutes, is amended to read:

409.979 Eligibility.—

(1) PREREQUISITE CRITERIA FOR ELIGIBILITY.—Medicaid recipients who meet all of the following criteria are eligible to receive long-term care services and, unless exempt under s. 409.965, must receive long-term care services by participating in the long-term care managed care program. The recipient must be:

(a) Sixty-five years of age or older, or age 18 or older and eligible for Medicaid by reason of a disability.

(b) Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) preadmission screening program to require nursing facility care as defined in s. 409.985(3).

Section 6. Subsections (1) and (2) of section 409.982,



716712

Florida Statutes, are amended to read:

409.982 Long-term care managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the long-term care managed care program must comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans may limit the providers in their networks based on credentials, quality indicators, and price. For the first 12 months of any contract period following a procurement for the long-term care managed care program under s. 409.981 between October 1, 2013, and September 30, 2014, each selected plan must offer a network contract to all nursing homes that meet the recredentialing requirements and hospices that meet the credentialing requirements specified in the plan's contract with the agency ~~the following providers in the region or regions for which the plan is awarded a contract.~~

~~(a) Nursing homes.~~

~~(b) Hospices.~~

~~(c) Aging network service providers that have previously participated in home and community-based waivers serving elders or community-service programs administered by the Department of Elderly Affairs.~~ During the remainder of the contract period, a ~~After 12 months of active participation in a managed care plan's network,~~ the plan may exclude any of the providers named in this subsection from the plan's network for failure to meet quality or performance criteria. If a ~~the~~ plan excludes a provider from its network under this subsection ~~the plan~~, the plan must provide written notice to all recipients who have chosen that provider for care. The notice must be provided at least 30 days



716712

before the effective date of the exclusion. The agency shall establish contract provisions governing the transfer of recipients from excluded residential providers. The agency shall require a plan that excludes a provider from its network or that fails to renew the plan's contract with a provider under this subsection to report to the agency the quality or performance criteria the plan used in deciding to exclude the provider and to demonstrate how the provider failed to meet those criteria.

(2) SELECT PROVIDER PARTICIPATION.—Except as provided in this subsection, providers may limit the managed care plans they join. Nursing homes and hospices that are enrolled Medicaid providers must participate in all eligible plans selected by the agency in the region in which the provider is located, with the exception of plans from which the provider has been excluded under subsection (1).

Section 7. Except as otherwise provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled
An act relating to Medicaid managed care; amending s.
400.141, F.S.; requiring that nursing home facilities
be prepared to provide confirmation within a specified
timeframe to the Agency for Health Care Administration
as to whether certain nursing home facility residents



716712

are candidates for certain services; amending s.
409.964, F.S.; providing that covered services for
long-term care under the Medicaid managed care program
are those specified in part IV of ch. 409, F.S.;
deleting an obsolete provision; amending s. 409.965,
F.S.; providing that certain residents of nursing
facilities are exempt from participation in the long-
term care managed care program; providing for
application of the exemption; providing that
eligibility for the Medicaid managed medical
assistance program is not affected by such provisions;
providing conditions under which the exemption does
not apply; requiring the agency to confirm whether
certain persons have been identified as candidates for
home and community-based services; requiring a certain
notice to the agency by nursing facility
administrators; amending s. 409.967, F.S.; requiring
the agency to impose fines and authorizing other
sanctions for willful failure to comply with specified
payment provisions; amending s. 409.979, F.S.;
providing that certain exempt Medicaid recipients are
not required to receive long-term care services
through the long-term care managed care program;
amending s. 409.982, F.S.; revising parameters under
which a long-term care managed care plan must contract
with nursing homes and hospices; specifying that the
agency must require certain plans to report
information on the quality or performance criteria
used in making a certain determination; providing



716712

214

effective dates.



204196

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
03/27/2017	.	
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The Committee on Health Policy (Young) recommended the following:

Senate Amendment to Amendment (716712) (with title amendment)

Delete lines 5 - 99
and insert:

Section 1. Section 409.964, Florida Statutes, is amended to read:

409.964 Managed care program; state plan; waivers.—The Medicaid program is established as a statewide, integrated managed care program for all covered services, including long-



204196

term care services as specified under this part. The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the program. Before seeking a waiver, the agency shall provide public notice and the opportunity for public comment and include public feedback in the waiver application. The agency shall hold one public meeting in each of the regions described in s. 409.966(2), and the time period for public comment for each region shall end no sooner than 30 days after the completion of the public meeting in that region. ~~The agency shall submit any state plan amendments, new waiver requests, or requests for extensions or expansions for existing waivers, needed to implement the managed care program by August 1, 2011.~~

Section 2. Effective October 1, 2018, section 409.965, Florida Statutes, is amended to read

409.965 Mandatory enrollment.—All Medicaid recipients shall receive covered services through the statewide managed care program, except as provided by this part pursuant to an approved federal waiver.

(1) The following Medicaid recipients are exempt from participation in the statewide managed care program:

(a) ~~(1)~~ Women who are eligible only for family planning services.

(b) ~~(2)~~ Women who are eligible only for breast and cervical cancer services.

(c) ~~(3)~~ Persons who are eligible for emergency Medicaid for aliens.

(2) (a) Persons who are assigned into level of care 1 under s. 409.983(4) and have resided in a nursing facility for 365



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consecutive days shall undergo a consultation and determination pursuant to subsection (3)(c) to determine whether they should be exempt from participation in the long-term care managed care program. For a person who becomes exempt under this paragraph while enrolled in the long-term care managed care program, the exemption shall take effect on the first day of the first month after the person meets the criteria for the exemption. This paragraph does not affect a person's eligibility for the Medicaid managed medical assistance program.

(b) Persons receiving hospice care while residing in a nursing facility are exempt from participation in the long-term care managed care program. For a person who becomes exempt under this paragraph while enrolled in the long-term care managed care program, the exemption takes effect on the first day of the first month after the person meets the criteria for the exemption. This paragraph does not affect a person's eligibility for the Medicaid managed medical assistance program.

(3) Notwithstanding subsection (2):

(a) A Medicaid recipient who is otherwise eligible for the long-term care managed care program, who is 18 years of age or older, and who is eligible for Medicaid by reason of a disability is not exempt from the long-term care managed care program under subsection (2).

(b) A person who is afforded priority enrollment for home and community-based services under s. 409.979(3)(f) is not exempt from the long-term care managed care program under subsection (2).

(c) A nursing facility resident is not exempt from the long-term care managed care program under paragraph (2)(a) if



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the resident has been identified as a candidate for home and community-based services by the nursing facility administrator and any long-term care plan case manager assigned to the resident pursuant to the consultation and determination set forth in this section. Such identification must be made in consultation with the following persons:

1. The resident or the resident's legal representative or designee;

2. The resident's personal physician or, if the resident does not have a personal physician, the facility's medical director; and

3. A registered nurse who has participated in developing, maintaining, or reviewing the individual's resident care plan as defined in s. 400.021.

(d) Before determining that a person is exempt from the long-term care managed care program under paragraph (2) (a), the agency shall confirm whether the person has been identified as a candidate for home and community-based services under paragraph (c). If a nursing facility resident who has been determined exempt is later identified as a candidate for home and community-based services, the nursing facility administrator shall promptly notify the agency.

(4) A nursing facility resident's eligibility for home and community-based services shall be re-determined every 90 days after the determination made pursuant to subsection (3) (c) until the nursing facility care resident has been in nursing care for 720 consecutive days. At 720 days of nursing facility care, there is a rebuttable presumption that the resident is no longer eligible for home and community-based services. This presumption



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may be rebutted by compelling evidence presented in an
evaluation as set forth in paragraph (c) of this section. The
agency must approve the final determination of eligibility.

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

And the title is amended as follows:

Delete lines 180 - 201

and insert:

An act relating to Medicaid managed care; amending s.
409.964, F.S.; providing that covered services for
long-term care under the Medicaid managed care program
are those specified in part IV of ch. 409, F.S.;
deleting an obsolete provision; amending s. 409.965,
F.S.; providing that certain residents of nursing
facilities are exempt from participation in the long-
term care managed care program; providing that
eligibility for the Medicaid managed medical
assistance program is not affected by such provisions;
providing conditions under which the exemption does
not apply; requiring re-determinations at specified
intervals; creating a rebuttable presumption for
nursing facility care; amending s. 409.967, F.S.;
requiring



307222

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Stargel) recommended the following:

Senate Amendment to Amendment (716712)

Delete lines 134 - 151
and insert:
indicators, and price. For the first 12 months of a contract
period following a procurement for the long-term care managed
care program under s. 409.981, if a plan is ~~period between~~
~~October 1, 2013, and September 30, 2014, each~~ selected for a
region and that region was not served by the plan after the most
recent procurement, the plan must offer a network contract to



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all nursing homes in that region which meet the recredentialing requirements and to all hospices in that region which meet the credentialing requirements specified in the plan's contract with the agency ~~the following providers in the region:~~

~~(a) Nursing homes.~~

~~(b) Hospices.~~

~~(c) Aging network service providers that have previously participated in home and community-based waivers serving elders or community-service programs administered by the Department of Elderly Affairs. After a provider specified in this subsection has actively participated in a managed care plan's network for 12 months of active participation in a managed care plan's network,~~ the plan may exclude the provider ~~any of the providers named in this subsection~~ from the plan's network for failure to meet quality

By Senator Stargel

22-00989F-17

2017682__

A bill to be entitled

An act relating to Medicaid managed care; amending s. 409.964, F.S.; revising parameters relating to the establishment of the Medicaid program; deleting obsolete provisions; amending s. 409.965, F.S.; revising exemptions from the mandatory enrollment of Medicaid recipients in statewide Medicaid managed care; providing exemptions from participation in the long-term care managed care program; requiring the Agency for Health Care Administration to authorize Medicaid recipients who are eligible for the long-term care managed care program to enroll or remain enrolled in the program, subject to specified requirements; amending s. 409.967, F.S.; requiring the agency to impose fines and authorizing other sanctions for willful failure to comply with specified payment provisions; amending s. 409.979, F.S.; revising eligibility criteria for the long-term care managed care program to conform to exemptions; amending s. 409.982, F.S.; revising parameters under which a long-term care managed care plan must contract with nursing homes and hospices; specifying that the agency must require certain plans to report information on the quality or performance criteria used in making a certain determination; providing effective dates.

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

Section 1. Section 409.964, Florida Statutes, is amended to read:

409.964 Managed care program; state plan; waivers.—The Medicaid program is established as a statewide, integrated

Page 1 of 6

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

22-00989F-17

2017682__

managed care program for all covered services, including long-term care services as specified under this part. The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the program. Before seeking a waiver, the agency shall provide public notice and the opportunity for public comment and include public feedback in the waiver application. The agency shall hold one public meeting in each of the regions described in s. 409.966(2), and the time period for public comment for each region shall end no sooner than 30 days after the completion of the public meeting in that region. ~~The agency shall submit any state plan amendments, new waiver requests, or requests for extensions or expansions for existing waivers, needed to implement the managed care program by August 1, 2011.~~

Section 2. Effective July 1, 2018, section 409.965, Florida Statutes, is amended to read:

409.965 Mandatory enrollment.—All Medicaid recipients shall receive covered services through the statewide managed care program, except as provided by this part pursuant to an approved federal waiver.

(1) The following Medicaid recipients are exempt from participation in the statewide managed care program:

(a) ~~(1)~~ Women who are eligible only for family planning services.

(b) ~~(2)~~ Women who are eligible only for breast and cervical cancer services.

(c) ~~(3)~~ Persons who are eligible for emergency Medicaid for aliens.

(2) Persons who are assigned into level of care 1 under s.

Page 2 of 6

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

22-00989F-17

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409.983(4) and have resided in a nursing facility for 60 or more consecutive days are exempt from participation in the long-term care managed care program. For a person who becomes exempt under this subsection while enrolled in the long-term care managed care program, the exemption shall take effect on the first day of the first month after the person meets the criteria for the exemption. Nothing in this subsection shall affect a person's eligibility for the Medicaid managed medical assistance program.

(3) Persons receiving hospice care while residing in a nursing facility are exempt from participation in the long-term care managed care program. For a person who becomes exempt under this subsection while enrolled in the long-term care managed care program, the exemption shall take effect on the first day of the first month after the person meets the criteria for the exemption. Nothing in this subsection shall affect a person's eligibility for the Medicaid managed medical assistance program.

(4) Notwithstanding subsections (2) and (3):

(a) The agency shall authorize a Medicaid recipient who is otherwise eligible for the long-term care managed care program, who is 18 years of age or older, and who is eligible for Medicaid by reason of a disability to enroll or remain enrolled in the long-term care managed care program under s. 409.979.

(b) The agency shall authorize a long-term care managed care program enrollee to remain enrolled in the program if the enrollee is residing in a nursing home for the purpose of rehabilitation and has been identified by the nursing home and the enrollee's case manager as a candidate for home and community-based services following rehabilitation.

Section 3. Paragraph (j) of subsection (2) of section

22-00989F-17

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409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(j) *Prompt payment.*—Managed care plans shall comply with ss. 641.315, 641.3155, and 641.513, and the agency shall impose fines, and may impose other sanctions, on a plan that willfully fails to comply with those sections or s. 409.982(5).

Section 4. Subsection (1) of section 409.979, Florida Statutes, is amended to read:

409.979 Eligibility.—

(1) PREREQUISITE CRITERIA FOR ELIGIBILITY.—Medicaid recipients who are not exempt under s. 409.965 and meet all of the following criteria are eligible to receive long-term care services and must receive long-term care services by participating in the long-term care managed care program. The recipient must be:

(a) Sixty-five years of age or older, or age 18 or older and eligible for Medicaid by reason of a disability.

(b) Determined by the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) preadmission screening program to require nursing facility care as defined in s. 409.985(3).

Section 5. Subsections (1) and (2) of section 409.982, Florida Statutes, are amended to read:

409.982 Long-term care managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers

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participating in the long-term care managed care program must comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans may limit the providers in their networks based on credentials, quality indicators, and price. For the first 12 months of any contract period following a procurement for the long-term care managed care program under s. 409.981 between October 1, 2013, and September 30, 2014, each selected plan must offer a network contract to all nursing homes that meet the recredentialing requirements and hospices that meet the credentialing requirements specified in the plan's contract with the agency ~~the following providers~~ in the region or regions for which the plan is awarded a contract.†

~~(a) Nursing homes.~~

~~(b) Hospices.~~

~~(c) Aging network service providers that have previously participated in home and community-based waivers serving elders or community service programs administered by the Department of Elderly Affairs. During the remainder of the contract period, a~~ After 12 months of active participation in a managed care plan's network, the plan may exclude any of the providers named in this subsection from the plan's network for failure to meet quality or performance criteria. If a ~~the~~ plan excludes a provider from its network the plan, the plan must provide written notice to all recipients who have chosen that provider for care. The notice must be provided at least 30 days before the effective date of the exclusion. The agency shall establish contract provisions governing the transfer of recipients from excluded residential providers. The agency shall require a plan that

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excludes a provider from its network or that fails to renew the plan's contract with a provider under this subsection to report to the agency the quality or performance criteria the plan used in deciding to exclude the provider and to demonstrate how the provider failed to meet the plan's criteria.

(2) SELECT PROVIDER PARTICIPATION.—Except as provided in this subsection, providers may limit the managed care plans they join. Nursing homes and hospices that are enrolled Medicaid providers must participate in all eligible plans selected by the agency in the region in which the provider is located, with the exception of plans from which the provider has been excluded under subsection (1).

Section 6. Except as otherwise provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2017.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR KELLI STARGEL
22nd District

COMMITTEES:

Appropriations Subcommittee on Finance and Tax,
Chair
Appropriations Subcommittee on Health and
Human Services, *Vice Chair*
Appropriations
Children, Families, and Elder Affairs
Communications, Energy, and Public Utilities
Military and Veterans Affairs, Space, and Domestic
Security

February 17, 2017

The Honorable Dana Young
Senate Health Policy Committee, Chair
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399

Dear Chair Young:

I respectfully request that SB 682, related to *Medicaid Managed Care*, be placed on the committee agenda at your earliest convenience.

Thank you for your consideration and please do not hesitate to contact me should you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Kelli Stargel". The signature is fluid and cursive, with a large loop at the end.

Kelli Stargel
State Senator, District 22

Cc: Sandra Stovall/ Staff Director
Celia Georgiades/ AA

REPLY TO:

- ☐ 2033 East Edgewood Drive, Suite 1, Lakeland, Florida 33803
- ☐ 322 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5022

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)

3/27/2017
Meeting Date

682
Bill Number (if applicable)

Topic Senate Bill 682 - Medicaid Managed Care

Amendment Barcode (if applicable)

Name Julie Ann Kemman

Job Title CEO

Address 4007 Baldwin Dr
Street

Phone (561) 262-7534

Sebastian FL 32976
City State Zip

Email jkemman@hcpcsconsulting.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Nursing Homes

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)

3/27

Meeting Date

682

Bill Number (if applicable)

Topic Medicaid Managed Care

Amendment Barcode (if applicable)

Name Tom Parker

Job Title Director of Reimbursement

Address 307 W. Park Ave, Ste 100 Phone 850-224-3907
Street

Tallahassee FL 32301 Email tparker@fhca.org
City State Zip

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Health Care Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/27/17
Meeting Date

SB 682
Bill Number (if applicable)

Topic Managed Care

Amendment Barcode (if applicable)

Name Deborah Franklin

Job Title Sr. Director of Quality

Address 307 W Park Ave

Phone 813 679 7533

Street
City Tallahassee, FL State FL Zip 32302

Email dfranklin@fhca.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Health Care Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

W/P

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/27/17

Meeting Date

SB 682

Bill Number (if applicable)

20496

Amendment Barcode (if applicable)

Topic Managed Care - Amendment

Name Deborah Franklin

Job Title Sr. Director of Quality

Address 307 W Park Ave

Street

Tallahassee, FL

City

State

Zip

Phone 8136797533

Email dfranklin@fhca.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Health Care Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3-27-17

Meeting Date

682

Bill Number (if applicable)

Topic Medicaid - LTC

Amendment Barcode (if applicable)

Name Audrey Brown

Job Title President + CEO

Address 200 W. College Ave.
Street

Phone (850) 386-2904

Tallahassee, FL 32301
City State Zip

Email audrey@fahp.net

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Association of Health Plans

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)

3/27/17

Meeting Date

682

Bill Number (if applicable)

Topic Long Term Care - Medicaid

Amendment Barcode (if applicable)

Name Tammy Perdue

Job Title Sr. VP of Gov't. Affairs

Address 301 S. Bronough St #500

Phone 850-483-8085

Tallahassee

FL

32301

Email tamela.i.perdue@centene.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Sunshine Health

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/27/17

Meeting Date

SB 682

Bill Number (if applicable)

Topic

Medicaid Managed Care

Amendment Barcode (if applicable)

Name

Patti Spears

Job Title

Nursing Home Administrator - Oakbrook Health & Rehabilitation Center

Address

250 Broward Ave

Phone

863-675-1440

Street

LaBelle

FL

33935

Email

pspears@gchc.com

City

State

Zip

Speaking:

☒

For

☐

Against

☐

Information

Waive Speaking:

☐

In Support

☐

Against

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

Representing

Residents of Oakbrook Health & Rehabilitation Center

Appearing at request of Chair:

☐

Yes

☒

No

Lobbyist registered with Legislature:

☐

Yes

☒

No

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

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

S-001 (10/14/14)

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 694

INTRODUCER: Health Policy Committee; and Senators Hutson and Passidomo

SUBJECT: Consolidation of Medicaid Waiver Programs

DATE: March 28, 2017

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. Lloyd	Stovall	HP	Fav/CS
2. _____	_____	AHS	_____
3. _____	_____	AP	_____
4. _____	_____	RC	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Technical Changes

I. Summary:

CS/SB 694 consolidates three Medicaid waivers and provides for a January 1, 2018, deadline for eligible waiver participants to transition to the Statewide Medicaid Managed Care (SMMC) Long-Term Care (LTC) program. The bill also terminates the Medication Therapy Management program.

The Agency for Health Care Administration (AHCA) is directed to seek federal approval to terminate the waivers after all Medicaid eligible participants have transitioned to the SMMC-LTC program. The bill updates eligibility requirements for the LTC component of the SMMC and conforms cross-references to changes made in CS/SB 694.

The bill has no fiscal impact on state government.

The effective date of the bill is July 1, 2017.

II. Present Situation:

Florida Medicaid

The Medicaid program is a partnership between the federal and state governments to provide medical care to low income children and disabled persons. Each state operates its own Medicaid

program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid serves as the safety net to Florida's healthcare delivery system. Medicaid currently is the second largest expenditure in Florida's budget behind education.

Over 4 million Floridians are currently enrolled in Medicaid accounting for 20 percent of Florida's population and estimated expenditures for the state fiscal year 2016-2017 of \$25.8 billion.¹ Florida has the fourth largest Medicaid population in the country.²

Medicaid currently covers:

- 47 percent of Florida's children;
- 63 percent of Florida's births;
- 61 percent of Florida's nursing homes days; and
- 1.7 million adults, - parents, aged, and disabled.³

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. Minimum eligibility coverage thresholds are established in federal law for certain population groups, such as children, as well as minimum benefits and maximum cost sharing.

However, Florida Medicaid does not cover all low-income Floridians. The maximum income limits for programs are illustrated below as a percentage of the federal poverty level (FPL).

Florida's Current Medicaid and CHIP Eligibility Levels in Florida⁴ (With Income Disregards and Modified Adjusted Gross Income)						
Children's Medicaid			CHIP (Kidcare)	Pregnant Women	Parents	Childless Adults
Age 0-1	Age 1-5	Age 6-18	Ages 0-18			
206% FPL	140% FPL	133% FPL	210% FPL	191% FPL	31% FPL	0% FPL

Florida Medicaid is administered by the AHCA and is financed with federal and state funds. The Department of Children and Families (DCF) determines Medicaid eligibility and transmits that

¹Agency for Health Care Administration, Senate Health and Human Services Appropriations Committee Presentation, *Agency for Health Care Administration - Florida Medicaid* (January 11, 2017), slide 2, http://www.flsenate.gov/PublishedContent/Committees/2016-2018/AHS/MeetingRecords/MeetingPacket_3554.pdf (last visited Mar. 17, 2017).

²Agency for Health Care Administration, Senate Health and Human Services Appropriations Committee Presentation, *Agency for Health Care Administration - Florida Medicaid* (January 11, 2017), slide 2, http://www.flsenate.gov/PublishedContent/Committees/2016-2018/AHS/MeetingRecords/MeetingPacket_3554.pdf (last visited Mar. 17, 2017).

³ Id at 10.

⁴ U.S. Centers for Medicare and Medicaid Services, Medicaid.gov, *Florida*, <http://www.medicaid.gov/medicaid-chip-program-information/by-state/florida.html> (last visited Mar. 17, 2017).

information to the AHCA. As the single state agency, the AHCA has the lead responsibility for the overall program.⁵

The structures of state Medicaid programs vary from state to state, and each state's share of expenditures also varies and is largely determined by the federal government. Federal law and regulations set the minimum amount, scope, and duration of services offered in the program, among other requirements. State Medicaid benefits are provided in statute under s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons).

Waivers to the state plan may be requested and negotiated by the state through the federal CMS by the AHCA. Florida has several such Medicaid waivers, including those which implemented the SMMC program. Current federal law requires the state to obtain a waiver to implement managed care. Through these waivers, the states have limited flexibility to design their Medicaid programs; however, even within waiver authorities, federal regulations prescribe requirements for benefits, delivery systems, cost sharing limitations, and population coverages. States may also seek federal waivers to expand populations or services.

Statewide Medicaid Managed Care (SMMC)

The SMMC has two components: Managed medical assistance (MMA) and long-term care managed care (LTC). The current MMA waiver expires on June 30, 2017, and the existing LTC waiver was recently extended through December 27, 2021.⁶ Florida's LTC program serves elderly and disabled individuals who require long-term nursing facility level of care.

Part IV of ch. 409, F.S., was created in 2011 by ch. 2011-134, Laws of Fla., and governs the SMMC program. The LTC component began enrolling recipients in August 2013, and completed its statewide rollout in March 2014. The MMA component began enrolling Medicaid recipients in May 2014, and finished its rollout in August 2014.

The LTC program provides services in two settings: nursing facilities or home and community based services (HCBS) such as a recipient's home, an assisted living facility, or an adult family care home. Nursing facility services are an entitlement program for eligible enrollees and no waitlist exists; however, HCBS are delivered through waivers and are dependent on the availability of annual funding in the General Appropriations Act (GAA).

Of those recipients enrolled in the LTC waiver, more than half or 47,465 recipients are receiving HCBS as of February 1, 2017. The remaining enrollees are receiving nursing facility services.⁷

⁵ See s. 409.963, F.S.

⁶ The current Managed Medical Assistance waiver is approved as an 1115 waiver and was last approved for the time period of July 31, 2014 through June 30, 2017. The Long-Term Care Managed Care waiver is approved as a section 1915(b) and section 1915(c) combination waiver and was most recently approved through December 27, 2021, by the federal Centers for Medicare and Medicaid Services.

⁷ Agency for Health Care Administration, *Senate Bill Analysis 682* (Feb. 13, 2017), pg. 2, (on file with the Senate Committee on Health Policy).

Statewide Medicaid Managed Care - February 1, 2017			
Component	Enrollment Start Date	Budget ⁸	Enrollment ⁹ (as of Feb. 2017)
Long-Term Care Plan	August 2013	\$3.97 billion	94,844
Home & Community Based Services			47,465 ¹⁰
Managed Medical Assistance	May 2014	\$14.4 billion	3,237,296

Services for LTC program enrollees are delivered through six managed care plans, which vary based on the recipient's region; however, each region has at least two plans. Plans are paid on a capitated basis meaning that a LTC plan must pay for all covered services under the contract regardless of whether the capitated rate covers the full cost of services for that recipient.

Enrollment in the HCBS portion of LTC is managed based on a priority system and wait list. For the 2016-2017 waiver year, the state is approved for 62,500 unduplicated recipients in the HCBS portion of the program.¹¹

Eligibility and Enrollment

The AHCA is the single state agency for Medicaid; however, through an interagency agreement with the Department of Elder Affairs (DOEA), the DOEA is Florida's federally mandated pre-admission screening program for nursing home applicants through its Long-Term Care Services (CARES) program, including for LTC services.¹² The CARES program has 18 field offices across the state, which are staffed with physicians, nurses, and other health care professionals who evaluate the level of care an individual may or may not need for waiver services. To receive long-term care services, an individual must be both financially eligible under Medicaid and be determined clinically eligible under the CARES program. The frailty-based assessment results in a priority score for an individual, who is then placed on the wait list based on his or her priority score if funding is not available.

The Legislature has specifically directed funding in the past several years through the GAA to serve elders off the waitlist who have a priority score of 4 or higher.¹³ Individuals who are more frail or have a more immediate need for services receive a higher rank on the waitlist. Those who have resided in a nursing facility for more than 60 days receive priority enrollment into the

⁸ Agency for Health Care Administration, *Statewide Medicaid Managed Care (Presentation to House Health and Human Services Committee - Jan. 10, 2017)*, slide 2,

http://ahca.myflorida.com/medicaid/recent_presentations/House_Health_Human_Services_Med_101_2017-01-10.pdf (last visited Mar. 1, 2017).

⁹ Agency for Health Care Administration, *SMMC MMA Enrollment by County by Plan* (as of February 1, 2017), http://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Mar. 1, 2017).

¹⁰ *Supra* note 10.

¹¹ Letter from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services to Beth Kidder, Interim Deputy Secretary for Medicaid, Agency for Health Care Administration (Dec. 19, 2016), *available at* http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/LTC_Approval_Letter_2016-12-19.pdf (last visited Mar. 1, 2017).

¹² Florida Dep't of Elder Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, <http://elderaffairs.state.fl.us/doea/cares.php> (last visited Mar. 1, 2017).

¹³ See Ch. Law 2016-66, line item 232; Ch. Law 2015-232, line item 226; and Ch. Law 2014-51, line item 242. In state fiscal year 2013-14, GAA provided funding during the first year of the LTC program for those on the wait list with priority scores of 5 or higher. (Ch. Law 2013-40, line item 414).

HCBS portion of the program. Other exemptions from the waitlist exist under s. 409.979(3)(f), F.S.

Before being released from the waitlist; however, individuals must meet the following eligibility requirements to enroll in the program:¹⁴

- Be age 65 years or older or age 18 and eligible for Medicaid by reason of a disability; and
- Be determined by the CARES preadmission screening program to require nursing facility care as defined in s. 409.985(3), F.S.

Individuals, both those who are enrolled in LTC and those on the wait list, must be re-screened at least annually or whenever there is a significant change in circumstances, such as change in caregivers or medical condition.¹⁵

Voluntary Enrollment in LTC Managed Care

Some individuals who are enrolled in waiver programs or other coverages may enroll in the LTC program, but are not required to, and those are:

- Developmental Disabilities waiver program;
- Traumatic Brain and Spinal Cord Injury waiver;
- Project AIDS Care (PAC) waiver;
- Adult Cystic Fibrosis waiver;
- Program of All-Inclusive Care for the Elderly (PACE);
- Familial Dysautonomia waiver;
- Model waiver; or
- Other creditable coverage excluding Medicare.¹⁶

Prior to the implementation of SMMC, at least 14 different waivers provided HCBS to these same groups of beneficiaries, in both the voluntary and mandatory enrollment groups, at a cost of \$1.47 billion to state agencies in the state fiscal year 2012-2013.¹⁷

Adult Cystic Fibrosis Waiver

The AHCA administers and the Department of Health (DOH) operates the waiver for individuals with a diagnosis of cystic fibrosis, a chronic, progressive, and terminal genetic disorder that affects a person's lungs and digestive system.¹⁸ To be eligible for the waiver, an individual must:

- Be 18 years of age or older;
- Be Medicaid eligible;
- Have a cystic fibrosis diagnosis; and

¹⁴ See s. 409.979, F.S.

¹⁵ Application for §1915(c) Home and Community-Based Services Waiver (Effective July 1, 2013), pp. 45-46, http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/LTC_1915c_Application.pdf (last visited Mar. 1, 2017).

¹⁶ See s. 409.972, F.S.

¹⁷ Office of Program Policy Analysis and Government Accountability, *Profile of Florida's Medicaid Home and Community-Based Services Waivers*, Report No. 13-07, March 2013, <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1307rpt.pdf> (last viewed Mar. 20, 2017).

¹⁸ *Id.*

- Meet inpatient hospital level of care.¹⁹

The waiver includes services such as case management, counseling, skilled nursing, prescribed drugs, respite care, therapies, dental, meal delivery, and specialized medical equipment.²⁰

There are approximately 140 people enrolled in this waiver.²¹

Project AIDS Care (PAC) Waiver

Preventing or delaying the institutionalizing through the promotion, maintenance, and optimization of the health of persons living with AIDS is the goal of the Project AIDS Care waiver. The waiver provides HCBS services to Medicaid eligible persons with a documented diagnosis of AIDS that choose to live at home or in the community.²²

The PAC Waiver provides services to recipients who:

- Are Medicaid eligible;
- Have an income of no more than 300 percent of the Social Security Income Federal Benefits Rate (approximately 222 percent of the federal poverty level);
- Have a diagnosis of Acquired Immune Deficiency Syndrome (AIDS);
- Have an AIDS-related opportunistic infection;
- Have been determined disabled by the Social Security Administration;
- Are not enrolled in a Medicaid managed care plan; and
- Meet hospital or nursing facility level of care.²³

The recipients enrolled in the PAC waiver are primarily receiving case management services while service utilization remains low due to the advances made over the past decade. The waiver facilitates coverage for Medicaid for those who might not otherwise have access. Some of the other services that are covered are chore services, home delivered meals, personal care, skilled nursing, specialized equipment and supplies, day health, and restorative massage.²⁴

Currently, approximately 7,800 people are enrolled in the PAC waiver.²⁵

Traumatic Brain and Spinal Cord Injury Waiver

The DOH operates the TBI/SCI waiver which provides services for individuals with traumatic brain injuries and spinal cord injuries. To be eligible for the waiver, an individual must:

- Be 18 year of age or older;

¹⁹ *Id.*

²⁰ Agency for Health Care Administration, *Adult Cystic Fibrosis Waiver Services - Procedures Codes and Fee Schedule - October 2013*,

http://ahca.myflorida.com/medicaid/review/Reimbursement/2013_10_31_Adult_Cystic_Fibrosis_FS_Adoption.pdf (last viewed Mar. 17, 2017).

²¹ Agency for Health Care Administration, *Senate Bill 694 Analysis*, p. 4, (March 7, 2017) (on file with the Senate Committee on Health Policy).

²² Agency for Health Care Administration, *Project AIDS Care Waiver Services Coverage and Limitations Handbook* (July 2003) http://ahca.myflorida.com/medicaid/review/Specific/CL_06_051201_Waiver_PAC_ver1_1.pdf (last visited Mar. 20, 2017).

²³ *Supra* note 21.

²⁴ *Supra* note 24.

²⁵ *Supra* note 25, at 3.

- Be Medicaid eligible;
- Have one of the following injuries:
 - traumatic brain injury, defined as an insult to the skull, brain, or its covering from external trauma, which produces an altered state of consciousness or anatomic, motor, or sensory, or cognitive/behavioral deficits; or
 - spinal cord injury, defined as a lesion to the spinal cord or cauda equine resulting from external trauma with evidence of significant involvement of two of the following: motor deficit, sensory deficit, or bowel or bladder dysfunction;
- Meet nursing home level of care;
- Be referred to the state's Brain and Spinal Cord Injury Program's central registry in accordance with s. 381.75, F.S.²⁶

Individuals enrolled in the waiver receive services and supports such as assistive technology, attendant care, counseling, life skills training, medical supplies, personal care, behavioral programming, and adaptive health and wellness.²⁷

The TBI/SCI population is already eligible for enrollment in the LTC program as a voluntary population. Currently, approximately, 300 people are enrolled in the TBI/SCI Waiver with an additional 350 on the waitlist.²⁸

Medication Therapy Management (MTM) Program

The AHCA is statutorily required to operate the prescription drug management program known as the Medicaid Therapy Management (MTM) program.²⁹ The goals of the MTM program are:

- Improve the quality of care and prescribing practices based on best-practice guidelines;
- Improve patient adherence to medication plans;
- Reduce clinical risk; and
- Lower prescribed drug costs and the rate of inappropriate spending for certain Medicaid prescription drugs.³⁰

The AHCA contracts with the University of Florida to conduct the comprehensive prescribed drug case management, if the Medicaid recipient chooses to participate. Trained pharmacists help resolve medication-related and health-related problems, optimize medication use for improved patient outcomes, and promote patient self-management of medication.³¹ The center notifies prescribers of potential issues or problems via phone or fax, depending on the urgency of the issue. MTM services to patients are mostly provided via telephone.³²

²⁶ *Supra* note 21, at 11.

²⁷ *Id.*

²⁸ *Supra* note 25, at 3.

²⁹ Section 409.912(8)(a)11, F.S.

³⁰ Agency for Health Care Administration, *1115 MEDS-AD Waiver - Post Award Forum* (April 21, 2016), slide 6, http://ahca.myflorida.com/medicaid/MEDS-AD/post_award_forum_2016-04-21.shtml (last visited Mar. 20, 2016).

³¹ Fla. Office of Attorney General and Agency for Health Care Admin., *The State's Efforts to Control Medicaid Fraud and Abuse* (FY 2015-16), p. 20, http://ahca.myflorida.com/Executive/Inspector_General/docs/Medicaid_Fraud_Abuse_Annual_Reports/2015-16_MedicaidFraudandAbuseAnnualReport.pdf (last visited Mar. 20, 2017).

³² University of Florida, *University of Florida Medicaid Management Center* <http://mmc.pharmacy.ufl.edu/services/mtm/> (last visited Mar. 20, 2017).

The MTM program provides services for up to 150 program recipients enrolled in the MEDS-AD program and not in a Medicaid managed care plan.

The MEDS-AD program is approved through a federal 1115 Demonstration grant waiver and provides coverage for certain aged and disabled individuals with incomes up to 88 percent of the federal poverty level and have assets of less than \$5,000 for individual or \$6,000 for couples. Quoting from the Special Terms and Conditions letter from the federal CMS in 2015, which extended the grant at that time through December 31, 2015: “The Demonstration was predicated on the assumption that continued access to medical care, including HCBS services and pharmacy management services, would delay deterioration in health status which drives hospitalization and/or institutionalization.”³³

Delivery System and Benefits

The AHCA conducted a competitive procurement to select LTC plans in each of the 11 regions in 2012. Contracts were awarded to health maintenance organizations (HMOs) and provider service networks (PSNs). Six non-specialty plans are currently contracted, including one PSN that is available in all 11 regions and one HMO that is in 10 regions. Recipients receive choice counseling services to assist them in selecting the plan that will best meet their needs.

Each plan under LTC is required to provide a minimum level of services. These required services include:

- Adult companion care;
- Adult day health care;
- Assisted living;
- Assistive care services;
- Attendant care;
- Behavioral management;
- Care coordination and case management;
- Caregiver training;
- Home accessibility training;
- Home-delivered meals;
- Homemaker;
- Hospice;
- Intermittent and skilled nursing;
- Medical equipment and supplies;
- Medication administration;
- Medicaid management;
- Nursing facility;
- Nutritional assessment/risk reduction;
- Personal care;
- Personal emergency response system;

³³ *Special Terms and Conditions - Florida MEDS-AD section 1115(a) Medicaid Demonstration extension (Jan. 1, 2015 - December 31, 2015)* http://ahca.myflorida.com/medicaid/MEDS-AD/docs/Special_Terms_and_Conditions.pdf, (last visited Mar. 20, 2017).

- Respite care;
- Therapies; and
- Non-emergency transportation.³⁴

A LTC plan may elect to offer expanded benefits to its enrollees. Some of the approved expanded benefits within LTC include:

- Cellular phone service;
- Dental services;
- Emergency financial assistance;
- Hearing evaluation;
- Mobile personal emergency response system;
- Non-medical transportation;
- Over-the-counter medication and supplies;
- Support to transition out of a nursing facility;
- Vision services; and
- Wellness grocery discount.³⁵

The LTC enrollees who are not eligible for Medicare also receive their medical services through an MMA plan. Some plans participate in both components in the same regions, and a recipient may choose the same managed care plan for both components, known as a comprehensive plan.

III. Effect of Proposed Changes:

Section 1 amends s. 409.904, F.S., relating to optional eligibility groups for Medicaid to add those individuals who have been diagnosed with Acquired Immune Deficiency Syndrome (AIDS), who have an AIDS-related opportunistic infection, who are at risk of hospitalization, as determined by the AHCA or its designee, and whose incomes are at or below 300 percent of the federal benefit rate (approximately 222 percent of the federal poverty level). Currently, to be eligible for Medicaid, an individual would need to meet one of the other eligibility categories such as being determined disabled or elderly with an income at or below 88 percent of the federal poverty level.

CS/SB 694 would transition approximately 7,800 of the existing enrollees from the waiver program if they meet nursing facility level of care into the Statewide Medicaid Managed Care LTC program. If the participant does not meet the nursing facility level of care, the participant would still receive his or her medical care services through the Managed Medical Assistance plan.

Section 2 removes obsolete language under s. 409.906, F.S., relating to services that are optional under the Medicaid program.

³⁴ See s. 409.98, F.S.

³⁵ Agency for Health Care Administration, MMA - Model Contract - Attachment I - Scope of Services (Effective date Feb. 1, 2017) pp. 4-6, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2017-02-01/02-01-17_MODEL_Attachment_I-Scope_of_Services.pdf (last visited Mar. 20, 2017).

Section 3 amends s. 409.912, F.S., relating to the cost-effective purchasing of health care to repeal the MTM Program. The bill removes all requirements for the AHCA to implement and maintain the MTM program.

The MTM program is available only to Medicaid recipients who are not enrolled in a Medicaid managed care plan. The program currently has 50 enrollees that would be impacted by the termination of the program and has a program capacity for 250 participants.

Section 4 amends s. 409.979, F.S., relating to eligibility for the Long-Term Care Managed Care program. The bill amends the criteria for eligibility to add alternative language for cystic fibrosis participants. CS/SB 694 recognizes that for cystic fibrosis, the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARE) preadmission screening services, standard for needed level of care is hospital-level, not nursing facility care.

The bill further amends this section to authorize enrollees in the following waivers to participate in the LTC managed care program when all of the eligibility criteria have been met and they shall be transitioned by January 1, 2018:

- Traumatic Brain and Spinal Cord Injury Waiver;
- Adult Cystic Fibrosis Waiver; and
- Project AIDS Care Waiver.

The AHCA is directed to seek federal approval to terminate these same waivers after all eligible Medicaid recipients have transitioned into the LTC managed care program.

Section 5 amends s. 393.0661, F.S., relating to home and community based services delivery systems for persons with developmental disabilities to conform cross references based on changes in this bill.

Section 6 amends s. 409.968, F.S., relating to managed care plan payments to conform a cross reference to changes contained in this bill.

Section 7 provides an effective date of July 1, 2017.

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:

Eligible participants in the waiver programs will be transitioned to the LTC managed care plans by January 1, 2018. This transition may impact which providers these participants access in the community from individual physicians to different health care facilities depending on which managed care plan the participant selects during the choice counseling process. While this is a small number of participants to roll into Medicaid from a statewide perspective, it could have an impact on certain doctors or facilities in smaller communities.

The participants in these waivers are also among some of the highest utilizers of health care services, and the most fragile. Depending on where these participants reside and if they congregate in one or two specific plans, it could have a financial effect on those select managed care plans.

C. Government Sector Impact:

If the former waiver enrollees select the same one or two plans, there may be an impact on the overall rates that cannot be offset by the rest of the plan's enrollment. This effect would have an impact on the state and the rates paid to the MMA and LTC plans in the future.

Secondly, the Medication Therapy Management program is a project of the University of Florida. The call center is staffed by 4th year student pharmacists and overseen by college faculty as an experiential practice site.³⁶ While Florida Medicaid is not the call center's only client, elimination of this program would have a financial and educational impact to the call center.

The AHCA believes this activity was duplicative of other efforts at the state level as participants in the MMA plans received these services through their managed care plans. For those enrolled in fee-for-service Medicaid, the AHCA noted that it was difficult to identify willing participants since the program was voluntary. With such a small pool, the AHCA reported that evaluation results were also unreliable.³⁷

The DOH would be relieved of oversight of two waivers: Adult Cystic Fibrosis Waiver and Traumatic Brain and Spinal Cord Injury Waiver. The AHCA would be gaining oversight of these participants as they would be transitioned into the SMMC program. Compared to the overall size of the Medicaid program, the numbers are small for the

³⁶ University of Florida, *Medication Management Center* <http://mmc.pharmacy.ufl.edu/> (last visited Mar. 20, 2017).

³⁷ Agency for Health Care Administration, *Senate Bill 694 Analysis* (Feb. 7, 2017) (on file with the Senate Committee on Health Policy).

enrollees in these waivers and the AHCA will be able to transition these members when appropriate. The DOH will have two fewer programs to administer.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The AHCA uses the MTM program to satisfy its research and demonstration component under the state's 1115 MEDS-AD waiver, a federal requirement. If this change is adopted and the MTM program is eliminated, the AHCA will need to identify other mechanisms to ensure that this requirement is met and that the MEDS-AD population continues to have access to services.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.904, 409.906, 409.912, 409.979, 393.0661, and 409.968.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

The CS amended the title to more accurately reflect the contents of the bill.

- B. **Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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The Committee on Health Policy (Hutson) recommended the following:

Senate Amendment

In title, delete line 2
and insert:
An act relating to consolidation of Medicaid waiver
programs; amending s. 409.904,

By Senator Hutson

7-00482A-17

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A bill to be entitled

An act relating to Medicaid; amending s. 409.904, F.S.; authorizing any state agency or department involved in providing health, social, or human services to make payments for medical assistance for certain persons diagnosed with Acquired Immune Deficiency Syndrome (AIDS); amending s. 409.906, F.S.; removing the Agency for Health Care Administration's ability to consolidate certain home and community-based services; amending s. 409.912, F.S.; deleting the requirement that the agency implement a Medicaid prescription drug management system; amending s. 409.979, F.S.; requiring that Medicaid recipients enrolled in certain home and community-based service Medicaid waivers be transitioned into the long-term care managed care program by January 1, 2018; requiring the agency to seek federal approval to terminate certain waiver programs once all eligible Medicaid recipients have transitioned into the long-term care managed care program; amending ss. 393.0661 and 409.968, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Subsection (11) is added to section 409.904, Florida Statutes, to read:

409.904 Optional payments for eligible persons.—The agency may make payments for medical assistance and related services on behalf of the following persons who are determined to be eligible subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on

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behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(11) Subject to federal waiver approval, a person diagnosed with Acquired Immune Deficiency Syndrome (AIDS), who has an AIDS-related opportunistic infection, who is at risk of hospitalization as determined by the agency or its designee, and whose income is at, or below, 300 percent of the federal benefit rate.

Section 2. Paragraph (b) of subsection (13) of section 409.906, Florida Statutes, is amended to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor

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may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(13) HOME AND COMMUNITY-BASED SERVICES.—

~~(b) The agency may consolidate types of services offered in the Aged and Disabled Waiver, the Channeling Waiver, the Project AIDS Care Waiver, and the Traumatic Brain and Spinal Cord Injury Waiver programs in order to group similar services under a single service, or continue a service upon evidence of the need for including a particular service type in a particular waiver. The agency is authorized to seek a Medicaid state plan amendment or federal waiver approval to implement this policy.~~

Section 3. Paragraph (a) of subsection (8) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies,

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including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based

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on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(8)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The

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agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

3. The agency shall develop and implement a process for

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178 managing the drug therapies of Medicaid recipients who are using
 179 significant numbers of prescribed drugs each month. The
 180 management process may include, but is not limited to,
 181 comprehensive, physician-directed medical-record reviews, claims
 182 analyses, and case evaluations to determine the medical
 183 necessity and appropriateness of a patient's treatment plan and
 184 drug therapies. The agency may contract with a private
 185 organization to provide drug-program-management services. The
 186 Medicaid drug benefit management program shall include
 187 initiatives to manage drug therapies for HIV/AIDS patients,
 188 patients using 20 or more unique prescriptions in a 180-day
 189 period, and the top 1,000 patients in annual spending. The
 190 agency shall enroll any Medicaid recipient in the drug benefit
 191 management program if he or she meets the specifications of this
 192 provision and is not enrolled in a Medicaid health maintenance
 193 organization.

194 4. The agency may limit the size of its pharmacy network
 195 based on need, competitive bidding, price negotiations,
 196 credentialing, or similar criteria. The agency shall give
 197 special consideration to rural areas in determining the size and
 198 location of pharmacies included in the Medicaid pharmacy
 199 network. A pharmacy credentialing process may include criteria
 200 such as a pharmacy's full-service status, location, size,
 201 patient educational programs, patient consultation, disease
 202 management services, and other characteristics. The agency may
 203 impose a moratorium on Medicaid pharmacy enrollment if it is
 204 determined that it has a sufficient number of Medicaid-
 205 participating providers. The agency must allow dispensing
 206 practitioners to participate as a part of the Medicaid pharmacy

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207 network regardless of the practitioner's proximity to any other
 208 entity that is dispensing prescription drugs under the Medicaid
 209 program. A dispensing practitioner must meet all credentialing
 210 requirements applicable to his or her practice, as determined by
 211 the agency.

212 5. The agency shall develop and implement a program that
 213 requires Medicaid practitioners who prescribe drugs to use a
 214 counterfeit-proof prescription pad for Medicaid prescriptions.
 215 The agency shall require the use of standardized counterfeit-
 216 proof prescription pads by Medicaid-participating prescribers or
 217 prescribers who write prescriptions for Medicaid recipients. The
 218 agency may implement the program in targeted geographic areas or
 219 statewide.

220 6. The agency may enter into arrangements that require
 221 manufacturers of generic drugs prescribed to Medicaid recipients
 222 to provide rebates of at least 15.1 percent of the average
 223 manufacturer price for the manufacturer's generic products.
 224 These arrangements shall require that if a generic-drug
 225 manufacturer pays federal rebates for Medicaid-reimbursed drugs
 226 at a level below 15.1 percent, the manufacturer must provide a
 227 supplemental rebate to the state in an amount necessary to
 228 achieve a 15.1-percent rebate level.

229 7. The agency may establish a preferred drug list as
 230 described in this subsection, and, pursuant to the establishment
 231 of such preferred drug list, negotiate supplemental rebates from
 232 manufacturers that are in addition to those required by Title
 233 XIX of the Social Security Act and at no less than 14 percent of
 234 the average manufacturer price as defined in 42 U.S.C. s. 1936
 235 on the last day of a quarter unless the federal or supplemental

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rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of

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the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

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294 (III) Assess Medicaid beneficiaries who are outliers in
 295 their use of behavioral health drugs with regard to the numbers
 296 and types of drugs taken, drug dosages, combination drug
 297 therapies, and other indicators of improper use of behavioral
 298 health drugs.

299 (IV) Alert prescribers to patients who fail to refill
 300 prescriptions in a timely fashion, are prescribed multiple same-
 301 class behavioral health drugs, and may have other potential
 302 medication problems.

303 (V) Track spending trends for behavioral health drugs and
 304 deviation from best practice guidelines.

305 (VI) Use educational and technological approaches to
 306 promote best practices, educate consumers, and train prescribers
 307 in the use of practice guidelines.

308 (VII) Disseminate electronic and published materials.

309 (VIII) Hold statewide and regional conferences.

310 (IX) Implement a disease management program with a model
 311 quality-based medication component for severely mentally ill
 312 individuals and emotionally disturbed children who are high
 313 users of care.

314 ~~11. The agency shall implement a Medicaid prescription drug~~
 315 ~~management system.~~

316 ~~a. The agency may contract with a vendor that has~~
 317 ~~experience in operating prescription drug management systems in~~
 318 ~~order to implement this system. Any management system that is~~
 319 ~~implemented in accordance with this subparagraph must rely on~~
 320 ~~cooperation between physicians and pharmacists to determine~~
 321 ~~appropriate practice patterns and clinical guidelines to improve~~
 322 ~~the prescribing, dispensing, and use of drugs in the Medicaid~~

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323 ~~program. The agency may seek federal waivers to implement this~~
 324 ~~program.~~

325 ~~b. The drug management system must be designed to improve~~
 326 ~~the quality of care and prescribing practices based on best~~
 327 ~~practice guidelines, improve patient adherence to medication~~
 328 ~~plans, reduce clinical risk, and lower prescribed drug costs and~~
 329 ~~the rate of inappropriate spending on Medicaid prescription~~
 330 ~~drugs. The program must:~~

331 ~~(I) Provide for the adoption of best practice guidelines~~
 332 ~~for the prescribing and use of drugs in the Medicaid program,~~
 333 ~~including translating best practice guidelines into practice;~~
 334 ~~reviewing prescriber patterns and comparing them to indicators~~
 335 ~~that are based on national standards and practice patterns of~~
 336 ~~clinical peers in their community, statewide, and nationally;~~
 337 ~~and determine deviations from best practice guidelines.~~

338 ~~(II) Implement processes for providing feedback to and~~
 339 ~~educating prescribers using best practice educational materials~~
 340 ~~and peer-to-peer consultation.~~

341 ~~(III) Assess Medicaid recipients who are outliers in their~~
 342 ~~use of a single or multiple prescription drugs with regard to~~
 343 ~~the numbers and types of drugs taken, drug dosages, combination~~
 344 ~~drug therapies, and other indicators of improper use of~~
 345 ~~prescription drugs.~~

346 ~~(IV) Alert prescribers to recipients who fail to refill~~
 347 ~~prescriptions in a timely fashion, are prescribed multiple drugs~~
 348 ~~that may be redundant or contraindicated, or may have other~~
 349 ~~potential medication problems.~~

350 11.12. The agency may contract for drug rebate
 351 administration, including, but not limited to, calculating

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rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

~~12.13.~~ The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

~~13.14.~~ The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

- a. For an indication not approved in labeling;
- b. To comply with certain clinical guidelines; or
- c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

~~14.15.~~ The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may

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preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

~~15.16.~~ The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

- a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;
- b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or
- c. Based on historic evidence and known characteristics of

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the patient and the drug, the drug is likely to be ineffective,
or the number of doses have been ineffective.

The agency shall work with the physician to determine the best
alternative for the patient. The agency may adopt rules waiving
the requirements for written clinical documentation for specific
drugs in limited clinical situations.

~~16.17.~~ The agency shall implement a return and reuse
program for drugs dispensed by pharmacies to institutional
recipients, which includes payment of a \$5 restocking fee for
the implementation and operation of the program. The return and
reuse program shall be implemented electronically and in a
manner that promotes efficiency. The program must permit a
pharmacy to exclude drugs from the program if it is not
practical or cost-effective for the drug to be included and must
provide for the return to inventory of drugs that cannot be
credited or returned in a cost-effective manner. The agency
shall determine if the program has reduced the amount of
Medicaid prescription drugs that which are destroyed on an
annual basis and if there are additional ways to ensure more
prescription drugs are not destroyed which could safely be
reused.

Section 4. Subsections (1) and (2) of section 409.979,
Florida Statutes, are amended to read:

409.979 Eligibility.—

(1) PREREQUISITE CRITERIA FOR ELIGIBILITY.—Medicaid
recipients who meet all of the following criteria are eligible
to receive long-term care services and must receive long-term
care services by participating in the long-term care managed

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care program. The recipient must be:

(a) Sixty-five years of age or older, or age 18 or older
and eligible for Medicaid by reason of a disability.

(b) Determined by the Comprehensive Assessment Review and
Evaluation for Long-Term Care Services (CARES) preadmission
screening program to require nursing facility care as defined in
s. 409.985(3) or, in the case of individuals diagnosed with
cystic fibrosis, determined by the CARES program to require
hospital-level of care.

(2) ENROLLMENT OFFERS.—

(a) Subject to the availability of funds, the Department of
Elderly Affairs shall make offers for enrollment to eligible
individuals based on a wait-list prioritization. Before making
enrollment offers, the agency and the Department of Elderly
Affairs shall determine that sufficient funds exist to support
additional enrollment into plans.

(b) Medicaid recipients enrolled in one of the following
home and community-based service Medicaid waivers are eligible
to participate in the long-term care managed care program when
all eligibility criteria requirements established in paragraph
(1) of this subsection are met and shall be transitioned into
the long-term care managed care program by January 1, 2018:

1. Traumatic Brain and Spinal Cord Injury Waiver.

2. Adult Cystic Fibrosis Waiver.

3. Project AIDS Care Waiver.

The agency shall seek federal approval to terminate the
Traumatic Brain and Spinal Cord Injury Waiver, the Adult Cystic
Fibrosis Waiver, and the Project AIDS Care Waiver after all

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468 eligible Medicaid recipients have transitioned into the long-
 469 term care managed care program.

470 Section 5. Subsection (7) of section 393.0661, Florida
 471 Statutes, is amended to read:

472 393.0661 Home and community-based services delivery system;
 473 comprehensive redesign.—The Legislature finds that the home and
 474 community-based services delivery system for persons with
 475 developmental disabilities and the availability of appropriated
 476 funds are two of the critical elements in making services
 477 available. Therefore, it is the intent of the Legislature that
 478 the Agency for Persons with Disabilities shall develop and
 479 implement a comprehensive redesign of the system.

480 (7) The agency shall collect premiums or cost sharing
 481 pursuant to s. 409.906(13) (c) ~~s. 409.906(13) (d)~~.

482 Section 6. Paragraph (a) of subsection (4) of section
 483 409.968, Florida Statutes, is amended to read:

484 409.968 Managed care plan payments.—

485 (4) (a) Subject to a specific appropriation and federal
 486 approval under s. 409.906(13) (d) ~~s. 409.906(13) (e)~~, the agency
 487 shall establish a payment methodology to fund managed care plans
 488 for flexible services for persons with severe mental illness and
 489 substance use disorders, including, but not limited to,
 490 temporary housing assistance. A managed care plan eligible for
 491 these payments must do all of the following:

492 1. Participate as a specialty plan for severe mental
 493 illness or substance use disorders or participate in counties
 494 designated by the General Appropriations Act;

495 2. Include providers of behavioral health services pursuant
 496 to chapters 394 and 397 in the managed care plan's provider

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497 network; and

498 3. Document a capability to provide housing assistance
 499 through agreements with housing providers, relationships with
 500 local housing coalitions, and other appropriate arrangements.

501 Section 7. This act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: February 22, 2017

I respectfully request that **Senate Bill #694**, relating to Medicaid, be placed on the:

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

A handwritten signature in black ink, appearing to read "Travis J. Hutson".

Senator Travis Hutson
Florida Senate, District 7

THE FLORIDA SENATE

APPEARANCE RECORD

327-17

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

SB 694

Meeting Date

Bill Number (if applicable)

Topic Medicaid

Amendment Barcode (if applicable)

Name David Poole

Job Title Dir. Legislative Affairs

Address 1825 Country Club Dr.

Phone 850-766-3323

Tallahassee FL 32301
City State Zip

Email david.poole@aidhealth
-org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing AIDS Healthcare Foundation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL: SB 916

INTRODUCER: Senator Grimsley

SUBJECT: Statewide Medicaid Managed Care Program

DATE: March 24, 2017

REVISED: _____

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

I. Summary:

SB 916 modifies the Statewide Medicaid Managed Care program (SMMC) and deletes obsolete provisions from the implementation of the program. The bill specifically:

- Deletes the fee-for-service reimbursement option for provider service networks (PSNs);
- Revises the requirements for the contents of the databook used for rate setting to be consistent with actuarial rate-setting practices and standards;
- Collapses regions, re-groups counties within new regions, and revises the plan limitations within the regions for the procurement process for the Medicaid Managed Medical Assistance (MMA) and Long-Term Care (LTC) components; and
- Removes obsolete provisions.

The bill has no fiscal impact on the Agency for Health Care Administration (AHCA); however, the collapse of the regions may have a positive effect on administrative costs and contracting for both the AHCA and on those bidding.

The effective date of the bill is July 1, 2017.

II. Present Situation:

Florida Medicaid

The Medicaid program is a partnership between the federal and state governments to provide medical care to low income children and disabled persons. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare and Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid serves as the safety net to Florida's healthcare delivery system. Medicaid currently is the second largest expenditure in Florida's budget behind education and covers 20 percent of all Floridians, including:

- 47 percent of Florida's children;
- 63 percent of Florida's births; and
- 61 percent of Florida's nursing home days.¹

However, Florida Medicaid does not cover all low-income Floridians. The maximum income limits for programs are illustrated below as a percentage of the federal poverty level (FPL).

Florida's Current Medicaid and CHIP Eligibility Levels in Florida² (With Income Disregards and Modified Adjusted Gross Income)						
Children's Medicaid			CHIP (Kidcare)	Pregnant Women	Parents Caretaker Relatives	Childless Adults
Age 0-1	Age 1-5	Age 6-18	Ages 0-18			
206% FPL	140% FPL	133% FPL	210% FPL	191% FPL	31% FPL	0% FPL

Florida Medicaid is administered by the AHCA and is financed with federal and state funds. The Department of Children and Families (DCF) determines Medicaid eligibility and transmits that information to the AHCA. As the single state agency, the AHCA has the lead responsibility for the overall program.³

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. While self-attestation is permitted for a number of data elements on the application, most components are matched through the Federal Data Services Hub.⁴ Applicants must also agree to cooperate with Child Support Enforcement during the application process.⁵

The structures of state Medicaid programs vary from state to state, and each state's share of expenditures also varies and is largely determined by the federal government. Federal law and regulations set the minimum amount, scope, and duration of services offered in the program, among other requirements. State Medicaid benefits are provided in statute under s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons).

¹ Agency for Health Care Admin., Senate Health and Human Services Appropriations Subcommittee Presentation, *Agency for Health Care Administration - Florida Medicaid* (January 11, 2017), slide 2, http://www.flsenate.gov/PublishedContent/Committees/2016-2018/AHS/MeetingRecords/MeetingPacket_3554.pdf (last visited Mar. 14, 2017).

² U.S. Centers for Medicare and Medicaid Services, Medicaid.gov, *Florida*, <http://www.medicaid.gov/medicaid-chip-program-information/by-state/florida.html> (last visited Mar. 14, 2017).

³ See s. 409.963, F.S.

⁴ Florida Dep't of Children and Families, *Family-Related Medicaid Programs Fact Sheet*, p. 3 (April 2016), <http://www.dcf.state.fl.us/programs/access/docs/Family-RelatedMedicaidFactSheet.pdf> (last visited Mar. 15, 2017).

⁵ Id.

Minimum eligibility coverage thresholds are established in federal law for certain population groups, such as children, as well as minimum benefits and maximum cost sharing. The minimum benefits include items such as physician services, hospital services, home health services, and family planning.⁶ States can add benefits, pending federal approval. Florida has added benefits, including prescription drugs, adult dental services, and dialysis.⁷ For children under age 21, the benefits must include the Early and Periodic Screening, Diagnostic and Treatment services, which are those health care and diagnostic services and treatment and measures that may be needed to correct or ameliorate defects or physical and mental illnesses and conditions discovered by screening services, consistent with federal law.⁸

Waivers to the state plan may be requested and negotiated by the state through the federal Centers for Medicare and Medicaid Services (CMS) by the AHCA. Florida has several such Medicaid waivers, including one which implemented the Statewide Medicaid Managed Care (SMMC) program. Current federal law requires the state to obtain a waiver to implement managed care. Through these waivers, the states have limited flexibility to design their Medicaid programs; however, even within waiver authorities, federal regulations prescribe requirements for benefits, delivery systems, cost sharing limitations, and population coverages.

Statewide Medicaid Managed Care (SMMC)

The SMMC program is currently designed for the AHCA to issue invitations to negotiate (ITN) and competitively procure contracts with managed care plans in 11 regions of the state to provide comprehensive Medicaid coverage for most of the state's enrollees in the Medicaid program. The 11 regions reflect areas that were initially set by the original Department of Health and Rehabilitative Services which was re-organized and downsized into several smaller agencies in the 1990s.

The SMMC has two components: Managed medical assistance (MMA) and long-term care managed care (LTC). The MMA waiver expires on June 30, 2017, and the LTC waiver was recently extended through December 27, 2021.⁹

The LTC component began enrolling in August 2013 and completed its statewide roll-out in March 2014. The MMA component began enrolling Medicaid recipients in May 2014 and finished its roll-out in August 2014. These contracts will be re-procured in 2017 with contract execution and implementation expected during the last part of 2018, according to the AHCA.

The chart below shows the enrollment in each of these components as of March 1, 2017:

⁶ Section 409.905, F.S.

⁷ Section 409.906, F.S.

⁸ See Section 1905 9(r) of the Social Security Act.

⁹ The current Managed Medical Assistance waiver is approved as an 1115 waiver and was last approved for the time period of July 31, 2014 through June 30, 2017. The Long-Term Care Managed Care waiver is approved as a section 1915(b) and section 1915(c) combination waiver and was most recently approved through December 27, 2021 by the federal Centers for Medicare and Medicaid Services.

Statewide Medicaid Managed Care - March 2017			
Component	Enrollment Start Date	Budget ¹⁰	Enrollment ¹¹ (as of Mar. 2017)
Long-Term Care Plan	August 2013	\$3.97 billion	94,803
Managed Medical Assistance	May 2014	\$14.4 billion	3,233,235

The LTC program provides services in two settings: nursing facilities or home and community based services (HCBS) such as a recipient's home, an assisted living facility, or an adult family care home. Nursing facility services are an entitlement program for eligible enrollees and no waitlist exists; however, HCBS are delivered through waivers and are dependent on the availability of annual funding in the General Appropriations Act (GAA).

Enrollment in the HCBS portion of LTC is managed based on a priority system and wait list. For the 2016-2017 waiver year, the state is approved for 62,500 unduplicated recipients in the HCBS portion of the program.¹² In order to be eligible for the program, a recipient must be both clinically eligible as required under s. 409.979, F.S., and financially eligible for Medicaid under s. 409.904, F.S.

Eligibility and Enrollment

The AHCA is the single state agency for Medicaid; however through an interagency agreement with the Department of Elderly Affairs (DOEA), the DOEA is Florida's federally mandated pre-admission screening program for nursing home applicants through its Long-Term Care Services (CARES) program, including for the LTC component.¹³ The frailty-based assessment results in a priority score for an individual, who is then placed on the wait list based on his or her priority score.

Individuals are released from the wait list periodically, based on the availability of funding and their priority scores. The Legislature has specifically directed funding in the past several years through the GAA to serve elders off the waitlist who have a priority score of 4 or higher.¹⁴ Individuals who are more frail or have a more immediate need for services receive a higher rank on the waitlist. Those who have resided in a nursing facility for more than 60 days receive prior enrollment into the HCBS portion of the program. Exemptions from the wait list also exist under s. 409.979(3)(f), F.S.

¹⁰ Agency for Health Care Admin., *Statewide Medicaid Managed Care (Presentation to House Health and Human Services Committee - Jan. 10, 2017)*, slide 2, http://ahca.myflorida.com/medicaid/recent_presentations/House_Health_Human_Services_Med_101_2017-01-10.pdf (last visited Mar. 14, 2017).

¹¹ Agency for Health Care Administration, *SMMC MMA Enrollment by County by Plan (As of Mar. 1, 2017)*, http://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Mar. 14, 2017).

¹² Letter from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services to Beth Kidder, Interim Deputy Secretary for Medicaid, Agency for Health Care Administration (Dec. 19, 2016), available at http://ahca.myflorida.com/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/LTC_Approval_Letter_2016-12-19.pdf (last visited Mar. 14, 2017).

¹³ Florida Dep't of Elderly Affairs, *Comprehensive Assessment and Review for Long-Term Care Services (CARES)*, <http://elderaffairs.state.fl.us/doea/cares.php> (last visited Mar. 14, 2017).

¹⁴ See Ch. Law 2016-66, line item 232; Ch. Law 2015-232, line item 226; and Ch. Law 2014-51, line item 242. In state fiscal year 2013-14, GAA provided funding during first year of the LTCMC program for those on the wait list with priority scores of 5 or higher. (Ch. Law 2013-40, line item 414).

Individuals who are enrolled in the following programs may enroll in the LTC program, but are not required to:

- Developmental Disabilities waiver program;
- Traumatic Brain and Spinal Injury waiver;
- Project AIDS Care waiver;
- Adult Cystic Fibrosis waiver;
- Program of All-Inclusive Care for the Elderly (PACE);
- Familial Dysautonomia waiver; or
- Model waiver.¹⁵

Individuals, both those who are enrolled in LTC and those on the wait list, must be re-screened at least annually or whenever there is a significant change in circumstances, such as change in caregivers or medical condition.¹⁶

Delivery System and Benefits

The AHCA conducted a competitive procurement to select LTC and MMA plans in each of the 11 regions in 2012. Under the Invitation to Negotiate for MMA plans, the AHCA selected 10 different companies to serve as the health care delivery system. Of the plans selected, 11 of the awarded contracts went to general, non-specialty plans, of which five were PSNs.¹⁷ Five different specialty plans and the Children's Medical Services plan were also awarded contracts.^{18,19} Currently, MMA recipients receive services through 11 different managed care plans, of which two are PSNs.

In 2012, the AHCA awarded seven LTC contracts, including one statewide contract.²⁰ One of the original LTC contracts operated as a PSN; however, that plan is no longer participating in SMMC. The LTC services are now delivered through six managed care plans, which vary based on the recipient's region. Each region has at least two plans to allow for recipient choice. For nursing facilities and hospices, the plans are required to pay those designated providers a rate set by the AHCA. All six of the LTC plans also participate in the MMA program.

In addition to these plans, there are six specialty plans that serve unique populations: Children's Medical Services for children with chronic conditions; two plans for individuals with HIV/AIDS; a plan for child welfare enrollees; a plan for recipients eligible for both Medicaid and Medicare

¹⁵ *Id.*

¹⁶ Application for §1915(c) Home and Community-Based Services Waiver (Effective July 1, 2013), pp. 45-46, http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/federal_authorities/federal_waivers/docs/mma/LTC_1915c_Application.pdf (last visited Mar. 15, 2017).

¹⁷ Agency for Health Care Admin., *Florida Managed Medical Assistance Program - 1115 Research and Demonstration Waiver (3rd Quarter Progress Report: January 1, 2014 - March 31, 2014)*, p. 15, (on file with the Senate Committee on Health Policy).

¹⁸ *Id.*

¹⁹ Agency for Health Care Administration, *Medicaid and Managed Care* (Sept. 3, 2014), http://ahca.myflorida.com/Medicaid/recent_presentations/Child_Protection_Summit_2014-09-03.pdf (last visited Mar. 20, 2017).

²⁰ Agency for Health Care Administration, *Statewide Medicaid Managed Care Update* (Oct. 8, 2013) (on file with the Senate Committee on Health Policy).

with chronic conditions, such as diabetes or congestive heart failure; and a plan for individuals with serious mental illness. Recipients in both components of the program receive choice counseling services to assist them in selecting the plan that will best meet their needs.

The total enrollment in the specialty plans as of March 1, 2017 is shown in the chart below:²¹

Specialty Plan Enrollment - March 2017	
Component	Enrollment (As of March 1, 2017)
Child Welfare Plan	31,810
Specialty Plans (Capitated)	78,842
Children's Medical Services Network	50,924
Total:	161,576

The managed care plans under both components are required to cover a minimum level of benefits as prescribed under s. 409.973, F.S., for the MMA plans, and s. 409.98, F.S., for the LTC plans. However, the statutes also permit the plans to offer an expanded menu of optional benefits.

Mandatory Benefits - Statewide Medicaid Managed Care	
Managed Medical Assistance	Long-Term Care
Advanced registered nurse practitioner services	Nursing facility care
Ambulatory surgical treatment center services	Services provided in assisted living facility
Birthing center services	Hospice
Chiropractic services	Adult day care
Dental services	Medical equipment and supplies, including incontinence supplies
Early periodic screening diagnostic and treatment services for recipients under age 21	Personal care
Emergency services	Home accessibility adaption
Family planning services and supplies	Behavior management
Healthy Start services (with exceptions)	Home-delivered meals
Hearing services	Case management
Home health agency services	Therapies
Hospice services	Occupational therapy
Hospital inpatient services	Speech therapy
Hospital outpatient services	Respiratory therapy
Laboratory and imaging services	Physical therapy
Medical supplies, equipment, prostheses, and orthoses	Intermittent and skilled nursing
Mental health services	Medication administration
Nursing care	Medication management
Optical services and supplies	Nutritional assessment and risk reduction

²¹ Agency for Health Care Administration, SMMC MMA Specialty Capitated Enrollment Report (As of Mar. 1, 2017).

Mandatory Benefits - Statewide Medicaid Managed Care	
Managed Medical Assistance	Long-Term Care
Optometrist services	Caregiver training
Physical, occupational, respiratory, and speech therapy services	Respite care
Physician services, including physician assistant services	Transportation
Podiatric services	Personal emergency response system
Prescription drugs	
Renal dialysis services	
Respiratory equipment and supplies	
Rural health clinic services	
Substance abuse treatment services	
Transportation to access covered services	

The LTC enrollees who are not eligible for Medicare also receive their medical services through an MMA plan. Some plans participate in both components in the same regions, and a recipient may elect the same managed care plan for both components. These plans are referred to as comprehensive plans.

Provider Service Networks

The payment design of the SMMC was intended to facilitate a smooth transition from a mix of fee-for-service, primary care case management, and managed care delivery to a statewide system of Medicaid managed care. The statute permitted the PSNs to be reimbursed on a fee-for-service or prepaid basis, but only for the first 2 years of the plan's operation or until the contract year beginning September 1, 2014, whichever is later. The AHCA is required to conduct cost reconciliations for the fee-for-service PSNs to determine cost reconciliations. All other managed care plans under SMMC are paid on a capitated basis meaning that a plan must pay for all covered services under the contract regardless of whether the capitated rate covers the cost of services for that recipient.

During the procurement process, at least one of the contract awards must be to a PSN if any PSNs submit a responsive bid. However, the AHCA must also issue an additional ITN following the end of a procurement, only for provider service networks, in those regions where no provider service networks submitted a responsive bid.

III. Effect of Proposed Changes:

Provider Service Networks (Sections 1, 3, 4, 6, 7, and 8)

The bill removes the option for PSNs, under both the MMA and LTC components, to be reimbursed on a fee-for-service basis. Prepaid PSNs shall be reimbursed only on a per-member, per month basis. Currently, PSNs could elect to receive payments for the first 2 years of a contract or until the contract year beginning September 1, 2014, whichever is later, under fee-for-service or on a capitated basis. The bill also deletes provisions relating to quality selection criteria specific to savings under PSNs, which are calculated under fee-for-service rates.

The reconciliation and cost savings review process sections relating to the PSN fee-for-service payment process are deleted from the MMA and LTC sections of the SMMC program. Provisions relating to how the cost reconciliations shall be conducted and the reconciliation deadline are removed to correspond to the removal of those now obsolete provisions.

The ITN process for both the MMA and LTC components is modified to no longer require the AHCA to conduct a separate procurement process within 12 months of the initial procurement process if no PSN is selected during the initial procurement.

Managed Care Plan Selection (Sections 3, 6, and 8)

The bill modifies the AHCA's responsibilities for compiling and publishing a databook as part of the ITN process to require a comprehensive set of utilization and spending data that is consistent with actuarial rate-setting practices and standards. The modification eliminates specific requirements that the data include the three most recent contract years for all Medicaid recipients by region or county, removes requirements for the breakdown of the data by specific components, or the inclusion of fee-for-service claims.

The health care delivery regions for both the MMA and LTC components are also collapsed and changed to letters from numbers. These modifications provide for administrative streamlining and will enhance plan stability through increased market share by the plans, according to the AHCA. Since the original regions were created in the 1990s, the AHCA believes these revised regions more accurately reflect the health care market and current utilization patterns.²² The larger regions will also assist the AHCA in ensuring compliance with the access and appointment standards by the managed care plans as a wider choice of plans is likely to be available to recipients. The pooling of additional membership across the collapsed regions will likely draw more interested parties to some of the less populated areas of the state.

The table below shows the proposed re-groupings of counties and the minimum and maximum number of plans for the procurement. The same range of plan limitations apply for MMA and LTC.

Proposed Region Changes and Plan Limitations							
Current Region	Counties	Plan Min.	Plan Max.	New Region	Counties	Plan Min.	Plan Max.
1	Escambia, Okaloosa, Santa Rosa, Walton	2	0	A	Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, Walton, Washington	2	4
2	Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla, Washington	2	0	B	Alachua, Baker, Bradford, Citrus, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Hernando, Lafayette, Lake,	3	5

²² Agency for Health Care Administration, *Senate Bill 916 Analysis* (Feb. 24, 2017), p. 3, (on file with the Senate Committee on Health Policy).

					Levy, Marion, Nassau, Putnam, St. Johns, Sumter, Suwannee, Union, Volusia		
3	Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, Union	3	5	C	Hardee, Highlands, Hillsborough, Manatee, Pasco, Pinellas, Polk	4	7
4	Baker, Clay, Duval, Flagler, Nassau, St. Johns, Volusia	3	5	D	Brevard, Orange, Osceola, Seminole	3	6
5	Pasco, Pinellas	2	4	E	Charlotte, Collier, Desoto, Glades, Hendry, Lee, Sarasota	2	4
6	Hardee, Highlands, Hillsborough, Manatee, Polk	4	7	F	Indian River, Martin, Okeechobee, Palm Beach, St. Lucie	2	4
7	Brevard, Orange, Osceola, Seminole	3	6	G	Broward	2	4
8	Charlotte, Collier, Desoto, Glades, Hendry, Lee, Sarasota	2	4	H	Miami-Dade and Monroe	5	10
9	Indian River, Martin, Okeechobee, Palm Beach, St. Lucie	2	4				
10	Broward	2	4				
11	Miami-Dade, Monroe	5	10				

Obsolete Language (Sections 2, 5, 6, and 7)

The bill removes obsolete language from ss. 409.964, 409.971, and 409.974(1), and 409.978(1), F.S. These sections contain references to dates or activities associated with program implementation, the initial procurement process, and expired deadlines.

Effective Date (Section 9)

The effective date of the bill is July 1, 2017.

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 916 reorganizes the regions and the number of plans that may be selected in each region. The AHCA plans to re-procure the SMMC contracts in late 2017 giving the health plan industry, both those currently with contracts and those who wish to gain a contract, an opportunity to bid on the new ITN. The AHCA believes the collapsing of regions will result in administrative streamlining and more accurately reflects today's health care utilization patterns. These changes may result in more competitive proposals from more managed care organizations during the upcoming procurement process, which could result in savings to the state and more choices for the consumer. In response to a voluntary Intent to Bid request, the AHCA had received 41 responses from PSNs and HMOs that were interested in all three types of plans: Long-term care, specialty, and managed medical assistance.²³

Any changes in which managed care organizations receive contracts under a new procurement would also impact the health care provider community in 2017 and 2018. Not only would Medicaid managed care enrollees possibly be transitioning to new providers, but the provider community would also have to adapt to a new group of managed care plans.

C. Government Sector Impact:

The AHCA reports that the bill has no fiscal impact.²⁴ However, the AHCA also believes, and notes in its bill analyses that the collapsing of regions will result in administrative streamlining and that these new regions will more accurately reflect today's health care utilization patterns. These changes in the regions may result in more competitive proposals from more managed care organizations during the upcoming procurement process, which could result in additional savings to the state and more choices for the consumer.

VI. Technical Deficiencies:

Remove the word, "Prepaid" from line 101.

²³ Agency for Health Administration, *Statewide Medicaid Managed Care (SMMC) Program Non-Binding Letters of Intent Received by 2/13/2017, in response to Intent to Bid Posted 2/3/2017*, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Intent_to_Bid_Responses.pdf (last visited Mar. 16, 2017).

²⁴ *Supra* note 20, at 4.

VII. Related Issues:

The AHCA plans to release an ITN in the summer of 2017. Non-binding letters of Intent to Bid were requested from interested bidders by February 13, 2017, using the current 11 regions.²⁵ With changes to the current business process, an effective date of July 1, 2017, may keep the AHCA from maintaining their current deadlines.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.912, 409.964, 409.966, 409.968, 409.971, 409.974, 409.978, and 409.981.

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.

²⁵ Agency for Health Care Administration, *Non-binding Letters of Intent from Potential SMMC Plans*, http://ahca.myflorida.com/medicaid/statewide_mc/SMMC_LOI.shtml (last visited Mar. 16, 2017).

By Senator Grimsley

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1 A bill to be entitled
 2 An act relating to the statewide Medicaid managed care
 3 program; amending s. 409.912, F.S.; deleting the fee-
 4 for-service option as a basis for the reimbursement of
 5 Medicaid provider service networks; amending s.
 6 409.964, F.S.; deleting an obsolete provision;
 7 amending s. 409.966, F.S.; requiring that a required
 8 databook consist of data that is consistent with
 9 actuarial rate-setting practices and standards;
 10 revising the designation and county makeup of regions
 11 of the state for purposes of procuring health plans
 12 that may participate in the Medicaid program; adding a
 13 factor that the Agency for Health Care Administration
 14 must consider in the selection of eligible plans;
 15 deleting a requirement related to fee-for-service
 16 provider service networks; amending s. 409.968, F.S.;
 17 requiring provider service networks to be prepaid
 18 plans; deleting a fee-for-service option for Medicaid
 19 reimbursement for provider service networks; amending
 20 s. 409.971, F.S.; deleting an obsolete provision;
 21 amending s. 409.974, F.S.; revising the number of
 22 eligible Medicaid health care plans the agency must
 23 procure for certain regions in the state; deleting an
 24 obsolete provision; amending s. 409.978, F.S.;
 25 deleting an obsolete provision; amending s. 409.981,
 26 F.S.; revising the number of eligible Medicaid health
 27 care plans the agency must procure for certain regions
 28 in the state; deleting a requirement that the agency
 29 consider a specific factor relating to the selection

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30 of managed medical assistance plans; providing an
 31 effective date.
 32

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

34
 35 Section 1. Subsection (2) of section 409.912, Florida
 36 Statutes, is amended to read:

37 409.912 Cost-effective purchasing of health care.—The
 38 agency shall purchase goods and services for Medicaid recipients
 39 in the most cost-effective manner consistent with the delivery
 40 of quality medical care. To ensure that medical services are
 41 effectively utilized, the agency may, in any case, require a
 42 confirmation or second physician's opinion of the correct
 43 diagnosis for purposes of authorizing future services under the
 44 Medicaid program. This section does not restrict access to
 45 emergency services or poststabilization care services as defined
 46 in 42 C.F.R. s. 438.114. Such confirmation or second opinion
 47 shall be rendered in a manner approved by the agency. The agency
 48 shall maximize the use of prepaid per capita and prepaid
 49 aggregate fixed-sum basis services when appropriate and other
 50 alternative service delivery and reimbursement methodologies,
 51 including competitive bidding pursuant to s. 287.057, designed
 52 to facilitate the cost-effective purchase of a case-managed
 53 continuum of care. The agency shall also require providers to
 54 minimize the exposure of recipients to the need for acute
 55 inpatient, custodial, and other institutional care and the
 56 inappropriate or unnecessary use of high-cost services. The
 57 agency shall contract with a vendor to monitor and evaluate the
 58 clinical practice patterns of providers in order to identify

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trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer

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review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(2) The agency may contract with a provider service network, ~~which may be reimbursed on a fee for service or prepaid basis.~~ Prepaid provider service networks shall receive per-member, per-month payments. ~~A provider service network that does not choose to be a prepaid plan shall receive fee-for-service rates with a shared savings settlement. The fee-for-service option shall be available to a provider service network only for the first 2 years of the plan's operation or until the contract year beginning September 1, 2014, whichever is later. The agency shall annually conduct cost reconciliations to determine the amount of cost savings achieved by fee-for-service provider service networks for the dates of service in the period being reconciled. Only payments for covered services for dates of service within the reconciliation period and paid within 6 months after the last date of service in the reconciliation period shall be included. The agency shall perform the necessary adjustments for the inclusion of claims incurred but not reported within the reconciliation for claims that could be~~

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~~received and paid by the agency after the 6-month claims processing time lag. The agency shall provide the results of the reconciliations to the fee-for-service provider service networks within 45 days after the end of the reconciliation period. The fee for service provider service networks shall review and provide written comments or a letter of concurrence to the agency within 45 days after receipt of the reconciliation results. This reconciliation shall be considered final.~~

(a) A provider service network that ~~which~~ is reimbursed by the agency on a prepaid basis shall be exempt from parts I and III of chapter 641, but must comply with the solvency requirements in s. 641.2261(2) and meet appropriate financial reserve, quality assurance, and patient rights requirements as established by the agency.

(b) A provider service network is a network established or organized and operated by a health care provider, or group of affiliated health care providers, which provides a substantial proportion of the health care items and services under a contract directly through the provider or affiliated group of providers and may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians, by other health professionals, or through the institutions. The health care providers must have a controlling interest in the governing body of the provider service network organization.

Section 2. Section 409.964, Florida Statutes, is amended to read:

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409.964 Managed care program; state plan; waivers.—The Medicaid program is established as a statewide, integrated managed care program for all covered services, including long-term care services. The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the program. Before seeking a waiver, the agency shall provide public notice and the opportunity for public comment and include public feedback in the waiver application. The agency shall hold one public meeting in each of the regions described in s. 409.966(2), and the time period for public comment for each region shall end no sooner than 30 days after the completion of the public meeting in that region. ~~The agency shall submit any state plan amendments, new waiver requests, or requests for extensions or expansions for existing waivers, needed to implement the managed care program by August 17, 2011.~~

Section 3. Subsection (2) and paragraphs (a), (d), and (e) of subsection (3) of section 409.966, Florida Statutes, are amended to read:

409.966 Eligible plans; selection.—

(2) ELIGIBLE PLAN SELECTION.—The agency shall select a limited number of eligible plans to participate in the Medicaid program using invitations to negotiate in accordance with s. 287.057(1)(c). At least 90 days before issuing an invitation to negotiate, the agency shall compile and publish a databook consisting of a comprehensive set of utilization and spending data consistent with actuarial rate-setting practices and standards ~~for the 3 most recent contract years consistent with the rate-setting periods for all Medicaid recipients by region~~

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or county. The source of the data in the report must include both historic fee-for-service claims and validated data from the Medicaid Encounter Data System. The report must be available in electronic form and delineate utilization use by age, gender, eligibility group, geographic area, and aggregate clinical risk score. Separate and simultaneous procurements shall be conducted in each of the following regions:

(a) Region A ~~Region 1~~, which consists of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, and Walton, and Washington Counties.

(b) Region B ~~Region 2~~, which consists of Alachua, Baker, Bradford, Citrus, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Nassau, Putnam, St. Johns, Sumter, Suwannee, Union, and Volusia Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla, and Washington Counties.

(c) Region C ~~Region 3~~, which consists of Hardee, Highlands, Hillsborough, Manatee, Pasco, Pinellas, and Polk ~~Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, and Union~~ Counties.

(d) Region D ~~Region 4~~, which consists of Brevard, Orange, Osceola, and Seminole ~~Baker, Clay, Duval, Flagler, Nassau, St. Johns, and Volusia~~ Counties.

(e) Region E ~~Region 5~~, which consists of Charlotte, Collier, DeSoto, Glades, Hendry, Lee, and Sarasota ~~Pasco and Pinellas~~ Counties.

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(f) Region F ~~Region 6~~, which consists of Indian River, Martin, Okeechobee, Palm Beach, and St. Lucie ~~Hardee, Highlands, Hillsborough, Manatee, and Polk~~ Counties.

(g) Region G ~~Region 7~~, which consists of Broward County ~~Brevard, Orange, Osceola, and Seminole~~ Counties.

(h) Region H ~~Region 8~~, which consists of Miami-Dade and Monroe ~~Charlotte, Collier, DeSoto, Glades, Hendry, Lee, and Sarasota~~ Counties.

~~(i) Region 9, which consists of Indian River, Martin, Okeechobee, Palm Beach, and St. Lucie Counties.~~

~~(j) Region 10, which consists of Broward County.~~

~~(k) Region 11, which consists of Miami Dade and Monroe Counties.~~

(3) QUALITY SELECTION CRITERIA.—

(a) The invitation to negotiate must specify the criteria and the relative weight of the criteria that will be used for determining the acceptability of the reply and guiding the selection of the organizations with which the agency negotiates. In addition to criteria established by the agency, the agency shall consider the following factors in the selection of eligible plans:

1. Accreditation by the National Committee for Quality Assurance, the Joint Commission, or another nationally recognized accrediting body.

2. Experience serving similar populations, including the organization's record in achieving specific quality standards with similar populations.

3. Availability and accessibility of primary care and specialty physicians in the provider network.

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233 4. Establishment of community partnerships with providers
234 that create opportunities for reinvestment in community-based
235 services.

236 5. Organization commitment to quality improvement and
237 documentation of achievements in specific quality improvement
238 projects, including active involvement by organization
239 leadership.

240 6. Provision of additional benefits, particularly dental
241 care and disease management, and other initiatives that improve
242 health outcomes.

243 7. Evidence that an eligible plan has written agreements or
244 signed contracts or has made substantial progress in
245 establishing relationships with providers before the plan
246 submitting a response.

247 8. Comments submitted in writing by any enrolled Medicaid
248 provider relating to a specifically identified plan
249 participating in the procurement in the same region as the
250 submitting provider.

251 9. Documentation of policies and procedures for preventing
252 fraud and abuse.

253 10. The business relationship an eligible plan has with any
254 other eligible plan that responds to the invitation to
255 negotiate.

256 11. Whether a plan is proposing to establish a
257 comprehensive long-term care plan.

258 (d) For the first year of the first contract term, the
259 agency shall negotiate capitation rates or fee for service
260 payments with each plan in order to guarantee aggregate savings
261 of at least 5 percent.

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262 ~~1.~~ For prepaid plans, determination of the amount of
263 savings shall be calculated by comparison to the Medicaid rates
264 that the agency paid managed care plans for similar populations
265 in the same areas in the prior year. In regions containing no
266 prepaid plans in the prior year, determination of the amount of
267 savings shall be calculated by comparison to the Medicaid rates
268 established and certified for those regions in the prior year.

269 ~~2. For provider service networks operating on a fee-for-~~
270 ~~service basis, determination of the amount of savings shall be~~
271 ~~calculated by comparison to the Medicaid rates that the agency~~
272 ~~paid on a fee-for-service basis for the same services in the~~
273 ~~prior year.~~

274 (e) To ensure managed care plan participation in Regions A
275 and E ~~Regions 1 and 2~~, the agency shall award an additional
276 contract to each plan with a contract award in Region A ~~Region 1~~
277 or Region E ~~Region 2~~. Such contract shall be in any other region
278 in which the plan submitted a responsive bid and negotiates a
279 rate acceptable to the agency. If a plan that is awarded an
280 additional contract pursuant to this paragraph is subject to
281 penalties pursuant to s. 409.967(2)(i) for activities in Region
282 A ~~Region 1~~ or Region E ~~Region 2~~, the additional contract is
283 automatically terminated 180 days after the imposition of the
284 penalties. The plan must reimburse the agency for the cost of
285 enrollment changes and other transition activities.

286 Section 4. Subsection (2) of section 409.968, Florida
287 Statutes, is amended to read:

288 409.968 Managed care plan payments.—

289 (2) Provider service networks shall ~~may~~ be prepaid plans
290 and receive per-member, per-month payments negotiated pursuant

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291 to the procurement process described in s. 409.966. Provider
 292 service networks that choose not to be prepaid plans shall
 293 receive fee-for-service rates with a shared savings settlement.
 294 The fee-for-service option shall be available to a provider
 295 service network only for the first 2 years of its operation. The
 296 agency shall annually conduct cost reconciliations to determine
 297 the amount of cost savings achieved by fee-for-service provider
 298 service networks for the dates of service within the period
 299 being reconciled. Only payments for covered services for dates
 300 of service within the reconciliation period and paid within 6
 301 months after the last date of service in the reconciliation
 302 period must be included. The agency shall perform the necessary
 303 adjustments for the inclusion of claims incurred but not
 304 reported within the reconciliation period for claims that could
 305 be received and paid by the agency after the 6-month claims
 306 processing time lag. The agency shall provide the results of the
 307 reconciliations to the fee-for-service provider service networks
 308 within 45 days after the end of the reconciliation period. The
 309 fee-for-service provider service networks shall review and
 310 provide written comments or a letter of concurrence to the
 311 agency within 45 days after receipt of the reconciliation
 312 results. This reconciliation is considered final.

313 Section 5. Section 409.971, Florida Statutes, is amended to
 314 read:

315 409.971 Managed medical assistance program.—The agency
 316 shall make payments for primary and acute medical assistance and
 317 related services using a managed care model. By January 1, 2013,
 318 the agency shall begin implementation of the statewide managed
 319 medical assistance program, with full implementation in all

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320 ~~regions by October 1, 2014.~~

321 Section 6. Subsections (1) and (2) of section 409.974,
 322 Florida Statutes, are amended to read:

323 409.974 Eligible plans.—

324 (1) ELIGIBLE PLAN SELECTION.—The agency shall select
 325 eligible plans through the procurement process described in s.
 326 409.966. The agency shall notice invitations to negotiate no
 327 later than January 1, 2013.

328 (a) The agency shall procure at least two plans and up to
 329 four plans for Region A ~~Region 1~~. At least one plan shall be a
 330 provider service network if any provider service networks submit
 331 a responsive bid.

332 (b) The agency shall procure at least three plans and up to
 333 five ~~two~~ plans for Region B ~~Region 2~~. At least one plan shall be
 334 a provider service network if any provider service networks
 335 submit a responsive bid.

336 (c) The agency shall procure at least four ~~three~~ plans and
 337 up to seven ~~five~~ plans for Region C ~~Region 3~~. At least one plan
 338 must be a provider service network if any provider service
 339 networks submit a responsive bid.

340 (d) The agency shall procure at least three plans and up to
 341 six ~~five~~ plans for Region D ~~Region 4~~. At least one plan must be
 342 a provider service network if any provider service networks
 343 submit a responsive bid.

344 (e) The agency shall procure at least two plans and up to
 345 four plans for Region E ~~Region 5~~. At least one plan must be a
 346 provider service network if any provider service networks submit
 347 a responsive bid.

348 (f) The agency shall procure at least two ~~four~~ plans and up

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to ~~four~~ seven plans for Region F ~~Region 6~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(g) The agency shall procure at least ~~two~~ three plans and up to ~~four~~ six plans for Region G ~~Region 7~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(h) The agency shall procure at least ~~five~~ two plans and up to ~~10~~ four plans for Region H ~~Region 8~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

~~(i) The agency shall procure at least two plans and up to four plans for Region 9. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(j) The agency shall procure at least two plans and up to four plans for Region 10. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(k) The agency shall procure at least five plans and up to 10 plans for Region 11. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~If no provider service network submits a responsive bid, the agency shall procure no more than one less than the maximum number of eligible plans permitted in that region. Within 12 months after the initial invitation to negotiate, the agency shall attempt to procure a provider service network. The agency~~

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~~shall notice another invitation to negotiate only with provider service networks in those regions where no provider service network has been selected.~~

(2) QUALITY SELECTION CRITERIA.—In addition to the criteria established in s. 409.966, the agency shall consider evidence that an eligible plan has written agreements or signed contracts or has made substantial progress in establishing relationships with providers before the plan submits ~~submitting~~ a response. The agency shall evaluate and give special weight to evidence of signed contracts with essential providers as defined by the agency pursuant to s. 409.975(1). The agency shall exercise a preference for plans with a provider network in which more than ~~over~~ 10 percent of the providers use electronic health records, as defined in s. 408.051. ~~When all other factors are equal, the agency shall consider whether the organization has a contract to provide managed long-term care services in the same region and shall exercise a preference for such plans.~~

Section 7. Subsection (1) of section 409.978, Florida Statutes, is amended to read:

409.978 Long-term care managed care program.—

(1) Pursuant to s. 409.963, the agency shall administer the long-term care managed care program described in ss. 409.978-409.985, but may delegate specific duties and responsibilities for the program to the Department of Elderly Affairs and other state agencies. ~~By July 1, 2012, the agency shall begin implementation of the statewide long-term care managed care program, with full implementation in all regions by October 1, 2013.~~

Section 8. Subsection (2) and paragraphs (c), (d), and (e)

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of subsection (3) of section 409.981, Florida Statutes, are amended to read:

409.981 Eligible long-term care plans.—

(2) ELIGIBLE PLAN SELECTION.—The agency shall select eligible plans through the procurement process described in s. 409.966. The agency shall procure:

(a) At least two plans and up to four plans for Region A ~~Region 1~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(b) At least three ~~Two~~ plans and up to five plans for Region B ~~Region 2~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(c) At least four ~~three~~ plans and up to seven ~~five~~ plans for Region C ~~Region 3~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(d) At least three plans and up to six ~~five~~ plans for Region D ~~Region 4~~. At least one plan must be a provider service network if any provider service network submits a responsive bid.

(e) At least two plans and up to four plans for Region E ~~Region 5~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(f) At least two ~~four~~ plans and up to four ~~seven~~ plans for Region F ~~Region 6~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(g) At least two ~~three~~ plans and up to four ~~six~~ plans for

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Region G ~~Region 7~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

(h) At least five ~~two~~ plans and up to 10 ~~four~~ plans for Region H ~~Region 8~~. At least one plan must be a provider service network if any provider service networks submit a responsive bid.

~~(i) At least two plans and up to four plans for Region 9. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(j) At least two plans and up to four plans for Region 10. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~(k) At least five plans and up to 10 plans for Region 11. At least one plan must be a provider service network if any provider service networks submit a responsive bid.~~

~~If no provider service network submits a responsive bid in a region other than Region 1 or Region 2, the agency shall procure no more than one less than the maximum number of eligible plans permitted in that region. Within 12 months after the initial invitation to negotiate, the agency shall attempt to procure a provider service network. The agency shall notice another invitation to negotiate only with provider service networks in regions where no provider service network has been selected.~~

(3) QUALITY SELECTION CRITERIA.—In addition to the criteria established in s. 409.966, the agency shall consider the following factors in the selection of eligible plans:

~~(c) Whether a plan is proposing to establish a~~

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465 ~~comprehensive long-term care plan and whether the eligible plan~~
466 ~~has a contract to provide managed medical assistance services in~~
467 ~~the same region.~~

468 (c) ~~(d)~~ Whether a plan offers consumer-directed care
469 services to enrollees pursuant to s. 409.221.

470 (d) ~~(e)~~ Whether a plan is proposing to provide home and
471 community-based services in addition to the minimum benefits
472 required by s. 409.98.

473 Section 9. This act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 14, 2017

I respectfully request that **Senate Bill #916**, relating to Statewide Medicaid Managed Care, and **Senate Bill #1760**, 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
Florida Senate, District 26

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 1124

INTRODUCER: Health Policy Committee and Senator Book

SUBJECT: Newborn Screenings

DATE: March 28, 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 1124 amends s. 383.17, F.S., modifying the Newborn Screening Program to require testing for any condition included in the federal Recommended Uniform Screening Panel (RUSP) and which the Genetics and Newborn Screening Advisory Council (GNSAC) has recommended for inclusion in the state's screening program.

The Department of Health (DOH) is required to expand testing statewide to include newborn screenings for any new conditions within 18 months after the council has made its recommendation for inclusion and if an approved test is available that meets state guidelines. If such a test is not available within 18 months after the council's recommendation, the DOH shall implement the screening as soon as a test offered by the FDA or an alternative vendor is available.

The bill also requires the GNSAC to consider whether a condition should be added to the state's screening program within 1 year after a condition is added to the RUSP.

The immediate fiscal impact to the DOH is \$1,331,492. For the implementation of future disorders, the DOH estimates a cost of \$850,000 to \$3 million per disorder.

The effective date of the bill is July 1, 2017.

II. Present Situation:

According to the Association of Maternal and Child Health Programs, nearly all infants born in the United States are screened by state Newborn Screening programs.¹ From these screening programs, approximately 12,500 newborns are diagnosed annually with detectable, treatable disorders.²

Advisory Committee on Heritable Disorders in Children and Newborns

At the federal level, the Secretary of the Department of Health and Human Services' Committee on Heritable Disorders in Children and Newborns (SACHDNC) is tasked with providing the Secretary with recommendations, advice, and technical information on the most appropriate use of technologies, policies, guidelines, and standards for two objectives:

- Effectively reducing morbidity and mortality in newborns and children having or at risk for, heritable disorders; and
- Enhancing the ability of the state and local health agencies to provide for newborn and child screening, counseling, and health care services for newborns and children having, or at risk for, heritable disorders.³

The SACHDNC was re-established in federal law in 2014⁴ and the committee was chartered on May 7, 2015.⁵ The committee is authorized to operate through the end of the 2019 fiscal year.⁶ Up to 15 individuals may serve as an organizational representative on the committee. These organizations represent broad health care interests in public health, primary care, specialty care, consumer and family organizations, and professional societies.⁷ The committee must meet at least four times per year.⁸

The SACHDNC's Nomination and Prioritization Workgroup reviews nominated conditions to decide if sufficient evidence is available for an external evidence review by the Condition Review Workgroup (CRW). The CRW performs an independent, evidence-based review of the

¹ Kate Taft, Association of Maternal and Child Health Programs, *National Newborn Screening Contingency Plan Update* (Presentation to Advisory Committee on Heritable Disorders in Newborns and Children Meeting (Feb. 9, 2017), <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/meetings/2017/0209/newbornscreeningconplan.PDF> (last visited Mar. 21, 2017).

² Association of Maternal and Child Health Programs, *Issue Brief: State Newborn Screening and Birth Defects Program Roles in Screening for Critical Congenital Heart Defects (CCHD)* (October 2013), pg. 2, http://www.amchp.org/programsandtopics/CHILD-HEALTH/projects/newborn-screening/Documents/AMCHP_Screening_for_CCHD_Issue_Brief_FINAL-Oct2013.pdf#search=newborn%20screening%20programs%20detectable%20diseases, (last visited Mar. 22, 2017).

³ Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, *2013 Annual Report*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/heritabledisordersnewbornschildrenannualrpt13.pdf> (last visited Mar. 21, 2017).

⁴ Public Health Service Act, Title XI, s. 1111 (42 U.S.C. 300b-10), as amended by P.L. 113-240.

⁵ Advisory Committee on Heritable Disorders in Newborns and Children, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/index.html>, (last visited Mar. 21, 2017).

⁶ Advisory Committee on Heritable Disorders in Newborns and Children, *Charter*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/charterdachdnc.pdf>, (last visited Mar. 21, 2017).

⁷ Advisory Committee on Heritable Disorders in Newborns and Children, *About the Committee*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/about/index.html>, (last visited Mar. 21, 2017).

⁸ *Supra* note 6.

condition if received to determine the suitability and potential net benefit of screening for the condition.⁹ The review process includes a review of the results of controlled trials, observational studies, case studies, expert opinions, focus groups, cost-effectiveness analysis, policy analysis, and an ethical analysis.

After the CRW completes its review, the SACHDNC votes on whether to recommend the addition of a condition to recommended uniform screening panel (RUSP) to the Secretary. The Secretary makes the final decision on whether or not to add a condition to the RUSP.¹⁰ States make their own determination as to which conditions they will add to their own screening programs.

Currently, the RUSP recommends screening for 32 core disorders and 26 secondary disorders.¹¹ The most recently added disorder to the RUSP was in February 2016, when the Secretary approved the committee's recommendation to add Adrenoleukodystrophy (X-ALD).¹²

Florida Newborn Screening Program

Florida has had a newborn screening program since 1965¹³ and currently screens for 31 core disorders and 22 secondary disorders unless a parent objects in writing. Of these disorders, 50 are included on the RUSP.¹⁴ In Florida, the state's Genetics and Newborn Screening and Advisory Council (GNSAC) advises the DOH on which disorders to include under Florida's screening program.

Before leaving the hospital, a few drops of blood are taken from a baby's heel and the ears are also tested for hearing. Results are sent back to the hospital and then forwarded to the baby's doctor or the doctor can retrieve the results from a provider portal.¹⁵ Children's Medical Services will contact parents for additional testing when there is an abnormal test result.¹⁶

Newborn screenings are funded by billing Medicaid and private insurance for the screening tests and a \$15 fee paid by birthing facilities.¹⁷ Families without insurance or Medicaid coverage are not billed.

⁹ *Id.*

¹⁰ *Id.*

¹¹ Advisory Committee on Heritable Disorders in Newborns and Children, *Recommended Uniform Screening Panel*, <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/uniformscreeningpanel.pdf> (last visited Mar. 21, 2017).

¹² Letter from Sylvia M. Burwell, Secretary, Health and Human Services, to Joseph A. Bocchini, Jr., M.D., Committee Chairperson, Advisory Committee on Heritable Disorders in Newborns and Children (February 16, 2016), <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/secretary-final-response-x-ald.pdf>, (last visited Mar. 21, 2017).

¹³ Rick Scott, Proclamation, *Florida's 50th Anniversary of Newborn Screening*, (June 25, 2015) (on file with the Senate Committee on Health Policy).

¹⁴ Department of Health, *Senate Bill 1124 Analysis* (Feb. 22, 2017) (on file with the Senate Committee on Health Policy).

¹⁵ Department of Health, *Newborn Screening* <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html> (last visited Mar. 21, 2017).

¹⁶ *Id.*

¹⁷ Department of Health, *Bureau of Public Health Laboratories Newborn Screening*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/BPHL/index.html> (last visited Mar. 21, 2017).

The 15-member GNSAC is established within the DOH.¹⁸ The council includes consumer members, pediatricians, medical school representatives, the State Surgeon General, a Florida Hospital Association representative, an individual with experience in newborn screening programs, an individual who represents audiologists, and a representative from the Agency for Persons with Disabilities. The council is directed to meet at least twice per year.

The GNSAC is given three purposes under the statute. The council is to advise the DOH about:

- Conditions for which testing should be included under the screening program and the genetics program;
- Procedures for collecting and transmitting specimens and recording results; and
- Methods to more effectively evaluate, coordinate, and consolidate screening programs and genetics services for children.¹⁹

When the SACHDNC makes a recommendation and adds a disorder to the RUSP, the GNSAC carefully reviews the recommendation to ensure:

- The disorder is known to result in significant impairment in health, intellect, or functional ability, if not treated before clinical signs appear;
- The disorder can be detected using screening methods which are accepted by current medical practice;
- The disorder can be detected prior to the infant's becoming 2 weeks of age, or at the appropriate age as accepted medical practice indicates;
- After screening for the disorder, reasonable cost benefits can be anticipated through a comparison of tangible program costs with those medical, institutional, and special educational costs likely to be incurred by an undetected population; and
- When screening for a disorder, sufficient pediatric medical infrastructure is available to provide continued services for patients' diagnostic services and medical maintenance.²⁰

Historically, it has taken the DOH a minimum of a year and half to implement a new disorder to the screening panel.²¹ The most recently added disorders, Severe Combined Immunodeficiency and Critical Congenital Heart Defect, took 1 year and 10 months and 2 years and 6 months respectively to add in Florida.²² Currently, there are three disorders on the RUSP that are not on Florida's panel: X-ALD, Pompe, and Muccopolysaccharidosis Type I.²³

When the GNSAC recommends adding a new disorder to the state's screening panel, the DOH's newborn screening laboratory prepares a fiscal impact analysis and requests a specific legislative appropriation if funding is needed. When all of the criteria is met, the condition is then added to the screening program.

¹⁸ Section 383.14, F.S.

¹⁹ Section 383.14(5), F.S.

²⁰ *Supra* note 14.

²¹ *Supra* note 14.

²² *Supra* note 14.

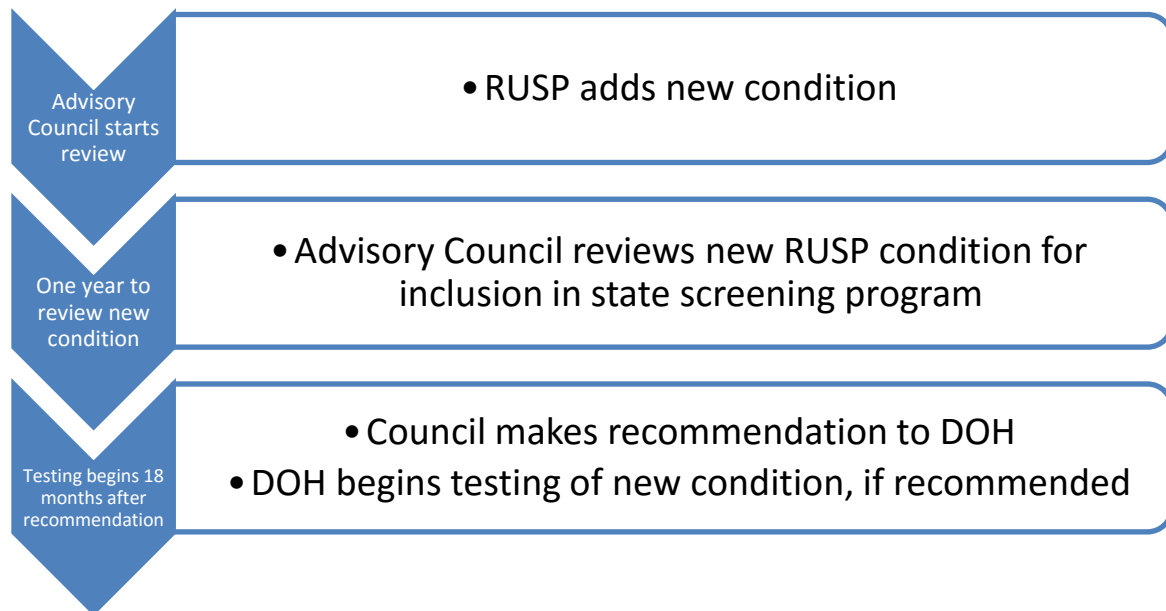
²³ *Supra* note 14.

III. Effect of Proposed Changes:

The bill amends s. 383.14, F.S., modifying the state's Newborn Screening Program to require the GNSAC to consider conditions included on the federal RUSP and make recommendations to the DOH on which conditions should be included on the state's Newborn Screening Program. The DOH would also be required to implement any new condition testing within 18 months after the council provides such a recommendation and a test is available that has been approved by the United States Food and Drug Administration (FDA) or an alternative test is offered by an alternative vendor that meets state standards. If such a test is not available within 18 months of a council recommendation, the DOH shall implement the proposed screening as soon as a test is offered by the FDA or by an alternative vendor.

The GNSAC's mission is updated to include a requirement to review for inclusion in the state's screening program any new condition that is added to the federal RUSP within 1 year.

The chart below illustrates the review and recommendation process under the bill.



The effective date of the bill is July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Under this bill, the GNSAC will recommend to the DOH new conditions that should be included on the state's Newborn Screening Program as they are added to the federal RUSP. If this advisory panel makes the recommendation to include this new condition, the DOH is required to expand the screening of that new condition statewide within 18 months of receipt of that recommendation. This might violate the non-delegation doctrine in article 2, section 3 of the Florida Constitution because "fundamental and primary policy decisions must be made by the Legislature."²⁴

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Private health care providers and facilities may be impacted by any change in testing requirements. Tests for additional conditions may result in more results that will need follow-ups with either additional testing or referrals for specialty care. There may be a need for a supplemental pediatric infrastructure to address the needs of infants and children who are identified through the screening process. In the month of January 2017 alone, the DOH reports in excess of 23,000 newborn screenings.²⁵

For some conditions, FDA approved tests have not yet been developed. Laboratories that can conduct this work with non-FDA tests would be in high demand and would make these non-FDA approved tests available at a high cost to the states.

There may be some long-term cost savings to the health care system as health conditions are caught in the earliest of stages allowing for treatment plans, intervention services, and preventive care to begin as soon as possible.

C. Government Sector Impact:

The DOH is not able to provide an exact fiscal impact; however, for the X-ALD condition which has already been approved by the Secretary of Health and Human Services but has not yet been implemented in Florida, the DOH estimates a fiscal impact of \$1,331,492.²⁶

²⁴ See *Askew v. Cross Key Waterways*, 372 So. 2d 913 (Fla. 1978).

²⁵ Department of Health, *Newborn Screening Program Profile Data (Jan. 1, 2017 - Jan. 31, 2017)*, <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/January17inprof.pdf>, (last visited Mar. 21, 2017).

²⁶ *Supra* note 14, at 5.

The Public Health Laboratory in Jacksonville has estimated a fiscal impact of \$850,000 to \$3,000,000 per disorder that is added to the panel. The cost range is based on:

- Is the testing kit FDA approved?
- Can the test be run on an existing test's platform?
- Will it require additional instrumentation to perform the test?
- How many additional FTEs will be required? The exact number is unknown and is dependent upon the additional labor required to perform the tests and analyze, interpret, record, review, and report the results.²⁷

VI. Technical Deficiencies:

None.

VII. Related Issues:

Advisory Councils

An “advisory council” is defined in state law as an advisory body created by specific statutory enactment and appointed to function on a continuing basis and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.²⁸

This bill authorizes the GNSAC, an advisory council comprised of members appointed by the Governor, President of the Senate, and the Speaker of the House of Representatives, to recommend to the DOH new conditions that should be included in the state's Newborn Screening Program as they are added to the federal RUSP. If this advisory panel makes the recommendation to include a condition for screening, the DOH is required to expand statewide screening of that new condition within 18 months of receiving that recommendation, if a test is available from the FDA or another alternative source which meets state standards. By requiring the DOH to expand its screening program within 18 months of a recommendation, the GNSAC may be acting in more than an advisory capacity.

Non-Binding Authority

This legislation; however, will be “frozen in time” and only those conditions not currently covered by the state as of the date of enactment would be added to Florida's screening program. The Florida Supreme Court has held that one legislature cannot bind the actions of a future legislature.²⁹ If the RUSP is updated, this statute must be re-enacted for the new conditions to take effect.

Implementation Costs

According to the DOH, adding a condition to the screening program can cost the state anywhere from \$850,000 to \$3 million. The bill does not include any provision for the costs of adding the

²⁷ *Supra* note 14, at 5.

²⁸ Section 20.03(7), F.S.

²⁹ *Scott v. Williams*, 107 So. 3d 379 (Fla. 2013).

new condition if the advisory council makes a positive recommendation or for making the addition of the new condition subject to a specific appropriation.

Additionally, the DOH has indicated that for the last two new conditions, the quickest the DOH has been able to implement a new test has been 22 months. The bill does not address what happens if the DOH is unable to meet the implementation deadline of 18 months.

VIII. Statutes Affected:

This bill substantially amends section 383.14 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2017:

The DOH is required to expand statewide screening for any conditions within 18 months (rather than within one year) after the council renders their advice to the DOH for additions to the screening panel, if a test approved by the United States Food and Drug Administration (FDA) or a compatible alternative test that meets state guidelines is available. If such a test is not available within 18 months of the council's recommendation, the DOH shall implement the new screening as soon as a test approved by the FDA or an alternative vendor is available.

B. Amendments:

None.



778848

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 25 - 30
and insert:

2. Be tested for any condition included on the federal
Recommended Uniform Screening Panel which the council advises
the department should be included under the state's screening
program. The department shall expand statewide screening of
newborns to include screening for such conditions within 18
months after the council renders such advice, if a test approved
by the United States Food and Drug Administration or a test



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12 offered by an alternative vendor which is compatible with the
13 clinical standards established under part I of chapter 483 is
14 available. If such a test is not available within 18 months
15 after the council makes its recommendation, the department shall
16 implement such screening as soon as a test offered by the United
17 States Food and Drug Administration or by an alternative vendor
18 is available;

By Senator Book

32-00862-17

20171124__

A bill to be entitled

An act relating to newborn screenings; amending s. 383.14, F.S.; requiring the Department of Health, upon the advice of the Genetics and Newborn Screening Advisory Council, to expand within a specified period the statewide screening of newborns to include any condition on the federal Recommended Uniform Screening Panel; requiring the council to determine whether a condition should be included in the state's screening program within a specified period after its addition to the federal panel; providing an effective date.

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

Section 1. Subsection (2) and paragraph (a) of subsection (5) of section 383.14, Florida Statutes, are amended to read:

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

(2) RULES.—

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

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

2. At the appropriate age, be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. The department shall expand statewide screening of newborns to include screening for such

Page 1 of 3

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

32-00862-17

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conditions within 1 year after the council renders such advice;
and

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

(b) After consultation with the Office of Early Learning, the department shall ~~also~~ adopt and enforce rules requiring every newborn in this state to be screened for environmental risk factors that place children and their families at risk for increased morbidity, mortality, and other negative outcomes.

(c) The department shall adopt such additional rules as are found necessary for the administration of this section and s. 383.145, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice indicates, rules relating to charging and collecting fees for the administration of the newborn screening program authorized by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for these conditions to the department.

(5) ADVISORY COUNCIL.—There is established a Genetics and Newborn Screening Advisory Council made up of 15 members appointed by the State Surgeon General. The council shall be composed of two consumer members, three practicing pediatricians, at least one of whom must be a pediatric hematologist, one representative from each of the four medical schools in the state, the State Surgeon General or his or her designee, one representative from the Department of Health representing Children's Medical Services, one representative

Page 2 of 3

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

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59 from the Florida Hospital Association, one individual with
60 experience in newborn screening programs, one individual
61 representing audiologists, and one representative from the
62 Agency for Persons with Disabilities. All appointments shall be
63 for a term of 4 years. The chairperson of the council shall be
64 elected from the membership of the council and shall serve for a
65 period of 2 years. The council shall meet at least semiannually
66 or upon the call of the chairperson. The council may establish
67 ad hoc or temporary technical advisory groups to assist the
68 council with specific topics which come before the council.
69 Council members shall serve without pay. Pursuant to the
70 provisions of s. 112.061, the council members are entitled to be
71 reimbursed for per diem and travel expenses. It is the purpose
72 of the council to advise the department about:

73 (a) Conditions for which testing should be included under
74 the screening program and the genetics program. Within 1 year
75 after a condition is added to the federal Recommended Uniform
76 Screening Panel, the council shall consider whether the
77 condition should be included under the state's screening
78 program.

79 Section 2. This act shall take effect July 1, 2017.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Environmental Preservation and
Conservation, *Chair*
Appropriations Subcommittee on the Environment
and Natural Resources, *Vice Chair*
Appropriations
Appropriations Subcommittee on Health and
Human Services
Health Policy
Rules

SENATOR LAUREN FRANCES BOOK

Democratic Leader Pro Tempore
32nd District

March 7, 2017

The Honorable Dana Young
Chair
Health Policy Committee

Via email

Dear Chair Young

SB 1124, Newborn Screenings, has been referenced to Health Policy; I would appreciate it if you would agenda the bill at the next available opportunity.

Thank you for your consideration.

Sincerely,

Lauren Book
Senator, District 32

Cc: Ms. Sandra Stovall, Staff Director;
Ms. Celia Georgiades, Committee Administrative Assistant

REPLY TO:

- ☐ 967 N. 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)

3/27/17
Meeting Date1124
Bill Number (if applicable)Topic Newborn Screening

Amendment Barcode (if applicable)

Name Donna FogleJob Title Insurance AgentAddress 4108 Pine Run CirclePhone 904-461-2119St. Augustine, FL 32086Email DFogle@UBaileygroup.comSpeaking: ☒ For ☐ Against ☐ InformationWaive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing _____

Appearing at request of Chair: ☐ Yes ☒ NoLobbyist 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)

3/27/17

Meeting Date

1124

Bill Number (if applicable)

Topic Newborn Screening

Amendment Barcode (if applicable)

Name DONNA FOGLE

Job Title Insurance Agent

Address 4108 Pine Run Circle

Phone 904-461-2119

St. Augustine, FL 32086
City State Zip

Email DFogle@MBaileygroup.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.

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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)

3/27/17

Meeting Date

1124

Bill Number (if applicable)

Topic Newborn Screening

Amendment Barcode (if applicable)

Name Cassandra Herring

Job Title _____

Address 6621 SW 131st PlacePhone 215-429-0184

Street

Ocala FL 34473

City

State

Zip

Email Cherring03@hotmail.comSpeaking: ☒ For ☐ Against ☐ InformationWaive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing _____

Appearing at request of Chair: ☐ Yes ☒ NoLobbyist 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)

3/27/17
Meeting Date

1124
Bill Number (if applicable)

Topic Newborn Screening

Amendment Barcode (if applicable)

Name Kelly Mallette

Job Title _____

Address 104 West Jefferson Street
Street
Tallahassee, FL 32301
City State Zip

Phone (850) 224-3427

Email kelly@rlbookpa.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Everylife Foundation for Rare Diseases

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)

3/27/17

Meeting Date

1124

Bill Number (if applicable)

Topic Newborn Screenings

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr.

Phone 878-7364

Street

Tallahassee

FL

32301

City

State

Zip

Email winnsr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ 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 1144

INTRODUCER: Health Policy Committee and Senator Montford

SUBJECT: Laboratory Screening

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1144 amends the Department of Health's (DOH's) powers and duties pertaining to:

- Human Immunodeficiency Virus (HIV) - The bill:
 - Deletes the requirement for providers in a health care setting to inform the person to be tested that a positive test result will be reported to the county health department (CHD) and provide that person with locations for anonymous testing; and
 - Requires only providers in nonhealth care settings to inform persons to be tested of those facts.
- Laboratory Screening for other states - The bill authorizes the DOH to perform public health lab testing for other states on a fee-for-service basis.
- Lead Poison Screening - The bill:
 - Changes the DOH's role from maintaining a program for early identification of persons at risk of having elevated blood-lead levels through systematically screening certain children under age six to establishing guidelines for early identification of these persons;
 - Amends the definition of an elevated blood-lead level (BLL);
 - Deletes the numerical description of an elevated BLL;
 - Deletes the requirement that BLL testing be performed only on whole venous blood;
 - Expands the permissive BLL tests to include a capillary draw;
 - Requires the DOH to specify by rule the BLL test result defining an elevated BLL based on national recommendations;

- Amends the DOH's reporting and record keeping requirements to require the DOH to maintain only records of testees with elevated BLL;
- Deletes the DOH requirement to notify the testee, or his or her legal guardian, of the BLL test results; and requires the provider conducting or ordering the BLL test to notify the testee.
- Newborn Screening - The bill:
 - Amends the composition of the Genetics and Newborn Screening Advisory Council (GNSAC) to include a representative from four of the 10 Florida medical schools;
 - Authorizes the State Public Health Laboratory (state laboratory) to release newborn hearing or metabolic screening test results to a parent, legal guardian, personal representative, or designated person; and
 - Requires the DOH to promote detection, and the availability of genetic services, for parents, siblings and affected newborns with disorders with no known treatment.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

Human Immunodeficiency Virus (HIV)

HIV is an immune system virus that can lead to acquired immunodeficiency syndrome, or AIDS. HIV affects specific cells in the immune system and, over time, the virus can destroy so many of those cells that the body cannot fight off infections and disease.¹ There is no cure for HIV but it can be controlled with proper medical care, including antiretroviral therapy (ART). If taken properly, ART can dramatically prolong the lives of people infected with HIV, keep them healthy, and greatly lower the chance of infecting others.² A person diagnosed with HIV and treated, before the disease advances, can live nearly as long as someone who does not have HIV. Untreated, HIV is almost always fatal.³

In the U.S., HIV is spread mainly through unprotected sex with someone who has HIV or by sharing needles, syringes, or other equipment used to inject, drugs with someone who has HIV. HIV can also be spread from mother to baby during pregnancy, birth or breastfeeding.⁴ The Centers for Disease Control and Prevention (CDC) estimated that in 2013, the most recent year for which the information is available, that more than 1.2 million persons in the U.S. were living with HIV, including 13 percent (one in eight) who were unaware they were infected. However, the annual number of new HIV cases declined by 19 percent from 2005 to 2014. In 2015, approximately 39,513 persons were diagnosed with HIV; and gay and bisexual African American men were the population group most affected.⁵

¹ Centers for Disease Control and Prevention, *About HIV/AIDS* (updated November 30, 2016), available at <http://www.cdc.gov/hiv/basics/whatishiv.html>, (last visited March 20, 2017).

² Id.

³ Id.

⁴ Centers for Disease Control and Prevention, *HIV Transmission*, (updated December 21, 2016), available at <http://www.cdc.gov/hiv/basics/transmission.html>, (last visited March 20, 2017).

⁵ Centers for Disease Control and Prevention, *HIV in the United States: At A Glance* (updated December 2, 2016), available at <http://www.cdc.gov/hiv/statistics/basics/ata glance.html>, (last visited March 20, 2017).

HIV Testing

An HIV test is a medical test ordered to determine the presence or absence of antibodies or antigens to the human immunodeficiency virus, or the presence or absence of human immunodeficiency virus itself.⁶ The CDC supports HIV testing that occurs during an individual's routine health care visit.⁷ This is especially important for people who may not consider themselves at risk for HIV.⁸

The most common test for HIV is an HIV antibody test, where blood or saliva are checked for specific HIV fighting proteins known as HIV antibodies.⁹ This test is considered “preliminary,” and can take between 3 to 12 weeks for the body to produce sufficient HIV antibodies for the test to detect the presence of the antibodies.¹⁰ If the test result is positive, follow-up diagnostic testing is required to confirm the presence of the HIV.

Follow-up HIV testing is for the detection of both antibodies and antigens. The antibody-antigen test can find a recent HIV infection earlier than tests that detect only antibodies; but antibody-antigen tests are only available for blood, not other body fluids.¹¹

Nucleic acid tests (NATs) are another, less common, form of HIV testing. NATs can detect an HIV infection in a blood sample one to four weeks after a person is first infected.¹² If the result is positive, additional follow-up diagnostic testing should be done to confirm the presence of HIV.

HIV in Florida

The DOH estimates that approximately 127,589 persons living in Florida are infected with HIV.¹³ In 2016, Florida ranked first in the nation in the number of new HIV cases, with over 5,300 new cases; however, this was down from 2014, when there were more than 6,000 newly reported HIV infections in Florida.¹⁴

HIV Testing in Florida

Section 381.004, F.S., governs HIV testing in Florida. It creates a statewide network of confidential and anonymous HIV testing and counseling sites; and establishes procedures for HIV testing, informed consent, and reporting requirements. The DOH CHDs are the primary

⁶ Section 381.004(1)(b), F.S.

⁷ Centers for Disease Control and Prevention, *State HIV Testing Laws: Consent and Counseling Requirements* (updated March 18, 2015), available at <http://www.cdc.gov/hiv/policies/law/states/testing.html>, (last visited March 20, 2017).

⁸ In Florida, only 42.2 percent of adults reported having ever been tested for HIV; Florida Department of Health, *Florida Charts*, available at <http://www.flhealthcharts.com/charts/Brfss/StateDataViewer.aspx?bid=119> (last visited March 20, 2017).

⁹ The U.S. Department of Health and Human Services, *Types of HIV Tests*, (updated Mar. 7, 2017) available at <http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html>, (last visited March 20, 2017).

¹⁰ *Id.*

¹¹ Centers for Disease Control and Prevention, *Testing* (updated December 6, 2016), available at <http://www.cdc.gov/hiv/basics/testing.html>, (last visited March 20, 2017).

¹² *Id.*

¹³ Department of Health, *HIV Data Center*, available at <http://www.floridahealth.gov/%5C/diseases-and-conditions/aids/surveillance/index.html>, (last visited March 20, 2017).

¹⁴ Department of Health, *HIV Disease: United States vs. Florida*, available at <http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/documents/fact-sheet/2014/2014-us-vs-fl-fact-sheet.pdf>, (last visited March 20, 2017).

source for state-sponsored HIV programs and provide testing, counseling, prevention outreach, and education to the public. The CHDs, and any other person conducting an AIDS or HIV testing program, must register with the DOH and meet necessary requirements.¹⁵ The statute was enacted to create an environment in which people would agree to seek out HIV testing because they would be sufficiently informed about the infection and assured about the privacy of a decision to be tested.¹⁶

Notification and Informed Consent

Section 381.004(2), F.S., differentiates between a “health care setting” and a “nonhealth care setting” when delineating the procedures required to obtain a person’s consent to perform an HIV test.

In the health care setting the person to be tested must be notified, either orally or in writing, that the test is planned; and that he or she has a right to refuse. If the person consents, and has a current, signed general medical consent form, no separate consent form is required for the HIV test. If the person refuses the HIV test, it must be documented in the medical records.¹⁷ A “health care setting” is defined as a setting devoted to the diagnosis and care of persons or the provision of medical services to persons, such as:

- CHD clinics;
- Hospitals;
- Urgent care clinics;
- Substance abuse treatment clinics;
- Primary care settings;
- Community clinics;
- Blood banks;
- Mobile medical clinics; and
- Correctional health care facilities.¹⁸

In a “nonhealth care setting,” a provider is required to obtain a subject’s informed consent before performing a HIV test. Informed consent, must be preceded by an explanation of the subject’s right to confidential treatment of the test results, and the information identifying him or her as the test subject.¹⁹ A “nonhealth care setting” is defined as a site that conducts HIV testing for the sole purpose of identifying HIV infection, but does not provide medical treatment. Nonhealth care settings include:

- Community-based organizations;
- Outreach settings;
- CHD HIV testing programs; and
- Mobile clinics.²⁰

¹⁵ Section 381.004(1), F.S.

¹⁶ Florida Department of Health, “*Florida’s Omnibus AIDS Act: A Brief Legal Guide for Health Care Professionals*,” Jack P. Hartog, Esq., (August 2013), available at http://www.floridahealth.gov/diseases-and-conditions/aids/administration/_documents/Omnibus-booklet-update-2013.pdf, (last visited March 20, 2017).

¹⁷ Section 381.004(2), F.S.

¹⁸ Section 381.004(1)(a), F.S.

¹⁹ *Supra* note 17.

²⁰ Section 381.004(1)(d), F.S.

In either the healthcare or nonhealth care setting, every person tested for HIV must first give his or her informed consent, except as specified in s. 381.004(2)(h), F.S. Informed consent for HIV testing requires:

- An explanation that the identity of the person to be tested, and the results of the test, are confidential and protected from disclosure to the extent permitted by law;
- Notice that persons with a positive HIV test will be reported to the local CHD; and
- Notice that anonymous testing is available and the locations of the anonymous testing sites.²¹

Informed consent must be in writing when it is:

- From the potential donor, or donor's legal representative, prior to donating blood, blood components, organs, skin, semen, or other human tissue or body part;
- For insurance purposes; and
- For contract purposes in a health maintenance organization.²²

Currently, test results contained in medical records of hospitals licensed under ch. 395, F.S., can be released under s. 395.3025, F.S., if the hospital has obtained written informed consent for the HIV test. Informed consent is not required in numerous situations, including when a significant exposure has occurred.²³

The DOH Laboratory Testing for Other States

Section 381.0202, F.S., directs the DOH to establish and maintain laboratories in the state for microbiological and chemical analysis and any other purpose it determines necessary for the protection of public health, safety and welfare. The DOH operates the Bureau of Public Health Laboratories that provides diagnostic screening, monitoring, reference, research and emergency public health laboratory services to CHDs and other official agencies, physicians, hospitals and private laboratories.²⁴

Due to costs and resource limitations, it is not feasible for all 50 states to maintain public health testing infrastructure.²⁵ Furthermore, reagents to test for rare or emerging pathogens are often only available in limited quantities from the CDC.²⁶ In response, the CDC advocates for the establishment of regional testing centers to perform specialized testing for multiple states.²⁷

Current statutory language does not give the DOH authority to perform public health laboratory testing for samples from other states.

²¹ *Id.*

²² *Id.*

²³ See s. 381.004(2)(e)14., F.S.

²⁴ Department of Health, *Bureau of Public Health Laboratories*, available at <http://www.floridahealth.gov/programs-and-services/public-health-laboratories/index.html>, (last visited Mar. 21, 2017).

²⁵ Department of Health, *House Bill 1041 Analysis (identical to SB 1144)*, (March 1, 2017) (on file with the Senate Committee on Health Policy).

²⁶ *Id.*

²⁷ *Id.*

Lead Poison Screening and Education

“Lead poisoning” or “lead toxicity” are both defined as high levels of lead, which is a heavy metal, typically associated with severe health effects. The amount of lead in the body and tissues, as well as the length of time of the exposure, determines the toxicity level and the signs and symptoms exhibited by a person.²⁸ The CDC has termed excessive absorption to lead as one of the most common pediatric health problems in the U.S. today; and it is entirely preventable.²⁹ Enough is known about lead poisoning to prevent lead exposure and permanently eradicate this condition. This makes the persistence of lead poisoning in the U.S. a singular and direct challenge to public health authorities, clinicians, regulatory agencies, and society.³⁰ While the U.S. has not eradicated lead poisoning completely, it has made tremendous progress in reducing lead exposure.³¹

Adult Lead Poisoning

Lead poisoning in adults is a medical condition caused by increased BLLs in the body, which can be from, among other things, food, water, soil, home building materials including lead paint, exhaust fumes, and industrial and recycling waste. Lead interferes with a variety of biologic processes and is toxic to many organs and tissues, including the heart, bones, intestines, kidneys and reproductive and nervous systems. The CDC states that a BLL of five micrograms per deciliter (5 µg/dL) or above for an adult is cause for concern; however, lead may impair development and have harmful health effects at even lower levels. There is no known safe level of lead exposure.³² In 2015, the National Institute for Occupational Safety and Health also designated five micrograms per deciliter (5 µg/dL) or above from whole blood, in a venipuncture blood sample, as an elevated BLL for adults.

Childhood Lead Poisoning

In the U.S. today, there are approximately 3,600,000 families with a child under 6 years of age, who live in homes with one or more conditions that can expose a child to lead levels that the U.S. Environmental Protection Agency (EPA) considers hazardous. The CDC recognizes a reference level of five micrograms of lead per deciliter (5 µg/dL) of blood to identify children whose BLLs are high enough for the CDC to recommend public health actions be initiated. Approximately 500,000 children each year, ages 1 to 5 years, exceed the reference level, which is based on an extrapolation of the U.S. population of children, ages 1 to 5 years, who are tested for BLLs. However, there is no safe BLL for children that has been identified.³³ The median concentration of BLLs for U.S. children, 1 to 5 years of age, has declined from 15 µg/dL in

²⁸ Department of Health, *Adult Lead Poisoning*, available at http://www.floridahealth.gov/environmental-health/lead-poisoning/adults.html#heading_2, (last visited March 21, 2017).

²⁹ Centers for Disease Control and Prevention, *Preventing Lead Poisoning in Young Children, Chapter 1*, (last updated October 1991) available at <https://www.cdc.gov/nceh/lead/publications/books/plpyc/Chapter1.htm>, (last visited March 21, 2017).

³⁰ Id.

³¹ See *Supra* note 28.

³² Id.

³³ President’s Task Force on Environmental Health Risks and Safety Risks to Children, *Key Federal Program to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts* (November 2016) available at https://ptfceph.niehs.nih.gov/features/assets/files/key_federal_programs_to_reduce_childhood_lead_exposures_and_eliminate_associated_health_impacts/presidents_508.pdf, (last visited March 21, 2017).

1976-1980 to 0.7 µg/dL in 2013-2014, a decrease of 95 percent.³⁴ However, the largest decline occurred between 1970 and 1990 following the elimination of lead in motor vehicle gasoline, the ban on lead paint for residential use, the removal of lead from food cans, bans on the use of lead pipes and plumbing fixtures, and other limitations on lead uses.³⁵

Signs and Symptoms of Lead Poisoning

Lead poisoning is classified acute or chronic depending upon the length of time the individual has been exposed to the source of the lead.³⁶ Signs and symptoms of acute lead poisoning include:

- Pain;
- Muscle weakness;
- Paresthesia;³⁷
- Abdominal pain;
- Nausea;
- Vomiting;
- Diarrhea;
- Constipation;
- Poor appetite;
- Weight loss;
- Encephalitis;³⁸
- Mouth astringency and metallic taste;
- “Lead hue” or pallor;
- Hemolysis;³⁹ and
- Kidney damage.⁴⁰

Chronic lead poisoning usually presents itself with symptoms affecting multiple body systems. It is associated with three main types of symptoms: gastrointestinal, neuromuscular, and neurological. Central nervous system and neuromuscular symptoms usually result from intense exposure, while gastrointestinal symptoms usually result from exposure over longer periods of time. Signs of chronic lead exposure include:

- Loss of short-term memory or concentration;
- Depression;
- Nausea;
- Abdominal pain;

³⁴ Supra note 33, at p. 6, citing Centers for Disease Control and Prevention, National Center for Health Statistics, *National Health and Nutrition Examination Survey* (updated January 25, 2017) available at <https://www.cdc.gov/nchs/nhanes.htm>, (last visited March 21, 2017); See also U.S. Environmental Protection Agency, *America’s Children and the Environment (ACE)* available at <https://www.epa.gov/ace>, (last visited March 21, 2017).

³⁵ Id. at p. 5.

³⁶ Supra note 28.

³⁷ Id. Paresthesia is the sensation of “pins” and “needles” in an effected area.

³⁸ Id. Encephalitis is an inflammation of the brain with or without seizure activity.

³⁹ Id. Hemolysis is the rupture of red blood cells in the body causing anemia and hemoglobin in the urine.

⁴⁰ Supra note 28.

- Loss of coordination;
- Numbness and tingling in the extremities;
- Fatigue;
- Problems with sleep;
- Headache;
- Stupor;
- Slurred speech;
- Anemia;
- “Lead hue” or “pallor”;
- “Burton’s Line”;⁴¹
- High blood pressure;
- Declines in mental functioning;
- Memory loss;
- Mood disorders;
- Reduced sperm count, abnormal sperm; and
- Miscarriage or premature birth in pregnant women.⁴²

Lead Toxicity Testing

In 2012, the CDC adopted the BLL as its preferred method of testing children and adults for elevated levels of lead in the body; and five micrograms per deciliter (5 µg/dL) as the level where environmental or educational public health intervention is required.⁴³ While testing is available to detect lead in any body tissue, the primary tests used in the last 30 years to evaluate lead exposure, that are readily available to practitioners, to determine lead exposure levels in the human body are:

- Venipuncture⁴⁴ - BLL, Complete Blood Count, or EP and ZPP⁴⁵ blood levels;⁴⁶
- Capillary stick^{47,48} - for BLLs;

⁴¹ Id. “Burton’s Line” is a blue line along the gum, with bluish black edging to the teeth.

⁴² Id.

⁴³ U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Environmental and Health Medicine Education, *Lead Toxicity: What Tests Can Assist with Diagnosis and Treatment of Lead Toxicity?* available at: <https://www.atsdr.cdc.gov/cssem/cssem.asp?cssem=7&po=12>, (last visited March 21, 2017).

⁴⁴ Medicare defines venipuncture, for purposes of reimbursement using CPT code 36415, as the process of puncturing a vein and withdrawing a blood sample for purposes of analysis for testing. The most common method and site of venipuncture is the insertion of a needle into the cubital vein of the anterior forearm at the elbow fold. It is fee scheduled at \$3.10, the same as a capillary stick. See Medicare Fee, Payment, Procedure code, ICD, Denial, *CPT code venipuncture - 36415 and 36416 - Billing Tips - Not separately paid*, available at: <http://www.medicarepaymentandreimbursement.com/2010/06/cpt-venipuncture-36415-not-seperately.html>, (last visited March 22, 2017).

⁴⁵ Id. Erythrocyte protoporphyrin (EP), commonly assayed as zinc protoporphyrin (ZPP), was previously considered the best test for screening for asymptomatic children; however, is not sufficiently sensitive at lower BLLs and therefore is not as useful a screening test for lead exposure as previously thought.

⁴⁶ Id. For individuals with high or chronic past exposure; however, BLLs often under-represent the total body burden because most lead is stored in the bone and may have “normal” levels in the blood.

⁴⁷ Id. The CDC recommends, that given the greater risk of contamination using the capillary stick method, an elevated BLL obtained through a capillary stick should always be confirmed through venipuncture.

⁴⁸ *Supra* note 43. Medicare defines a capillary stick, for purposes of reimbursement using CPT code 36416, as the collection of a blood specimen from the stick of the finger, heel, or ear. It is fee scheduled at \$3.10, the same as venipuncture.

- Radiographs -Abdominal to detect the presence of radio-dense lead foreign bodies in the gastrointestinal tract; or long bone to detect the presence of lead lines;⁴⁹ and
- Hair and fingernail scrapings.⁵⁰

Federal Regulations to Address Lead Exposures in Children and Adults

The U.S. Consumer Product and Safety Commission, the EPA, the Food and Drug Administration, the Department of Housing and Urban Development, the OSHA, the Department of Labor, the Department of Transportation, the Federal Aviation Administration, and the Department Health and Human Services (HHS) all have regulations in place to address lead exposure in adults and children.⁵¹ Details of those agencies comprehensive lead exposure regulations and protection activities is beyond the scope of this analysis.

Lead Poisoning Prevention Screening and Education Act

In 2006, the Florida Legislature created the Lead Poisoning Prevention Screening and Education Act (Act). The Act requires the DOH to establish a program for the early identification of persons at risk for having elevated BLLs. Section 381.985(1), F.S., requires the program to systematically screen children under the age of 6 in certain targeted populations for the presence of elevated BLLs. The DOH is required to consult with professional medical groups and other sources, and adopt rules that establish procedural guidelines for the screening of children under six, the appropriate intervals for re-screening, and the follow-up for children found to have elevated BLLs.⁵² The Act defines, “elevated blood-lead level,” as a quantity of lead in whole venous blood that exceeds ten micrograms per deciliter (10 µg/dL) or such other level as provided in the Act.⁵³

The Act requires the DOH to establish a statewide, multifaceted, ongoing educational program designed to meet the needs of tenants, property owners, health care providers, early childhood educators, care providers, and realtors concerning lead poisoning prevention.⁵⁴ This educational program requires the DOH to:

- Sponsor public service announcements on radio, television, print media, and the internet about the nature of lead-based paint hazards, the importance of standards for lead poisoning prevention, and the purposes and responsibilities of the Act; and
- Develop culturally and linguistically appropriate information pamphlets regarding lead poisoning, testing, prevention, treatment, and the purposes of the Act.⁵⁵

The DOH previously had federal funding to conduct a lead poisoning prevention program, including funding for a large media campaign. However, the federal funding for this program ended in 2012.⁵⁶

⁴⁹ Id. These are lines of increased density on the metaphysis growth plate of the bone, showing radiological growth retardation. This is not a routine procedure to identify lead poisoning, but a radiological finding of chronic exposure.

⁵⁰ Id. to detect their lead content is an uncertain estimate of body burden and is not recommended.

⁵¹ *Supra* note 28.

⁵² Section 381.985(1), F.S.

⁵³ Section 381.983(3), F.S.

⁵⁴ Section 381.984(1), F.S.

⁵⁵ Sections 381.984(2) and (3), F.S.

⁵⁶ *Supra* note 25.

The Act also requires the DOH to maintain records of all screenings conducted, indexed geographically and by owner, to determine the location of areas of relatively high incidence of lead poisoning and elevated BLLs. All confirmed and probable cases of lead poisoning found in the course of screening must be reported to the affected individual, his or her parent or legal guardian if he or she is a minor, and the State Surgeon General.⁵⁷

Florida Newborn Screening Program

The Newborn Screening Program (NSP) screens all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.⁵⁸

The Florida Genetics and Newborn Screening Advisory Council (GNSAC) advises the DOH on which disorders should be added to the panel of screening for disorders, and the procedures for collecting and transmitting specimens.⁵⁹ The GNASC is made up of 15 members, including consumer members, various state agency representatives and healthcare providers, and one representative from each of the four medical schools in the state.⁶⁰ When the GNSAC was created, the state only had four medical schools. Currently there are ten medical schools in Florida.

The NSP currently screens for 50 of the 58 disorders listed in the federal Recommended Uniform Screening Panel (RUSP),⁶¹ including 31 core conditions and 22 secondary conditions.⁶² Currently, every disorder on the NSP panel has known treatment options.

The NSP involves coordination among several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory in Jacksonville (state laboratory), Children's Medical Services (CMS) Newborn Screening Follow-up Program, and referral centers, birthing centers, and physicians throughout the state.⁶³

⁵⁷ Section 381.985(3), F.S.

⁵⁸ Department of Health, *Florida Newborn Screening Guidelines* (2012), available at https://www.peds.ufl.edu/divisions/genetics/programs/newborn_screening/2012%20newborn%20screening%20guidelines%20OFL.pdf, (last visited March 21, 2017).

⁵⁹ Section 383.14(5), F.S.

⁶⁰ *Id.*

⁶¹ The federal Advisory Committee on Heritable Disorders in Newborns and Children (committee) advises the Secretary of the U.S. Department of Health and Human Services on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines, and standards. The committee established the Recommended Uniform Screening Panel (RUSP), and periodically updates it. See U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children*, available at <https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>, (last visited March 23, 2017).

⁶² Department of Health, *Disorder List* (December 17, 2013), available at <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/documents/newborn-screening-disorders.pdf>, (last visited March 21, 2017); this list is also maintained by the DOH as a Rule. See also Rule 64C-7.002, F.A.C.

⁶³ Department of Health, *Newborn Screening*, available at <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/> (last visited March 21, 2017).

Currently, the state laboratory is only authorized to release the results of a newborn's metabolic tests or screenings to the newborn's health care practitioner.⁶⁴ Federal regulations require public health laboratories to release screening results, upon request, to the patient, the patient's parent or legal guardian, the patient's personal representative, or person designated by the patient or legal guardian.⁶⁵

III. Effect of Proposed Changes:

Section 1: Human Immunodeficiency Virus (HIV)

The bill removes the requirement for a provider in the health care setting, to inform a person seeking an HIV test that a positive test result will be reported to the CHD and of the availability and locations for anonymous testing. The bill requires only providers in the nonhealth care settings to inform persons seeking HIV testing of those facts.

Providers in health care settings will still be required to report positive HIV test results to the DOH. The bill does not remove the reporting requirement, only the requirement for providers to provide the person seeking the HIV test the information that a positive result will be reported to the DOH and the information on the availability and locations for anonymous testing.

Section 2: The DOH Laboratory Testing for Other States

The bill authorizes the DOH to perform laboratory testing related to public health for other states on a fee-for-service basis.

Sections 3 - 5: Lead Poison Screening and Education

The bill amends the definition of an, "elevated blood-lead level." The bill removes the requirement that, in determining a person's BLL, the blood sample tested must be only whole venous blood. The bill broadens the permissible test samples for BLLs to include blood from a capillary draw, but does not define the term, "draw". The use of a capillary sample to test for an elevated BLL might increase the cost of testing as, according to the CDC, all elevated BLLs from a capillary stick should be confirmed with a second testing with a whole blood sample.⁶⁶

The bill eliminates the specific, numerical level of 10 µg/dL as the quantity of lead in the blood, which constitutes an, "elevated blood-lead level." The bill requires the DOH to specify by rule the test result level defining an elevated BLL based on national recommendations developed by the Council of State and Territorial Epidemiologists and the CDC. This change allows for the adjustment of reporting and screening requirements as the science relating to BLLs changes.

The bill provides alternative media options for the DOH to use as it sponsors public service announcements and develops educational pamphlets regarding lead based paint hazards, lead poisoning prevention and the purposes and responsibilities set out in the Lead Poisoning

⁶⁴ Section 383.14(1)(c), F.S.

⁶⁵ 42 C.F.R. s. 493.1291(l) (2016).

⁶⁶ *Supra* note 48.

Prevention Screening and Education Act.⁶⁷ This creates flexibility and may result in a cost savings for the distribution of educational materials regarding lead poisoning.

The bill requires the DOH to establish guidelines for the early identification of persons at risk of having elevated BLLs and for the systematic screening of children under age six in targeted populations. This replaces the responsibility for the DOH to establish a program for the early identification of persons at risk for having elevated BLLs, which shall systematically screen children under the age of 6 in certain targeted populations for the presence of elevated BLLs. This change in focus, to developing guidelines for systematically screening, may have the effect of repealing the authority for the DOH to conduct screening activities, either directly or indirectly.⁶⁸

The bill reduces the DOH reporting and record keeping requirements regarding BLLs. The bill requires the DOH to maintain only records of all screenings with an elevated BLL rather than all screenings; and removes the requirement to report all screening results to affected individuals and maintain geographically indexed records. The bill places the requirement to notify the individual tested, or the individual's parent or legal guardian if he or she is a minor, on the provider conducting or ordering the lead level screening.

Section 6: Newborn Screening for Metabolic, Hereditary or Congenital Disorders

The bill updates the composition of the GNSAC to include a representative from four of the 10 medical schools in the state. The number of medical school representatives remains the same, but this change allows representatives from all medical schools in the state the potential to be appointed to the GNSAC, not just those medical schools in existence when the GNSAC was created.

The bill allows the state laboratory to release metabolic tests or screenings to a newborn's parent or legal guardian, the newborn's personal representative, or a person designated by the newborn's parent or legal guardian. This change aligns state law with federal regulations relating to public health laboratories.

The bill expands the DOH's duties in the newborn screening program to also promote the availability of genetic services, in addition to the availability of genetic studies and counseling so that family members may benefit from detection and available knowledge of conditions.

The bill provides an effective date of July 1, 2017.

⁶⁷ Sections 381.982 - 381.985, F.S.

⁶⁸ Blood lead screening were conduct at none CHDs: Alachua, Broward, Duval, Hillsborough, Miami-Dade, Orange, Palm Beach, Pinellas, and Polk. Screenings in most CHDs were discontinued when federal funding ended in FY 2011-2012. Miami-Dade County is the only CHD where blood lead screening are still conducted on a regular basis. E-mail from DOH to Senate Health Policy staff (March 23, 2017) (on file with the Senate Committee on Health Policy).

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:

Sections 3 - 5: Lead Poison Screening and Education- The use of a capillary draw sample to test for an elevated BLL might increase the cost of mandatory state testing of children under 6 years of age. According to the CDC, all elevated BLLs from a capillary stick should be confirmed with a second testing of whole venous blood sample.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.004, 381.0202, 381.983, 381.984, 381.985, and 383.14.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

The CS reinstates the requirement for the DOH to sponsor and seek participation from the private sector for public service announcements about lead poisoning prevention but adds a choice of media for the announcements including radio, television, the internet, or in print media, rather than requiring the use of all methods.

- B. **Amendments:**

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 106 - 114

and insert:

designee, shall sponsor a series of public service announcements on radio, television, or the Internet, or in ~~and~~ print media about the nature of lead-based-paint hazards, the importance of standards for lead poisoning prevention in properties, and the purposes and responsibilities set forth in this act. In developing and coordinating this public information initiative,



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the sponsors shall seek the participation and involvement of
private industry organizations, including those involved in real
estate, insurance, mortgage banking, or ~~and~~

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

And the title is amended as follows:

Delete lines 11 - 14

and insert:

F.S.; revising requirements of a public information
initiative on lead-based-paint hazards; revising
requirements on the distribution of information on
childhood lead poisoning developed by the State
Surgeon General or his or her designee; amending s.
381.985, F.S.;

By Senator Montford

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1 A bill to be entitled
 2 An act relating to laboratory screening; amending s.
 3 381.004, F.S.; clarifying that certain requirements
 4 related to the reporting of positive HIV test results
 5 to county health departments apply only to testing
 6 performed in a nonhealth care setting; amending s.
 7 381.0202, F.S.; authorizing the Department of Health
 8 to perform laboratory testing for other states;
 9 amending s. 381.983, F.S.; redefining the term
 10 "elevated blood-lead levels"; amending s. 381.984,
 11 F.S.; authorizing, rather than requiring, that the
 12 Governor, in conjunction with the State Surgeon
 13 General, sponsor a public information initiative on
 14 lead-based paint hazards; amending s. 381.985, F.S.;
 15 revising requirements for the State Surgeon General's
 16 program for early identification of persons at risk of
 17 having elevated blood-lead levels; requiring the
 18 department to maintain records showing elevated blood-
 19 lead levels; requiring that health care providers
 20 report to the individual who was screened the results
 21 that indicate elevated blood-lead levels; amending s.
 22 383.14, F.S.; authorizing the State Public Health
 23 Laboratory to release the results of a newborn's
 24 hearing and metabolic tests to certain individuals;
 25 requiring the department to promote the availability
 26 of services to promote detection of genetic
 27 conditions; clarifying that the membership of the
 28 Genetics and Newborn Screening Advisory Council must
 29 include one member representing each of four medical

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

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30 schools in this state; providing an effective date.
 31
 32 Be It Enacted by the Legislature of the State of Florida:
 33
 34 Section 1. Paragraph (a) of subsection (2) of section
 35 381.004, Florida Statutes, is amended to read:
 36 381.004 HIV testing.—
 37 (2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT;
 38 RESULTS; COUNSELING; CONFIDENTIALITY.—
 39 (a) Before performing an HIV test:
 40 1. In a health care setting, the person to be tested shall
 41 be notified orally or in writing that the test is planned and
 42 that he or she has the right to decline the test. If the person
 43 to be tested declines the test, such decision shall be
 44 documented in the medical record. A person who has signed a
 45 general consent form for medical care is not required to sign or
 46 otherwise provide a separate consent for an HIV test during the
 47 period in which the general consent form is in effect.
 48 2. In a nonhealth care setting, a provider shall obtain the
 49 informed consent of the person upon whom the test is to be
 50 performed. Informed consent shall be preceded by an explanation
 51 of the right to confidential treatment of information
 52 identifying the subject of the test and the results of the test
 53 as provided by law. The provider shall also inform the test
 54 subject that a positive HIV test result will be reported to the
 55 county health department with sufficient information to identify
 56 the test subject and provide him or her with information on the
 57 availability and location of sites where anonymous testing is
 58 performed. As required in paragraph (3)(c), each county health

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department shall maintain a list of sites where anonymous testing is performed which includes site locations, telephone numbers, and hours of operation.

~~The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and of the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone numbers, and hours of operation of the sites.~~

Section 2. Section 381.0202, Florida Statutes, is amended to read:

381.0202 Laboratory services.—

(1) The department shall establish and maintain, in suitable and convenient places in the state, laboratories for microbiological and chemical analyses and any other purposes it determines necessary for the protection of the public health.

(2) The department may contract or agree with any person or public or private agency to provide laboratory services relating to or having potential impact on the public health or relating to the health of clients directly under the care of the state.

(3) The department is authorized to establish and collect reasonable fees and charges for laboratory services provided. Such fees and charges shall be deposited in a trust fund administered by the department and shall be used solely for this purpose.

(4) The department may perform laboratory testing related

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to public health for other states on a fee-for-service basis.

Section 3. Subsection (3) of section 381.983, Florida Statutes, is amended to read:

381.983 Definitions.—As used in this act, the term:

(3) "Elevated blood-lead level" means a quantity of lead in the whole venous blood, measured from a venous or capillary draw expressed in micrograms per deciliter (ug/dL), which exceeds the cutpoint specified in department rule. The determination of elevated blood-lead level must be based on national recommendations developed by the Council of State and Territorial Epidemiologists and the Centers for Disease Control and Prevention. 10 ug/dL or such other level as specifically ~~provided in this act.~~

Section 4. Subsections (2) and (3) of section 381.984, Florida Statutes, are amended to read:

381.984 Educational programs.—

(2) PUBLIC INFORMATION INITIATIVE.—The Governor, in conjunction with the State Surgeon General and his or her designee, may ~~shall~~ sponsor a series of public service announcements on radio, television, and the Internet, and in print media about the nature of lead-based-paint hazards, the importance of standards for lead poisoning prevention in properties, and the purposes and responsibilities set forth in this act. In developing and coordinating this public information initiative, the sponsors may ~~shall~~ seek the participation and involvement of private industry organizations, including those involved in real estate, insurance, mortgage banking, and pediatrics.

(3) DISTRIBUTION OF INFORMATION LITERATURE ABOUT CHILDHOOD

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117 LEAD POISONING. ~~By January 1, 2007,~~ The State Surgeon General or
 118 his or her designee shall develop culturally and linguistically
 119 appropriate information and distribution methods ~~pamphlets~~
 120 regarding childhood lead poisoning, the importance of testing
 121 for elevated blood-lead levels, prevention of childhood lead
 122 poisoning, treatment of childhood lead poisoning, and, as where
 123 appropriate, the requirements of this act. ~~This~~ These
 124 information ~~pamphlets~~ shall be distributed to parents or the
 125 ~~other~~ legal guardians of children 6 years of age or younger on
 126 the following occasions:

127 (a) By a health care provider at the time of a child's
 128 birth and at the time of any childhood immunization or
 129 vaccination unless it is established that such information
 130 ~~pamphlet~~ has been provided ~~previously~~ to the parent or legal
 131 guardian by the health care provider within the prior 12 months.

132 (b) By the owner or operator of any child care facility or
 133 preschool or kindergarten class on or before each October 15 ~~of~~
 134 ~~the calendar year.~~

135 Section 5. Section 381.985, Florida Statutes, is amended to
 136 read:

137 381.985 Screening program.—

138 (1) The State Surgeon General shall establish guidelines ~~a~~
 139 ~~program~~ for early identification of persons at risk of having
 140 elevated blood-lead levels and for the systematic screening of ~~—~~
 141 ~~Such program shall systematically screen~~ children under 6 years
 142 of age in the target populations identified in subsection (2)
 143 for the presence of elevated blood-lead levels. Children within
 144 the specified target populations shall be screened with a blood-
 145 lead test at age 12 months and age 24 months, or between the

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146 ages of 36 months and 72 months if they have not previously been
 147 screened. The State Surgeon General shall, after consultation
 148 with recognized professional medical groups and such other
 149 sources as the State Surgeon General deems appropriate, adopt
 150 rules to follow established national guidelines or
 151 recommendations such as those issued by the Council of State and
 152 Territorial Epidemiologists and the Centers for Disease Control
 153 and Prevention related to reporting elevated blood-lead levels
 154 and screening results to the department pursuant to this
 155 section. ~~promulgate rules establishing:~~

156 ~~(a) The means by which and the intervals at which such~~
 157 ~~children under 6 years of age shall be screened for lead~~
 158 ~~poisoning and elevated blood lead levels.~~

159 ~~(b) Guidelines for the medical followup on children found~~
 160 ~~to have elevated blood-lead levels.~~

161 (2) In developing screening programs to identify persons at
 162 risk with elevated blood-lead levels, priority shall be given to
 163 persons within the following categories:

164 (a) All children enrolled in the Medicaid program at ages
 165 12 months and 24 months, or between the ages of 36 months and 72
 166 months if they have not previously been screened.

167 (b) Children under the age of 6 years exhibiting delayed
 168 cognitive development or other symptoms of childhood lead
 169 poisoning.

170 (c) Persons at risk residing in the same household, or
 171 recently residing in the same household, as another person at
 172 risk with an elevated ~~a~~ blood-lead level ~~of 10 ug/dl or greater.~~

173 (d) Persons at risk residing, or who have recently resided,
 174 in buildings or geographical areas in which significant numbers

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of cases of lead poisoning or elevated blood-lead levels have recently been reported.

(e) Persons at risk residing, or who have recently resided, in an affected property contained in a building that during the preceding 3 years has been subject to enforcement for violations of lead-poisoning-prevention statutes, ordinances, rules, or regulations ~~as specified by the State Surgeon General.~~

(f) Persons at risk residing, or who have recently resided, in a room or group of rooms contained in a building whose owner also owns a building containing affected properties which, during the preceding 3 years, has been subject to an enforcement action for a violation of lead-poisoning-prevention statutes, ordinances, rules, or regulations.

(g) Persons at risk residing in other buildings or geographical areas in which the State Surgeon General reasonably determines there is to be a significant risk of affected individuals having an elevated blood-lead level. ~~a blood-lead level of 10 ug/dL or greater.~~

(3) The ~~department~~ State Surgeon General shall maintain comprehensive records of all screenings indicating an elevated blood-lead level. ~~conducted pursuant to this section. Such records shall be indexed geographically and by owner in order to determine the location of areas of relatively high incidence of lead poisoning and other elevated blood-lead levels.~~

~~All cases or probable cases of lead poisoning found in the course of screenings conducted pursuant to this section shall be reported to the affected individual, to his or her parent or legal guardian if he or she is a minor, and to the State Surgeon~~

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~~General.~~

(4) The results of screenings conducted pursuant to this section shall be reported by the health care provider who conducted or ordered the screening to the individual who was screened, or to the individual's parent or legal guardian if he or she is a minor.

Section 6. Paragraph (c) of subsection (1), paragraph (f) of subsection (3), and subsection (5) of section 383.14, Florida Statutes, are amended to read:

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

(1) SCREENING REQUIREMENTS.—To help ensure access to the maternal and child health care system, the Department of Health shall promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, as screening programs accepted by current medical practice become available and practical in the judgment of the department. The department shall also promote the identification and screening of all newborns in this state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services, including, but not limited to, parent support and training programs, home visitation, and case management. Identification, perinatal screening, and intervention efforts shall begin prior to and immediately following the birth of the child by the attending health care

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provider. Such efforts shall be conducted in hospitals, perinatal centers, county health departments, school health programs that provide prenatal care, and birthing centers, and reported to the Office of Vital Statistics.

(c) *Release of screening results.*—Notwithstanding any law to the contrary, the State Public Health Laboratory may release, directly or through the Children's Medical Services program, the results of a newborn's hearing and metabolic tests or screenings to the newborn's health care practitioner, the newborn's parent or legal guardian, the newborn's personal representative, or a person designated by the newborn's parent or legal guardian. As used in this paragraph, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458; an osteopathic physician or physician assistant licensed under chapter 459; an advanced registered nurse practitioner, registered nurse, or licensed practical nurse licensed under part I of chapter 464; a midwife licensed under chapter 467; a speech-language pathologist or audiologist licensed under part I of chapter 468; or a dietician or nutritionist licensed under part X of chapter 468.

(3) DEPARTMENT OF HEALTH; POWERS AND DUTIES.—The department shall administer and provide certain services to implement the provisions of this section and shall:

(f) Promote the availability of genetic studies, services, and counseling in order that the parents, siblings, and affected newborns may benefit from detection and available knowledge of the condition.

All provisions of this subsection must be coordinated with the

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provisions and plans established under this chapter, chapter 411, and Pub. L. No. 99-457.

(5) ADVISORY COUNCIL.—There is established a Genetics and Newborn Screening Advisory Council made up of 15 members appointed by the State Surgeon General. The council shall be composed of two consumer members, three practicing pediatricians, at least one of whom must be a pediatric hematologist, ~~a~~ one representative from each of ~~the~~ four medical schools in this ~~the~~ state, the State Surgeon General or his or her designee, one representative from the Department of Health representing Children's Medical Services, one representative from the Florida Hospital Association, one individual with experience in newborn screening programs, one individual representing audiologists, and one representative from the Agency for Persons with Disabilities. All appointments shall be for a term of 4 years. The chairperson of the council shall be elected from the membership of the council and shall serve for a period of 2 years. The council shall meet at least semiannually or upon the call of the chairperson. The council may establish ad hoc or temporary technical advisory groups to assist the council with specific topics which come before the council. Council members shall serve without pay. Pursuant to the provisions of s. 112.061, the council members are entitled to be reimbursed for per diem and travel expenses. It is the purpose of the council to advise the department about:

(a) Conditions for which testing should be included under the screening program and the genetics program.

(b) Procedures for collection and transmission of specimens and recording of results.

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291 (c) Methods whereby screening programs and genetics
292 services for children now provided or proposed to be offered in
293 the state may be more effectively evaluated, coordinated, and
294 consolidated.

295 Section 7. This act shall take effect July 1, 2017.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Commerce and Tourism, *Chair*
Communications, Energy, and Public Utilities,
Vice Chair
Appropriations
Appropriations Subcommittee on Pre-K - 12
Education
Health Policy
Rules

SENATOR BILL MONTFORD

3rd District

March 14 , 2017

Senator Dana Young, Chair
Senate Committee on Health Policy
530 Knott Building
Tallahassee, Florida 32399-1100

Dear Chair Young:

I respectfully request that the following bills be placed on the agenda for the next Health Policy Committee Meeting:

SB 1144 – Laboratory Screening
SB 1206 – Rights and Responsibilities of Patients

Your consideration is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Bill Montford".

William "Bill" Montford
Senate District 3

MD/WM

Cc: Sandra Stovall Staff Director
Celia Georgiades, Administrative Assistant

REPLY TO:

- ☐ 410 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5003
- ☐ 20 East Washington Street, Suite D, Quincy, Florida 32351 (850) 627-9100

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

3/27/17
Meeting Date

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

1144
Bill Number (if applicable)
682720
Amendment Barcode (if applicable)

Topic LAB SCREENING

Name DAVID CULLEN

Job Title _____

Address 1674 UNIVERSITY AVE #296
Street

Phone 941-323-2404

SARASOTA FL 34243
City State Zip

Email cullen@advocacyinstitute.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing ADVOCACY INSTITUTE FOR CHILDREN

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

3-27-17

Meeting Date

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

1144

Bill Number (if applicable)

Topic Lab Screening

Amendment Barcode (if applicable)

Name Tom Joos

Job Title Department of Health

Address 2585 Merchants Row Blvd.

Phone 850-245-4006

Street

Tallahassee

FL

32399

City

State

Zip

Email _____

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Department of Health

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/27/17
Meeting Date

1144
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Noland

Job Title _____

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jacksonville, FL 32204

City

State

Zip

Email nolandnola@aol.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Public Health Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

3/27/17
Meeting Date

1144
Bill Number (if applicable)

Topic Laboratory Screening

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blainstone Pines Dr
Street

Phone 878-7364

Tallahassee FL 32301
City State Zip

Email winnsvr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ 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)

3/27/17

Meeting Date

SB 1144

Bill Number (if applicable)

Topic Laboratory Screening

Amendment Barcode (if applicable)

Name Aimee Diaz Lyon

Job Title _____

Address 119 South Monroe Street, 200

Phone 850-205-9000

Street

Tallahassee FL 32301

Email aimce.diazlyon@mhdm.com

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

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

Representing The AIDS Institute

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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 1206

INTRODUCER: Health Policy Committee and Senator Montford

SUBJECT: Rights and Responsibilities of Patients

DATE: March 29, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1206 amends the Florida Patient's Bill of Rights to include the right for a patient to bring any person of his or her choosing to the patient-accessible areas of a health care facility or provider's office while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider unless doing so would risk the health of the patient, other patients, or staff of the facility or office or doing so cannot be reasonably accommodated by the facility. The bill also requires this right be added to the summary of rights and responsibilities that must be made available by health care providers to patients.

II. Present Situation:

Florida Patient's Bill of Rights and Responsibilities

Florida Patient's Bill of Rights and Responsibilities¹ (Bill of Rights) establishes a list of rights that each patient has when seeking health care in specified settings. The Bill of Rights requires that all health care facilities² and providers³ must ensure:

- The patient's dignity is respected through ensuring the patient has the right to privacy, with some exceptions; the right to a prompt and reasonable response to a question; and the right to retain and use personal clothing and possessions as space permits.

¹ Section 381.026, F.S.

² Defined as hospitals and ambulatory surgical centers licensed under ch. 395, F.S.,

³ Defined as physicians licensed under chs. 458, 459, and 461, F.S.

- The patient has access to pertinent information including, but not limited to, information on services offered by the provider; the patient's diagnosis, planned course of treatment, alternatives, risks, and prognosis with some exceptions; and the right to express grievances with the healthcare provider; and information on facility rules and regulations.
- The patient has access to financial information including, but not limited to, information on financial resources for the patient's healthcare, a reasonable estimate of charges, and a link to financial information disseminated by the Agency for Health Care Administration.⁴
- The patient has access to health care including impartial access to medical treatment regardless of race, national origin, religion, handicap, or source of payment; treatment for any emergency medical condition that will deteriorate from failure to provide such treatment; and access to any mode of treatment that is, in the patient's judgement and the judgement of his or her health care practitioner, in the best interests of the patient.
- That the patient knows whether or not the treatment he or she is receiving is for purposes of experimental research.

The Bill of Rights requires that patients respect the health care provider's and health care facility's right to expect behavior that is reasonable and responsible. A patient is responsible for:

- Providing to the health care provider, to the best of his or her knowledge, accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health.
- Reporting unexpected changes in his or her condition to the health care provider.
- Reporting to the health care provider whether he or she comprehends a contemplated course of action and what is expected of him or her.
- Following the treatment plan recommended by the health care provider.
- Keeping appointments and, when he or she is unable to do so for any reason, for notifying the health care provider or health care facility.
- His or her actions if he or she refuses treatment or does not follow the health care provider's instructions.
- Assuring that the financial obligations of his or her health care are fulfilled as promptly as possible.
- Following health care facility rules and regulations affecting patient care and conduct.

The Bill of Rights also requires that health care providers and health care facilities make available a written summary of the Florida Patient's Bill of Rights.

III. Effect of Proposed Changes:

CS/SB 1206 amends the Florida Patient's Bill of Rights to include the right for a patient to bring any person of his or her choosing to the patient-accessible areas of a health care facility or provider's office while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider unless doing so would risk the health of the patient, other patients, or staff of the facility or office or doing so cannot be reasonably accommodated by the facility. The bill also requires this right be added to the summary of rights and responsibilities that must be made available by health care providers to patients.

⁴ Pursuant to s. 408.05(3), F.S.

An additional potential effect of the bill may be to resolve a perceived statutory restriction on discussing a patient's condition with others present in the room that is created in s. 456.057(7)(a) and (c), F.S., related to the ownership and control of patient records. This section prohibits a health care practitioner from discussing the medical condition of a patient or information disclosed to the practitioner by a patient in the course of care and treatment of the patient with any person other than the patient, the patient's legal representative, or other health care practitioners and providers involved in the patient's care or treatment, except upon written authorization from the patient. This restriction may be more restrictive than the Health Insurance Portability and Accountability Act (HIPAA) provision which allows a provider to share or discuss information if the patient is present and does not object.⁵ The new right created in this bill would clarify the physician may discuss the patient's condition and treatment while a person of the patient's choosing is in the room.

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:

None.

VI. Technical Deficiencies:

None.

⁵ See Summary of the HIPAA Privacy Rule at Permitted Uses and Disclosures: (3) Uses and Disclosures with Opportunity to Agree or Object, available at <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/> (last visited on Mar. 24, 2017).

VII. Related Issues:

The term “patient-accessible areas” is not defined in the bill. Additionally the bill does not include rulemaking authority so it may be difficult to clarify the meaning of the term.

VIII. Statutes Affected:

This bill substantially amends section 381.026 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 26, 2017:

The CS clarifies that a patient does not have the right to bring a person with him or her to a consultation or in-patient or out-patient surgery if doing so would risk the health and safety of the patient, other patients, or facility or office staff or if the health care facility or provider cannot reasonably accommodate the person. Additionally, the amendment removes language restricting any person or entity with a fiduciary interest in the patient’s treatment from attending the patient’s consultations or attempting to change the course of the patient’s treatment.

- B. **Amendments:**

None.



312436

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Amendment

Delete lines 55 - 97
and insert:
consulting with his or her health care provider, unless doing so
would risk the safety or health of the patient, other patients,
or staff of the facility or office or cannot be reasonably
accommodated by the facility or provider.

(6) SUMMARY OF RIGHTS AND RESPONSIBILITIES.—Any health care
provider who treats a patient in an office or any health care



312436

facility licensed under chapter 395 that provides emergency services and care or outpatient services and care to a patient, or admits and treats a patient, shall adopt and make available to the patient, in writing, a statement of the rights and responsibilities of patients, including the following:

SUMMARY OF THE FLORIDA PATIENT'S BILL
OF RIGHTS AND RESPONSIBILITIES

Florida law requires that your health care provider or health care facility recognize your rights while you are receiving medical care and that you respect the health care provider's or health care facility's right to expect certain behavior on the part of patients. You may request a copy of the full text of this law from your health care provider or health care facility. A summary of your rights and responsibilities follows:

A patient has the right to be treated with courtesy and respect, with appreciation of his or her individual dignity, and with protection of his or her need for privacy.

A patient has the right to a prompt and reasonable response to questions and requests.

A patient has the right to know who is providing medical services and who is responsible for his or her care.

A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak English.

A patient has the right to bring any person of his or her choosing to the patient-accessible areas of the health care



312436

40 facility or provider's office to accompany the patient while the
41 patient is receiving inpatient or outpatient treatment or is
42 consulting with his or her health care provider, unless doing so
43 would risk the safety or health of the patient, other patients,
44 or staff of the facility or office or cannot be reasonably
45 accommodated by the facility or provider.

By Senator Montford

3-00124A-17

20171206__

A bill to be entitled

An act relating to the rights and responsibilities of patients; amending s. 381.026, F.S.; requiring health care facilities and providers to authorize patients to bring in any person of the patients' choosing to specified areas of the facilities or providers' offices under certain circumstances; requiring health care facilities and providers to include such authorization as an additional patient standard in the statement of rights and responsibilities made available to patients by health care providers; providing an effective date.

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

Section 1. Paragraph (a) of subsection (4) and subsection (6) of section 381.026, Florida Statutes, are amended to read:
381.026 Florida Patient's Bill of Rights and Responsibilities.—

(4) RIGHTS OF PATIENTS.—Each health care facility or provider shall observe the following standards:

(a) *Individual dignity*.—

1. The individual dignity of a patient must be respected at all times and upon all occasions.

2. Every patient who is provided health care services retains certain rights to privacy, which must be respected without regard to the patient's economic status or source of payment for his or her care. The patient's rights to privacy must be respected to the extent consistent with providing

3-00124A-17

20171206__

adequate medical care to the patient and with the efficient administration of the health care facility or provider's office. However, this subparagraph does not preclude necessary and discreet discussion of a patient's case or examination by appropriate medical personnel.

3. A patient has the right to a prompt and reasonable response to a question or request. A health care facility shall respond in a reasonable manner to the request of a patient's health care provider for medical services to the patient. The health care facility shall also respond in a reasonable manner to the patient's request for other services customarily rendered by the health care facility to the extent such services do not require the approval of the patient's health care provider or are not inconsistent with the patient's treatment.

4. A patient in a health care facility has the right to retain and use personal clothing or possessions as space permits, unless for him or her to do so would infringe upon the right of another patient or is medically or programmatically contraindicated for documented medical, safety, or programmatic reasons.

5. A patient receiving care in a health care facility or in a provider's office has the right to bring any person of his or her choosing to the patient-accessible areas of the health care facility or provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider. Any person or entity that may have a fiduciary interest affected by the patient's course of treatment may not attend a consultation or attempt to change a prescribed course of treatment without the

3-00124A-17

20171206__

59 health care provider's consent.

60 (6) SUMMARY OF RIGHTS AND RESPONSIBILITIES.—Any health care
61 provider who treats a patient in an office or any health care
62 facility licensed under chapter 395 that provides emergency
63 services and care or outpatient services and care to a patient,
64 or admits and treats a patient, shall adopt and make available
65 to the patient, in writing, a statement of the rights and
66 responsibilities of patients, including the following:

67
68 SUMMARY OF THE FLORIDA PATIENT'S BILL
69 OF RIGHTS AND RESPONSIBILITIES
70

71 Florida law requires that your health care provider or
72 health care facility recognize your rights while you are
73 receiving medical care and that you respect the health care
74 provider's or health care facility's right to expect certain
75 behavior on the part of patients. You may request a copy of the
76 full text of this law from your health care provider or health
77 care facility. A summary of your rights and responsibilities
78 follows:

79 A patient has the right to be treated with courtesy and
80 respect, with appreciation of his or her individual dignity, and
81 with protection of his or her need for privacy.

82 A patient has the right to a prompt and reasonable response
83 to questions and requests.

84 A patient has the right to know who is providing medical
85 services and who is responsible for his or her care.

86 A patient has the right to know what patient support
87 services are available, including whether an interpreter is

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20171206__

88 available if he or she does not speak English.

89 A patient has the right to bring any person of his or her
90 choosing to the patient-accessible areas of the health care
91 facility or provider's office to accompany the patient while the
92 patient is receiving inpatient or outpatient treatment or is
93 consulting with his or her health care provider, except that any
94 person or entity that may have a fiduciary interest affected by
95 the patient's course of treatment may not attend a consultation
96 or attempt to change a prescribed course of treatment without
97 the health care provider's consent.

98 A patient has the right to know what rules and regulations
99 apply to his or her conduct.

100 A patient has the right to be given by the health care
101 provider information concerning diagnosis, planned course of
102 treatment, alternatives, risks, and prognosis.

103 A patient has the right to refuse any treatment, except as
104 otherwise provided by law.

105 A patient has the right to be given, upon request, full
106 information and necessary counseling on the availability of
107 known financial resources for his or her care.

108 A patient who is eligible for Medicare has the right to
109 know, upon request and in advance of treatment, whether the
110 health care provider or health care facility accepts the
111 Medicare assignment rate.

112 A patient has the right to receive, upon request, prior to
113 treatment, a reasonable estimate of charges for medical care.

114 A patient has the right to receive a copy of a reasonably
115 clear and understandable, itemized bill and, upon request, to
116 have the charges explained.

3-00124A-17

20171206__

117 A patient has the right to impartial access to medical
118 treatment or accommodations, regardless of race, national
119 origin, religion, handicap, or source of payment.

120 A patient has the right to treatment for any emergency
121 medical condition that will deteriorate from failure to provide
122 treatment.

123 A patient has the right to know if medical treatment is for
124 purposes of experimental research and to give his or her consent
125 or refusal to participate in such experimental research.

126 A patient has the right to express grievances regarding any
127 violation of his or her rights, as stated in Florida law,
128 through the grievance procedure of the health care provider or
129 health care facility which served him or her and to the
130 appropriate state licensing agency.

131 A patient is responsible for providing to the health care
132 provider, to the best of his or her knowledge, accurate and
133 complete information about present complaints, past illnesses,
134 hospitalizations, medications, and other matters relating to his
135 or her health.

136 A patient is responsible for reporting unexpected changes
137 in his or her condition to the health care provider.

138 A patient is responsible for reporting to the health care
139 provider whether he or she comprehends a contemplated course of
140 action and what is expected of him or her.

141 A patient is responsible for following the treatment plan
142 recommended by the health care provider.

143 A patient is responsible for keeping appointments and, when
144 he or she is unable to do so for any reason, for notifying the
145 health care provider or health care facility.

Page 5 of 6

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

3-00124A-17

20171206__

146 A patient is responsible for his or her actions if he or
147 she refuses treatment or does not follow the health care
148 provider's instructions.

149 A patient is responsible for assuring that the financial
150 obligations of his or her health care are fulfilled as promptly
151 as possible.

152 A patient is responsible for following health care facility
153 rules and regulations affecting patient care and conduct.

154 Section 2. This act shall take effect July 1, 2017.

Page 6 of 6

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



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Commerce and Tourism, *Chair*
Communications, Energy, and Public Utilities,
Vice Chair
Appropriations
Appropriations Subcommittee on Pre-K - 12
Education
Health Policy
Rules

SENATOR BILL MONTFORD

3rd District

March 14 , 2017

Senator Dana Young, Chair
Senate Committee on Health Policy
530 Knott Building
Tallahassee, Florida 32399-1100

Dear Chair Young:

I respectfully request that the following bills be placed on the agenda for the next Health Policy Committee Meeting:

SB 1144 – Laboratory Screening
SB 1206 – Rights and Responsibilities of Patients

Your consideration is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Bill Montford".

William "Bill" Montford
Senate District 3

MD/WM

Cc: Sandra Stovall Staff Director
Celia Georgiades, Administrative Assistant

REPLY TO:

- ☐ 410 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5003
- ☐ 20 East Washington Street, Suite D, Quincy, Florida 32351 (850) 627-9100

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)

27 Mar 2017
Meeting Date

1206
Bill Number (if applicable)

Topic Patient Bill of Rights

Amendment Barcode (if applicable)

Name Cynthia Henderson

Job Title _____

Address 108 E. Jefferson St
Street

Phone 850 559 0855

Tallahassee FL 32301
City State Zip

Email Cyhenderson@me.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Crowne Consulting

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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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)

3/27/17
Meeting Date

1206
Bill Number (if applicable)

Topic Patient Bill of Rights

Amendment Barcode (if applicable)

Name Susan Scherer

Job Title CEO/RN

Address 8875 Hidden River Pkwy Suite 300
Street
Tampa, FL 33637
City State Zip

Phone 813-205-9936

Email sscherer@rncancersolutions.com

Speaking: ☒ For ☐ Against ☒ Information

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

Representing RN Cancer Guides Solutions

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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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 1324

INTRODUCER: Health Policy Committee and Senator Garcia

SUBJECT: Hair Restoration or Transplant

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1324 prohibits anyone other than a physician or physician assistant (PA), licensed under the medical or osteopathic practice act, or an advanced registered nurse practitioner (ARNP) from performing a hair restoration or transplant, or making incisions for the purpose of performing a hair restoration or transplant.

The bill defines “hair restoration or transplant” as a surgical procedure that removes hair follicles from one location on a living human body to another location on the same body by:

- Coring with a hollow punch or a robotic instrument and removing the tissue,
- Removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip, or
- Extracting or removing hair follicles.

The bill affirmatively states that it does not restrict a physician’s ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

The bill has no fiscal impact on state government.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

Hair Restoration Procedures

There are several techniques a physician can employ to restore hair to bald or balding portions of the human scalp. The most recently developed procedure is the follicular unit transplant. This procedure involves the removal of a strip of tissue from the donor area of a patient's scalp, which is then divided into a number of individual follicular units. The physician then grafts the individual follicular units into tiny holes made in the bald area of the scalp, called recipient sites.¹

Another type of hair restoration procedure is the bald scalp reduction procedure. As implied by the name, a bald scalp reduction procedure entails the removal of a bald area of the patient's scalp, and hair-producing areas of the scalp are stretched to cover the area removed. A similar procedure, the scalp flap surgery, involves the cutting and grafting of an entire flap of hair-producing scalp onto a bald area of the scalp. Both bald scalp reduction and scalp flap surgeries can have rapid results, but the follicular unit transplant surgery is generally preferred due to the more natural look produced and the risk of scarring or failure inherent with bald scalp reduction and scalp flap surgeries.²

Tissue or scalp expansion procedures can also be used to restore bald areas of the scalp. Tissue expansion uses a balloon, called an expander, to stretch the skin in order to create extra skin, which can be removed and grafted onto the bald area. Tissue expansion can be used for scalp repair since the stretched skin on the scalp retains normal hair growth.³

Regulation of Physician Assistants in Florida

Chapter 458, F.S., provides for the regulation of the practice of medicine by the Board of Medicine. Chapter 459, F.S., similarly provides for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine. Physician assistants are regulated by both boards. Licensure of PAs is overseen jointly by the boards through the Council on Physician Assistants.⁴

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.⁵ The Board of Medicine and the Board of Osteopathic Medicine have adopted rules that set out the general principles a supervising

¹ Bernstein Medical Center for Hair Restoration, *Follicular Unit Transplant* (updated June 6, 2014) available at <http://www.bernsteinmedical.com/fut-hair-transplant/>, (last visited on March 21, 2017).

² Foundation for Hair Restoration, *Bald Scalp Reduction and Scalp Flap Surgery: A Historical Perspective* <http://www.foundhair.com/pages/baldScalp.shtml>, (last visited on Mar. 21, 2017).

³ University of Pittsburgh Medical Center, Children's Hospital of Pittsburgh, *Tissue Expansion* <http://www.chp.edu/our-services/plastic-surgery/patient-procedures/tissue-expansion>, (last visited on Mar. 17, 2017).

⁴ The council on Physician Assistants consists of three physicians who are members of the Board of Medicine; one physician who is a member of the Board of Osteopathic Medicine; and a physician assistant appointed by the State Surgeon General. See ss. 458.347(9) and 459.022(9), F.S.

⁵ Sections 458.347(4) and 459.022(4), F.S.

physician must use in developing the scope of practice of the PA under both direct⁶ and indirect⁷ supervision.

A supervising physician's decision to permit a PA to perform a task or procedure under direct or indirect supervision must be based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. The supervising physician must be certain that the PA is knowledgeable and skilled in performing the tasks and procedures assigned.⁸ Each physician or group of physicians supervising a licensed PA must be qualified in the medical areas in which the PA is to perform and must be individually or collectively responsible and liable for the performance and the acts and omissions of the PA.⁹

Regulation of Advanced Registered Nurse Practitioners in Florida

Chapter 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health and are regulated by the Board of Nursing (BON).¹⁰ An ARNP is a licensed nurse who is certified in advanced or specialized nursing.¹¹ Florida recognizes three types of ARNPs: nurse practitioner (NP), certified registered nurse anesthetist (CRNA), and certified nurse midwife (CNM).¹²

To be certified as an ARNP, a nurse must hold a current license as a registered nurse¹³ and submit proof to the BON that he or she meets one of the following requirements:¹⁴

- Satisfactory completion of a formal post-basic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;¹⁵ or
- Graduation from a master's degree program in a nursing clinical specialty area with preparation in specialized practitioner skills.

Advanced or specialized nursing functions may only be performed under a protocol with a supervising physician or dentist. Within the established framework of the protocol, an ARNP may:¹⁶

⁶ "Direct supervision" requires the physician to be on the premises and immediately available. See Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

⁷ "Indirect supervision" refers to the easy availability of the supervising physician to the PA, which includes the ability to communicate by telecommunications, and requires the physician to be within reasonable physical proximity. See Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

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

⁹ Sections 458.347(3) and 459.022(3), F.S.

¹⁰ The BON is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. See s. 464.004, F.S.

¹¹ "Advanced or specialized nursing practice" is defined as the performance of advanced-level nursing acts approved by the BON, which by virtue of post-basic specialized education, training, and experience, are appropriately performed by an advanced registered nurse practitioner. See s. 464.003(2) and (3), F.S.

¹² Section 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from advanced registered nurse practitioners. See ss. 464.003(7) and 464.0115, F.S.

¹³ Also referred to as "practice of professional nursing," which is defined in s. 464.003(20), F.S.

¹⁴ Section 464.012(1), F.S.

¹⁵ Specialty boards expressly recognized by the BON are set forth in Rule 64B9-4.002(2), F.A.C.

¹⁶ Section 464.012(3), F.S.

- Prescribe, dispense, administer or order any drug;¹⁷
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by rule;¹⁸
- Order diagnostic tests and physical and occupational therapy; and
- Order any medication for a patient in a hospital, ambulatory surgical center, or nursing home.

Chapter 464, F.S., further describes additional functions that may be performed within an ARNP's specialty certification (CRNA, CNM, and NP).¹⁹

An ARNP must meet financial responsibility requirements, as determined by rule of the BON, and the practitioner profiling requirements.²⁰ The BON requires professional liability coverage of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000 or an unexpired irrevocable letter of credit in the same amounts payable to the ARNP.²¹

Regulation of Hair Restoration Procedures in Florida

Currently, there are no provisions under chs. 458 or 459, F.S., that define "hair restoration or transplant" or provide guidelines on who may perform a hair restoration or transplant procedure.

III. Effect of Proposed Changes:

This bill creates new sections of Florida Statutes relating to hair restoration or transplant in the medical practice act, ch. 458, F.S., and the osteopathic medical practice act, ch. 459, F.S. The bill defines hair restoration or transplant to mean a surgical procedure that removes hair follicles from the body by coring with a hollow punch and removing the tissue²² or robotic instrument,²³ by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip,²⁴ or by extracting or removing hair follicles from one location on a living person's body to another location on that person's body.

The bill prohibits anyone other than a physician, PA, or an ARNP from performing a hair restoration or transplant or making incisions for the purpose of performing a hair restoration or transplant. The bill affirmatively states that it does not restrict a physician's ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

¹⁷ However, an ARNP may prescribe or dispense controlled substances as defined in s. 893.03, F.S., only if he or she has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. See s. 464.012(3)(a), F.S.

¹⁸ An ARNP may perform acts of nursing diagnosis and nursing treatment for alterations in a patient's health status. The ARNP may also perform acts of medical diagnosis and treatment, prescription, and operation as authorized within the framework of his or her established supervisory protocol. See s. 464.003(2), F.S.

¹⁹ Section 464.012(4), F.S.

²⁰ Sections 456.0391, 456.041, and 456.048, F.S.

²¹ Rule 64B9-4.002(5), F.A.C.

²² See Bernstein Medical Center for Hair Restoration, *Follicular Unit Transplantation (FUT)*, available at <https://www.bernsteinmedical.com/robotic-hair-transplant/> (last visited March 27, 2017), describing coring with hollow punch and dissection of follicles off a tissue strip.

²³ Coring with a hollow punch or robotic instrument are two surgical methods of harvesting hair plugs from one area of the body to be transplanted to another part of the human body. See Bernstein Medical Center for Hair Restoration, *Robotic FUE Hair Transplants*, available at: <https://www.bernsteinmedical.com/robotic-hair-transplant/>, (last visited March 27, 2017).

²⁴ *Supra* note 22.

However, the effect of the bill is to restrict a physician from delegating certain aspects of a hair transplant or hair restoration surgery to anyone other than a licensed PA or an ARNP.

The bill has no fiscal impact on state government.

The effective date of the bill is July 1, 2017.

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:

Only licensed physicians, or PAs under the medical practice act or osteopathic practice act, and ARNPs, may perform a hair restoration or transplant. This may impact operations for some medical practices.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 458.352 and 459.027.

IX. Additional Information:**A. Committee Substitute – Substantial :**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 27, 2017:

The CS expands the definition of hair restoration or transplant to include surgical procedures that removes hair follicles from the body by coring with a hollow punch and removing the tissue or robotic instrument, or by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip of tissue.

The CS affirmatively states that it does not restrict a physician's ability to delegate or supervise an ARNP or a PA in the performance of hair restoration or transplant services.

B. Amendments:

None.

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



113088

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 458.352, Florida Statutes, is created to
read:

458.352 Hair restoration or transplant.—

(1) As used in this section, the term "hair restoration or
transplant" means a surgical procedure that removes hair
follicles after they have been cored by a hollow punch or



113088

robotic instrument, dissects hair follicles off of the body from a strip of tissue, or extracts or removes hair follicles from one location on a living human body for the purpose of redistributing the hair follicles to another location on such body.

(2) A person who is not licensed under this chapter or chapter 459 or certified under s. 464.012 may not perform a hair restoration or transplant or make incisions for the purpose of performing a hair restoration or transplant. This subsection does not restrict a physician's ability to delegate or supervise an advanced registered nurse practitioner or a physician assistant in the performance of hair restoration or transplant services.

Section 2. Section 459.027, Florida Statutes, is created to read:

459.027 Hair restoration or transplant.—

(1) As used in this section, the term "hair restoration or transplant" means a surgical procedure that removes hair follicles after they have been cored by a hollow punch or robotic instrument, dissects hair follicles off of the body from a strip of tissue, or extracts or removes hair follicles from one location on a living human body for the purpose of redistributing the hair follicles to another location on such body.

(2) A person who is not licensed under this chapter or chapter 458 or certified under s. 464.012 may not perform a hair restoration or transplant or make incisions for the purpose of performing a hair restoration or transplant. This subsection does not restrict a physician's ability to delegate or supervise



113088

an advanced registered nurse practitioner or a physician
assistant in the performance of hair restoration or transplant
services.

Section 3. This act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled

An act relating to hair restoration or transplant;
creating ss. 458.352 and 459.027, F.S.; defining the
term "hair restoration or transplant"; prohibiting a
person who is not licensed under ch. 458, F.S., or ch.
459, F.S., or certified under s. 464.012, F.S., from
performing a hair restoration or transplant or making
incisions for the purpose of performing a hair
restoration or transplant; providing construction;
providing an effective date.



108722

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
	.	
	.	
	.	

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

Senate Substitute for Amendment (113088) (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 458.352, Florida Statutes, is created to
read:

458.352 Hair restoration or transplant.—

(1) As used in this section, the term "hair restoration or



108722

transplant" means a surgical procedure that removes hair follicles from the body by coring with a hollow punch and removing the tissue or robotic instrument, by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip of tissue, or by extracting or removing hair follicles from one location on a living human body, for the purpose of redistributing the hair follicles to another location on the same human body.

(2) A person who is not licensed under this chapter or chapter 459 or certified under s. 464.012 may not perform a hair restoration or transplant or make incisions for the purpose of performing a hair restoration or transplant. This subsection does not restrict a physician's ability to delegate or supervise an advanced registered nurse practitioner or a physician assistant in the performance of hair restoration or transplant services.

Section 2. Section 459.027, Florida Statutes, is created to read:

459.027 Hair restoration or transplant.—

(1) As used in this section, the term "hair restoration or transplant" means a surgical procedure that removes hair follicles by coring with a hollow punch and removing the tissue or robotic instrument, by removing or dissecting a strip of tissue from the body containing hair follicles that may be dissected off the strip of tissue, or by extracting or removing hair follicles from one location on a living human body, for the purpose of redistributing the hair follicles to another location on the same human body.

(2) A person who is not licensed under this chapter or



108722

chapter 458 or certified under s. 464.012 may not perform a hair restoration or transplant or make incisions for the purpose of performing a hair restoration or transplant. This subsection does not restrict a physician's ability to delegate or supervise an advanced registered nurse practitioner or a physician assistant in the performance of hair restoration or transplant services.

Section 3. This act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled

An act relating to hair restoration or transplant;
creating ss. 458.352 and 459.027, F.S.; defining the
term "hair restoration or transplant"; prohibiting a
person who is not licensed under ch. 458, F.S., or ch.
459, F.S., or certified under s. 464.012, F.S., from
performing a hair restoration or transplant or making
incisions for the purpose of performing a hair
restoration or transplant; providing construction;
providing an effective date.

By Senator Garcia

36-01314-17

20171324__

A bill to be entitled

An act relating to hair restoration or transplant;
creating ss. 458.352 and 459.027, F.S.; defining the
term "hair restoration or transplant"; prohibiting a
person who is not licensed under ch. 458, F.S., or ch.
459, F.S., or certified under s. 464.012, F.S., from
performing a hair restoration or transplant or making
incisions for the purpose of performing a hair
restoration or transplant; providing an effective
date.

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

Section 1. Section 458.352, Florida Statutes, is created to
read:

458.352 Hair restoration or transplant.-

(1) As used in this section, the term "hair restoration or
transplant" means a surgical procedure that extracts or removes
hair follicles from one location on an individual living human
body for the purpose of redistributing the hair follicles to
another location on such body.

(2) A person who is not licensed under this chapter or
chapter 459 or certified under s. 464.012 may not perform a hair
restoration or transplant or make incisions for the purpose of
performing a hair restoration or transplant.

Section 2. Section 459.027, Florida Statutes, is created to
read:

459.027 Hair restoration or transplant.-

(1) As used in this section, the term "hair restoration or

Page 1 of 2

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

36-01314-17

20171324__

transplant" means a surgical procedure that extracts or removes
hair follicles from one location on an individual living human
body for the purpose of redistributing the hair follicles to
another location on such body.

(2) A person who is not licensed under this chapter or
chapter 458 or certified under s. 464.012 may not perform a hair
restoration or transplant or make incisions for the purpose of
performing a hair restoration or transplant.

Section 3. This act shall take effect July 1, 2017.

Page 2 of 2

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

The Florida Senate
State Senator René García
36th District

Please reply to:

District Office:

1490 West 68 Street
Suite # 201
Hialeah, FL. 33014
Phone# (305) 364-3100

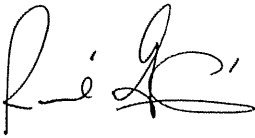
March 15th, 2017

The Honorable Dana Young
Chair, Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Senator Young,

Please have this letter serve as my formal request to have **SB 1324: Hair Restoration or Transplant** be heard during the next scheduled Health Policy Committee Meeting. Should you have any questions or concerns, please do not hesitate to contact my office.

Sincerely,



State Senator René García
District 36

CC: Sandra Stovall
Celia Georgiades

Committees: Children, Families, and Elder Affairs, Chairman, Banking and Insurance, Appropriations Subcommittee on General Government, Appropriations Subcommittee on Finance and Tax, Vice Chair, Judiciary

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/27/17

Meeting Date

1324

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title _____

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jacksonville, FL 32204

Email nulandlaw@aol.com

City

State

Zip

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Society of Plastic Surgeons / Florida Society of Dermatology & Dermatologic Surgeons

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

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 1406

INTRODUCER: Health Policy Committee; and Senator Powell and others

SUBJECT: Stroke Centers

DATE: March 28, 2017

REVISED: _____

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1406 requires the Agency for Health Care Administration (ACHA) to add acute stroke ready centers to the list of primary stroke centers and comprehensive stroke centers, which is made available to emergency medical services providers. All three levels of stroke centers are treated similarly for purposes of being added to, or removed from, the list. The bill removes language instructing the ACHA to base stroke center rules on criteria established solely by the Joint Commission; and expands rule criteria to be substantially similar to any nationally recognized accrediting organization.

The Department of Health (DOH) is directed to develop a statewide stroke registry to house data submitted by stroke centers which will include patient care quality assurance proceedings, records, or reports associated with the treatment or service provided to a person suffering a stroke. The data will be used to:

- Evaluate stroke care effectiveness;
- Ensure compliance with stroke center standards; and
- Monitor patient outcomes.

The AHCA must adopt by rule electronic standardized forms for stroke centers to report the data to the DOH.

The DOH may choose to establish and maintain the registry, or contract it out. The bill provides protection from liability for any entity that provides information required by the registry.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

What is a Stroke?

A stroke is a serious medical condition that occurs when the blood supply to the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients.¹ The brain needs a constant supply of oxygen and nutrients in order to function.² Even a brief interruption in blood supply from a stroke can cause significant problems.

During a stroke, brain cells begin to die after just a few minutes without blood or oxygen.³ Brain cell death causes loss of brain function, including impaired ability with movement, speech, thinking and memory, bowel and bladder, eating, emotional control, and other vital bodily functions. A small stroke may result in problems such as weakness in an arm or leg, whereas larger strokes may cause paralysis, loss of speech, or even death.⁴ A stroke is one of the leading causes of death in the United States.⁵

There are two main types of strokes: an ischemic stroke and a hemorrhagic stroke. The former, is the most common type, and occurs when an artery in the brain becomes blocked. The latter occurs when a brain artery leaks blood or ruptures.⁶

There are two types of ischemic strokes: thrombotic and embolic.⁷ In a thrombotic stroke, a blood clot (thrombus) forms in an artery that supplies blood to the brain.⁸ In an embolic stroke, a blood clot, or other substance such as plaque or fatty material, travels through the bloodstream to an artery in the brain.⁹ With both types of ischemic stroke, the blood clot or other substance blocks the flow of oxygenated blood to a portion of the brain.¹⁰

The two types of hemorrhagic stroke are intracerebral and subarachnoid.¹¹ In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.¹² In a subarachnoid hemorrhage, a blood vessel on the surface of the brain leaks blood or ruptures, and bleeding

¹ The Mayo Clinic, *Stroke*, available at <http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264>, (last visited Mar. 22, 2017).

² UCLA Health, *What is a Stroke?* available at <http://stroke.ucla.edu/what-is-a-stroke>, (last visited Mar. 23, 2017).

³ Id.

⁴ Id.

⁵ National Institutes of Health, National Heart, Lung and Blood Institute, *What Is a Stroke?* (updated Jan. 27, 2017) available at <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke>, (last visited Mar. 23, 2017).

⁶ Id.

⁷ Id.

⁸ Id.

⁹ Id. The blood clot or other substance traveling through the bloodstream is called an embolus.

¹⁰ Id.

¹¹ Id.

¹² Id.

occurs between the inner and middle layers of the membrane that covers the brain.¹³ In both types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull. This swelling and pressure causes brain damage.¹⁴

Signs and Symptoms of a Stroke

The signs and symptoms of a stroke often develop quickly. However, they can develop over hours or even days as well. Signs and symptoms of a stroke may include:

- Sudden weakness;
- Paralysis (an inability to move) or numbness of the face, arms, or legs, especially on one side of the body;
- Confusion;
- Trouble speaking or understanding speech;
- Trouble seeing in one or both eyes;
- Problems breathing;
- Dizziness, trouble walking, loss of balance or coordination, and unexplained falls;
- Loss of consciousness; and
- Sudden and severe headache.¹⁵

Stroke Treatment

Time is of the essence in the treatment of a stroke. Medical personnel begin treatment in the ambulance on the way to the hospital.¹⁶ Treatment for a stroke depends on how much time has elapsed since the symptoms began to appear; and whether the stroke is ischemic or hemorrhagic.¹⁷

Treatment for an ischemic stroke may include medicines,¹⁸ such as antiplatelet medicines and blood thinners, and medical procedures, but a hemorrhagic stroke may require surgery to find and stop the bleeding.¹⁹ In addition to emergency care to treat a stroke, an individual may also receive treatment to prevent another stroke and rehabilitation to treat the side effects of the stroke.²⁰ According to the Centers for Disease Control and Prevention (CDC), research indicates that patients receiving care at primary stroke centers have a higher incidence of survival and recovery than those treated in hospitals without this type of specialized care.²¹

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ Center for Disease Control and Prevention, *Stroke Treatment* (updated Feb. 10, 2017) available at <https://www.cdc.gov/stroke/treatments.htm>, (last visited Mar. 23, 2017).

¹⁷ National Institutes of Health, National Heart, Lung and Blood Institute, *How Is a Stroke Treated?* (updated Jan. 27, 2017) available at <https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment> (last visited Mar. 23, 2017).

¹⁸ Id. Such medication includes a tissue plasminogen activator (TPA), which dissolves, or breaks up the clot. TPA is an injection which must be given within 4 hours of stroke symptoms onset.

¹⁹ Id.

²⁰ *Supra* note 16.

²¹ Centers for Disease Control and Prevention, *A Summary Of Primary Stroke Center Policy In The United States* (2011), available at https://www.cdc.gov/dhdp/pubs/docs/primary_stroke_center_report.pdf, (last visited Mar. 23, 2017)

Stroke Centers in Florida

Florida first enacted legislation relating to primary and comprehensive stroke centers in 2004.²² The AHCA establishes the criteria for both the primary and comprehensive stroke centers.²³ There are 118 Florida hospitals designated as primary stroke centers in 37 counties, and 41 comprehensive stroke centers in 16 counties.²⁴

Primary Stroke Centers

A primary stroke center certification recognizes hospitals that meet standards to support better outcomes for stroke care.²⁵ Such hospitals must have a dedicated stroke-focused program, be staffed by qualified medical professionals trained in stroke care, and provide individualized care to meet stroke patients' needs based on recommendations of the Brain Attack Coalition and guidelines published by the American Heart Association/American Stroke Association or equivalent guidelines.²⁶ These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.²⁷

In order for the AHCA to designate a hospital program as a primary stroke center, the hospital program must be certified by the Joint Commission as a primary stroke center, or meet the certification criteria applicable to primary stroke centers as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.²⁸ The manual requires a primary stroke center to:²⁹

- Use a standardized method of delivering care;
- Support patient self-management activities;
- Tailor treatment and intervention to individual needs;
- Promote the flow of patient information across settings and providers, while protecting patient rights, security and privacy;
- Analyze and use standardized performance measure data to continually improve treatment plans; and

²² Section 3, ch. 2004-325, Laws of Fla.

²³ Section 395.3038, F.S.

²⁴ Agency for Health Care Administration, *Senate Bill 1406 Analysis* (Feb. 17, 2017) (on file with the Senate Committee on Health Policy). Although stroke services is dependent upon the availability of qualified health care professionals, the majority of primary stroke centers have fewer than 300 inpatient beds and the majority of comprehensive stroke centers have more than 300 beds.

²⁵ American Heart Association, *Primary Stroke Center Certification*, available at https://www.heart.org/HEARTORG/Professional/HospitalAccreditationCertification/PrimaryStrokeCenterCertification/Primary-Stroke-Center-Certification_UCM_439155_SubHomePage.jsp, (last visited Mar. 23, 2017).

²⁶ *Id.*

²⁷ *Id.*

²⁸ Rule 59A-3.2085(15)(a) F.A.C.

²⁹ The standards are published in the Comprehensive Certification Manual for Disease-Specific Care. They incorporate the "Recommendations for the Establishment of Primary Stroke Centers" developed by the Brain Attack Coalition. The chapters address program management, delivering or facilitating clinical care, supporting self-management, clinical information management, and performance improvement and measurement.

- Demonstrate their application of and compliance with clinical practice guidelines published by the American Heart Association/American Stroke Association or equivalent evidence-based guidelines.³⁰

Comprehensive Stroke Centers

A comprehensive stroke center certification recognizes hospitals that meet standards to treat the most complex stroke cases.³¹ These hospitals must meet all the criteria of a primary stroke center; they must also have advanced imaging techniques and personnel trained in vascular neurology, neurosurgery and endovascular procedures available 24 hours a day, seven days a week, as well as neuroscience intensive care unit (ICU) and experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage and subarachnoid hemorrhage.

In order for the AHCA to designate a hospital program as a comprehensive stroke center, the hospital program must have received primary stroke center designation and also have the following:

- Personnel with clinical expertise in specified disciplines available;³²
- Advanced diagnostic capabilities;³³
- Neurosurgical and endovascular interventions available;³⁴
- Specialized infrastructure;³⁵ and
- Quality improvement and clinical outcomes measurements.³⁶

The specialized infrastructure includes extensive requirements that the emergency medical services (EMS) and comprehensive stroke center leadership are linked to ensure:

- EMS use a stroke triage assessment tool;
- EMS patient assessment and management at the scene is consistent with evidence-based practice;
- Inter-facility transfers; and
- On-going communication with EMS providers regarding availability of services; and
- A comprehensive stroke center maintains:
 - An acute stroke team available 24 hours per day, 7 days per week;
 - A system for facilitating inter-facility transfers;
 - Defined access telephone numbers in a system for accepting appropriate transfer;

³⁰ The Joint Commission, *Facts about Primary Stroke Center Certification* (Jan. 6, 2015), available at https://www.jointcommission.org/facts_about_primary_stroke_center_certification/ (last visited Mar. 23, 2017).

³¹ The American Heart Association, *Comprehensive Stroke Center Certification*, available at https://www.heart.org/HEARTORG/Professional/HospitalAccreditationCertification/ComprehensiveStrokeCenterCertification/Comprehensive-Stroke-Center-Certification_UCM_455446_SubHomePage.jsp, (last visited Mar. 23, 2017).

³² See Fla. Admin. Code R. 59A-3.2085(15)(b), for specific qualifications. Medical personnel with neurosurgical expertise must be available in a CSC on a 24 hours per day, seven days per week basis and in-house within two hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, seven days per week.

³³ Id.

³⁴ Id.

³⁵ Id.

³⁶ Id.

- Specialized inpatient units including an ICU with medical and nursing personnel who have special training, skills and knowledge in the management of patients with all forms of neurological or neurosurgical conditions that require intensive care;
- An acute stroke unit with medical and nursing personnel who have training, skills and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and who are appropriately trained in neurological assessment and management;
- Inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- Its medical and paramedical professionals education by offering ongoing professional education for all disciplines; and provide education to the public and inpatients and families on risk factor reduction or management, primary and secondary prevention, the warning signs and symptoms of stroke, and medical management and rehabilitation for stroke patients;
- Provide a career development track to develop neuroscience nursing, particularly in the area of cerebrovascular disease; and
- Professional and administrative infrastructure necessary to conduct clinical trials and should have participated in stroke clinical trials within the last year and actively participate in ongoing clinical stroke trials.³⁷

Stroke Patient Transportation

The DOH has also developed a stroke assessment tool.³⁸ The tool is available on the DOH's website and is provided to emergency medical services providers.³⁹ Each licensed emergency medical services provider must use a stroke-triage assessment tool that is substantially similar to the DOH's stroke-triage assessment tool.⁴⁰ Annually, by June 1, each year the DOH sends the list of primary stroke centers and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in Florida.⁴¹

Stroke Center Inventory

The AHCA maintains an inventory of hospitals offering stroke services.⁴² A listing of hospitals meeting the criteria as either a primary stroke center or comprehensive stroke center is published on the AHCA's website.^{43,44}

Currently, there are no data reporting requirements for stroke centers related to quality measures.⁴⁵ There are 274 emergency medical service providers, 222 acute care hospitals and 25 medical examiner districts that report patient data to the DOH.⁴⁶ However, the data is not

³⁷ Id.

³⁸ Section 395.3041(2), F.S.

³⁹ Section 395.3041(2), F.S.

⁴⁰ Id.

⁴¹ Section 395.3041(1), F.S.

⁴² Section 395.3038, F.S.

⁴³ *Supra* note 24.

⁴⁴ Id. A list of hospitals with a stroke center designation is also available through the facility locator tool on www.floridahealthfinder.gov, (last visited Mar. 23, 2017).

⁴⁵ Id.

⁴⁶ *Supra* note 24.

standardized and much of the data that the DOH currently collects comes from voluntary participation in the DOH's EMS Tracking and Reporting System (EMSTARS) program⁴⁷ and only includes data on response, provider impression, procedures and medication, and destination.⁴⁸

Acute Stroke Ready Centers

Many patients with an acute stroke live in areas without ready access to a primary or comprehensive stroke center; more than half the U.S. population lives more than an hour away from a stroke center.⁴⁹ Hospitals in areas with low population densities and relatively small numbers of patients with strokes may be less likely to have the resources to become a stroke center and may lack the experience and expertise to provide ongoing care for a stroke.⁵⁰ In such settings, there is a need to distinguish between those that offer enhanced care and expertise for acute stroke versus those with only basic or no organized abilities and expertise.⁵¹

A recent study by the American Stroke Association proposed a new designation for hospitals that are not primary stroke centers, but can provide timely, evidence-based care to most patients with an acute stroke; these acute stroke-ready hospitals provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in their emergency department, and would then transfer these patients to a primary or comprehensive stroke center.⁵²

Accrediting Organizations

The Joint Commission, the Healthcare Facilities Accreditation Program, and the DNV GL (formerly known as Det Norske Veritas) offer certification as an acute stroke ready centers, as well as primary and comprehensive stroke centers.⁵³

III. Effect of Proposed Changes:

Acute Stroke Ready Centers

The bill includes a new level of stroke services: an acute stroke ready center. A hospital could receive an acute stroke ready center designation by attesting to the ACHA on the appropriate form that, among other things, it is accredited by a nationally recognized accrediting organization or meets the criteria for accreditation. A hospital with an acute stroke ready center designation is required to notify the ACHA if it no longer meets the criteria.

⁴⁷ The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.

⁴⁸ *Supra* note 46.

⁴⁹ Mark J. Alberts, et al, *Formation and Function of Acute Stroke-Ready Hospitals Within a Stroke System of Care Recommendations From the Brain Attack Coalition*, *Stroke*, Vol. 44, Issue 12 (Nov. 25, 2013), available at <http://stroke.ahajournals.org/content/44/12/3382.full>, (last visited Mar. 23, 2017).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Supra* note 24.

The bill removes language instructing the ACHA to base stroke center rules on criteria established solely by the Joint Commission; and expands criteria to be substantially similar to any nationally recognized accreditation organization's criteria for the level of stroke center.

Acute stroke ready centers must be added to the list of stroke centers the DOH supplies to emergency medical services providers in the state. The bill requires the AHCA to develop and adopt by rule electronic standardized forms for stroke centers to report data to the DOH, including patient care quality assurance proceedings, records, or reports associated with any treatment or service provided to a person suffering a stroke.

Currently, there are approximately 60 acute care hospitals that do not have primary or comprehensive stroke center designation and may be eligible for an acute stroke ready center designation. The majority of these hospitals have less than 100 beds.⁵⁴

Statewide Stroke Registry

The bill creates s. 395.30381, F.S., to require the DOH to develop a statewide stroke registry. All stroke centers must submit data, including patient care quality assurance proceedings, records, or reports associated with the treatment or service provided to a person suffering a stroke to the registry. The DOH is required to use this information to:

- Evaluate stroke care effectiveness;
- Ensure compliance with stroke center standards established pursuant to s. 395.3038, F.S.; and
- Monitor patient outcomes.

The DOH may choose to establish and maintain the registry, or contract it out to a private entity. The bill provides protection from liability for any entity that provides information required by the registry. The DOH is required to adopt rules to implement the registry.

Stroke centers that do not comply with the reporting requirements to the registry will be subject to licensure denial, modification, suspension, or revocation by the AHCA.⁵⁵ The bill removes obsolete deadlines for the DOH to implement the stroke-triage assessment tool.

The bill provides an effective date of July 1, 2017.

⁵⁴See The Joint Commission, *Certification for Primary Stroke Centers*, available at https://www.jointcommission.org/certification/primary_stroke_centers.aspx, and *Certification Comprehensive Stroke Centers*, available at https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx (last visited Mar. 28, 2017); DNV-GL, *Healthcare*, available at <http://dnvglhealthcare.com/search?q=stroke+centers&s=rank>; and Healthcare Facilities Accreditation Program, available at <http://www.hfap.org/AccreditationPrograms/stroke.aspx>, (last visited Mar. 28, 2017).

⁵⁵ Section 395.003(7)(a), F.S., authorizes the AHCA to deny, modify, suspend, and revoke a license for the substantial failure to comply with any requirements of part I of ch 395, F.S., which is where the statute establishing the stroke registry is located.

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:

Public hospitals that are required to submit data to the DOH under the bill, may be required to purchase new software and incur labor costs to collect, maintain and send the required data to the DOH. The estimated cost of this is unknown at this time.

C. Government Sector Impact:

The DOH will incur rulemaking costs to implement the registry. The DOH may also incur costs to develop and maintain the registry or to contract with a private entity to establish and maintain the registry. There is no appropriation provided in the bill to establish the registry.

The AHCA will incur rulemaking costs related to updating criteria for acute stroke ready centers and comprehensive stroke centers. According to the AHCA, current resources can absorb these costs.⁵⁶

VI. Technical Deficiencies:

None.

VII. Related Issues:

A public records exemption (separate bill) may be necessary to protect the confidentiality of information in the statewide stroke registry.

⁵⁶ *Supra* note 24.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.3038 and 395.3041.

This bill creates the following section 395.30381, of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 27, 2017:

Deletes emergency medical services providers and medical examiners from the list of entities required to submit to the DOH patient care quality assurance proceedings, records, or reports associated with any treatment or services provided to a person suffering a stroke.

- B. **Amendments:**

None.



169250

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/27/2017	.	
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	.	
	.	

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

Senate Amendment

Delete lines 76 - 94
and insert:
and comprehensive stroke center shall submit to the department
patient care quality assurance proceedings, records, or reports
associated with any treatment or service provided to a person
suffering a stroke. Such information shall be used to evaluate
stroke care system effectiveness, ensure compliance with
standards established pursuant to s. 395.3038, and monitor



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11 patient outcomes.

12 (2) The department shall establish a statewide stroke
13 registry to ensure that patient care quality assurance
14 proceedings, records, and reports required to be submitted under
15 subsection (1) are maintained and available for use to improve
16 or modify the stroke care system, ensure compliance with
17 standards, and monitor stroke patient outcomes. The department
18 may contract with a private entity to establish and maintain the
19 registry. No liability of any kind or character for damages or
20 other relief shall arise or be enforced against any acute ready
21 stroke center, primary stroke center, or comprehensive stroke
22 center

By Senator Powell

30-01468-17

20171406__

A bill to be entitled

An act relating to stroke centers; amending s. 395.3038, F.S.; directing the Agency for Health Care Administration to include hospitals that meet the criteria for acute stroke ready centers on a list of stroke centers; directing the agency to adopt rules governing such criteria and the development of certain electronic forms to provide reports to the Department of Health; creating s. 395.30381, F.S.; requiring stroke centers to provide certain information to the department; requiring the department to establish a statewide stroke registry; providing immunity from liability under certain circumstances; requiring the department to adopt rules; amending s. 395.3041, F.S.; conforming a provision and deleting obsolete dates; providing an effective date.

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

Section 1. Section 395.3038, Florida Statutes, is amended to read:

395.3038 State-listed ~~primary stroke centers and comprehensive~~ stroke centers; notification of hospitals.-

(1) The agency shall make available on its website and to the department a list of the name and address of each hospital that meets the criteria for an acute stroke ready center, a primary stroke center, ~~or and the name and address of each hospital that meets the criteria for~~ a comprehensive stroke center. The list of ~~primary and comprehensive~~ stroke centers

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

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must include only those hospitals that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as an acute stroke ready center, a primary stroke center, or a comprehensive stroke center by a nationally recognized ~~an~~ accrediting organization.

(2) (a) If a hospital no longer chooses to meet the criteria for an acute stroke ready center, a primary stroke center, or a comprehensive stroke center, the hospital shall notify the agency and the agency shall immediately remove the hospital from the list of stroke centers.

(b) 1. This subsection does not apply if the hospital is unable to provide stroke treatment services for a period of time not to exceed 2 months. The hospital shall immediately notify all local emergency medical services providers when the temporary unavailability of stroke treatment services begins and when the services resume.

2. If stroke treatment services are unavailable for more than 2 months, the agency shall remove the hospital from the list of ~~primary or comprehensive~~ stroke centers until the hospital notifies the agency that stroke treatment services have been resumed.

(3) The agency shall adopt by rule criteria for an acute stroke ready center, a primary stroke center, and a comprehensive stroke center which are substantially similar to the certification standards for the same categories of primary stroke centers of a nationally recognized accrediting organization ~~the Joint Commission~~.

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

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~~(4) The agency shall adopt by rule criteria for a comprehensive stroke center. However, if the Joint Commission establishes criteria for a comprehensive stroke center, agency rules shall be substantially similar.~~

~~(4)(5)~~ This act is not a medical practice guideline and may not be used to restrict the authority of a hospital to provide services for which it is licensed under chapter 395. The Legislature intends that all patients be treated individually based on each patient's needs and circumstances.

(5) The agency shall adopt by rule standardized electronic forms for each acute stroke ready center, primary stroke center, and comprehensive stroke center to report to the department such information as required in s. 395.30381.

Section 2. Section 395.30381, Florida Statutes, is created to read:

395.30381 Statewide stroke registry.—

(1) Each acute ready stroke center, primary stroke center, comprehensive stroke center, emergency medical service provider, and medical examiner shall submit to the department patient care quality assurance proceedings, records, or reports associated with any treatment or service provided to a person suffering a stroke. Such information shall be used to evaluate stroke care system effectiveness, ensure compliance with standards established pursuant to s. 395.3038, and monitor patient outcomes.

(2) The department shall establish a statewide stroke registry to ensure that patient care quality assurance proceedings, records, and reports required to be submitted under subsection (1) are maintained and available for use to improve

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or modify the stroke care system, ensure compliance with standards, and monitor stroke patient outcomes. The department may contract with a private entity to establish and maintain the registry. No liability of any kind or character for damages or other relief shall arise or be enforced against any acute ready stroke center, primary stroke center, comprehensive stroke center, emergency medical service provider, or medical examiner by reason of having provided such information to the department.

(3) The department shall adopt rules to administer this section.

Section 3. Subsections (1), (2), and (4) of section 395.3041, Florida Statutes, are amended to read:

395.3041 Emergency medical services providers; triage and transportation of stroke victims to a stroke center.—

(1) By June 1 of each year, the department shall send the list of acute stroke ready centers, primary stroke centers, and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in this state.

(2) The department shall develop a sample stroke-triage assessment tool. The department must post this sample assessment tool on its website and provide a copy of the assessment tool to each licensed emergency medical services provider ~~no later than June 1, 2005~~. Each licensed emergency medical services provider must use a stroke-triage assessment tool that is substantially similar to the sample stroke-triage assessment tool provided by the department.

(4) Each emergency medical services provider licensed under chapter 401 must comply with all sections of this act ~~by July 1, 2005~~.

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Section 4. This act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

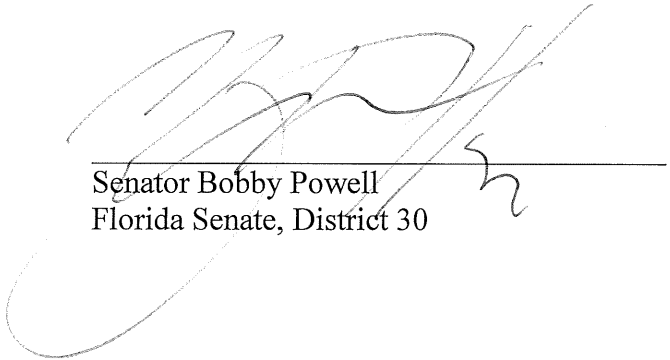
To: Senator Dana D. Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 14, 2017

I respectfully request that **Senate Bill # 1406**, relating to stroke centers and providing electronic forms to the Department of Health, be placed on the:

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



Senator Bobby Powell
Florida Senate, District 30

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/27/17

Meeting Date

1406

Bill Number (if applicable)

Topic Shore Bill

Amendment Barcode (if applicable)

Name Fely Curva, Ph.D.

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Tallahassee

City

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State

32312

Zip

Email fely.curva@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Budd Bell Clearinghouse on Human Services

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

3/27/17

Meeting Date

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

1406

Bill Number (if applicable)

Topic Stroke

Amendment Barcode (if applicable)

Name Mark Landreth

Job Title Sr. Director Govt Relations

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City State Zip

Phone 850 544 3376
Email Mark.Landreth@heart.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Heart Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

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

3/27/16
Meeting Date

1406
Bill Number (if applicable)

Topic STROKES

Amendment Barcode (if applicable)

Name Rivers H. Buford, III

Job Title DIRECTOR OF GOVERNMENTAL AFFAIRS

Address 2851 REMINGTON GREEN
Street

Phone 850-566-9119

JALAHASSEE FL 32308
City State Zip

Email Rivers.Buford@heart.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AMERICAN HEART ASSOCIATION

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate
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 1760

INTRODUCER: Senator Grimsley

SUBJECT: Health Care Facility Regulation

DATE: March 24, 2017

REVISED: _____

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

I. Summary:

SB 1760 includes regulatory reductions, revisions to minimize or eliminate conflicts with federal or state requirements, and new provisions to recognize changing needs, and deletes obsolete provisions in the regulation of health care facilities by the Agency for Health Care Administration (AHCA or agency). The bill:

- Abolishes the licensure of clinical laboratories and health care risk managers. The requirement for clinical laboratories to be certified under federal requirements remains in effect. Health care risk managers remain an integral part of a comprehensive risk management program, but will no longer require licensure.
- Removes mobile surgical facilities from health care facility regulation.
- Authorizes hospitals to use alternate-site testing for certain laboratory services.
- Requires the agency to adopt rules for minimum licensure requirements relating to pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, and comprehensive medical rehabilitation.
- Requires each home health agency to identify the home health services it provides and indicate whether each service is considered skilled care. Additional regulatory requirements will apply to home health agencies providing skilled services.
- Establishes a voluntary process to apply for a certificate of exemption from licensure for a person providing home health services that are exempt from licensure.
- Enhances and clarifies the provisions affecting unlicensed activity for nurse registries and assisted living facilities.
- Clarifies responsibilities of nurse registries to reinforce the status of persons they refer to be independent contractors rather than employees.
- Removes prohibitions on a nurse registry providing remuneration to certain individuals who may provide referrals.

- Deletes certain provisions within specific facility licensing chapters to eliminate inconsistencies with the general facility licensing chapter, or to reduce regulatory burdens.
- Authorizes a licensee to request the alignment of the expiration date for multiple licenses held by the licensee.
- Repeals the subscriber assistance program and the statewide managed care ombudsman committee.

The AHCA estimates a total annual revenue reduction of \$1,448,266 due to repeal of licensure for clinical laboratories and health care risk managers.

The act is effective July 1, 2017, except as otherwise expressly provided in the act.

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, assisted living facilities, and home health agencies. In total, the agency licenses, certifies, regulates or provides exemptions for more than 42,000 providers.¹

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:

Clinical Laboratories and Clinical Laboratory Personnel

Clinical Laboratories

The federal Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).³ 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.⁴

¹ See the Agency for Health Care Administration, Division of Health Quality Assurance web page available at: <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited March 22, 2017).

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

³ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA> (last visited Mar. 17, 2017).

⁴ 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

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, optometrists, or dentists, exclusively in connection with the diagnosis and treatment of their own patients.⁵

As of July 1, 2016, the agency licenses 3,862 clinical laboratories and collects an average of \$1,129,000 per year in recurring licensure fees and an average of \$254,400 per year in recurring biennial assessments required by s. 408.033, F.S. The federal CLIA program certifies another 17,877 Florida-based laboratories that only perform waived testing which is exempt from state licensure requirements.⁶

Section 72 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.

Conforming amendments:

- Sections 5, 7, 10, 16 amend ss. 381.0031, 381.004, 384.31, 395.009, F.S., respectively, to remove references to a laboratory licensed under ch. 483, F.S., and to instead refer to a laboratory certified by the CMS under the CLIA.
- Section 6 amends s. 381.0034, F.S., to conform a cross-reference to the repeal of part I of ch. 483, F.S.
- Section 8 amends s. 383.313, F.S., to conform the performance of laboratory services by a birth center with the repeal of clinical laboratory licensure and the changes in the licensure of clinical laboratory personnel.
- Section 33 amends s. 395.7015, F.S., to remove licensed clinical laboratories from the annual assessment imposed on health care entities.
- Section 34 amends s. 400.0625, F.S., to require all clinical laboratory tests performed for a nursing home to be performed by a licensed clinical laboratory, with certain exceptions. (See comment under technical deficiencies.) The bill also deletes the requirement that clinical laboratory tests performed prior to admission in the nursing home by qualified labs shall be accepted in lieu of additional laboratory tests that might be required as a part of the routine examinations for admission.

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 Mar. 17, 2017).

⁵ Section 483.035(1), F.S.

⁶ Agency for Health Care Administration, *Senate Bill 1760 Analysis* (March 10, 2017), p. 5, (on file with the Senate Committee on Health Policy).

- Section 47 amends s. 400.9905, F.S., relating to health care clinics, to remove cross-reference to licensure under part I of ch. 483.
- Section 48 amends s. 408.033, F.S., relating to local and state health planning, to remove the assessment imposed on clinical laboratories as a funding source of local health councils.
- Section 51 amends s. 408.07, F.S., relating to the Florida Center for Health Information and Transparency and related reporting by licensed health care facilities to remove the definition of clinical laboratories.
- Section 54 amends s. 408.802, F.S., to delete clinical laboratories from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of clinical laboratories.
- Section 60 amends s. 409.905, F.S., to delete reference to licensure under ch. 483 and adds the requirement for certification by the CMS under CLIA for laboratory services that are paid for by Medicaid.
- Sections 62 and 71 amend ss. 409.975 and 458.345, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 408.07, F.S., in section 51.
- Sections 68 and 69 amend ss. 456.001, and 456.057 F.S., to conform cross-references that have changed due to the repeal of part I of ch. 483, F.S.
- Section 75 amends s. 483.803, F.S., to conform definitions to the repeal of part I of ch. 483, F.S.
- Sections 76 and 77 amend ss. 483.813 and 491.003, F.S., to remove references to provisions in part I of ch. 483, F.S.
- Section 78 amends s. 627.351, F.S., relating to medical malpractice risk apportionment to remove clinical laboratories from the definition of health care provider.
- Section 94 amends s. 945.36, F.S., to affirmatively authorize certain law enforcement personnel to administer a urine screen drug test on inmates and releases, rather than exempting the law enforcement personnel from part I of ch. 483, F.S.

Clinical Laboratory Personnel

Individuals who perform testing in licensed clinical laboratories are required to be licensed by the Department of Health, Board of Clinical Laboratory Personnel (board). Licenses issued by the board are specific to the role of the individuals and the specialties in which they perform that role. Certain exemptions from licensure by the board apply, such as for physicians, chiropractors, podiatrists, or dentists, and certain researchers.⁷ The board is composed of seven members and has authority to adopt rules to implement the provisions of part III of ch. 483, F.S., relating to clinical laboratory personnel.

Section 1 amends s. 20.43, F.S., to repeal the Board of Clinical Laboratory Personnel under the Division of Medical Quality Assurance in the Department of Health.

Section 74 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

⁷ Sections 483.801 and 483.813, F.S.

laboratory work is performed for patients referred by a health care provider who is not a member of the same group.

Hospital and Health Care Facility Licensure

The regulation of, and all references to, mobile surgical facilities are removed from health care facility regulation. Part I of ch. 395, F.S., was amended to include mobile surgical facility as a license type in 1998. A definition of a mobile surgical facility restricts its use to the Department of Corrections (DOC) or a private correctional facility to provide surgical procedures to inmates. No license has ever been issued for a mobile surgical facility and none are anticipated. The DOC operates one hospital which does not offer surgical services directly to its inmates; rather it contracts with a licensed ambulatory surgical center (ASC). A separate license type is not needed in order to meet the surgical needs of the inmate population.⁸

Conforming amendments:

- Sections 11, 12, 61, 62, and 80 amend ss. 385.211, 394.4787, 409.9116, 409.975, and 627.64194, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 395.002, F.S.
- Sections 13, 14, 15, 18, 19, 92, and 93 amend ss. 395.001, 395.002, 395.003, 395.0161, 395.0163, 766.118, and 766.202, F.S., respectively, to remove reference to a mobile surgical facility in the section.
- Section 33 amends s. 395.7015, F.S., to remove mobile surgical facilities from the annual assessment imposed on health care entities.
- Section 49 amends s. 408.036, F.S., to remove mobile surgical facilities as a project subject to an exemption for certificates of need (CON).
- Section 54 amends s. 408.802, F.S., to delete mobile surgical facilities from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of mobile surgical facilities.

Section 17 creates s. 395.0091, F.S., relating to alternate-site testing to enable hospitals to use a laboratory testing site in which the testing is done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory. The bill directs the agency, in consultation with the Board of Clinical Laboratory Personnel, to adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The rule must address, at a minimum, a hospital internal needs assessment, a protocol of implementation, criteria to be used in selecting the method of testing, minimum training and education requirements of professionals in the laboratory, an internal and external quality control protocol, tracking mechanisms between the alternate-site and the central laboratory, and recordkeeping. An alternate-site testing location must be registered when the hospital renews its license.

Sections 20 and 26. Section 26 repeals s. 395.10974, F.S., which establishes the licensure requirements for health care risk managers. Section 20 amends s. 395.0197, F.S., to require an internal risk manager of a health care facility to demonstrate to the hiring facility or its governing

⁸ *Supra* note 6, p. 3.

board, competence, by education or experience in the same areas⁹ as required to be demonstrated to the agency for licensure as a health care risk manager. This section also removes references to licensure under s. 395.10974, F.S., as a risk manager.

Conforming amendments:

- Section 23 repeals s. 395.10971, F.S., which provides Legislative findings and intent with respect to the health care risk manager program.
- Section 24 repeals s. 395.10972, F.S., which establishes a health care risk manager advisory council within the agency. There are no current council members and have been no council meetings for at least 10 years. In addition, the statute contains no defined role or responsibilities for the council.¹⁰
- Section 25 amends s. 395.10973, F.S., to remove the agency's rulemaking authority for licensure standards, determination of qualification, and licensure of a health care risk manager.
- Section 27 repeals s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license.
- Section 54 amends s. 408.802, F.S., to delete health care risk managers from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of health care risk managers.
- Sections 70 and 88 amend ss. 458.307 and 641.55, F.S., to remove reference to the licensure requirement for a health care risk manager.

Section 21 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.¹¹ 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, that the agency proposes is an unnecessary level of confidentiality.¹²

⁹ These areas include: applicable standards of health care risk management; applicable federal, state, and local health and safety laws and rules; general risk management administration; patient care; medical care; personal and social care; accident prevention; departmental organization and management; community interrelationships; and medical terminology. See s. 395.10974(1), F.S.

¹⁰ *Supra* n. 6, p. 4.

¹¹ 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 March 18, 2017).

¹² *Supra* n. 6, p. 3.

Section 22 amends s. 395.1055, F.S., to requires the agency to adopt rules to ensure that all hospitals providing pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. The licensure requirement shall include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards. The agency indicates that adopted rules for all these procedures may take some time due to the interaction of various stakeholders.¹³ The CON process includes standards; however, these conditions are not required to be met for continued licensure.¹⁴

Section 28 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.¹⁵

Conforming amendments:

- Section 29 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 30 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.
- Section 31 repeals s. 395.605, F.S., relating to licensing emergency care hospitals which is now an obsolete program.
- Section 95 amends s. 1009.65, F.S., to conform a cross-reference to the renumbered definitions in s. 395.602, F.S.

Section 32 amends s. 395.701, 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.¹⁶

Home Health Agencies

Section 35 amends s. 400.464, F.S., to require any license issued after June 30, 2017, to specify the home health services that the organization is authorized to perform and indicate whether each service is considered skilled care. In addition, providing or advertising services that require licensure and which are not specified on the face of the license issued after June 30, 2017, constitutes prohibited unlicensed activity.

¹³ *Supra* note 6, p. 4.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

The bill 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.

Conforming amendment:

Section 40 amends s. 400.497, F.S., relating to agency rulemaking to include applications for certificates of exemption from licensure.

Section 36 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.

Section 36 and 37 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 38 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 39 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

Section 41 amends s. 400.506, F.S., to remove a grace period of 10-working days after notification from the agency that licensure is required, for an unlicensed nurse registry to cease operating to avoid committing a misdemeanor of the second degree. Under the bill, the unlicensed nurse registry must cease operations immediately. The agency is authorized to impose a fine of \$1,000 per day in accordance with s. 408.812, F.S., in the general licensing provisions pertaining to unlicensed activity, rather than the \$500 fine specified in this statute specifically relating to nurse registries.

This section clarifies the status of persons referred by the nurse registry as independent contractors rather than employees. Current law provides that is in not the obligation of a nurse registry to monitor, supervise, manage, or train a referred caregiver. The bill strengthens this concept by providing that a nurse registry is not permitted to do any of those activities. Similarly,

although a nurse registry is required to act as a repository of records, the bill provides that the nurse registry is not permitted to review or act upon such records, except for providing patients with information and notifying applicable licensing boards if a referred caregiver has credentialing deficiencies.

In addition, this section of 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 already 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.

Assisted Living Facilities (ALF)

Section 63 amends s. 429.02, F.S., to revise the definition of personal services to prohibit an ALF from providing personal services to individuals who are not residents of the facility unless the ALF is providing authorized adult days care services within the licensed ALF. Section 67 amends s. 429.41, F.S., to require rulemaking for reasonable and fair minimum standards on this prohibition.

Section 64 amends s. 429.04, F.S., relating to exemptions from licensure to clarify and expand the exemptions to include a licensed hospital, nursing home, inpatient hospice, home for special services,¹⁷ intermediate care facility, or transitional living facility. 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 65 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. Similarly, 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 six-month window after a statutory or rule change takes place if the change

¹⁷ 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.

placed the person in the position of violating this provision before the violation occurs. This six-month timeframe is repealed in the bill.

Section 66 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.

Multiphasic Health Testing Centers

Section 73 amends s. 483.294, F.S., to remove the requirement that a multiphasic health testing center must be inspected at least annually. Inspections are to be done in accordance with s. 408.811, F.S., which provides that inspections for relicensure shall occur biennially; however, an inspection may be performed at any time as needed. The general licensing provisions in part II of ch. 408, F.S., allow for accreditation inspections to be accepted in lieu of a full licensure inspection.

Amendments referencing General Licensing Provisions and Technical Amendments

Hospices

Section 42 amends s. 400.606, F.S., to remove the required submission of certain financial information at licensure renewal. This requirement conflicts with submission requirements in the general licensure requirements in part II of ch. 408, F.S.

Home Medical Equipment Providers

Section 43 is a technical amendment to s. 400.925, F.S., to move wheelchairs and related seating and positioning devices to a separate paragraph within the definition of home medical equipment.

Section 44 amends s. 400.931, F.S., to require a licensed home medical equipment provider to notify the agency 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.

Section 45 is a technical amendment to s. 400.933, F.S., correcting the name of the state agency that issues medical oxygen retail establishment permits. It is now the Department of Business and Professional Regulation.

Health Care Service Pools

Section 46 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.

General Licensing Provisions

Section 55 amends s. 408.803, F.S., to add a definition of “relative.”

Section 56 amends s. 408.806, F.S., relating to the license application process to require the licensee to ensure that no person has any ownership interest in a licensee, directly or indirectly, who is ineligible pursuant to s. 408.809(4), F.S., which lists additional disqualifying offenses, most of which are fraud-related activity. Additionally, the licensee is required to ensure that no person holds or has held any ownership interest in a provider that has had a license or change of ownership application denied, revoked, or excluded pursuant to s. 408.815, F.S., which includes false representation; intentional or negligent acts affecting a client; demonstrated pattern of deficient performance; or being excluded, suspended, or terminated from participation in any state's Medicaid program or Medicare.

This section also authorizes 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 57 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 five 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, 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.¹⁸

Section 58 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.¹⁹ 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.

Subscriber Assistance Program

Section 53 of the bill repeals s. 408.7056, F.S., relating to the subscriber assistance program, effective January 1, 2018.

¹⁸ *Supra* note 6, pp. 6-7.

¹⁹ 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.

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),²⁰ 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.²¹

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 policies²² 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.²³

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.²⁴

Conforming amendments:

- Sections 2, 3, 4, 85, and 87 amend ss. 220.1845, 376.30781, 376.86, 641.51, and 641.515, F.S., respectively, to strike a cross-reference to s. 408.7056, F.S., to conform those provisions to repeal of the subscriber assistance program.
- Sections 79, 81, and 83 amend ss. 627.602, 627.6531, and 641.312, F.S., respectively, to delete an exemption for a health insurance policy, group health insurance policy, and health maintenance organization (HMO) contract that is subject to the subscriber assistance program.
- Section 82 amends s. 641.185, F.S., to remove a principle concerning regulatory oversight by various state entities relating to an HMO's expedited review of unresolved grievances pursuant to the subscriber assistance program.

²⁰ Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).

²¹ 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, with the latest full year of data showing 350 cases received and 53 cases heard. The predominant outcome of the cases in FY 2015-2016 was a determination of non-jurisdiction (#221), followed by submission of an incomplete application (#31) and found in favor of the subscriber (#27). See the chart prepared by the agency for activity since FY 2009-2010 at *supra* note 4, p. 7.

²² 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 Mar. 23, 2017).

²³ *Supra* note 6, p. 7.

²⁴ *Id.*

- Section 84 amends s. 641.3154, F.S., to remove reference to an action after a recommendation is made by the SAP.
- Section 86 amends s. 641.511, F.S., relating to HMOs, to remove notice requirements to subscribers regarding the subscriber assistance program and authorizations for a subscriber to submit a grievance to the subscriber assistance program. This section also repeals a requirement for the HMO to maintain records of all grievances and report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievance, and the final disposition of the grievances.

Managed Care Ombudsman Committees

The Statewide Managed Care Ombudsman Committee (statewide committee) and the district managed care ombudsman committees (district committees) were established in 1996.²⁵ 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.²⁶

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 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.²⁷

Section 89 repeals s. 641.60, F.S., which authorizes the Statewide Managed Care Ombudsman Council.

Conforming amendments:

- Section 90 amends s. 641.70, F.S., relating to district managed care ombudsman committees, to remove all references to the statewide Managed Care Ombudsman Council.
- Section 91 amends s. 641.75, F.S., to conform cross-references to the repeal of s. 641.60, F.S.

Obsolete and Miscellaneous Provisions

Section 9 repeals s. 383.335, F.S., to remove a birth center exemption to one aspect of licensure for providers in existence over 30 years ago. Currently no providers meet this exemption.²⁸

Conforming Amendment:

²⁵ Chapter 96-391, L.O.F.

²⁶ Section 641.65(2), F.S.

²⁷ *Supra* note 6, p. 8.

²⁸ *Supra* note 6, p. 10.

- Section 47 amends s. 400.9905, F.S., relating to health care clinics to correct the cross-reference to statutes affecting birth centers.

Section 50 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.

The effective date of the bill is July 1, 2017, except as otherwise expressly provided in the bill.

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.²⁹

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.³⁰

²⁹ See the Application checklist available at:

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml (last visited Mar. 24, 2017).

³⁰ See AHCA Clinical laboratory fees, available at:

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml (last visited Mar. 24, 2017).

C. Government Sector Impact:

The AHCA indicates a revenue reduction related to risk manager application fees of approximately \$64,866 per year and for laboratory licensure application fees \$1,383,400 per year. The total annual revenue reduction is approximately \$1,448,266.

VI. Technical Deficiencies:

The bill repeals the Board of Clinical Laboratory Personnel within the DOH, authorized by s. 20.43(3)(g)22, F.S. However, the bill creates a new section of law, s. 395.0091, relating to alternate-site testing that requires the agency to act in consultation with the Board of Clinical Laboratory Personnel to adopt rules pertaining to alternate-site testing.

Section 34 amends s. 400.0625, F.S., to require all clinical laboratory tests performed for a nursing home to be performed by a licensed clinical laboratory, with certain exceptions. Given the repeal of clinical laboratory licensure in this bill, and the corresponding substitution of CMS issued certificates under CLIA, an amendment might be needed for clarity.

Section 56 amends s. 408.806, F.S., relating to the license application process. The new language in the bill for subsection (1) refers to a licensee. For an initial application, a license has not yet been issued. It may be appropriate to assign the responsibilities to the applicant.

Section 89 of the bill repeals the Statewide Managed Care Ombudsman Committee, but fails to conform references to the statewide committee in ss. 641.65 and 641.75(1) and (2), F.S.

VII. Related Issues:

Section 86 amends s. 641.511, F.S., relating to HMOs. Among other things, it repeals a requirement for the HMO to maintain records of all grievances and report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievance, and the final disposition of the grievances. Repealing this provision may be overly broad, if a similar recordkeeping / reporting provision does not exist, because it is not apparent how regulators could monitor subscriber grievances.

The bill repeals the Statewide Managed Care Ombudsman Committee, but does not repeal the district managed care ombudsman committees. District committees have never been established in most of the districts and no committees have been active since 2010. Other resources exist for protecting the rights of subscribers in managed care plans. For example, the Office of the Insurance Consumer Advocate is established in s. 627.0613, F.S., which represents subscribers as appropriate.³¹ Repealing the district committees or revising their structure might also be considered.

³¹ See also The Office of the Insurance Consumer Advocate Overview website: <http://www.myfloridacfo.com/division/ICA/Overview.htm> (last visited March 23, 2017).

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, 383.313, 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, 400.464, 400.471, 400.474, 400.476, 400.484, 400.497, 400.506, 400.606, 400.925, 400.931, 400.933, 400.980, 400.9905, 408.033, 408.036, 408.061, 408.07, 408.20, 408.802, 408.803, 408.806, 408.810, 408.812, 408.820, 409.905, 409.9116, 409.975, 429.02, 429.04, 429.08, 429.176, 429.41, 456.001, 456.057, 458.307, 458.345, 483.294, 483.801, 483.803, 483.813, 491.003, 627.351, 627.602, 627.64194, 627.6513, 641.185, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 641.70, 641.75, 766.118, 766.202, 945.36, and 1009.65.

This bill creates section 395.0091 of the Florida Statutes.

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, 408.7056, 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, and 641.60.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.



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LEGISLATIVE ACTION

Senate	.	House
Comm: FC	.	
03/27/2017	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

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

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



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

1. The Board of Acupuncture, created under chapter 457.
2. The Board of Medicine, created under chapter 458.
3. The Board of Osteopathic Medicine, created under chapter 459.
4. The Board of Chiropractic Medicine, created under chapter 460.
5. The Board of Podiatric Medicine, created under chapter 461.
6. Naturopathy, as provided under chapter 462.
7. The Board of Optometry, created under chapter 463.
8. The Board of Nursing, created under part I of chapter 464.
9. Nursing assistants, as provided under part II of chapter 464.
10. The Board of Pharmacy, created under chapter 465.
11. The Board of Dentistry, created under chapter 466.
12. Midwifery, as provided under chapter 467.
13. The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.
14. The Board of Nursing Home Administrators, created under part II of chapter 468.
15. The Board of Occupational Therapy, created under part III of chapter 468.
16. Respiratory therapy, as provided under part V of chapter 468.
17. Dietetics and nutrition practice, as provided under



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part X of chapter 468.

18. The Board of Athletic Training, created under part XIII of chapter 468.

19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.

20. Electrolysis, as provided under chapter 478.

21. The Board of Massage Therapy, created under chapter 480.

~~22. The Board of Clinical Laboratory Personnel, created under part III of chapter 483.~~

~~22.23.~~ Medical physicists, as provided under part III ~~IV~~ of chapter 483.

~~23.24.~~ The Board of Opticianry, created under part I of chapter 484.

~~24.25.~~ The Board of Hearing Aid Specialists, created under part II of chapter 484.

~~25.26.~~ The Board of Physical Therapy Practice, created under chapter 486.

~~26.27.~~ The Board of Psychology, created under chapter 490.

~~27.28.~~ School psychologists, as provided under chapter 490.

~~28.29.~~ The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

~~29.30.~~ Emergency medical technicians and paramedics, as provided under part III of chapter 401.

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

220.1845 Contaminated site rehabilitation tax credit.—

(2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.—



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

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

376.30781 Tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.-

(3)

(f) In order to encourage the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or, s. 408.07, ~~or s. 408.7056~~, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed \$500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider



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by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 4. Subsection (1) of section 376.86, Florida Statutes, is amended to read:

376.86 Brownfield Areas Loan Guarantee Program.—

(1) The Brownfield Areas Loan Guarantee Council is created to review and approve or deny, by a majority vote of its membership, the situations and circumstances for participation in partnerships by agreements with local governments, financial institutions, and others associated with the redevelopment of brownfield areas pursuant to the Brownfields Redevelopment Act for a limited state guaranty of up to 5 years of loan guarantees or loan loss reserves issued pursuant to law. The limited state loan guaranty applies only to 50 percent of the primary lenders loans for redevelopment projects in brownfield areas. If the redevelopment project is for affordable housing, as defined in s. 420.0004, in a brownfield area, the limited state loan guaranty applies to 75 percent of the primary lender's loan. If the redevelopment project includes the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or s. 408.07, ~~or s.~~ ~~408.7056~~, on a brownfield site and the applicant has obtained documentation in accordance with s. 376.30781 indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health



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care provider, the limited state loan guaranty applies to 75 percent of the primary lender's loan. A limited state guaranty of private loans or a loan loss reserve is authorized for lenders licensed to operate in the state upon a determination by the council that such an arrangement would be in the public interest and the likelihood of the success of the loan is great.

Section 5. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of public health significance to department.—

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments of 1988 which ~~licensed under chapter 483 that~~ diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 6. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

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



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shall be allowed 6 months to complete this requirement.

Section 7. Paragraph (c) of subsection (4) of section 381.004, Florida Statutes, is amended to read:

381.004 HIV testing.—

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

(c) The program shall have all laboratory procedures performed in a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments of 1988 ~~licensed under the provisions of chapter 483.~~

Section 8. Subsection (1) of section 383.313, Florida Statutes, is amended to read:

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

(1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center may perform simple laboratory tests, as defined by rule of the agency, and is exempt from the requirements of chapter 483, ~~provided no more than five physicians are employed by the birth center and testing is conducted exclusively in connection with the diagnosis and treatment of clients of the~~



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~~birth center.~~

Section 9. Section 383.335, Florida Statutes, is repealed.

Section 10. Section 384.31, Florida Statutes, is amended to read:

384.31 Testing of pregnant women; duty of the attendant.—
Every person, including every physician licensed under chapter 458 or chapter 459 or midwife licensed under part I of chapter 464 or chapter 467, attending a pregnant woman for conditions relating to pregnancy during the period of gestation and delivery shall cause the woman to be tested for sexually transmissible diseases, including HIV, as specified by department rule. Testing shall be performed by a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments of 1988 ~~approved~~ for such purposes ~~under part I of chapter 483.~~ The woman shall be informed of the tests that will be conducted and of her right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the woman, shall be placed in the woman's medical record and no testing shall occur.

Section 11. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

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

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(27) ~~s. 395.002(28)~~ that contracts with the Department of Health, may conduct



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research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 12. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

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

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

Section 13. Section 395.001, Florida Statutes, is amended to read:

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

Section 14. Present subsections (22) through (33) of section 395.002, Florida Statutes, are renumbered as subsections (21) through (32), respectively, and subsections (3) and (16)



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and present subsections (21) and (23) of that section are amended, to read:

395.002 Definitions.—As used in this chapter:

(3) “Ambulatory surgical center” ~~or “mobile surgical facility”~~ means 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. ~~Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.~~

(16) “Licensed facility” means a hospital or, ambulatory surgical center, ~~or mobile surgical facility~~ licensed in accordance with this chapter.

~~(21) “Mobile surgical facility” is a mobile facility in which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957 and in which inmate patients are admitted to and discharged~~



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~~from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.~~

~~(22)~~ ~~(23)~~ "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or, ambulatory surgical, ~~or mobile surgical~~ care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07(44) ~~s. 408.07(45)~~, reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

Section 15. Paragraphs (a) and (b) of subsection (1) and paragraph (b) of subsection (2) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for



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Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital or, ambulatory surgical center, ~~or mobile surgical facility~~ in this state.

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

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

(2)

(b) The agency shall, at the request of a licensee that is a teaching hospital as defined in s. 408.07(44) ~~s. 408.07(45)~~, issue a single license to a licensee for facilities that have been previously licensed as separate premises, provided such separately licensed facilities, taken together, constitute the same premises as defined in s. 395.002(22) ~~s. 395.002(23)~~. Such license for the single premises shall include all of the beds, services, and programs that were previously included on the licenses for the separate premises. The granting of a single license under this paragraph shall not in any manner reduce the number of beds, services, or programs operated by the licensee.

Section 16. Subsection (1) of section 395.009, Florida Statutes, is amended to read:

395.009 Minimum standards for clinical laboratory test



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results and diagnostic X-ray results; prerequisite for issuance or renewal of license.—

(1) As a requirement for issuance or renewal of its license, each licensed facility shall require that all clinical laboratory tests performed by or for the licensed facility be performed by a clinical laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments of 1988 ~~licensed under the provisions of chapter 483.~~

Section 17. Section 395.0091, Florida Statutes, is created to read:

395.0091 Alternate-site testing.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation, including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional backgrounds not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping requirements. Alternate-site testing locations must register



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when the hospital applies to renew its license. For purposes of this section, the term "alternate-site testing" means any laboratory testing done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory.

Section 18. Paragraph (f) of subsection (1) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.—

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

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

Section 19. Subsection (3) of section 395.0163, Florida Statutes, is amended to read:

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

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

Section 20. Subsection (2), paragraph (c) of subsection (6), and subsections (16) and (17) of section 395.0197, Florida



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Statutes, are amended to read:

395.0197 Internal risk management program.—

(2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager, ~~licensed under s. 395.10974,~~ who is responsible for implementation and oversight of such facility's internal risk management program and who demonstrates competence, by education or experience, in the following areas: ~~as required by this section. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.~~

(a) Applicable standards of health care risk management.

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

(c) General risk management administration.

(d) Patient care.

(e) Medical care.

(f) Personal and social care.

(g) Accident prevention.

(h) Departmental organization and management.

(i) Community interrelationships.

(j) Medical terminology.

(6)

(c) The report submitted to the agency shall also contain the name ~~and license number~~ of the risk manager of the licensed facility, a copy of its policy and procedures which govern the



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measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

(16) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager, ~~licensed under s. 395.10974,~~ for the implementation and oversight of the internal risk management program in a facility licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such internal risk management program if the risk manager acts without intentional fraud.

(17) A privilege against civil liability is hereby granted to any ~~licensed~~ risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the ~~licensed~~ risk manager or facility acted in bad faith or with



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malice in providing such information.

Section 21. Section 395.1046, Florida Statutes, is repealed.

Section 22. Subsection (2) of section 395.1055, Florida Statutes, is amended, and paragraph (i) is added to subsection (1), to read:

395.1055 Rules and enforcement.—

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

(i) All hospitals providing pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. Such licensure requirements shall include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards.

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

Section 23. Section 395.10971, Florida Statutes, is repealed.

Section 24. Section 395.10972, Florida Statutes, is repealed.

Section 25. Section 395.10973, Florida Statutes, is amended to read:

395.10973 Powers and duties of the agency.—It is the



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function of the agency to:

(1) Adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part and part II of chapter 408 conferring duties upon it.

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

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

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

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

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

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

(3) ~~(8)~~ Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate



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residential treatment facilities, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

Section 26. Section 395.10974, Florida Statutes, is repealed.

Section 27. Section 395.10975, Florida Statutes, is repealed.

Section 28. Subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

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

~~(a) "Emergency care hospital" means a medical facility which provides:~~

~~1. Emergency medical treatment; and~~

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

~~(b) "Essential access community hospital" means any facility which:~~

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

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

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

~~4. Provides emergency and medical backup services to rural~~



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~~primary care hospitals in its rural health network;~~

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

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

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

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

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

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

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

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

4. A hospital classified as a sole community hospital under 42 C.F.R. s. 412.92 which has up to 175 licensed beds;

5. A hospital with a service area that has a population of up to 100 persons per square mile. As used in this subparagraph,



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the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency; or

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

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

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

- ~~1. Twenty-four-hour emergency medical care;~~
- ~~2. Temporary inpatient care for periods of 72 hours or less to patients requiring stabilization before discharge or transfer~~



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~~to another hospital. The 72-hour limitation does not apply to
respite, skilled nursing, hospice, or other nonacute care
patients; and~~

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

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

Section 29. Section 395.603, Florida Statutes, is amended
to read:

395.603 ~~Deactivation of general hospital beds;~~ Rural
hospital impact statement.—

~~(1) The agency shall establish, by rule, a process by which
a rural hospital, as defined in s. 395.602, that seeks licensure
as a rural primary care hospital or as an emergency care
hospital, or becomes a certified rural health clinic as defined
in Pub. L. No. 95-210, or becomes a primary care program such as
a county health department, community health center, or other
similar outpatient program that provides preventive and curative
services, may deactivate general hospital beds. Rural primary
care hospitals and emergency care hospitals shall maintain the
number of actively licensed general hospital beds necessary for
the facility to be certified for Medicare reimbursement.~~

~~Hospitals that discontinue inpatient care to become rural health
care clinics or primary care programs shall deactivate all
licensed general hospital beds. All hospitals, clinics, and
programs with inactive beds shall provide 24-hour emergency
medical care by staffing an emergency room. Providers with
inactive beds shall be subject to the criteria in s. 395.1041.~~



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~~The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate of need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.~~

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

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

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

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

(4) ~~(d)~~ What impact will the proposed action have on the ability of rural hospitals to recruit the affected personnel to



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practice in their facilities?

(5)~~(e)~~ What impact will the proposed action have on the limited financial resources of rural hospitals through increased salaries and benefits necessary to recruit or retain such health personnel?

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

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

Section 30. Section 395.604, Florida Statutes, is repealed.

Section 31. Section 395.605, Florida Statutes, is repealed.

Section 32. Paragraph (c) of subsection (1) of section 395.701, Florida Statutes, is amended to read:

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

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

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

Section 33. Paragraph (b) of subsection (2) of section 395.7015, Florida Statutes, is amended to read:

395.7015 Annual assessment on health care entities.—

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

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



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1. Ambulatory surgical centers ~~and mobile surgical facilities licensed under s. 395.003. This subsection shall only apply to mobile surgical facilities operating under contracts entered into on or after July 1, 1998.~~

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

~~2.3.~~ Diagnostic-imaging centers that are freestanding outpatient facilities that provide specialized services for the identification or determination of a disease through examination and also provide sophisticated radiological services, and in which services are rendered by a physician licensed by the Board of Medicine under s. 458.311, s. 458.313, or s. 458.317, or by an osteopathic physician licensed by the Board of Osteopathic Medicine under s. 459.0055 or s. 459.0075. For purposes of this paragraph, "sophisticated radiological services" means the



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following: magnetic resonance imaging; nuclear medicine; angiography; arteriography; computed tomography; positron emission tomography; digital vascular imaging; bronchography; lymphangiography; splenography; ultrasound, excluding ultrasound providers that are part of a private physician's office practice or when ultrasound is provided by two or more physicians licensed under chapter 458 or chapter 459 who are members of the same professional association and who practice in the same medical specialties; and such other sophisticated radiological services, excluding mammography, as adopted in rule by the board.

Section 34. Subsection (1) of section 400.0625, Florida Statutes, is amended to read:

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

(1) Each nursing home, as a requirement for issuance or renewal of its license, shall require that all clinical laboratory tests performed for the nursing home be performed by a licensed clinical laboratory ~~licensed under the provisions of chapter 483~~, except for such self-testing procedures as are approved by the agency by rule. ~~Results of clinical laboratory tests performed prior to admission which meet the minimum standards provided in s. 483.181(3) shall be accepted in lieu of routine examinations required upon admission and clinical laboratory tests which may be ordered by a physician for residents of the nursing home.~~

Section 35. Subsection (1) and paragraphs (b), (e), and (f) of subsection (4) of section 400.464, Florida Statutes, are amended, and subsection (6) is added to that section, to read:



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

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and entities licensed or registered by or applying for such licensure or registration from the Agency for Health Care Administration pursuant to this part. A license issued by the agency is required in order to operate a home health agency in this state. A license issued after June 30, 2017, must specify the home health services that the organization is authorized to perform and indicate whether such specified services are considered skilled care. The provision or advertising of services which require licensure pursuant to this part without such services being specified on the face of the license issued after June 30, 2017, constitutes unlicensed activity as prohibited under s. 408.812.

(4)

(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of this part is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of this part or part II of chapter 408, until compliance with this part or the rules adopted under this part has been demonstrated to the satisfaction of the agency.

(e) Any person who owns, operates, or maintains an



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unlicensed home health agency and who, ~~within 10 working days~~
after receiving notification from the agency, fails to cease
operation and apply for a license under this part commits a
misdemeanor of the second degree, punishable as provided in s.
775.082 or s. 775.083. Each day of continued operation is a
separate offense.

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

(6) Any person, entity, or organization providing home
health services which is exempt from licensure under subsection
(5) may voluntarily apply for a certificate of exemption from
licensure under its exempt status with the agency on a form that
sets forth its name or names and addresses, a statement of the
reasons why it is exempt from licensure as a home health agency,
and other information deemed necessary by the agency. A
certificate of exemption is valid for a period of not more than
2 years and is not transferable. The agency may charge an
applicant for a certificate of exemption in an amount equal to
\$100 or the actual cost of processing the certificate.

Section 36. Present subsections (7) through (10) of section
400.471, Florida Statutes, are redesignated as subsections (6)
through (9), respectively, and subsection (2), present
subsection (6), and present subsection (10) of that section are
amended, to read:

400.471 Application for license; fee.—

(2) In addition to the requirements of part II of chapter
408, the initial applicant, the applicant for a change of
ownership, and the applicant for the addition of skilled care



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services must file with the application satisfactory proof that the home health agency is in compliance with this part and applicable rules, including:

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

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

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

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

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

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

(f)~~(g)~~ All other ownership interests in health care



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entities for each controlling interest, as defined in part II of chapter 408.

(g) ~~(h)~~ In the case of an application for initial licensure, an application for a change of ownership, or an application for the addition of skilled care services, documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408. A home health agency that ~~is not Medicare or Medicaid certified and~~ does not provide skilled care is exempt from this paragraph. Notwithstanding s. 408.806, an initial applicant that has applied for accreditation must provide proof of accreditation that is not conditional or provisional and submit a survey demonstrating compliance with the requirements of this part, part II of chapter 408, and applicable rules from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408 within 120 days after the date of the agency's receipt of the application for licensure ~~or the application shall be withdrawn from further consideration.~~ Such accreditation must be continuously maintained by the home health agency to maintain licensure. The agency shall accept, in lieu of its own periodic licensure survey, the submission of the survey of an accrediting organization that is recognized by the agency if the accreditation of the licensed home health agency is not provisional and if the licensed home health agency authorizes releases of, and the agency receives the report of, the accrediting organization.



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

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

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

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

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

(d) Failing to provide at least one service directly to a patient for a period of 60 days;

(e) Demonstrating a pattern of falsifying documents



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relating to the training of home health aides or certified nursing assistants or demonstrating a pattern of falsifying health statements for staff who provide direct care to patients. A pattern may be demonstrated by a showing of at least three fraudulent entries or documents;

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

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

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

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

(j) Demonstrating a pattern of billing the Medicaid program for services to Medicaid recipients which are medically



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unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period;

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

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

Section 37. Subsection (5) of section 400.474, Florida Statutes, is amended to read:

400.474 Administrative penalties.—

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



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with a patient or the plan of care for that patient.

Section 38. Paragraph (c) of subsection (2) of section 400.476, Florida Statutes, is amended to read:

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

(2) DIRECTOR OF NURSING.—

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

Section 39. Subsection (2) of section 400.484, Florida Statutes, is amended to read:

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

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

(a) Class I violations are defined in s. 408.813 ~~A class I deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury.~~ Upon finding a class I violation ~~deficiency~~, the agency shall impose an administrative fine in the amount of \$15,000 for each occurrence and each day that the violation ~~deficiency~~ exists.

(b) Class II violations are defined in s. 408.813 ~~A class II deficiency is any act, omission, or practice that has a direct adverse effect on the health, safety, or security of a~~



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968 ~~patient.~~ Upon finding a class II violation ~~deficiency~~, the
969 agency shall impose an administrative fine in the amount of
970 \$5,000 for each occurrence and each day that the violation
971 ~~deficiency~~ exists.

972 (c) Class III violations are defined in s. 408.813 ~~A class~~
973 ~~III deficiency is any act, omission, or practice that has an~~
974 ~~indirect, adverse effect on the health, safety, or security of a~~
975 ~~patient.~~ Upon finding an uncorrected or repeated class III
976 violation ~~deficiency~~, the agency shall impose an administrative
977 fine not to exceed \$1,000 for each occurrence and each day that
978 the uncorrected or repeated violation ~~deficiency~~ exists.

979 (d) Class IV violations are defined in s. 408.813 ~~A class~~
980 ~~IV deficiency is any act, omission, or practice related to~~
981 ~~required reports, forms, or documents which does not have the~~
982 ~~potential of negatively affecting patients.~~ These violations are
983 of a type that the agency determines do not threaten the health,
984 safety, or security of patients. Upon finding an uncorrected or
985 repeated class IV violation ~~deficiency~~, the agency shall impose
986 an administrative fine not to exceed \$500 for each occurrence
987 and each day that the uncorrected or repeated violation
988 ~~deficiency~~ exists.

989 Section 40. Subsection (4) of section 400.497, Florida
990 Statutes, is amended to read:

991 400.497 Rules establishing minimum standards.—The agency
992 shall adopt, publish, and enforce rules to implement part II of
993 chapter 408 and this part, including, as applicable, ss. 400.506
994 and 400.509, which must provide reasonable and fair minimum
995 standards relating to:

996 (4) Licensure and certificate of exemption application and



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renewal.

Section 41. Subsection (5), paragraphs (d) and (e) of subsection (6), paragraph (a) of subsection (15), and subsections (19) and (20) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

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

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

(6)

(d) A registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide referred for contract under this chapter by a nurse registry is deemed an independent contractor and not an employee of the nurse registry under any chapter, regardless of the obligations imposed on a nurse registry under this chapter or chapter 408.

(e) Upon referral of a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide for contract in a private residence or facility, the nurse registry shall advise the patient, the patient's family, or any other person acting on behalf of the



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patient, at the time of the contract for services, that the caregiver referred by the nurse registry is an independent contractor and that ~~the it is not the obligation of a nurse registry is not permitted~~ to monitor, supervise, manage, or train a caregiver referred for contract under this chapter.

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

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

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

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

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

~~5. Gives remuneration to a physician, a member of the physician's office staff, or an immediate family member of the~~



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~~physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician's office staff. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.~~

(19) ~~It is not the obligation of~~ A nurse registry is not permitted to monitor, supervise, manage, or train a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide referred for contract under this chapter. In the event of a violation of this chapter or a violation of any other law of this state by a referred registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide, or a deficiency in credentials which comes to the attention of the nurse registry, the nurse registry shall advise the patient to terminate the referred person's contract, providing the reason for the suggested termination; cease referring the person to other patients or facilities; and, if practice violations are involved, notify the licensing board. This section does not affect or negate any other obligations imposed on a nurse registry under chapter 408.

(20) Records required to be filed under this chapter with the nurse registry as a repository of records must be kept in accordance with rules adopted by the agency. The nurse registry is not permitted ~~has no obligation~~ to review or act upon such records except as specified in subsection (19).

Section 42. Subsection (1) of section 400.606, Florida



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Statutes, is amended to read:

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

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

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

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

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

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

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

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

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

(h) A plan for attracting and training volunteers.

~~If the applicant is an existing licensed health care provider, the application must be accompanied by a copy of the most recent profit-loss statement and, if applicable, the most recent~~



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~~licensure inspection report.~~

Section 43. Subsection (6) of section 400.925, Florida Statutes, is amended to read:

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

(6) “Home medical equipment” includes any product as defined by the Federal Drug Administration’s Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes:

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

(b) Motorized scooters;

(c) Personal transfer systems; and

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

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

Section 44. Subsection (4) of section 400.931, Florida Statutes, is amended to read:

400.931 Application for license; fee.—

(4) When a change of the general manager of a home medical equipment provider occurs, the licensee must notify the agency of the change within the timeframes established in part II of



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chapter 408 and applicable rules ~~45 days~~.

Section 45. Subsection (2) of section 400.933, Florida Statutes, is amended to read:

400.933 Licensure inspections and investigations.—

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

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

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

Section 46. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.—

(2) The requirements of part II of chapter 408 apply to the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall adopt rules and provide forms required for such registration and shall impose a registration



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fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within the timeframes established in this part, part II of chapter 408, and applicable rules ~~14 days prior to the change.~~

Section 47. Paragraphs (a) through (d) of subsection (4) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.—

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

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



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395.

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

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



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services by licensed practitioners solely within a hospital under chapter 395.

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

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

Section 48. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care



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facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, ~~clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035,~~ home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Section 49. Paragraph (e) and present paragraph (p) of subsection (3) of section 408.036, Florida Statutes, are amended to read:

408.036 Projects subject to review; exemptions.—

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

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

(o) ~~(p)~~ For replacement of a licensed nursing home on the same site, or within 5 miles of the same site if within the same subdistrict, if the number of licensed beds does not increase except as permitted under paragraph (e) ~~(f)~~.

Section 50. Subsection (4) of section 408.061, Florida



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Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(4) Within 120 days after the end of its fiscal year, each health care facility, excluding continuing care facilities as defined in s. 408.07(13), hospitals operated by state agencies, and nursing homes as defined in s. 408.07(36) ~~s. 408.07(14) and (37)~~, shall file with the agency, on forms adopted by the agency and based on the uniform system of financial reporting, its actual financial experience for that fiscal year, including expenditures, revenues, and statistical measures. Such data may be based on internal financial reports which are certified to be complete and accurate by the provider. However, hospitals' actual financial experience shall be their audited actual experience. Every nursing home shall submit to the agency, in a format designated by the agency, a statistical profile of the nursing home residents. The agency, in conjunction with the Department of Elderly Affairs and the Department of Health, shall review these statistical profiles and develop recommendations for the types of residents who might more appropriately be placed in their homes or other noninstitutional settings.

Section 51. Subsection (11) of section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.—As used in this chapter, with the exception of ss. 408.031-408.045, the term:

~~(11) "Clinical laboratory" means a facility licensed under s. 483.091, excluding: any hospital laboratory defined under s.~~



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~~483.041(6); any clinical laboratory operated by the state or a political subdivision of the state; any blood or tissue bank where the majority of revenues are received from the sale of blood or tissue and where blood, plasma, or tissue is procured from volunteer donors and donated, processed, stored, or distributed on a nonprofit basis; and any clinical laboratory which is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that same group practice.~~

Section 52. Subsection (4) of section 408.20, Florida Statutes, is amended to read:

408.20 Assessments; Health Care Trust Fund.—

(4) Hospitals operated by state agencies ~~the Department of Children and Families, the Department of Health, or the Department of Corrections~~ are exempt from the assessments required under this section.

Section 53. Section 408.7056, Florida Statutes, is repealed.

Section 54. Subsections (10), (11), and (27) of section 408.802, Florida Statutes, are amended to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

~~(10) Mobile surgical facilities, as provided under part I of chapter 395.~~



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~~(11) Health care risk managers, as provided under part I of chapter 395.~~

~~(27) Clinical laboratories, as provided under part I of chapter 483.~~

Section 55. Present subsections (12) and (13) of section 408.803, Florida Statutes, are renumbered as subsections (13) and (14), respectively, and a new subsection (12) is added to that section, to read:

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

(12) "Relative" means an individual who is the father, mother, stepfather, stepmother, son, daughter, brother, sister, grandmother, grandfather, great-grandmother, great-grandfather, grandson, granddaughter, uncle, aunt, first cousin, nephew, niece, husband, wife, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepson, stepdaughter, stepbrother, stepsister, half-brother, or half-sister of a patient or client.

Section 56. Paragraph (a) of subsection (1) and paragraph (c) of subsection (7) of section 408.806, Florida Statutes, are amended, and subsection (9) is added to that section, to read:

408.806 License application process.—

(1) An application for licensure must be made to the agency on forms furnished by the agency, submitted under oath or attestation, and accompanied by the appropriate fee in order to be accepted and considered timely. The application must contain information required by authorizing statutes and applicable rules and must include:

(a) The name, address, and social security number, or individual taxpayer identification number if a social security



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number cannot legally be obtained, of:

1. The applicant;
2. The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider;
3. The financial officer or similarly titled person who is responsible for the financial operation of the licensee or provider; and
4. Each controlling interest if the applicant or controlling interest is an individual.

The licensee shall ensure that no person who is ineligible for licensure under s. 408.809(4) has any direct or indirect ownership interest in the licensee, regardless of ownership structure. The licensee shall ensure that no person holds or has held any ownership interest, directly or indirectly, regardless of ownership structure, in a provider that has had a license or change of ownership application denied, revoked, or excluded pursuant to s. 408.815.

(7)

(c) If an inspection is required by the authorizing statute for a license application other than an initial application, the inspection must be unannounced. This paragraph does not apply to inspections required pursuant to ss. 383.324, 395.0161(4), and ~~429.67(6), and 483.061(2).~~

(9) A licensee that holds a license for multiple providers licensed by the agency may request that all related license expiration dates be aligned. Upon such a request, the agency may issue a license for an abbreviated licensure period with a prorated licensure fee.



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Section 57. Subsection (8) of section 408.810, Florida Statutes, is amended, and subsection (11) is added to that section to read:

408.810 Minimum licensure requirements.—In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license.

(8) Upon application for initial licensure or change of ownership licensure, the applicant shall furnish satisfactory proof of the applicant's financial ability to operate in accordance with the requirements of this part, authorizing statutes, and applicable rules. The agency shall establish standards for this purpose, including information concerning the applicant's controlling interests. The agency shall also establish documentation requirements, to be completed by each applicant, that show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A current certificate of authority, pursuant to chapter 651, may be provided as proof of financial ability to operate. The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to, unpaid expenses necessary for the basic operations of the provider. An applicant applying for change of ownership licensure is exempt from furnishing proof of the applicant's financial ability to operate if the provider has been licensed for at least 5 years and:



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(a) The ownership change is a result of a corporate reorganization under which the controlling interest is unchanged and the applicant submits organizational charts that represent the current and proposed structure of the reorganized corporation; or

(b) The ownership change is due solely to the death of a person holding a controlling interest, and the persons holding the surviving controlling interests continue to hold at least 51 percent of ownership after the change of ownership.

(11) The agency may adopt rules that govern the circumstances under which a controlling interest, an administrator, an employee, or 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, power of attorney, or guardian of a patient or client. Such rules may include requirements related to disclosure, bonding, restrictions, and client protections.

Section 58. Section 408.812, Florida Statutes, is amended to read:

408.812 Unlicensed activity.—

(1) A person or entity may not offer or advertise services that require licensure as defined by this part, authorizing statutes, or applicable rules to the public without obtaining a valid license from the agency. A licenseholder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

(2) The operation or maintenance of an unlicensed provider or the performance of any services that require licensure without proper licensure is a violation of this part and



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authorizing statutes. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients, and abuse and neglect as defined in s. 415.102. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the unlicensed provider or the performance of any services in violation of this part and authorizing statutes, until compliance with this part, authorizing statutes, and agency rules has been demonstrated to the satisfaction of the agency.

(3) It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. If, after receiving notification from the agency, such person or entity fails to cease operation ~~and apply for a license under this part and authorizing statutes,~~ the person or entity is ~~shall be~~ subject to penalties as prescribed by authorizing statutes and applicable rules. Each day of ~~continued~~ operation is a separate offense.

(4) Any person or entity that fails to cease operation after agency notification may be fined \$1,000 for each day of noncompliance.

(5) When a controlling interest or licensee has an interest in more than one provider and fails to license a provider rendering services that require licensure, the agency may revoke all licenses, ~~and~~ impose actions under s. 408.814, and, regardless of correction, impose a fine of \$1,000 per day, unless otherwise specified by authorizing statutes, against each licensee until such time as the appropriate license is obtained or the unlicensed activity ceases ~~for the unlicensed operation.~~



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(6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

(7) Any person aware of the operation of an unlicensed provider must report that provider to the agency.

Section 59. Subsections (10), (11), (26), and (27) of section 408.820, Florida Statutes, are amended to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

~~(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)–(10).~~

~~(11) Health care risk managers, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810(4)–(10), and 408.811.~~

~~(26) Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)–(10).~~

(24)~~(27)~~ Multiphasic health testing centers, as provided under part I ~~II~~ of chapter 483, are exempt from s. 408.810(5)–(10).

Section 60. Subsection (7) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the



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state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law.

Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(7) INDEPENDENT LABORATORY SERVICES.—The agency shall pay for medically necessary diagnostic laboratory procedures ordered by a licensed physician or other licensed practitioner of the healing arts which are provided for a recipient in a laboratory that meets the requirements for Medicare participation and appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments of 1988 ~~is licensed under chapter 483, if required.~~

Section 61. Subsection (6) of section 409.9116, Florida Statutes, is amended to read:

409.9116 Disproportionate share/financial assistance program for rural hospitals.—In addition to the payments made under s. 409.911, the Agency for Health Care Administration shall administer a federally matched disproportionate share program and a state-funded financial assistance program for statutory rural hospitals. The agency shall make



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disproportionate share payments to statutory rural hospitals that qualify for such payments and financial assistance payments to statutory rural hospitals that do not qualify for disproportionate share payments. The disproportionate share program payments shall be limited by and conform with federal requirements. Funds shall be distributed quarterly in each fiscal year for which an appropriation is made. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(6) This section applies only to hospitals that were defined as statutory rural hospitals, or their successor-in-interest hospital, prior to January 1, 2001. Any additional hospital that is defined as a statutory rural hospital, or its successor-in-interest hospital, on or after January 1, 2001, is not eligible for programs under this section unless additional funds are appropriated each fiscal year specifically to the rural hospital disproportionate share and financial assistance programs in an amount necessary to prevent any hospital, or its successor-in-interest hospital, eligible for the programs prior to January 1, 2001, from incurring a reduction in payments because of the eligibility of an additional hospital to participate in the programs. A hospital, or its successor-in-interest hospital, which received funds pursuant to this section before January 1, 2001, and which qualifies under s. 395.602(2)(b) ~~395.602(2)(e)~~, shall be included in the programs under this section and is not required to seek additional appropriations under this subsection.



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Section 62. Paragraphs (a) and (b) of subsection (1) of section 409.975, Florida Statutes, are amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(a) Plans must include all providers in the region that are classified by the agency as essential Medicaid providers, unless the agency approves, in writing, an alternative arrangement for securing the types of services offered by the essential providers. Providers are essential for serving Medicaid enrollees if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of the Medicaid patients. The agency may not classify physicians and other practitioners as essential providers. The agency, at a minimum, shall determine which providers in the following categories are essential Medicaid providers:

1. Federally qualified health centers.
2. Statutory teaching hospitals as defined in s. 408.07(44)



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~~408.07(45).~~

3. Hospitals that are trauma centers as defined in s.
395.4001(14).

4. Hospitals located at least 25 miles from any other
hospital with similar services.

Managed care plans that have not contracted with all essential
providers in the region as of the first date of recipient
enrollment, or with whom an essential provider has terminated
its contract, must negotiate in good faith with such essential
providers for 1 year or until an agreement is reached, whichever
is first. Payments for services rendered by a nonparticipating
essential provider shall be made at the applicable Medicaid rate
as of the first day of the contract between the agency and the
plan. A rate schedule for all essential providers shall be
attached to the contract between the agency and the plan. After
1 year, managed care plans that are unable to contract with
essential providers shall notify the agency and propose an
alternative arrangement for securing the essential services for
Medicaid enrollees. The arrangement must rely on contracts with
other participating providers, regardless of whether those
providers are located within the same region as the
nonparticipating essential service provider. If the alternative
arrangement is approved by the agency, payments to
nonparticipating essential providers after the date of the
agency's approval shall equal 90 percent of the applicable
Medicaid rate. Except for payment for emergency services, if the
alternative arrangement is not approved by the agency, payment
to nonparticipating essential providers shall equal 110 percent



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of the applicable Medicaid rate.

(b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(27) ~~395.002(28)~~.

4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.



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Section 63. Subsections (5) and (17) of section 429.02, Florida Statutes, are amended to read:

429.02 Definitions.—When used in this part, the term:

(5) "Assisted living facility" means any building or buildings, section or distinct part of a building, private home, boarding home, home for the aged, or other residential facility, whether operated for profit or not, which, ~~undertakes~~ through its ownership or management, provides ~~to provide~~ housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.

(17) "Personal services" means direct physical assistance with or supervision of the activities of daily living, ~~and~~ the self-administration of medication, or ~~and~~ other similar services which the department may define by rule. The term may "Personal services" shall not be construed to mean the provision of medical, nursing, dental, or mental health services, or, with the exception of authorized adult day care services provided within a licensed assisted living facility, personal services to individuals who are not residents of the facility.

Section 64. Paragraphs (b) and (d) of subsection (2) of section 429.04, Florida Statutes, are amended, and subsection (3) is added to that section, to read:

429.04 Facilities to be licensed; exemptions.—

(2) The following are exempt from licensure under this part:

(b) Any facility or part of a facility licensed by the Agency for Persons with Disabilities under chapter 393, a mental health facility licensed under ~~or~~ chapter 394, a hospital



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licensed under chapter 395, a nursing home licensed under part
II of chapter 400, an inpatient hospice licensed under part IV
of chapter 400, a home for special services licensed under part
V of chapter 400, an intermediate care facility licensed under
part VIII of chapter 400, or a transitional living facility
licensed under part XI of chapter 400.

(d) Any person who provides housing, meals, and 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 person who provides the housing, meals, and
personal services must own or rent the home and must have
established the home as his or her permanent residence. For
purposes of this paragraph, any person holding a homestead
exemption at an address other than that at which the person
asserts this exemption is presumed to not have established
permanent residence ~~reside therein~~. This exemption does not
apply to a person or entity that previously held a license
issued by the agency which was revoked or for which renewal was
denied by final order of the agency, or when the person or
entity voluntarily relinquished the license during agency
enforcement proceedings.

(3) Upon agency investigation of unlicensed activity, any
person or entity asserting an exemption pursuant to this section
has the burden of providing documentation substantiating that
the person or entity is entitled to the exemption.

Section 65. Paragraphs (b) and (d) of subsection (1) of
section 429.08, Florida Statutes, are amended, to read:

429.08 Unlicensed facilities; referral of person for
residency to unlicensed facility; penalties.—



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(1)

(b) ~~Except as provided under paragraph (d),~~ Any person who owns, rents, or otherwise maintains a building or property that operates, or maintains an unlicensed assisted living facility commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

(d) In addition to the requirements of s. 408.812, any person who owns, operates, or maintains an unlicensed assisted living facility after receiving notice from the agency due to a change in this part or a modification in rule within 6 months after the effective date of such change and who, within 10 working days after receiving notification from the agency, fails to cease operation or apply for a license under this part commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

Section 66. Section 429.176, Florida Statutes, is amended to read:

429.176 Notice of change of administrator.—If, during the period for which a license is issued, the owner changes administrators, the owner must notify the agency of the change within 10 days and provide documentation within 90 days that the new administrator has completed the applicable core educational requirements under s. 429.52. A facility may not be operated for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Section 67. Paragraph (h) of subsection (1) of section 429.41, Florida Statutes, is amended to read:



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429.41 Rules establishing standards.—

(1) It is the intent of the Legislature that rules published and enforced pursuant to this section shall include criteria by which a reasonable and consistent quality of resident care and quality of life may be ensured and the results of such resident care may be demonstrated. Such rules shall also ensure a safe and sanitary environment that is residential and noninstitutional in design or nature. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a facility. Uniform firesafety standards for assisted living facilities shall be established by the State Fire Marshal pursuant to s. 633.206. The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter 408. In order to provide safe and sanitary facilities and the highest quality of resident care accommodating the needs and preferences of residents, the department, in consultation with the agency, the Department of Children and Families, and the Department of Health, shall adopt rules, policies, and procedures to administer this part, which must include reasonable and fair minimum standards in relation to:

(h) The care and maintenance of residents, which must include, but is not limited to:

1. The supervision of residents;
2. The provision of personal services. With the exception of authorized adult day care services provided within a licensed assisted living facility, an assisted living facility may not provide personal services to individuals who are not residents



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of the facility;

3. The provision of, or arrangement for, social and leisure activities;

4. The arrangement for appointments and transportation to appropriate medical, dental, nursing, or mental health services, as needed by residents;

5. The management of medication;

6. The nutritional needs of residents;

7. Resident records; and

8. Internal risk management and quality assurance.

Section 68. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

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

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III ~~or part IV~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 69. Paragraphs (h) and (i) of subsection (2) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(2) As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized



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under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(h) Clinical laboratory personnel licensed under part II ~~III~~ of chapter 483.

(i) Medical physicists licensed under part III ~~IV~~ of chapter 483.

Section 70. Subsection (2) of section 458.307, Florida Statutes, is amended to read:

458.307 Board of Medicine.—

(2) Twelve members of the board must be licensed physicians in good standing in this state who are residents of the state and who have been engaged in the active practice or teaching of medicine for at least 4 years immediately preceding their appointment. One of the physicians must be on the full-time faculty of a medical school in this state, and one of the physicians must be in private practice and on the full-time staff of a statutory teaching hospital in this state as defined in s. 408.07. At least one of the physicians must be a graduate of a foreign medical school. The remaining three members must be residents of the state who are not, and never have been, licensed health care practitioners. One member must be a health care risk manager ~~licensed under s. 395.10974~~. At least one member of the board must be 60 years of age or older.

Section 71. Subsection (1) of section 458.345, Florida Statutes, is amended to read:

458.345 Registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.—



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(1) Any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07(44) ~~408.07(45)~~ or s. 395.805(2), who does not hold a valid, active license issued under this chapter shall apply to the department to be registered and shall remit a fee not to exceed \$300 as set by the board. The department shall register any applicant the board certifies has met the following requirements:

(a) Is at least 21 years of age.

(b) Has not committed any act or offense within or without the state which would constitute the basis for refusal to certify an application for licensure pursuant to s. 458.331.

(c) Is a graduate of a medical school or college as specified in s. 458.311(1)(f).

Section 72. Subsection (1) of section 459.021, Florida Statutes, is amended to read:

459.021 Registration of resident physicians, interns, and fellows; list of hospital employees; penalty.—

(1) Any person who holds a degree of Doctor of Osteopathic Medicine from a college of osteopathic medicine recognized and approved by the American Osteopathic Association who desires to practice as a resident physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice



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as a resident physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07(44) ~~s. 408.07(45)~~ or s. 395.805(2), who does not hold an active license issued under this chapter shall apply to the department to be registered, on an application provided by the department, before commencing such a training program and shall remit a fee not to exceed \$300 as set by the board.

Section 73. Part I of chapter 483, Florida Statutes, consisting of sections 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, and 483.26, is repealed.

Section 74. Section 483.294, Florida Statutes, is amended to read:

483.294 Inspection of centers.—In accordance with s. 408.811, the agency shall, ~~at least once annually,~~ inspect the premises and operations of all centers subject to licensure under this part.

Section 75. Subsection (3) of section 483.801, Florida Statutes, is amended to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

(3) Persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466 who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by any health care



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provider who is not a member of that group practice regulated
~~under s. 483.035(1) or exempt from regulation under s.~~
~~483.031(2).~~

Section 76. Subsections (2), (3), and (4) of section
483.803, Florida Statutes, are amended to read:

483.803 Definitions.—As used in this part, the term:
~~(2) "Clinical laboratory" means a clinical laboratory as~~
~~defined in s. 483.041.~~

~~(3) "Clinical laboratory examination" means a clinical~~
~~laboratory examination as defined in s. 483.041.~~

(2)(4) "Clinical laboratory personnel" includes a clinical
laboratory director, supervisor, technologist, blood gas
analyst, or technician who performs or is responsible for
laboratory test procedures, but the term does not include
trainees, persons who perform screening for blood banks or
plasmapheresis centers, phlebotomists, or persons employed by a
clinical laboratory to perform manual pretesting duties or
clerical, personnel, or other administrative responsibilities,
~~or persons engaged in testing performed by laboratories~~
~~regulated under s. 483.035(1) or exempt from regulation under s.~~
~~483.031(2).~~

Section 77. Section 483.813, Florida Statutes, is amended
to read:

483.813 Clinical laboratory personnel license.—A person may
not conduct a clinical laboratory examination or report the
results of such examination unless such person is licensed under
this part to perform such procedures. However, this provision
does not apply to any practitioner of the healing arts
authorized to practice in this state ~~or to persons engaged in~~



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~~testing performed by laboratories regulated under s. 483.035(1)~~
~~or exempt from regulation under s. 483.031(2).~~ The department
may grant a temporary license to any candidate it deems properly
qualified, for a period not to exceed 1 year.

Section 78. Paragraph (c) of subsection (7), paragraph (c)
of subsection (8), and paragraph (c) of subsection (9) of
section 491.003, Florida Statutes, are amended to read:

491.003 Definitions.—As used in this chapter:

(7) The "practice of clinical social work" is defined as
the use of scientific and applied knowledge, theories, and
methods for the purpose of describing, preventing, evaluating,
and treating individual, couple, marital, family, or group
behavior, based on the person-in-situation perspective of
psychosocial development, normal and abnormal behavior,
psychopathology, unconscious motivation, interpersonal
relationships, environmental stress, differential assessment,
differential planning, and data gathering. The purpose of such
services is the prevention and treatment of undesired behavior
and enhancement of mental health. The practice of clinical
social work includes methods of a psychological nature used to
evaluate, assess, diagnose, treat, and prevent emotional and
mental disorders and dysfunctions (whether cognitive, affective,
or behavioral), sexual dysfunction, behavioral disorders,
alcoholism, and substance abuse. The practice of clinical social
work includes, but is not limited to, psychotherapy,
hypnotherapy, and sex therapy. The practice of clinical social
work also includes counseling, behavior modification,
consultation, client-centered advocacy, crisis intervention, and
the provision of needed information and education to clients,



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when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of clinical social work may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, may ~~shall~~ not be construed to permit the performance of any act which clinical social workers are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483~~, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

(8) The "practice of marriage and family therapy" is defined as the use of scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family systems,



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including the context of marital formation and dissolution, and is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic and marriage and family therapy theories and techniques. The practice of marriage and family therapy includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of marriage and family therapy includes, but is not limited to, marriage and family therapy, psychotherapy, including behavioral family therapy, hypnotherapy, and sex therapy. The practice of marriage and family therapy also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of marriage and family therapy may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, shall not be construed to permit the performance of any act which marriage and family



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therapists are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483~~, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

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



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The practice of mental health counseling also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), behavioral disorders, sexual dysfunction, alcoholism, or substance abuse. The practice of mental health counseling may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, shall not be construed to permit the performance of any act which mental health counselors are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures pursuant to ~~chapter 483~~, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

Section 79. Paragraph (h) of subsection (4) of section 627.351, Florida Statutes, is amended to read:



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627.351 Insurance risk apportionment plans.—

(4) MEDICAL MALPRACTICE RISK APPORTIONMENT.—

(h) As used in this subsection:

1. "Health care provider" means hospitals licensed under chapter 395; physicians licensed under chapter 458; osteopathic physicians licensed under chapter 459; podiatric physicians licensed under chapter 461; dentists licensed under chapter 466; chiropractic physicians licensed under chapter 460; naturopaths licensed under chapter 462; nurses licensed under part I of chapter 464; midwives licensed under chapter 467; ~~clinical laboratories registered under chapter 483~~; physician assistants licensed under chapter 458 or chapter 459; physical therapists and physical therapist assistants licensed under chapter 486; health maintenance organizations certificated under part I of chapter 641; ambulatory surgical centers licensed under chapter 395; other medical facilities as defined in subparagraph 2.; blood banks, plasma centers, industrial clinics, and renal dialysis facilities; or professional associations, partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.

2. "Other medical facility" means a facility the primary purpose of which is to provide human medical diagnostic services or a facility providing nonsurgical human medical treatment, to which facility the patient is admitted and from which facility the patient is discharged within the same working day, and which facility is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy or an office maintained by a physician or dentist for the practice of medicine shall not be construed to be an "other



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medical facility."

3. "Health care facility" means any hospital licensed under chapter 395, health maintenance organization certificated under part I of chapter 641, ambulatory surgical center licensed under chapter 395, or other medical facility as defined in subparagraph 2.

Section 80. Paragraph (h) of subsection (1) of section 627.602, Florida Statutes, is amended to read:

627.602 Scope, format of policy.—

(1) Each health insurance policy delivered or issued for delivery to any person in this state must comply with all applicable provisions of this code and all of the following requirements:

(h) 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. This paragraph does not apply ~~to a health insurance policy that is subject to the Subscriber Assistance Program under s. 408.7056~~ or to the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 81. Paragraphs (b) and (e) of subsection (1) of 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(29) ~~s. 395.002(30)~~.

(e) "Nonparticipating provider" means a provider who is not



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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(29) ~~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 82. 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.
- (4) Workers' compensation or similar insurance.
- (5) Automobile medical payment insurance.
- (6) Credit-only insurance.
- (7) Coverage for onsite medical clinics, including prepaid health clinics under part II of chapter 641.
- (8) Other similar insurance coverage, specified in rules adopted by the commission, under which benefits for medical care are secondary or incidental to other insurance benefits. To the



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extent possible, such rules must be consistent with regulations adopted by the United States Department of Health and Human Services.

(9) Limited scope dental or vision benefits, if offered separately.

(10) Benefits for long-term care, nursing home care, home health care, or community-based care, or any combination thereof, if offered separately.

(11) Other similar, limited benefits, if offered separately, as specified in rules adopted by the commission.

(12) Coverage only for a specified disease or illness, if offered as independent, noncoordinated benefits.

(13) Hospital indemnity or other fixed indemnity insurance, if offered as independent, noncoordinated benefits.

(14) Benefits provided through a Medicare supplemental health insurance policy, as defined under s. 1882(g)(1) of the Social Security Act, coverage supplemental to the coverage provided under 10 U.S.C. chapter 55, and similar supplemental coverage provided to coverage under a group health plan, which are offered as a separate insurance policy and as independent, noncoordinated benefits.

Section 83. Effective January 1, 2018, paragraph (j) of subsection (1) of section 641.185, Florida Statutes, is amended to read:

641.185 Health maintenance organization subscriber protections.—

(1) With respect to the provisions of this part and part III, the principles expressed in the following statements shall serve as standards to be followed by the commission, the office,



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the department, and the Agency for Health Care Administration in exercising their powers and duties, in exercising administrative discretion, in administrative interpretations of the law, in enforcing its provisions, and in adopting rules:

~~(j) A health maintenance organization should receive timely and, if necessary, urgent review by an independent state external review organization for unresolved grievances and appeals pursuant to s. 408.7056.~~

Section 84. Effective January 1, 2018, section 641.312, Florida Statutes, is amended to read:

641.312 Scope.—The Office of Insurance Regulation may adopt rules to administer the provisions of the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act, issued by the National Association of Insurance Commissioners and dated April 2010. This section does not apply to ~~a health maintenance contract that is subject to the Subscriber Assistance Program under s. 408.7056 or to the~~ types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 85. Effective January 1, 2018, subsection (4) of section 641.3154, Florida Statutes, is amended to read:

641.3154 Organization liability; provider billing prohibited.—

(4) A provider or any representative of a provider, regardless of whether the provider is under contract with the health maintenance organization, may not collect or attempt to collect money from, maintain any action at law against, or report to a credit agency a subscriber of an organization for payment of services for which the organization is liable, if the



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provider in good faith knows or should know that the organization is liable. This prohibition applies during the pendency of any claim for payment made by the provider to the organization for payment of the services and any legal proceedings or dispute resolution process to determine whether the organization is liable for the services if the provider is informed that such proceedings are taking place. It is presumed that a provider does not know and should not know that an organization is liable unless:

(a) The provider is informed by the organization that it accepts liability;

(b) A court of competent jurisdiction determines that the organization is liable; or

~~(c) The office or agency makes a final determination that the organization is required to pay for such services subsequent to a recommendation made by the Subscriber Assistance Panel pursuant to s. 408.7056; or~~

(c) ~~(d)~~ The agency issues a final order that the organization is required to pay for such services subsequent to a recommendation made by a resolution organization pursuant to s. 408.7057.

Section 86. Effective January 1, 2018, paragraph (c) of subsection (5) of section 641.51, Florida Statutes, is amended to read:

641.51 Quality assurance program; second medical opinion requirement.—

(5)

(c) For second opinions provided by contract physicians the organization is prohibited from charging a fee to the subscriber



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in an amount in excess of the subscriber fees established by contract for referral contract physicians. The organization shall pay the amount of all charges, which are usual, reasonable, and customary in the community, for second opinion services performed by a physician not under contract with the organization, but may require the subscriber to be responsible for up to 40 percent of such amount. The organization may require that any tests deemed necessary by a noncontract physician shall be conducted by the organization. The organization may deny reimbursement rights granted under this section in the event the subscriber seeks in excess of three such referrals per year if such subsequent referral costs are deemed by the organization to be evidence that the subscriber has unreasonably overutilized the second opinion privilege. A subscriber thus denied reimbursement under this section shall have recourse to grievance procedures as specified in ss. ~~408.7056~~, 641.495, and 641.511. The organization's physician's professional judgment concerning the treatment of a subscriber derived after review of a second opinion shall be controlling as to the treatment obligations of the health maintenance organization. Treatment not authorized by the health maintenance organization shall be at the subscriber's expense.

Section 87. Effective January 1, 2018, section 641.511, Florida Statutes, is amended to read:

641.511 Subscriber grievance reporting and resolution requirements.—

(1) Every organization must have a grievance procedure available to its subscribers for the purpose of addressing complaints and grievances. ~~Every organization must notify its~~



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~~subscribers that a subscriber must submit a grievance within 1 year after the date of occurrence of the action that initiated the grievance, and may submit the grievance for review to the Subscriber Assistance Program panel as provided in s. 408.7056 after receiving a final disposition of the grievance through the organization's grievance process. An organization shall maintain records of all grievances and shall report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievances, and the final disposition of the grievances.~~

(2) When an organization receives an initial complaint from a subscriber, the organization must respond to the complaint within a reasonable time after its submission. At the time of receipt of the initial complaint, the organization shall inform the subscriber that the subscriber has a right to file a written grievance at any time and that assistance in preparing the written grievance shall be provided by the organization.

(3) Each organization's grievance procedure, as required under subsection (1), must include, at a minimum:

(a) An explanation of how to pursue redress of a grievance.

(b) The names of the appropriate employees or a list of grievance departments that are responsible for implementing the organization's grievance procedure. The list must include the address and the toll-free telephone number of each grievance department, the address of the agency and its toll-free telephone hotline number, and the address of the Subscriber Assistance Program and its toll-free telephone number.

(c) The description of the process through which a subscriber may, at any time, contact the toll-free telephone



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hotline of the agency to inform it of the unresolved grievance.

(d) A procedure for establishing methods for classifying grievances as urgent and for establishing time limits for an expedited review within which such grievances must be resolved.

(e) A notice that a subscriber may voluntarily pursue binding arbitration in accordance with the terms of the contract if offered by the organization, after completing the organization's grievance procedure ~~and as an alternative to the Subscriber Assistance Program~~. Such notice shall include an explanation that the subscriber may incur some costs if the subscriber pursues binding arbitration, depending upon the terms of the subscriber's contract.

(f) A process whereby the grievance manager acknowledges the grievance and investigates the grievance in order to notify the subscriber of a final decision in writing.

(g) A procedure for providing individuals who are unable to submit a written grievance with access to the grievance process, which shall include assistance by the organization in preparing the grievance and communicating back to the subscriber.

(4)(a) With respect to a grievance concerning an adverse determination, an organization shall make available to the subscriber a review of the grievance by an internal review panel; such review must be requested within 30 days after the organization's transmittal of the final determination notice of an adverse determination. A majority of the panel shall be persons who previously were not involved in the initial adverse determination. A person who previously was involved in the adverse determination may appear before the panel to present information or answer questions. The panel shall have the



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authority to bind the organization to the panel's decision.

(b) An organization shall ensure that a majority of the persons reviewing a grievance involving an adverse determination are providers who have appropriate expertise. An organization shall issue a copy of the written decision of the review panel to the subscriber and to the provider, if any, who submits a grievance on behalf of a subscriber. In cases where there has been a denial of coverage of service, the reviewing provider shall not be a provider previously involved with the adverse determination.

(c) An organization shall establish written procedures for a review of an adverse determination. Review procedures shall be available to the subscriber and to a provider acting on behalf of a subscriber.

~~(d) In any case when the review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber, the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.~~

(5) Except as provided in subsection (6), the organization shall resolve a grievance within 60 days after receipt of the grievance, or within a maximum of 90 days if the grievance involves the collection of information outside the service area. These time limitations are tolled if the organization has notified the subscriber, in writing, that additional information is required for proper review of the grievance and that such time limitations are tolled until such information is provided. After the organization receives the requested information, the



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time allowed for completion of the grievance process resumes. The Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, is adopted and incorporated by reference as applicable to all organizations that administer small and large group health plans that are subject to 29 C.F.R. s. 2560.503-1. The claims procedures of the regulations of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, shall be the minimum standards for grievance processes for claims for benefits for small and large group health plans that are subject to 29 C.F.R. s. 2560.503-1.

(6)(a) An organization shall establish written procedures for the expedited review of an urgent grievance. A request for an expedited review may be submitted orally or in writing and shall be subject to the review procedures of this section, if it meets the criteria of this section. Unless it is submitted in writing, for purposes of the grievance reporting requirements in subsection (1), the request shall be considered an appeal of a utilization review decision and not a grievance. Expedited review procedures shall be available to a subscriber and to the provider acting on behalf of a subscriber. For purposes of this subsection, "subscriber" includes the legal representative of a subscriber.

(b) Expedited reviews shall be evaluated by an appropriate clinical peer or peers. The clinical peer or peers shall not have been involved in the initial adverse determination.

(c) In an expedited review, all necessary information, including the organization's decision, shall be transmitted between the organization and the subscriber, or the provider



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2389 acting on behalf of the subscriber, by telephone, facsimile, or
2390 the most expeditious method available.

2391 (d) In an expedited review, an organization shall make a
2392 decision and notify the subscriber, or the provider acting on
2393 behalf of the subscriber, as expeditiously as the subscriber's
2394 medical condition requires, but in no event more than 72 hours
2395 after receipt of the request for review. If the expedited review
2396 is a concurrent review determination, the service shall be
2397 continued without liability to the subscriber until the
2398 subscriber has been notified of the determination.

2399 (e) An organization shall provide written confirmation of
2400 its decision concerning an expedited review within 2 working
2401 days after providing notification of that decision, if the
2402 initial notification was not in writing.

2403 (f) An organization shall provide reasonable access, not to
2404 exceed 24 hours after receiving a request for an expedited
2405 review, to a clinical peer who can perform the expedited review.

2406 ~~(g) In any case when the expedited review process does not~~
2407 ~~resolve a difference of opinion between the organization and the~~
2408 ~~subscriber or the provider acting on behalf of the subscriber,~~
2409 ~~the subscriber or the provider acting on behalf of the~~
2410 ~~subscriber may submit a written grievance to the Subscriber~~
2411 ~~Assistance Program.~~

2412 ~~(g)(h)~~ (g) An organization shall not provide an expedited
2413 retrospective review of an adverse determination.

2414 ~~(7) Each organization shall send to the agency a copy of~~
2415 ~~its quarterly grievance reports submitted to the office pursuant~~
2416 ~~to s. 408.7056(12).~~

2417 ~~(7)(8)~~ (7) The agency shall investigate all reports of



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unresolved quality of care grievances received from:

~~(a)~~ annual and quarterly grievance reports submitted by the organization to the office.

~~(b)~~ Review requests of subscribers whose grievances remain unresolved after the subscriber has followed the full grievance procedure of the organization.

~~(9)(a)~~ The agency shall advise subscribers with grievances to follow their organization's formal grievance process for resolution prior to review by the Subscriber Assistance Program. The subscriber may, however, submit a copy of the grievance to the agency at any time during the process.

~~(b)~~ Requiring completion of the organization's grievance process before the Subscriber Assistance Program panel's review does not preclude the agency from investigating any complaint or grievance before the organization makes its final determination.

~~(10)~~ Each organization must notify the subscriber in a final decision letter that the subscriber may request review of the organization's decision concerning the grievance by the Subscriber Assistance Program, as provided in s. 408.7056, if the grievance is not resolved to the satisfaction of the subscriber. The final decision letter must inform the subscriber that the request for review must be made within 365 days after receipt of the final decision letter, must explain how to initiate such a review, and must include the addresses and toll-free telephone numbers of the agency and the Subscriber Assistance Program.

~~(11)~~ (8) Each organization, as part of its contract with any provider, must require the provider to post a consumer assistance notice prominently displayed in the reception area of



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the provider and clearly noticeable by all patients. The consumer assistance notice must state the addresses and toll-free telephone numbers of the Agency for Health Care Administration, ~~the Subscriber Assistance Program,~~ and the Department of Financial Services. The consumer assistance notice must also clearly state that the address and toll-free telephone number of the organization's grievance department shall be provided upon request. The agency may adopt rules to implement this section.

(9) ~~(12)~~ The agency may impose administrative sanction, in accordance with s. 641.52, against an organization for noncompliance with this section.

Section 88. Effective January 1, 2018, subsection (1) of section 641.515, Florida Statutes, is amended to read:

641.515 Investigation by the agency.—

(1) The agency shall investigate further any quality of care issue contained in recommendations and reports submitted pursuant to s. 641.511 ~~ss. 408.7056 and 641.511~~. The agency shall also investigate further any information that indicates that the organization does not meet accreditation standards or the standards of the review organization performing the external quality assurance assessment pursuant to reports submitted under s. 641.512. Every organization shall submit its books and records and take other appropriate action as may be necessary to facilitate an examination. The agency shall have access to the organization's medical records of individuals and records of employed and contracted physicians, with the consent of the subscriber or by court order, as necessary to carry out the provisions of this part.



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Section 89. Effective January 1, 2018, subsection (2) of section 641.55, Florida Statutes, is amended to read:

641.55 Internal risk management program.—

(2) The risk management program shall be the responsibility of the governing authority or board of the organization. Every organization which has an annual premium volume of \$10 million or more and which directly provides health care in a building owned or leased by the organization shall hire a risk manager, ~~certified under ss. 395.10971-395.10975,~~ who shall be responsible for implementation of the organization's risk management program required by this section. A part-time risk manager shall not be responsible for risk management programs in more than four organizations or facilities. Every organization which does not directly provide health care in a building owned or leased by the organization and every organization with an annual premium volume of less than \$10 million shall designate an officer or employee of the organization to serve as the risk manager.

The gross data compiled under this section or s. 395.0197 shall be furnished by the agency upon request to organizations to be utilized for risk management purposes. The agency shall adopt rules necessary to carry out the provisions of this section.

Section 90. Section 641.60, Florida Statutes, is repealed.

Section 91. Section 641.70, Florida Statutes, is amended to read:

641.70 Agency duties relating to ~~the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman~~ committees.—



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(1) The agency shall adopt rules that specify:

(a) Procedures by which ~~the statewide committee and~~ district committees receive reports of enrollee complaints from the agency.

(b) Procedures by which enrollee information shall be made available ~~to members of the statewide committee and~~ to the district committees.

(c) Procedures by which recommendations made by the committees shall be considered for incorporation into policies and procedures of the agency.

~~(d) Procedures by which statewide committee members shall be reimbursed for authorized expenditures.~~

~~(d) (e)~~ Any other procedures that are necessary to administer this section and s. 641.65 ~~ss. 641.60 and 641.65~~.

(2) The Agency for Health Care Administration shall provide a meeting place for district committees in agency offices and shall provide the necessary administrative support to assist ~~the statewide committee and~~ district committees, within available resources.

(3) The secretary of the agency shall ensure the full cooperation and assistance of agency employees with ~~members of the statewide committee and~~ district committees.

Section 92. Subsection (3) of section 641.75, Florida Statutes, is amended to read:

641.75 Immunity from liability; limitation on testimony.—

(3) Members of any state or district ombudsman committee shall not be required to testify in any court with respect to matters held to be confidential except as may be necessary to enforce ss. 641.61-641.75 ~~ss. 641.60-641.75~~.



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Section 93. Paragraph (b) of subsection (6) of section 766.118, Florida Statutes, is amended to read:

766.118 Determination of noneconomic damages.—

(6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF A PRACTITIONER PROVIDING SERVICES AND CARE TO A MEDICAID RECIPIENT.—Notwithstanding subsections (2), (3), and (5), with respect to a cause of action for personal injury or wrongful death arising from medical negligence of a practitioner committed in the course of providing medical services and medical care to a Medicaid recipient, regardless of the number of such practitioner defendants providing the services and care, noneconomic damages may not exceed \$300,000 per claimant, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. A practitioner providing medical services and medical care to a Medicaid recipient is not liable for more than \$200,000 in noneconomic damages, regardless of the number of claimants, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. The fact that a claimant proves that a practitioner acted in a wrongful manner does not preclude the application of the limitation on noneconomic damages prescribed elsewhere in this section. For purposes of this subsection:

(b) The term "practitioner," in addition to the meaning prescribed in subsection (1), includes any hospital or ambulatory surgical center, ~~or mobile surgical facility~~ as defined and licensed under chapter 395.

Section 94. Subsection (4) of section 766.202, Florida Statutes, is amended to read:



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766.202 Definitions; ss. 766.201-766.212.—As used in ss. 766.201-766.212, the term:

(4) "Health care provider" means any hospital or ambulatory surgical center, ~~or mobile surgical facility~~ as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; ~~a clinical lab licensed under chapter 483~~; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Section 95. Subsection (1) of section 945.36, Florida Statutes, is amended to read:

945.36 ~~Exemption from health testing regulations for~~ Law enforcement personnel authorized to conduct ~~conducting~~ drug tests on inmates and releasees.—

(1) Any law enforcement officer, state or county probation officer, or employee of the Department of Corrections, who is certified by the Department of Corrections pursuant to subsection (2), may administer ~~is exempt from part I of chapter 483, for the limited purpose of administering~~ a urine screen drug test to:

(a) Persons during incarceration;

(b) Persons released as a condition of probation for either a felony or misdemeanor;

(c) Persons released as a condition of community control;



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- (d) Persons released as a condition of conditional release;
- (e) Persons released as a condition of parole;
- (f) Persons released as a condition of provisional release;
- (g) Persons released as a condition of pretrial release; or
- (h) Persons released as a condition of control release.

Section 96. Paragraph (b) of subsection (2) of section 1009.65, Florida Statutes, is amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(b) All payments shall be contingent on continued proof of primary care practice in an area defined in s. 395.602(2)(b) ~~395.602(2)(c)~~, or an underserved area designated by the Department of Health, provided the practitioner accepts Medicaid reimbursement if eligible for such reimbursement. Correctional facilities, state hospitals, and other state institutions that employ medical personnel shall be designated by the Department of Health as underserved locations. Locations with high incidences of infant mortality, high morbidity, or low Medicaid participation by health care professionals may be designated as underserved.

Section 97. Paragraph (e) of subsection (2) of section 1011.52, Florida Statutes, is amended to read:

1011.52 Appropriation to first accredited medical school.—

(2) In order for a medical school to qualify under the provisions of this section and to be entitled to the benefits herein, such medical school:



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(a) Must be primarily operated and established to offer, afford, and render a medical education to residents of the state qualifying for admission to such institution;

(b) Must be operated by a municipality or county of this state, or by a nonprofit organization heretofore or hereafter established exclusively for educational purposes;

(c) Must, upon the formation and establishment of an accredited medical school, transmit and file with the Department of Education documentary proof evidencing the facts that such institution has been certified and approved by the council on medical education and hospitals of the American Medical Association and has adequately met the requirements of that council in regard to its administrative facilities, administrative plant, clinical facilities, curriculum, and all other such requirements as may be necessary to qualify with the council as a recognized, approved, and accredited medical school;

(d) Must certify to the Department of Education the name, address, and educational history of each student approved and accepted for enrollment in such institution for the ensuing school year; and

(e) Must have in place an operating agreement with a government-owned hospital that is located in the same county as the medical school and that is a statutory teaching hospital as defined in s. 408.07(44) ~~s. 408.07(45)~~. The operating agreement shall provide for the medical school to maintain the same level of affiliation with the hospital, including the level of services to indigent and charity care patients served by the hospital, which was in place in the prior fiscal year. Each



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year, documentation demonstrating that an operating agreement is in effect shall be submitted jointly to the Department of Education by the hospital and the medical school prior to the payment of moneys from the annual appropriation.

Section 98. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled
An act relating to health care facility regulation;
amending ss. 381.0031, 381.004, 384.31, 395.009, and
409.905, F.S.; eliminating state licensure
requirements for clinical laboratories; requiring
clinical laboratories to be federally certified;
amending s. 383.313, F.S.; revising requirements for a
birth center to perform certain laboratory tests;
repealing s. 383.335, F.S., relating to partial
exemptions from licensure requirements for certain
facilities that provide obstetrical and gynecological
surgical services; amending s. 395.002, F.S.; revising
and deleting definitions; creating s. 395.0091, F.S.;
authorizing the Agency for Health Care Administration
to adopt rules establishing criteria for alternate-
site laboratory testing; defining the term "alternate-
site testing"; amending ss. 395.0161 and 395.0163,
F.S.; deleting licensure and inspection requirements



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2679 for mobile surgical facilities to conform to changes
2680 made by the act; amending s. 395.0197, F.S.; requiring
2681 the manager of a hospital or ambulatory surgical
2682 center internal risk management program to demonstrate
2683 competence in certain administrative and health care
2684 service areas; conforming references; repealing s.
2685 395.1046, F.S., relating to hospital complaint
2686 investigation procedures; amending s. 395.1055, F.S.;
2687 requiring hospitals providing specified services to
2688 meet agency licensure requirements; conforming a
2689 reference; repealing ss. 395.10971 and 395.10972,
2690 F.S., relating to the purpose and establishment of the
2691 Health Care Risk Manager Advisory Council; amending s.
2692 395.10973, F.S.; deleting duties of the agency
2693 relating to health care risk managers; repealing s.
2694 395.10974, F.S., relating to licensure of health care
2695 risk managers; repealing s. 395.10975, F.S., relating
2696 to grounds for denial, suspension, or revocation of a
2697 health care risk manager's license; amending s.
2698 395.602, F.S.; deleting definitions; amending s.
2699 395.603, F.S.; deleting provisions relating to
2700 deactivation of general hospital beds by certain rural
2701 and emergency care hospitals; repealing s. 395.604,
2702 F.S., relating to other rural hospital programs;
2703 repealing s. 395.605, F.S., relating to emergency care
2704 hospitals; amending s. 395.701, F.S.; revising the
2705 definition of the term "hospital" to exclude hospitals
2706 operated by state agencies; amending s. 400.464, F.S.;
2707 revising licensure requirements for a home health



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2708 agency; providing conditions for advertising certain
2709 services that require licensure; providing for a fine;
2710 providing conditions for application for a certificate
2711 of exemption from licensure as a home health agency;
2712 specifying the duration of the certificate of
2713 exemption; authorizing a fee; amending s. 400.471,
2714 F.S.; revising home health agency licensure
2715 requirements; providing requirements for proof of
2716 accreditation for home health agencies applying for
2717 change of ownership or addition of skilled care
2718 services; amending s. 400.474, F.S.; revising
2719 conditions for the imposition of a fine against a home
2720 health agency; amending s. 400.476, F.S.; requiring a
2721 home health agency providing skilled nursing care to
2722 have a director of nursing; amending s. 400.484, F.S.;
2723 providing for the imposition of administrative fines
2724 on home health agencies for specified classes of
2725 violations; amending s. 400.497, F.S.; authorizing the
2726 agency to adopt rules establishing standards for
2727 certificate of exemption applications; amending s.
2728 400.506, F.S.; revising penalties for a nurse registry
2729 directed by the agency to cease operation; providing
2730 that registered nurses, licensed practical nurses,
2731 certified nursing assistants, companions or
2732 homemakers, and home health aides are independent
2733 contractors and not employees of the nurse registries
2734 that referred them; requiring a nurse registry to
2735 inform the patient, the patient's family, or a person
2736 acting on behalf of the patient that the referred



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2737 caregiver is an independent contractor and that the
2738 nurse registry is not permitted to monitor, supervise,
2739 manage, or train the referred caregiver; revising
2740 provisions relating to activities for which the agency
2741 is authorized to deny, suspend, or revoke a nurse
2742 registry license and impose fines; providing that a
2743 nurse registry is not permitted to review or act upon
2744 certain records except under certain circumstances;
2745 amending s. 400.606, F.S.; revising content
2746 requirements of the plan accompanying an initial or
2747 change of ownership application for a hospice;
2748 amending s. 400.925, F.S.; revising the definition of
2749 the term "home medical equipment"; amending s.
2750 400.931, F.S.; providing a timeframe for a home
2751 medical equipment provider to notify the agency of
2752 certain personnel changes; amending s. 400.933, F.S.;
2753 authorizing the agency to accept certain medical
2754 oxygen permits issued by the Department of Business
2755 and Professional Regulation in lieu of agency
2756 licensure inspections; amending s. 400.980, F.S.;
2757 revising timeframe requirements for change of
2758 registration information submitted to the agency by a
2759 health care services pool; amending s. 408.061, F.S.;
2760 excluding hospitals operated by state agencies from
2761 certain financial reporting requirements; conforming a
2762 cross-reference; amending s. 408.07, F.S.; deleting
2763 the definition of the term "clinical laboratory";
2764 amending s. 408.20, F.S.; exempting hospitals operated
2765 by state agencies from assessments against the Health



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2766 Care Trust Fund to fund certain agency activities;
2767 repealing s. 408.7056, F.S., relating to the
2768 Subscriber Assistance Program; amending s. 408.803,
2769 F.S.; defining the term "relative" for the Health Care
2770 Licensing Procedures Act; amending s. 408.806, F.S.;
2771 requiring additional information on a licensure
2772 application; authorizing licensees who hold licenses
2773 for multiple providers to request that the agency
2774 align related license expiration dates; authorizing
2775 the agency to issue licenses for an abbreviated
2776 licensure period and to charge prorated fees; amending
2777 s. 408.810, F.S.; exempting certain applicants for
2778 change of ownership from furnishing proof of financial
2779 ability to operate; authorizing the agency to adopt
2780 rules governing circumstances under which a
2781 controlling interest may act in certain legal
2782 capacities on behalf of a patient or client; amending
2783 s. 408.812, F.S.; providing that unlicensed activity
2784 by a provider constitutes abuse and neglect;
2785 authorizing the agency to impose a fine under certain
2786 circumstances; amending s. 429.02, F.S.; revising a
2787 definition; conforming a cross reference amending s.
2788 429.04, F.S.; providing additional exemptions from
2789 licensure as an assisted living facility; imposing a
2790 burden of proof on the person or entity asserting the
2791 exemption; providing applicability; amending s.
2792 429.08, F.S.; providing criminal penalties and fines
2793 for ownership, rental, or maintenance of a real
2794 property used as an unlicensed assisted living



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2795 facility; providing that engaging a third party to
2796 provide certain services at an unlicensed location
2797 constitutes unlicensed activity; amending s. 429.176,
2798 F.S.; prohibiting an assisted living facility from
2799 operating beyond a specified period without an
2800 administrator who has completed certain educational
2801 requirements; amending s. 429.41, F.S.; prohibiting an
2802 assisted living facility from providing personal
2803 services to nonresidents; repealing part I of ch. 483,
2804 F.S., relating to clinical laboratories; amending s.
2805 483.294, F.S.; revising agency inspection schedules
2806 for multiphasic health testing centers; amending s.
2807 483.801, F.S.; revising an exemption from regulation
2808 for persons employed by certain laboratories; amending
2809 s. 483.803, F.S.; deleting definitions; conforming
2810 provisions to changes made by the act; amending s.
2811 641.511, F.S.; revising health maintenance
2812 organization subscriber grievance reporting
2813 requirements; conforming a provision to changes made
2814 by the act; repealing s. 641.60, F.S., relating to the
2815 Statewide Managed Care Ombudsman Committee; amending
2816 s. 945.36, F.S.; authorizing law enforcement personnel
2817 to conduct drug tests on certain inmates and
2818 releasees; amending ss. 20.43, 220.1845, 376.30781,
2819 376.86, 381.0034, 385.211, 394.4787, 395.001, 395.003,
2820 395.7015, 400.0625, 400.9905, 408.033, 408.036,
2821 408.802, 408.820, 409.9116, 409.975, 456.001, 456.057,
2822 458.307, 458.345, 459.021, 483.813, 491.003, 627.351,
2823 627.602, 627.64194, 627.6513, 641.185, 641.312,



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2824 641.3154, 641.51, 641.515, 641.55, 641.70, 641.75,
2825 766.118, 766.202, 1009.65, and 1011.52, F.S.;
2826 conforming provisions to changes made by the act;
2827 providing effective dates.

By Senator Grimsley

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1 A bill to be entitled
 2 An act relating to health care facility regulation;
 3 amending ss. 381.0031, 381.004, 384.31, 395.009, and
 4 409.905, F.S.; eliminating state licensure
 5 requirements for clinical laboratories; requiring
 6 clinical laboratories to be federally certified;
 7 amending s. 383.313, F.S.; revising requirements for a
 8 birth center to perform certain laboratory tests;
 9 repealing s. 383.335, F.S., relating to partial
 10 exemptions from licensure requirements for certain
 11 facilities that provide obstetrical and gynecological
 12 surgical services; amending s. 395.002, F.S.; revising
 13 and deleting definitions; creating s. 395.0091, F.S.;
 14 authorizing the Agency for Health Care Administration
 15 to adopt rules establishing criteria for alternate-
 16 site laboratory testing; defining the term "alternate-
 17 site testing"; amending ss. 395.0161 and 395.0163,
 18 F.S.; deleting licensure and inspection requirements
 19 for mobile surgical facilities to conform to changes
 20 made by the act; amending s. 395.0197, F.S.; requiring
 21 the manager of a hospital or ambulatory surgical
 22 center internal risk management program to demonstrate
 23 competence in certain administrative and health care
 24 service areas; conforming references; repealing s.
 25 395.1046, F.S., relating to hospital complaint
 26 investigation procedures; amending s. 395.1055, F.S.;
 27 requiring hospitals providing specified services to
 28 meet agency licensure requirements; conforming a
 29 reference; repealing ss. 395.10971 and 395.10972,

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30 F.S., relating to the purpose and establishment of the
 31 Health Care Risk Manager Advisory Council; amending s.
 32 395.10973, F.S.; deleting duties of the agency
 33 relating to health care risk managers; repealing s.
 34 395.10974, F.S., relating to licensure of health care
 35 risk managers; repealing s. 395.10975, F.S., relating
 36 to grounds for denial, suspension, or revocation of a
 37 health care risk manager's license; amending s.
 38 395.602, F.S.; deleting definitions; amending s.
 39 395.603, F.S.; deleting provisions relating to
 40 deactivation of general hospital beds by certain rural
 41 and emergency care hospitals; repealing s. 395.604,
 42 F.S., relating to other rural hospital programs;
 43 repealing s. 395.605, F.S., relating to emergency care
 44 hospitals; amending s. 395.701, F.S.; revising the
 45 definition of the term "hospital" to exclude hospitals
 46 operated by state agencies; amending s. 400.464, F.S.;
 47 revising licensure requirements for a home health
 48 agency; providing conditions for advertising certain
 49 services that require licensure; providing for a fine;
 50 providing conditions for application for a certificate
 51 of exemption from licensure as a home health agency;
 52 specifying the duration of the certificate of
 53 exemption; authorizing a fee; amending s. 400.471,
 54 F.S.; revising home health agency licensure
 55 requirements; providing requirements for proof of
 56 accreditation for home health agencies applying for
 57 change of ownership or addition of skilled care
 58 services; amending s. 400.474, F.S.; revising

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59 conditions for the imposition of a fine against a home
 60 health agency; amending s. 400.476, F.S.; requiring a
 61 home health agency providing skilled nursing care to
 62 have a director of nursing; amending s. 400.484, F.S.;
 63 providing for the imposition of administrative fines
 64 on home health agencies for specified classes of
 65 violations; amending s. 400.497, F.S.; authorizing the
 66 agency to adopt rules establishing standards for
 67 certificate of exemption applications; amending s.
 68 400.506, F.S.; revising penalties for a nurse registry
 69 directed by the agency to cease operation; providing
 70 that registered nurses, licensed practical nurses,
 71 certified nursing assistants, companions or
 72 homemakers, and home health aides are independent
 73 contractors and not employees of the nurse registries
 74 that referred them; requiring a nurse registry to
 75 inform the patient, the patient's family, or a person
 76 acting on behalf of the patient that the referred
 77 caregiver is an independent contractor and that the
 78 nurse registry is not permitted to monitor, supervise,
 79 manage, or train the referred caregiver; revising
 80 provisions relating to activities for which the agency
 81 is authorized to deny, suspend, or revoke a nurse
 82 registry license and impose fines; providing that a
 83 nurse registry is not permitted to review or act upon
 84 certain records except under certain circumstances;
 85 amending s. 400.606, F.S.; revising content
 86 requirements of the plan accompanying an initial or
 87 change of ownership application for a hospice;

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88 amending s. 400.925, F.S.; revising the definition of
 89 the term "home medical equipment"; amending s.
 90 400.931, F.S.; providing a timeframe for a home
 91 medical equipment provider to notify the agency of
 92 certain personnel changes; amending s. 400.933, F.S.;
 93 authorizing the agency to accept certain medical
 94 oxygen permits issued by the Department of Business
 95 and Professional Regulation in lieu of agency
 96 licensure inspections; amending s. 400.980, F.S.;
 97 revising timeframe requirements for change of
 98 registration information submitted to the agency by a
 99 health care services pool; amending s. 408.061, F.S.;
 100 excluding hospitals operated by state agencies from
 101 certain financial reporting requirements; conforming a
 102 cross-reference; amending s. 408.07, F.S.; deleting
 103 the definition of the term "clinical laboratory";
 104 amending s. 408.20, F.S.; exempting hospitals operated
 105 by state agencies from assessments against the Health
 106 Care Trust Fund to fund certain agency activities;
 107 repealing s. 408.7056, F.S., relating to the
 108 Subscriber Assistance Program; amending s. 408.803,
 109 F.S.; defining the term "relative" for the Health Care
 110 Licensing Procedures Act; amending s. 408.806, F.S.;
 111 requiring additional information on a licensure
 112 application; authorizing the agency to issue licenses
 113 with an abbreviated licensure period and prorated fee
 114 for alignment of multiple provider license expiration
 115 dates; amending s. 408.810, F.S.; exempting an
 116 applicant for change of ownership from furnishing

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117 proof of ability to operate under certain conditions;
 118 authorizing the agency to adopt rules governing
 119 circumstances under which a controlling interest may
 120 act in certain legal capacities on behalf of a patient
 121 or client; amending s. 408.812, F.S.; citing failure
 122 to discharge residents by the license expiration date
 123 as unlicensed activity; providing that certain
 124 unlicensed activity by a provider constitutes abuse
 125 and neglect; requiring the agency to refer certain
 126 findings to the state attorney; requiring the agency
 127 to impose a fine under certain circumstances; amending
 128 s. 429.02, F.S.; revising definitions; amending s.
 129 429.04, F.S.; providing additional exemptions from
 130 licensure as an assisted living facility; imposing a
 131 burden of proof on the person or entity asserting the
 132 exemption; providing applicability; amending s.
 133 429.08, F.S.; providing criminal penalties and fines
 134 for ownership, rental, or maintenance of a real
 135 property used as an unlicensed assisted living
 136 facility; providing that engaging a third party to
 137 provide certain services at an unlicensed location
 138 constitutes unlicensed activity; amending s. 429.176,
 139 F.S.; prohibiting an assisted living facility from
 140 operating beyond a specified period without an
 141 administrator who has completed certain educational
 142 requirements; amending s. 429.41, F.S.; prohibiting an
 143 assisted living facility from providing personal
 144 services to nonresidents; repealing part I of ch. 483,
 145 F.S., relating to clinical laboratories; amending s.

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146 483.294, F.S.; revising agency inspection schedules
 147 for multiphasic health testing centers; amending s.
 148 483.801, F.S.; revising an exemption from regulation
 149 for persons employed by certain laboratories; amending
 150 s. 483.803, F.S.; deleting definitions; conforming
 151 provisions to changes made by the act; amending s.
 152 641.511, F.S.; revising health maintenance
 153 organization subscriber grievance reporting
 154 requirements; repealing s. 641.60, F.S., relating to
 155 the Statewide Managed Care Ombudsman Committee;
 156 amending s. 945.36, F.S.; authorizing law enforcement
 157 personnel to conduct drug tests on certain inmates and
 158 releasees; amending ss. 20.43, 220.1845, 376.30781,
 159 376.86, 381.0034, 385.211, 394.4787, 395.001, 395.003,
 160 395.7015, 400.0625, 400.9905, 408.033, 408.036,
 161 408.802, 408.820, 409.9116, 409.975, 456.001, 456.057,
 162 458.307, 458.345, 483.813, 491.003, 627.351, 627.602,
 163 627.64194, 627.6513, 641.185, 641.312, 641.3154,
 164 641.51, 641.515, 641.55, 641.70, 641.75, 766.118,
 165 766.202, and 1009.65, F.S.; conforming provisions to
 166 changes made by the act; providing effective dates.

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

169
 170 Section 1. Paragraph (g) of subsection (3) of section
 171 20.43, Florida Statutes, is amended to read:

172 20.43 Department of Health.—There is created a Department
 173 of Health.

174 (3) The following divisions of the Department of Health are

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175 established:

176 (g) Division of Medical Quality Assurance, which is

177 responsible for the following boards and professions established

178 within the division:

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

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

181 3. The Board of Osteopathic Medicine, created under chapter

182 459.

183 4. The Board of Chiropractic Medicine, created under

184 chapter 460.

185 5. The Board of Podiatric Medicine, created under chapter

186 461.

187 6. Naturopathy, as provided under chapter 462.

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

189 8. The Board of Nursing, created under part I of chapter

190 464.

191 9. Nursing assistants, as provided under part II of chapter

192 464.

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

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

195 12. Midwifery, as provided under chapter 467.

196 13. The Board of Speech-Language Pathology and Audiology,

197 created under part I of chapter 468.

198 14. The Board of Nursing Home Administrators, created under

199 part II of chapter 468.

200 15. The Board of Occupational Therapy, created under part

201 III of chapter 468.

202 16. Respiratory therapy, as provided under part V of

203 chapter 468.

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204 17. Dietetics and nutrition practice, as provided under

205 part X of chapter 468.

206 18. The Board of Athletic Training, created under part XIII

207 of chapter 468.

208 19. The Board of Orthotists and Prosthetists, created under

209 part XIV of chapter 468.

210 20. Electrolysis, as provided under chapter 478.

211 21. The Board of Massage Therapy, created under chapter

212 480.

213 ~~22. The Board of Clinical Laboratory Personnel, created~~

214 ~~under part III of chapter 483.~~

215 22.23. Medical physicists, as provided under part III ~~IV~~ of

216 chapter 483.

217 23.24. The Board of Opticianry, created under part I of

218 chapter 484.

219 24.25. The Board of Hearing Aid Specialists, created under

220 part II of chapter 484.

221 25.26. The Board of Physical Therapy Practice, created

222 under chapter 486.

223 26.27. The Board of Psychology, created under chapter 490.

224 27.28. School psychologists, as provided under chapter 490.

225 28.29. The Board of Clinical Social Work, Marriage and

226 Family Therapy, and Mental Health Counseling, created under

227 chapter 491.

228 29.30. Emergency medical technicians and paramedics, as

229 provided under part III of chapter 401.

230 Section 2. Paragraph (k) of subsection (2) of section

231 220.1845, Florida Statutes, is amended to read:

232 220.1845 Contaminated site rehabilitation tax credit.—

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(2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.—

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

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

376.30781 Tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.—

(3)

(f) In order to encourage the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or s. 408.07, ~~or s. 408.7056~~, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed \$500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the

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construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 4. Subsection (1) of section 376.86, Florida Statutes, is amended to read:

376.86 Brownfield Areas Loan Guarantee Program.—

(1) The Brownfield Areas Loan Guarantee Council is created to review and approve or deny, by a majority vote of its membership, the situations and circumstances for participation in partnerships by agreements with local governments, financial institutions, and others associated with the redevelopment of brownfield areas pursuant to the Brownfields Redevelopment Act for a limited state guaranty of up to 5 years of loan guarantees or loan loss reserves issued pursuant to law. The limited state loan guaranty applies only to 50 percent of the primary lenders loans for redevelopment projects in brownfield areas. If the redevelopment project is for affordable housing, as defined in s. 420.0004, in a brownfield area, the limited state loan guaranty applies to 75 percent of the primary lender's loan. If the redevelopment project includes the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or s. 408.07, ~~or s. 408.7056~~, on a brownfield site and the applicant has obtained documentation in accordance with s. 376.30781 indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been

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issued for the operation of the health care facility or health care provider, the limited state loan guaranty applies to 75 percent of the primary lender's loan. A limited state guaranty of private loans or a loan loss reserve is authorized for lenders licensed to operate in the state upon a determination by the council that such an arrangement would be in the public interest and the likelihood of the success of the loan is great.

Section 5. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of public health significance to department.—

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments of 1988 ~~licensed under chapter 483~~ that diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 6. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

(3) The department shall require, as a condition of granting a license under chapter 467 or part II ~~III~~ of chapter 483, that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. Upon submission of an affidavit showing good cause, an

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applicant who has not taken a course at the time of licensure shall be allowed 6 months to complete this requirement.

Section 7. Paragraph (c) of subsection (4) of section 381.004, Florida Statutes, is amended to read:

381.004 HIV testing.—

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

(c) The program shall have all laboratory procedures performed in a laboratory appropriately certified by the Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments of 1988 ~~licensed under the provisions of chapter 483~~.

Section 8. Subsection (1) of section 383.313, Florida Statutes, is amended to read:

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

(1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center may perform simple laboratory tests, as defined by rule of the agency, and is exempt from the requirements of chapter 483, ~~provided no more than five physicians are employed by the birth center and testing is conducted exclusively in~~

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~~connection with the diagnosis and treatment of clients of the birth center.~~

Section 9. Section 383.335, Florida Statutes, is repealed.

Section 10. Section 384.31, Florida Statutes, is amended to read:

384.31 Testing of pregnant women; duty of the attendant.— Every person, including every physician licensed under chapter 458 or chapter 459 or midwife licensed under part I of chapter 464 or chapter 467, attending a pregnant woman for conditions relating to pregnancy during the period of gestation and delivery shall cause the woman to be tested for sexually transmissible diseases, including HIV, as specified by department rule. Testing shall be performed by a laboratory appropriately certified by the Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments of 1988 ~~approved~~ for such purposes ~~under part I of chapter 483.~~ The woman shall be informed of the tests that will be conducted and of her right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the woman, shall be placed in the woman's medical record and no testing shall occur.

Section 11. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

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

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(27) ~~395.002(28)~~ that

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contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 12. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

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

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

Section 13. Section 395.001, Florida Statutes, is amended to read:

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

Section 14. Present subsections (22) through (33) of section 395.002, Florida Statutes, are renumbered as subsections

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(21) through (32), respectively, and subsections (3) and (16) and present subsections (21) and (23) of that section are amended, to read:

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" ~~or "mobile surgical facility"~~ means 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. ~~Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.~~

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

~~(21) "Mobile surgical facility" is a mobile facility in which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter~~

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~~957 and in which inmate patients are admitted to and discharged from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.~~

(22)~~(23)~~ "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or, ambulatory surgical, ~~or mobile surgical~~ care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07(44) ~~408.07(45)~~, reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

Section 15. Paragraphs (a) and (b) of subsection (1) and paragraph (b) of subsection (2) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1) (a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities

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licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital ~~or~~, ambulatory surgical center, ~~or mobile surgical facility~~ in this state.

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

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

(2)

(b) The agency shall, at the request of a licensee that is a teaching hospital as defined in s. ~~408.07(44)~~ ~~408.07(45)~~, issue a single license to a licensee for facilities that have been previously licensed as separate premises, provided such separately licensed facilities, taken together, constitute the same premises as defined in s. 395.002(22) ~~395.002(23)~~. Such license for the single premises shall include all of the beds, services, and programs that were previously included on the licenses for the separate premises. The granting of a single license under this paragraph shall not in any manner reduce the number of beds, services, or programs operated by the licensee.

Section 16. Subsection (1) of section 395.009, Florida Statutes, is amended to read:

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

(1) As a requirement for issuance or renewal of its license, each licensed facility shall require that all clinical laboratory tests performed by or for the licensed facility be performed by a clinical laboratory appropriately certified by the Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments of 1988 licensed under the provisions of chapter 483.

Section 17. Section 395.0091, Florida Statutes, is created to read:

395.0091 Alternate-site testing.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation, including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional backgrounds not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping

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523 requirements. Alternate-site testing locations must register
 524 when the hospital applies to renew its license. For purposes of
 525 this section, the term "alternate-site testing" means any
 526 laboratory testing done under the administrative control of a
 527 hospital but performed out of the physical or administrative
 528 confines of the central laboratory.

529 Section 18. Paragraph (f) of subsection (1) of section
 530 395.0161, Florida Statutes, is amended to read:

531 395.0161 Licensure inspection.—

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

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

540 Section 19. Subsection (3) of section 395.0163, Florida
 541 Statutes, is amended to read:

542 395.0163 Construction inspections; plan submission and
 543 approval; fees.—

544 ~~(3) In addition to the requirements of s. 408.811, the~~
 545 ~~agency shall inspect a mobile surgical facility at initial~~
 546 ~~licensure and at each time the facility establishes a new~~
 547 ~~location, prior to admission of patients. However, such~~
 548 ~~inspections shall not be required when a mobile surgical~~
 549 ~~facility is moved temporarily to a location where medical~~
 550 ~~treatment will not be provided.~~

551 Section 20. Subsection (2), paragraph (c) of subsection

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552 (6), and subsections (16) and (17) of section 395.0197, Florida
 553 Statutes, are amended to read:

554 395.0197 Internal risk management program.—

555 (2) The internal risk management program is the
 556 responsibility of the governing board of the health care
 557 facility. Each licensed facility shall hire a risk manager,
 558 ~~licensed under s. 395.10974,~~ who is responsible for
 559 implementation and oversight of such facility's internal risk
 560 management program and who demonstrates competence, by education
 561 or experience, in the following areas: as required by this
 562 section. A risk manager must not be made responsible for more
 563 than four internal risk management programs in separate licensed
 564 facilities, unless the facilities are under one corporate
 565 ownership or the risk management programs are in rural
 566 hospitals.

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

568 (b) Applicable federal, state, and local health and safety
 569 laws and rules.

570 (c) General risk management administration.

571 (d) Patient care.

572 (e) Medical care.

573 (f) Personal and social care.

574 (g) Accident prevention.

575 (h) Departmental organization and management.

576 (i) Community interrelationships.

577 (j) Medical terminology.

578 (6)

579 (c) The report submitted to the agency shall also contain
 580 the name ~~and license number~~ of the risk manager of the licensed

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581 facility, a copy of its policy and procedures which govern the
 582 measures taken by the facility and its risk manager to reduce
 583 the risk of injuries and adverse incidents, and the results of
 584 such measures. The annual report is confidential and is not
 585 available to the public pursuant to s. 119.07(1) or any other
 586 law providing access to public records. The annual report is not
 587 discoverable or admissible in any civil or administrative
 588 action, except in disciplinary proceedings by the agency or the
 589 appropriate regulatory board. The annual report is not available
 590 to the public as part of the record of investigation for and
 591 prosecution in disciplinary proceedings made available to the
 592 public by the agency or the appropriate regulatory board.
 593 However, the agency or the appropriate regulatory board shall
 594 make available, upon written request by a health care
 595 professional against whom probable cause has been found, any
 596 such records which form the basis of the determination of
 597 probable cause.

598 (16) There shall be no monetary liability on the part of,
 599 and no cause of action for damages shall arise against, any risk
 600 manager, ~~licensed under s. 395.10974,~~ for the implementation and
 601 oversight of the internal risk management program in a facility
 602 licensed under this chapter or chapter 390 as required by this
 603 section, for any act or proceeding undertaken or performed
 604 within the scope of the functions of such internal risk
 605 management program if the risk manager acts without intentional
 606 fraud.

607 (17) A privilege against civil liability is hereby granted
 608 to any ~~licensed~~ risk manager or licensed facility with regard to
 609 information furnished pursuant to this chapter, unless the

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610 ~~licensed~~ risk manager or facility acted in bad faith or with
 611 malice in providing such information.

612 Section 21. Section 395.1046, Florida Statutes, is
 613 repealed.

614 Section 22. Subsection (2) of section 395.1055, Florida
 615 Statutes, is amended, and paragraph (i) is added to subsection
 616 (1), to read:

617 395.1055 Rules and enforcement.—

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

621 (i) All hospitals providing pediatric cardiac
 622 catheterization, pediatric open-heart surgery, organ
 623 transplantation, neonatal intensive care services, psychiatric
 624 services, or comprehensive medical rehabilitation meet the
 625 minimum licensure requirements adopted by the agency. Such
 626 licensure requirements shall include quality of care, nurse
 627 staffing, physician staffing, physical plant, equipment,
 628 emergency transportation, and data reporting standards.

629 (2) Separate standards may be provided for general and
 630 specialty hospitals, ambulatory surgical centers, ~~mobile~~
 631 ~~surgical facilities,~~ and statutory rural hospitals as defined in
 632 s. 395.602.

633 Section 23. Section 395.10971, Florida Statutes, is
 634 repealed.

635 Section 24. Section 395.10972, Florida Statutes, is
 636 repealed.

637 Section 25. Section 395.10973, Florida Statutes, is amended
 638 to read:

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639 395.10973 Powers and duties of the agency.—It is the
 640 function of the agency to:

641 (1) Adopt rules pursuant to ss. 120.536(1) and 120.54 to
 642 implement the provisions of this part and part II of chapter 408
 643 conferring duties upon it.

644 ~~(2) Develop, impose, and enforce specific standards within~~
 645 ~~the scope of the general qualifications established by this part~~
 646 ~~which must be met by individuals in order to receive licenses as~~
 647 ~~health care risk managers. These standards shall be designed to~~
 648 ~~ensure that health care risk managers are individuals of good~~
 649 ~~character and otherwise suitable and, by training or experience~~
 650 ~~in the field of health care risk management, qualified in~~
 651 ~~accordance with the provisions of this part to serve as health~~
 652 ~~care risk managers, within statutory requirements.~~

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

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

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

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

664 (2)(7) Develop a model risk management program for health
 665 care facilities which will satisfy the requirements of s.
 666 395.0197.

667 (3)(8) Enforce the special-occupancy provisions of the

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668 Florida Building Code which apply to hospitals, intermediate
 669 residential treatment facilities, and ambulatory surgical
 670 centers in conducting any inspection authorized by this chapter
 671 and part II of chapter 408.

672 Section 26. Section 395.10974, Florida Statutes, is
 673 repealed.

674 Section 27. Section 395.10975, Florida Statutes, is
 675 repealed.

676 Section 28. Subsection (2) of section 395.602, Florida
 677 Statutes, is amended to read:

678 395.602 Rural hospitals.—

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

680 (a) “Emergency care hospital” means a medical facility
 681 which provides:

682 1. Emergency medical treatment; and

683 2. Inpatient care to ill or injured persons prior to their
 684 transportation to another hospital or provides inpatient medical
 685 care to persons needing care for a period of up to 96 hours. The
 686 96-hour limitation on inpatient care does not apply to respite,
 687 skilled nursing, hospice, or other nonacute care patients.

688 (b) “Essential access community hospital” means any
 689 facility which:

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

691 2. ~~Is located more than 35 miles from any other essential~~
 692 ~~access community hospital, rural referral center, or urban~~
 693 ~~hospital meeting criteria for classification as a regional~~
 694 ~~referral center;~~

695 3. ~~Is part of a network that includes rural primary care~~
 696 ~~hospitals;~~

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- 697 ~~4. Provides emergency and medical backup services to rural~~
 698 ~~primary care hospitals in its rural health network;~~
 699 ~~5. Extends staff privileges to rural primary care hospital~~
 700 ~~physicians in its network; and~~
 701 ~~6. Accepts patients transferred from rural primary care~~
 702 ~~hospitals in its network.~~
 703 ~~(e) "Inactive rural hospital bed" means a licensed acute~~
 704 ~~care hospital bed, as defined in s. 395.002(13), that is~~
 705 ~~inactive in that it cannot be occupied by acute care inpatients.~~
 706 (a)(d) "Rural area health education center" means an area
 707 health education center (AHEC), as authorized by Pub. L. No. 94-
 708 484, which provides services in a county with a population
 709 density of up to no greater than 100 persons per square mile.
 710 (b)(e) "Rural hospital" means an acute care hospital
 711 licensed under this chapter, having 100 or fewer licensed beds
 712 and an emergency room, which is:
 713 1. The sole provider within a county with a population
 714 density of up to 100 persons per square mile;
 715 2. An acute care hospital, in a county with a population
 716 density of up to 100 persons per square mile, which is at least
 717 30 minutes of travel time, on normally traveled roads under
 718 normal traffic conditions, from any other acute care hospital
 719 within the same county;
 720 3. A hospital supported by a tax district or subdistrict
 721 whose boundaries encompass a population of up to 100 persons per
 722 square mile;
 723 4. A hospital classified as a sole community hospital under
 724 42 C.F.R. s. 412.92 which has up to 175 licensed beds;
 725 5. A hospital with a service area that has a population of

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- 726 up to 100 persons per square mile. As used in this subparagraph,
 727 the term "service area" means the fewest number of zip codes
 728 that account for 75 percent of the hospital's discharges for the
 729 most recent 5-year period, based on information available from
 730 the hospital inpatient discharge database in the Florida Center
 731 for Health Information and Transparency at the agency; or
 732 6. A hospital designated as a critical access hospital, as
 733 defined in s. 408.07.
 734
 735 Population densities used in this paragraph must be based upon
 736 the most recently completed United States census. A hospital
 737 that received funds under s. 409.9116 for a quarter beginning no
 738 later than July 1, 2002, is deemed to have been and shall
 739 continue to be a rural hospital from that date through June 30,
 740 2021, if the hospital continues to have up to 100 licensed beds
 741 and an emergency room. An acute care hospital that has not
 742 previously been designated as a rural hospital and that meets
 743 the criteria of this paragraph shall be granted such designation
 744 upon application, including supporting documentation, to the
 745 agency. A hospital that was licensed as a rural hospital during
 746 the 2010-2011 or 2011-2012 fiscal year shall continue to be a
 747 rural hospital from the date of designation through June 30,
 748 2021, if the hospital continues to have up to 100 licensed beds
 749 and an emergency room.
 750 ~~(f) "Rural primary care hospital" means any facility~~
 751 ~~meeting the criteria in paragraph (e) or s. 395.605 which~~
 752 ~~provides:~~
 753 ~~1. Twenty-four hour emergency medical care;~~
 754 ~~2. Temporary inpatient care for periods of 72 hours or less~~

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to patients requiring stabilization before discharge or transfer to another hospital. The 72-hour limitation does not apply to respite, skilled nursing, hospice, or other nonacute care patients; and

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

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

Section 29. Section 395.603, Florida Statutes, is amended to read:

395.603 ~~Deactivation of general hospital beds~~; Rural hospital impact statement.—

~~(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with inactive beds shall provide 24-hour emergency medical care by staffing an emergency room. Providers with~~

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~~inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate of need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.~~

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

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

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

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

(4)(d) What impact will the proposed action have on the

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813 ability of rural hospitals to recruit the affected personnel to
814 practice in their facilities?

815 ~~(5)(e)~~ What impact will the proposed action have on the
816 limited financial resources of rural hospitals through increased
817 salaries and benefits necessary to recruit or retain such health
818 personnel?

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

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

824 Section 30. Section 395.604, Florida Statutes, is repealed.

825 Section 31. Section 395.605, Florida Statutes, is repealed.

826 Section 32. Paragraph (c) of subsection (1) of section
827 395.701, Florida Statutes, is amended to read:

828 395.701 Annual assessments on net operating revenues for
829 inpatient and outpatient services to fund public medical
830 assistance; administrative fines for failure to pay assessments
831 when due; exemption.—

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

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

836 Section 33. Paragraph (b) of subsection (2) of section
837 395.7015, Florida Statutes, is amended to read:

838 395.7015 Annual assessment on health care entities.—

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

841 (b) For the purpose of this section, "health care entities"

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842 include the following:

843 1. Ambulatory surgical centers ~~and mobile surgical~~
844 ~~facilities licensed under s. 395.003. This subsection shall only~~
845 ~~apply to mobile surgical facilities operating under contracts~~
846 ~~entered into on or after July 1, 1998.~~

847 2. ~~Clinical laboratories licensed under s. 483.091,~~
848 ~~excluding any hospital laboratory defined under s. 483.041(6),~~
849 ~~any clinical laboratory operated by the state or a political~~
850 ~~subdivision of the state, any clinical laboratory which~~
851 ~~qualifies as an exempt organization under s. 501(c)(3) of the~~
852 ~~Internal Revenue Code of 1986, as amended, and which receives 70~~
853 ~~percent or more of its gross revenues from services to charity~~
854 ~~patients or Medicaid patients, and any blood, plasma, or tissue~~
855 ~~bank procuring, storing, or distributing blood, plasma, or~~
856 ~~tissue either for future manufacture or research or distributed~~
857 ~~on a nonprofit basis, and further excluding any clinical~~
858 ~~laboratory which is wholly owned and operated by 6 or fewer~~
859 ~~physicians who are licensed pursuant to chapter 458 or chapter~~
860 ~~459 and who practice in the same group practice, and at which no~~
861 ~~clinical laboratory work is performed for patients referred by~~
862 ~~any health care provider who is not a member of the same group.~~

863 2.3. Diagnostic-imaging centers that are freestanding
864 outpatient facilities that provide specialized services for the
865 identification or determination of a disease through examination
866 and also provide sophisticated radiological services, and in
867 which services are rendered by a physician licensed by the Board
868 of Medicine under s. 458.311, s. 458.313, or s. 458.317, or by
869 an osteopathic physician licensed by the Board of Osteopathic
870 Medicine under s. 459.0055 or s. 459.0075. For purposes of this

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 paragraph, "sophisticated radiological services" means the following: magnetic resonance imaging; nuclear medicine; angiography; arteriography; computed tomography; positron emission tomography; digital vascular imaging; bronchography; lymphangiography; splenography; ultrasound, excluding ultrasound providers that are part of a private physician's office practice or when ultrasound is provided by two or more physicians licensed under chapter 458 or chapter 459 who are members of the same professional association and who practice in the same medical specialties; and such other sophisticated radiological services, excluding mammography, as adopted in rule by the board.

Section 34. Subsection (1) of section 400.0625, Florida Statutes, is amended to read:

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

(1) Each nursing home, as a requirement for issuance or renewal of its license, shall require that all clinical laboratory tests performed for the nursing home be performed by a licensed clinical laboratory ~~licensed under the provisions of chapter 483~~, except for such self-testing procedures as are approved by the agency by rule. ~~Results of clinical laboratory tests performed prior to admission which meet the minimum standards provided in s. 483.181(3) shall be accepted in lieu of routine examinations required upon admission and clinical laboratory tests which may be ordered by a physician for residents of the nursing home.~~

Section 35. Subsection (1) and paragraphs (b), (e), and (f) of subsection (4) of section 400.464, Florida Statutes, are

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 amended, and subsection (6) is added to that section, to read:
 400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—
 (1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and entities licensed or registered by or applying for such licensure or registration from the Agency for Health Care Administration pursuant to this part. A license issued by the agency is required in order to operate a home health agency in this state. A license issued after June 30, 2017, must specify the home health services that the organization is authorized to perform and indicate whether such specified services are considered skilled care. The provision or advertising of services which require licensure pursuant to this part without such services being specified on the face of the license issued after June 30, 2017, constitutes unlicensed activity as prohibited under s. 408.812.

(4)

(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of this part is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of this part or part II of chapter 408, until compliance with this part or the rules adopted under this part has been demonstrated to the satisfaction of the agency.

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

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

(6) Any person, entity, or organization providing home health services which is exempt from licensure under subsection (5) may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that sets forth its name or names and addresses, a statement of the reasons why it is exempt from licensure as a home health agency, and other information deemed necessary by the agency. A certificate of exemption is valid for a period of not more than 2 years and is not transferable. The agency may charge an applicant for a certificate of exemption in an amount equal to \$100 or the actual cost of processing the certificate.

Section 36. Present subsections (7), (8), and (9) of section 400.471, Florida Statutes, are renumbered as subsections (6), (7), and (8), respectively, and subsection (2), present subsection (6), and paragraph (g) of subsection (10) are amended, to read:

400.471 Application for license; fee.—

(2) In addition to the requirements of part II of chapter 408, the initial applicant, the applicant for a change of

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ownership, and the applicant for the addition of skilled care services, must file with the application satisfactory proof that the home health agency is in compliance with this part and applicable rules, including:

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

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

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

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

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

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

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987 ~~(f)(g)~~ All other ownership interests in health care
 988 entities for each controlling interest, as defined in part II of
 989 chapter 408.
 990 ~~(g)(h)~~ In the case of an application for initial licensure,
 991 an application for a change of ownership, or an application for
 992 the addition of skilled care services, documentation of
 993 accreditation, or an application for accreditation, from an
 994 accrediting organization that is recognized by the agency as
 995 having standards comparable to those required by this part and
 996 part II of chapter 408. A home health agency that ~~is not~~
 997 ~~Medicare or Medicaid certified and~~ does not provide skilled care
 998 is exempt from this paragraph. Notwithstanding s. 408.806, an
 999 initial applicant that has applied for accreditation must
 1000 provide proof of accreditation that is not conditional or
 1001 provisional and submit a survey demonstrating compliance with
 1002 the requirements of this part, part II of chapter 408, and
 1003 applicable rules from an accrediting organization that is
 1004 recognized by the agency as having standards comparable to those
 1005 required by this part and part II of chapter 408 within 120 days
 1006 after the date of the agency's receipt of the application for
 1007 licensure ~~or the application shall be withdrawn from further~~
 1008 ~~consideration.~~ Such accreditation must be continuously
 1009 maintained by the home health agency to maintain licensure. The
 1010 agency shall accept, in lieu of its own periodic licensure
 1011 survey, the submission of the survey of an accrediting
 1012 organization that is recognized by the agency if the
 1013 accreditation of the licensed home health agency is not
 1014 provisional and if the licensed home health agency authorizes
 1015 releases of, and the agency receives the report of, the

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1016 accrediting organization.
 1017 ~~(6) The agency may not issue a license designated as~~
 1018 ~~certified to a home health agency that fails to satisfy the~~
 1019 ~~requirements of a Medicare certification survey from the agency.~~
 1020 ~~(9)(10)~~ The agency may not issue a renewal license for a
 1021 home health agency in any county having at least one licensed
 1022 home health agency and that has more than one home health agency
 1023 per 5,000 persons, as indicated by the most recent population
 1024 estimates published by the Legislature's Office of Economic and
 1025 Demographic Research, if the applicant or any controlling
 1026 interest has been administratively sanctioned by the agency
 1027 during the 2 years prior to the submission of the licensure
 1028 renewal application for one or more of the following acts:
 1029 (g) Demonstrating a pattern of failing to provide a service
 1030 specified in the home health agency's written agreement with a
 1031 patient or the patient's legal representative, or the plan of
 1032 care for that patient, except unless a reduction in service is
 1033 ~~mandated by Medicare, Medicaid, or a state program or~~ as
 1034 provided in s. 400.492(3). A pattern may be demonstrated by a
 1035 showing of at least three incidents, regardless of the patient
 1036 or service, in which the home health agency did not provide a
 1037 service specified in a written agreement or plan of care during
 1038 a 3-month period;
 1039 Section 37. Subsection (5) of section 400.474, Florida
 1040 Statutes, is amended to read:
 1041 400.474 Administrative penalties.—
 1042 (5) The agency shall impose a fine of \$5,000 against a home
 1043 health agency that demonstrates a pattern of failing to provide
 1044 a service specified in the home health agency's written

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

Section 38. Paragraph (c) of subsection (2) of section 400.476, Florida Statutes, is amended to read:

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

(2) DIRECTOR OF NURSING.—

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

Section 39. Subsection (2) of section 400.484, Florida Statutes, is amended to read:

400.484 Right of inspection; violations deficiencies; fines.—

(2) The agency shall impose fines for various classes of

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violations deficiencies in accordance with the following schedule:

(a) Class I violations are defined in s. 408.813 ~~A class I deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury.~~ Upon finding a class I violation deficiency, the agency shall impose an administrative fine in the amount of \$15,000 for each occurrence and each day that the violation deficiency exists.

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

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

(d) Class IV violations are defined in s. 408.813 ~~A class IV deficiency is any act, omission, or practice related to required reports, forms, or documents which does not have the potential of negatively affecting patients.~~ These violations are of a type that the agency determines do not threaten the health,

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safety, or security of patients. Upon finding an uncorrected or repeated class IV ~~violation deficiency~~, the agency shall impose an administrative fine not to exceed \$500 for each occurrence and each day that the uncorrected or repeated violation ~~deficiency~~ exists.

Section 40. Subsection (4) of section 400.497, Florida Statutes, is amended to read:

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

(4) Licensure and certificate of exemption application and renewal.

Section 41. Subsection (5), paragraphs (d) and (e) of subsection (6), paragraph (a) of subsection (15), and subsections (19) and (20) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

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

(b) If a nurse registry fails to cease operation after agency notification, the agency may impose a fine in accordance

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with s. 408.812 ~~of \$500 for each day of noncompliance.~~

(6)

(d) A registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide referred for contract under this chapter by a nurse registry is deemed an independent contractor and not an employee of the nurse registry under any chapter, regardless of the obligations imposed on a nurse registry under this chapter or chapter 408.

(e) Upon referral of a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide for contract in a private residence or facility, the nurse registry shall advise the patient, the patient's family, or any other person acting on behalf of the patient, at the time of the contract for services, that the caregiver referred by the nurse registry is an independent contractor and that the it is not the obligation of a nurse registry is not permitted to monitor, supervise, manage, or train a caregiver referred for contract under this chapter.

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

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

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

3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were

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executed within the last 5 years.

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

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

~~(19) It is not the obligation of~~ A nurse registry is not permitted to monitor, supervise, manage, or train a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide referred for contract under this chapter. In the event of a violation of this chapter or a violation of any other law of this state by a referred registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide, or a deficiency in credentials which comes to the attention of

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the nurse registry, the nurse registry shall advise the patient to terminate the referred person's contract, providing the reason for the suggested termination; cease referring the person to other patients or facilities; and, if practice violations are involved, notify the licensing board. This section does not affect or negate any other obligations imposed on a nurse registry under chapter 408.

(20) Records required to be filed under this chapter with the nurse registry as a repository of records must be kept in accordance with rules adopted by the agency. The nurse registry is not permitted ~~has no obligation~~ to review or act upon such records except as specified in subsection (19).

Section 42. Subsection (1) of section 400.606, Florida Statutes, is amended to read:

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

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

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

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

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

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1219 (d) Provisions for the implementation of hospice home care
 1220 within 3 months after licensure.
 1221 (e) Provisions for the implementation of hospice homelike
 1222 inpatient care within 12 months after licensure.
 1223 (f) The number and disciplines of professional staff to be
 1224 employed.
 1225 (g) The name and qualifications of any existing or
 1226 potential contractee.
 1227 (h) A plan for attracting and training volunteers.
 1228
 1229 ~~If the applicant is an existing licensed health care provider,~~
 1230 ~~the application must be accompanied by a copy of the most recent~~
 1231 ~~profit loss statement and, if applicable, the most recent~~
 1232 ~~licensure inspection report.~~
 1233 Section 43. Subsection (6) of section 400.925, Florida
 1234 Statutes, is amended to read:
 1235 400.925 Definitions.—As used in this part, the term:
 1236 (6) "Home medical equipment" includes any product as
 1237 defined by the Federal Drug Administration's Drugs, Devices and
 1238 Cosmetics Act, any products reimbursed under the Medicare Part B
 1239 Durable Medical Equipment benefits, or any products reimbursed
 1240 under the Florida Medicaid durable medical equipment program.
 1241 Home medical equipment includes:
 1242 (a) Oxygen and related respiratory equipment; manual,
 1243 ~~motorized, or customized wheelchairs and related seating and~~
 1244 ~~positioning, but does not include prosthetics or orthotics or~~
 1245 ~~any splints, braces, or aids custom fabricated by a licensed~~
 1246 ~~health care practitioner;~~
 1247 (b) Motorized scooters;

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1248 (c) Personal transfer systems; and
 1249 (d) Specialty beds, for use by a person with a medical
 1250 need; and
 1251 (e) Manual, motorized, or customized wheelchairs and
 1252 related seating and positioning, but does not include
 1253 prosthetics, orthotics, or any splints, braces, or aids custom
 1254 fabricated by a licensed health care practitioner.
 1255 Section 44. Subsection (4) of section 400.931, Florida
 1256 Statutes, is amended to read:
 1257 400.931 Application for license; fee.—
 1258 (4) When a change of the general manager of a home medical
 1259 equipment provider occurs, the licensee must notify the agency
 1260 of the change within the timeframes established in part II of
 1261 chapter 408 and applicable rules 45 days.
 1262 Section 45. Subsection (2) of section 400.933, Florida
 1263 Statutes, is amended to read:
 1264 400.933 Licensure inspections and investigations.—
 1265 (2) The agency shall accept, in lieu of its own periodic
 1266 inspections for licensure, submission of the following:
 1267 (a) The survey or inspection of an accrediting
 1268 organization, provided the accreditation of the licensed home
 1269 medical equipment provider is not provisional and provided the
 1270 licensed home medical equipment provider authorizes release of,
 1271 and the agency receives the report of, the accrediting
 1272 organization; or
 1273 (b) A copy of a valid medical oxygen retail establishment
 1274 permit issued by the Department of Business and Professional
 1275 Regulation Health, pursuant to chapter 499.
 1276 Section 46. Subsection (2) of section 400.980, Florida

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Statutes, is amended to read:

400.980 Health care services pools.—

(2) The requirements of part II of chapter 408 apply to the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall adopt rules and provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within the timeframes established in this part, part II of chapter 408, and applicable rules ~~14 days prior to the change.~~

Section 47. Paragraphs (a) through (d) of subsection (4) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.—

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

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

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

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1335 (c) Entities that are owned, directly or indirectly, by an
 1336 entity licensed or registered by the state pursuant to chapter
 1337 395; entities that are owned, directly or indirectly, by an
 1338 entity licensed or registered by the state and providing only
 1339 health care services within the scope of services authorized
 1340 pursuant to their respective licenses under ss. 383.30-383.332
 1341 ~~ss. 383.30-383.335~~, chapter 390, chapter 394, chapter 397, this
 1342 chapter except part X, chapter 429, chapter 463, chapter 465,
 1343 chapter 466, chapter 478, ~~part I of chapter 483~~, chapter 484, or
 1344 chapter 651; end-stage renal disease providers authorized under
 1345 42 C.F.R. part 405, subpart U; providers certified under 42
 1346 C.F.R. part 485, subpart B or subpart H; or any entity that
 1347 provides neonatal or pediatric hospital-based health care
 1348 services by licensed practitioners solely within a hospital
 1349 under chapter 395.

1350 (d) Entities that are under common ownership, directly or
 1351 indirectly, with an entity licensed or registered by the state
 1352 pursuant to chapter 395; entities that are under common
 1353 ownership, directly or indirectly, with an entity licensed or
 1354 registered by the state and providing only health care services
 1355 within the scope of services authorized pursuant to their
 1356 respective licenses under ss. 383.30-383.332 ~~ss. 383.30-383.335~~,
 1357 chapter 390, chapter 394, chapter 397, this chapter except part
 1358 X, chapter 429, chapter 463, chapter 465, chapter 466, chapter
 1359 478, ~~part I of chapter 483~~, chapter 484, or chapter 651; end-
 1360 stage renal disease providers authorized under 42 C.F.R. part
 1361 405, subpart U; providers certified under 42 C.F.R. part 485,
 1362 subpart B or subpart H; or any entity that provides neonatal or
 1363 pediatric hospital-based health care services by licensed

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1364 practitioners solely within a hospital licensed under chapter
 1365 395.

1366
 1367 Notwithstanding this subsection, an entity shall be deemed a
 1368 clinic and must be licensed under this part in order to receive
 1369 reimbursement under the Florida Motor Vehicle No-Fault Law, ss.
 1370 627.730-627.7405, unless exempted under s. 627.736(5)(h).

1371 Section 48. Paragraph (a) of subsection (2) of section
 1372 408.033, Florida Statutes, is amended to read:

1373 408.033 Local and state health planning.—

1374 (2) FUNDING.—

1375 (a) The Legislature intends that the cost of local health
 1376 councils be borne by assessments on selected health care
 1377 facilities subject to facility licensure by the Agency for
 1378 Health Care Administration, including abortion clinics, assisted
 1379 living facilities, ambulatory surgical centers, birthing
 1380 centers, ~~clinical laboratories except community nonprofit blood~~
 1381 ~~banks and clinical laboratories operated by practitioners for~~
 1382 ~~exclusive use regulated under s. 483.035~~, home health agencies,
 1383 hospices, hospitals, intermediate care facilities for the
 1384 developmentally disabled, nursing homes, health care clinics,
 1385 and multiphasic testing centers and by assessments on
 1386 organizations subject to certification by the agency pursuant to
 1387 chapter 641, part III, including health maintenance
 1388 organizations and prepaid health clinics. Fees assessed may be
 1389 collected prospectively at the time of licensure renewal and
 1390 prorated for the licensure period.

1391 Section 49. Paragraph (e) and present paragraph (p) of
 1392 subsection (3) of section 408.036, Florida Statutes, are amended

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1393 to read:

1394 408.036 Projects subject to review; exemptions.—

1395 (3) EXEMPTIONS.—Upon request, the following projects are
1396 subject to exemption from the provisions of subsection (1):

1397 ~~(e) For mobile surgical facilities and related health care~~
1398 ~~services provided under contract with the Department of~~
1399 ~~Corrections or a private correctional facility operating~~
1400 ~~pursuant to chapter 957.~~

1401 (o) (p) For replacement of a licensed nursing home on the
1402 same site, or within 5 miles of the same site if within the same
1403 subdistrict, if the number of licensed beds does not increase
1404 except as permitted under paragraph (e) ~~(f)~~.

1405 Section 50. Subsection (4) of section 408.061, Florida
1406 Statutes, is amended to read:

1407 408.061 Data collection; uniform systems of financial
1408 reporting; information relating to physician charges;
1409 confidential information; immunity.—

1410 (4) Within 120 days after the end of its fiscal year, each
1411 health care facility, excluding continuing care facilities as
1412 defined in s. 408.07(13), hospitals operated by state agencies,
1413 and nursing homes as defined in s. 408.07(36) 408.07(14) and
1414 (37), shall file with the agency, on forms adopted by the agency
1415 and based on the uniform system of financial reporting, its
1416 actual financial experience for that fiscal year, including
1417 expenditures, revenues, and statistical measures. Such data may
1418 be based on internal financial reports which are certified to be
1419 complete and accurate by the provider. However, hospitals'
1420 actual financial experience shall be their audited actual
1421 experience. Every nursing home shall submit to the agency, in a

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1422 format designated by the agency, a statistical profile of the
1423 nursing home residents. The agency, in conjunction with the
1424 Department of Elderly Affairs and the Department of Health,
1425 shall review these statistical profiles and develop
1426 recommendations for the types of residents who might more
1427 appropriately be placed in their homes or other noninstitutional
1428 settings.

1429 Section 51. Subsection (11) of section 408.07, Florida
1430 Statutes, is amended to read:

1431 408.07 Definitions.—As used in this chapter, with the
1432 exception of ss. 408.031-408.045, the term:

1433 ~~(11) "Clinical laboratory" means a facility licensed under~~
1434 ~~s. 483.091, excluding: any hospital laboratory defined under s.~~
1435 ~~483.041(6); any clinical laboratory operated by the state or a~~
1436 ~~political subdivision of the state; any blood or tissue bank~~
1437 ~~where the majority of revenues are received from the sale of~~
1438 ~~blood or tissue and where blood, plasma, or tissue is procured~~
1439 ~~from volunteer donors and donated, processed, stored, or~~
1440 ~~distributed on a nonprofit basis; and any clinical laboratory~~
1441 ~~which is wholly owned and operated by physicians who are~~
1442 ~~licensed pursuant to chapter 458 or chapter 459 and who practice~~
1443 ~~in the same group practice, and at which no clinical laboratory~~
1444 ~~work is performed for patients referred by any health care~~
1445 ~~provider who is not a member of that same group practice.~~

1446 Section 52. Subsection (4) of section 408.20, Florida
1447 Statutes, is amended to read:

1448 408.20 Assessments; Health Care Trust Fund.—

1449 (4) Hospitals operated by state agencies ~~the Department of~~
1450 ~~Children and Families, the Department of Health, or the~~

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1451 ~~Department of Corrections~~ are exempt from the assessments
1452 required under this section.

1453 Section 53. Section 408.7056, Florida Statutes, is
1454 repealed.

1455 Section 54. Subsections (10), (11), and (27) of section
1456 408.802, Florida Statutes, are amended to read:

1457 408.802 Applicability.—The provisions of this part apply to
1458 the provision of services that require licensure as defined in
1459 this part and to the following entities licensed, registered, or
1460 certified by the agency, as described in chapters 112, 383, 390,
1461 394, 395, 400, 429, 440, 483, and 765:

1462 ~~(10) Mobile surgical facilities, as provided under part I~~
1463 ~~of chapter 395.~~

1464 ~~(11) Health care risk managers, as provided under part I of~~
1465 ~~chapter 395.~~

1466 ~~(27) Clinical laboratories, as provided under part I of~~
1467 ~~chapter 483.~~

1468 Section 55. Present subsections (12) and (13) of section
1469 408.803, Florida Statutes, are renumbered as subsections (13)
1470 and (14), respectively, and a new subsection (12) is added to
1471 that section, to read:

1472 408.803 Definitions.—As used in this part, the term:

1473 (12) "Relative" means an individual who is the father,
1474 mother, stepfather, stepmother, son, daughter, brother, sister,
1475 grandmother, grandfather, great-grandmother, great-grandfather,
1476 grandson, granddaughter, uncle, aunt, first cousin, nephew,
1477 niece, husband, wife, father-in-law, mother-in-law, son-in-law,
1478 daughter-in-law, brother-in-law, sister-in-law, stepson,
1479 stepdaughter, stepbrother, stepsister, half-brother, or half-

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1480 sister of a patient or client.

1481 Section 56. Paragraph (a) of subsection (1) and paragraph
1482 (c) of subsection (7) of section 408.806, Florida Statutes, are
1483 amended, and subsection (9) is added to that section, to read:

1484 408.806 License application process.—

1485 (1) An application for licensure must be made to the agency
1486 on forms furnished by the agency, submitted under oath or
1487 attestation, and accompanied by the appropriate fee in order to
1488 be accepted and considered timely. The application must contain
1489 information required by authorizing statutes and applicable
1490 rules and must include:

1491 (a) The name, address, and social security number, or
1492 individual taxpayer identification number if a social security
1493 number cannot legally be obtained, of:

1494 1. The applicant;

1495 2. The administrator or a similarly titled person who is
1496 responsible for the day-to-day operation of the provider;

1497 3. The financial officer or similarly titled person who is
1498 responsible for the financial operation of the licensee or
1499 provider; and

1500 4. Each controlling interest if the applicant or
1501 controlling interest is an individual.

1502 The licensee shall ensure that no person has any ownership
1503 interest in the licensee, directly or indirectly, regardless of
1504 ownership structure, who is ineligible pursuant to s.
1505 408.809(4). The licensee shall ensure that no person holds or
1506 has held any ownership interest, directly or indirectly,
1507 regardless of ownership structure, in a provider that has had a

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1509 license or change of ownership application denied, revoked, or
 1510 excluded pursuant to s. 408.815.

1511 (7)

1512 (c) If an inspection is required by the authorizing statute
 1513 for a license application other than an initial application, the
 1514 inspection must be unannounced. This paragraph does not apply to
 1515 inspections required pursuant to ss. 383.324, 395.0161(4), and
 1516 429.67(6), and 483.061(2).

1517 (9) A licensee that holds a license for multiple providers
 1518 licensed by the agency may request that all related license
 1519 expiration dates be aligned. The agency may issue a license for
 1520 an abbreviated licensure period with a prorated licensure fee.

1521 Section 57. Subsection (8) of section 408.810, Florida
 1522 Statutes, is amended, and subsection (11) is added to that
 1523 section to read:

1524 408.810 Minimum licensure requirements.—In addition to the
 1525 licensure requirements specified in this part, authorizing
 1526 statutes, and applicable rules, each applicant and licensee must
 1527 comply with the requirements of this section in order to obtain
 1528 and maintain a license.

1529 (8) Upon application for initial licensure or change of
 1530 ownership licensure, the applicant shall furnish satisfactory
 1531 proof of the applicant's financial ability to operate in
 1532 accordance with the requirements of this part, authorizing
 1533 statutes, and applicable rules. The agency shall establish
 1534 standards for this purpose, including information concerning the
 1535 applicant's controlling interests. The agency shall also
 1536 establish documentation requirements, to be completed by each
 1537 applicant, that show anticipated provider revenues and

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1538 expenditures, the basis for financing the anticipated cash-flow
 1539 requirements of the provider, and an applicant's access to
 1540 contingency financing. A current certificate of authority,
 1541 pursuant to chapter 651, may be provided as proof of financial
 1542 ability to operate. The agency may require a licensee to provide
 1543 proof of financial ability to operate at any time if there is
 1544 evidence of financial instability, including, but not limited
 1545 to, unpaid expenses necessary for the basic operations of the
 1546 provider. An applicant applying for change of ownership
 1547 licensure is exempt from furnishing proof of the applicant's
 1548 financial ability to operate if the provider has been licensed
 1549 for at least 5 years and:

1550 (a) The licensee change is a result of a corporate
 1551 reorganization under which the controlling interest is unchanged
 1552 and the applicant submits organization charts that represent the
 1553 current and proposed structure of the reorganized corporation;
 1554 or

1555 (b) The licensee change is due solely to the death of a
 1556 controlling interest, and the surviving controlling interests
 1557 continue to hold at least 51 percent of ownership after the
 1558 change of ownership.

1559 (11) The agency may adopt rules that govern the
 1560 circumstances under which a controlling interest, an
 1561 administrator, an employee, a contractor, or a representative
 1562 thereof who is not a relative of the patient or client may act
 1563 as a legal representative, agent, health care surrogate, power
 1564 of attorney, or guardian of a patient or client. Such rules may
 1565 include requirements related to disclosure, bonding,
 1566 restrictions, and client protections.

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1567 Section 58. Section 408.812, Florida Statutes, is amended
 1568 to read:
 1569 408.812 Unlicensed activity.—
 1570 (1) A person or entity may not offer or advertise services
 1571 that require licensure as defined by this part, authorizing
 1572 statutes, or applicable rules to the public without obtaining a
 1573 valid license from the agency. A licenseholder may not advertise
 1574 or hold out to the public that he or she holds a license for
 1575 other than that for which he or she actually holds the license.
 1576 (2) The operation or maintenance of an unlicensed provider
 1577 or the performance of any services that require licensure
 1578 without proper licensure is a violation of this part and
 1579 authorizing statutes. Unlicensed activity constitutes harm that
 1580 materially affects the health, safety, and welfare of clients
 1581 and constitutes abuse and neglect as defined in s. 415.102. The
 1582 agency or any state attorney may, in addition to other remedies
 1583 provided in this part, bring an action for an injunction to
 1584 restrain such violation, or to enjoin the future operation or
 1585 maintenance of the unlicensed provider or the performance of any
 1586 services in violation of this part and authorizing statutes,
 1587 until compliance with this part, authorizing statutes, and
 1588 agency rules has been demonstrated to the satisfaction of the
 1589 agency.
 1590 (3) It is unlawful for any person or entity to own,
 1591 operate, or maintain an unlicensed provider. If after receiving
 1592 notification from the agency, such person or entity fails to
 1593 cease operation ~~and apply for a license under this part and~~
 1594 ~~authorizing statutes,~~ the person or entity shall be subject to
 1595 penalties as prescribed by authorizing statutes and applicable

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1596 rules. Each day of ~~continued~~ operation is a separate offense.
 1597 (4) Any person or entity that fails to cease operation
 1598 after agency notification may be fined \$1,000 for each day of
 1599 noncompliance.
 1600 (5) When a controlling interest or licensee has an interest
 1601 in more than one provider and fails to license a provider
 1602 rendering services that require licensure, the agency may revoke
 1603 all licenses and impose actions under s. 408.814 and, regardless
 1604 of correction, impose a fine of \$1,000 per day, unless otherwise
 1605 specified by authorizing statutes, against each licensee until
 1606 such time as the appropriate license is obtained or the
 1607 unlicensed activity ceases for the unlicensed operation.
 1608 (6) In addition to granting injunctive relief pursuant to
 1609 subsection (2), if the agency determines that a person or entity
 1610 is operating or maintaining a provider without obtaining a
 1611 license and determines that a condition exists that poses a
 1612 threat to the health, safety, or welfare of a client of the
 1613 provider, the person or entity is subject to the same actions
 1614 and fines imposed against a licensee as specified in this part,
 1615 authorizing statutes, and agency rules.
 1616 (7) Any person aware of the operation of an unlicensed
 1617 provider must report that provider to the agency.
 1618 Section 59. Subsections (10), (11), (26), and (27) of
 1619 section 408.820, Florida Statutes, are amended to read:
 1620 408.820 Exemptions.—Except as prescribed in authorizing
 1621 statutes, the following exemptions shall apply to specified
 1622 requirements of this part:
 1623 ~~(10) Mobile surgical facilities, as provided under part I~~
 1624 ~~of chapter 395, are exempt from s. 408.810(7)-(10).~~

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

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1625 ~~(11) Health care risk managers, as provided under part I of~~
 1626 ~~chapter 395, are exempt from ss. 408.806(7), 408.810(4)-(10),~~
 1627 ~~and 408.811.~~

1628 ~~(26) Clinical laboratories, as provided under part I of~~
 1629 ~~chapter 483, are exempt from s. 408.810(5)-(10).~~

1630 ~~(24)-(27)~~ Multiphasic health testing centers, as provided
 1631 under part I ~~II~~ of chapter 483, are exempt from s. 408.810(5)-
 1632 (10).

1633 Section 60. Subsection (7) of section 409.905, Florida
 1634 Statutes, is amended to read:

1635 409.905 Mandatory Medicaid services.—The agency may make
 1636 payments for the following services, which are required of the
 1637 state by Title XIX of the Social Security Act, furnished by
 1638 Medicaid providers to recipients who are determined to be
 1639 eligible on the dates on which the services were provided. Any
 1640 service under this section shall be provided only when medically
 1641 necessary and in accordance with state and federal law.
 1642 Mandatory services rendered by providers in mobile units to
 1643 Medicaid recipients may be restricted by the agency. Nothing in
 1644 this section shall be construed to prevent or limit the agency
 1645 from adjusting fees, reimbursement rates, lengths of stay,
 1646 number of visits, number of services, or any other adjustments
 1647 necessary to comply with the availability of moneys and any
 1648 limitations or directions provided for in the General
 1649 Appropriations Act or chapter 216.

1650 (7) INDEPENDENT LABORATORY SERVICES.—The agency shall pay
 1651 for medically necessary diagnostic laboratory procedures ordered
 1652 by a licensed physician or other licensed practitioner of the
 1653 healing arts which are provided for a recipient in a laboratory

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1654 that meets the requirements for Medicare participation and
 1655 appropriately certified by the Centers for Medicare and Medicaid
 1656 Services (CMS) under the federal Clinical Laboratory Improvement
 1657 Amendments of 1988 is licensed under chapter 483, if required.

1658 Section 61. Subsection (6) of section 409.9116, Florida
 1659 Statutes, is amended to read:

1660 409.9116 Disproportionate share/financial assistance
 1661 program for rural hospitals.—In addition to the payments made
 1662 under s. 409.911, the Agency for Health Care Administration
 1663 shall administer a federally matched disproportionate share
 1664 program and a state-funded financial assistance program for
 1665 statutory rural hospitals. The agency shall make
 1666 disproportionate share payments to statutory rural hospitals
 1667 that qualify for such payments and financial assistance payments
 1668 to statutory rural hospitals that do not qualify for
 1669 disproportionate share payments. The disproportionate share
 1670 program payments shall be limited by and conform with federal
 1671 requirements. Funds shall be distributed quarterly in each
 1672 fiscal year for which an appropriation is made. Notwithstanding
 1673 the provisions of s. 409.915, counties are exempt from
 1674 contributing toward the cost of this special reimbursement for
 1675 hospitals serving a disproportionate share of low-income
 1676 patients.

1677 (6) This section applies only to hospitals that were
 1678 defined as statutory rural hospitals, or their successor-in-
 1679 interest hospital, prior to January 1, 2001. Any additional
 1680 hospital that is defined as a statutory rural hospital, or its
 1681 successor-in-interest hospital, on or after January 1, 2001, is
 1682 not eligible for programs under this section unless additional

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1683 funds are appropriated each fiscal year specifically to the
 1684 rural hospital disproportionate share and financial assistance
 1685 programs in an amount necessary to prevent any hospital, or its
 1686 successor-in-interest hospital, eligible for the programs prior
 1687 to January 1, 2001, from incurring a reduction in payments
 1688 because of the eligibility of an additional hospital to
 1689 participate in the programs. A hospital, or its successor-in-
 1690 interest hospital, which received funds pursuant to this section
 1691 before January 1, 2001, and which qualifies under s.
 1692 395.602(2)(b) ~~395.602(2)(e)~~, shall be included in the programs
 1693 under this section and is not required to seek additional
 1694 appropriations under this subsection.

1695 Section 62. Paragraphs (a) and (b) of subsection (1) of
 1696 section 409.975, Florida Statutes, are amended to read:

1697 409.975 Managed care plan accountability.—In addition to
 1698 the requirements of s. 409.967, plans and providers
 1699 participating in the managed medical assistance program shall
 1700 comply with the requirements of this section.

1701 (1) PROVIDER NETWORKS.—Managed care plans must develop and
 1702 maintain provider networks that meet the medical needs of their
 1703 enrollees in accordance with standards established pursuant to
 1704 s. 409.967(2)(c). Except as provided in this section, managed
 1705 care plans may limit the providers in their networks based on
 1706 credentials, quality indicators, and price.

1707 (a) Plans must include all providers in the region that are
 1708 classified by the agency as essential Medicaid providers, unless
 1709 the agency approves, in writing, an alternative arrangement for
 1710 securing the types of services offered by the essential
 1711 providers. Providers are essential for serving Medicaid

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1712 enrollees if they offer services that are not available from any
 1713 other provider within a reasonable access standard, or if they
 1714 provided a substantial share of the total units of a particular
 1715 service used by Medicaid patients within the region during the
 1716 last 3 years and the combined capacity of other service
 1717 providers in the region is insufficient to meet the total needs
 1718 of the Medicaid patients. The agency may not classify physicians
 1719 and other practitioners as essential providers. The agency, at a
 1720 minimum, shall determine which providers in the following
 1721 categories are essential Medicaid providers:

1722 1. Federally qualified health centers.

1723 2. Statutory teaching hospitals as defined in s. 408.07(44)
 1724 ~~408.07(45)~~.

1725 3. Hospitals that are trauma centers as defined in s.
 1726 395.4001(14).

1727 4. Hospitals located at least 25 miles from any other
 1728 hospital with similar services.

1729 Managed care plans that have not contracted with all essential
 1730 providers in the region as of the first date of recipient
 1731 enrollment, or with whom an essential provider has terminated
 1732 its contract, must negotiate in good faith with such essential
 1733 providers for 1 year or until an agreement is reached, whichever
 1734 is first. Payments for services rendered by a nonparticipating
 1735 essential provider shall be made at the applicable Medicaid rate
 1736 as of the first day of the contract between the agency and the
 1737 plan. A rate schedule for all essential providers shall be
 1738 attached to the contract between the agency and the plan. After
 1739 1 year, managed care plans that are unable to contract with
 1740

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 1741 essential providers shall notify the agency and propose an
 1742 alternative arrangement for securing the essential services for
 1743 Medicaid enrollees. The arrangement must rely on contracts with
 1744 other participating providers, regardless of whether those
 1745 providers are located within the same region as the
 1746 nonparticipating essential service provider. If the alternative
 1747 arrangement is approved by the agency, payments to
 1748 nonparticipating essential providers after the date of the
 1749 agency's approval shall equal 90 percent of the applicable
 1750 Medicaid rate. Except for payment for emergency services, if the
 1751 alternative arrangement is not approved by the agency, payment
 1752 to nonparticipating essential providers shall equal 110 percent
 1753 of the applicable Medicaid rate.

1754 (b) Certain providers are statewide resources and essential
 1755 providers for all managed care plans in all regions. All managed
 1756 care plans must include these essential providers in their
 1757 networks. Statewide essential providers include:

1758 1. Faculty plans of Florida medical schools.
 1759 2. Regional perinatal intensive care centers as defined in
 1760 s. 383.16(2).

1761 3. Hospitals licensed as specialty children's hospitals as
 1762 defined in s. ~~395.002(27)~~ 395.002(28).

1763 4. Accredited and integrated systems serving medically
 1764 complex children which comprise separately licensed, but
 1765 commonly owned, health care providers delivering at least the
 1766 following services: medical group home, in-home and outpatient
 1767 nursing care and therapies, pharmacy services, durable medical
 1768 equipment, and Prescribed Pediatric Extended Care.
 1769

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 1770 Managed care plans that have not contracted with all statewide
 1771 essential providers in all regions as of the first date of
 1772 recipient enrollment must continue to negotiate in good faith.
 1773 Payments to physicians on the faculty of nonparticipating
 1774 Florida medical schools shall be made at the applicable Medicaid
 1775 rate. Payments for services rendered by regional perinatal
 1776 intensive care centers shall be made at the applicable Medicaid
 1777 rate as of the first day of the contract between the agency and
 1778 the plan. Except for payments for emergency services, payments
 1779 to nonparticipating specialty children's hospitals shall equal
 1780 the highest rate established by contract between that provider
 1781 and any other Medicaid managed care plan.

1782 Section 63. Subsections (5) and (17) of section 429.02,
 1783 Florida Statutes, are amended to read:

1784 429.02 Definitions.—When used in this part, the term:

1785 (5) "Assisted living facility" means any building or
 1786 buildings, section or distinct part of a building, private home,
 1787 boarding home, home for the aged, or other residential facility,
 1788 whether operated for profit or not, which, undertakes through
 1789 its ownership or management, provides ~~to provide~~ housing, meals,
 1790 and one or more personal services for a period exceeding 24
 1791 hours to one or more adults who are not relatives of the owner
 1792 or administrator.

1793 (17) "Personal services" means direct physical assistance
 1794 with or supervision of the activities of daily living, and the
 1795 self-administration of medication, or ~~and~~ other similar services
 1796 which the department may define by rule. "Personal services" may
 1797 ~~shall~~ not be construed to mean the provision of medical,
 1798 nursing, dental, or mental health services, or, with the

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1799 exception of authorized adult day care services provided within
 1800 a licensed assisted living facility, personal services to
 1801 individuals who are not residents of the facility.

1802 Section 64. Paragraphs (b) and (d) of subsection (2) of
 1803 section 429.04, Florida Statutes, are amended, and subsection
 1804 (3) is added to that section, to read:

1805 429.04 Facilities to be licensed; exemptions.—

1806 (2) The following are exempt from licensure under this
 1807 part:

1808 (b) Any facility or part of a facility licensed by the
 1809 Agency for Persons with Disabilities under chapter 393, a mental
 1810 health facility licensed under ~~or~~ chapter 394, a hospital
 1811 licensed under chapter 395, a nursing home licensed under part
 1812 II of chapter 400, an inpatient hospice licensed under part IV
 1813 of chapter 400, a home for special services licensed under part
 1814 V of chapter 400, an intermediate care facility licensed under
 1815 part VIII of chapter 400, or a transitional living facility
 1816 licensed under part XI of chapter 400.

1817 (d) Any person who provides housing, meals, and one or more
 1818 personal services on a 24-hour basis in the person's own home to
 1819 not more than two adults who do not receive optional state
 1820 supplementation. The person who provides the housing, meals, and
 1821 personal services must own or rent the home and must have
 1822 established the home as the person's permanent residence. Any
 1823 person holding a homestead exemption at an address other than
 1824 that at which the person asserts this exemption shall be
 1825 presumed to not have established permanent residence under this
 1826 exemption reside therein. This exemption does not apply to a
 1827 person or entity who previously held licensure issued by the

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1828 agency and such licensure was revoked or the licensure renewal
 1829 was denied by final order of the agency, or when the person or
 1830 entity voluntarily relinquished licensure during agency
 1831 enforcement proceedings.

1832 (3) Upon agency investigation of unlicensed activity, any
 1833 person or entity asserting an exemption pursuant to this section
 1834 shall have the burden of providing documentation substantiating
 1835 that the person or entity is entitled to the licensure
 1836 exemption.

1837 Section 65. Paragraphs (b) and (d) of subsection (1) of
 1838 section 429.08, Florida Statutes, are amended, to read:

1839 429.08 Unlicensed facilities; referral of person for
 1840 residency to unlicensed facility; penalties.—

1841 (1)

1842 (b) ~~Except as provided under paragraph (d),~~ Any person who
 1843 owns, rents, or otherwise maintains a building or property that
 1844 operates, or maintains an unlicensed assisted living facility
 1845 commits a felony of the third degree, punishable as provided in
 1846 s. 775.082, s. 775.083, or s. 775.084. Each day of continued
 1847 operation is a separate offense.

1848 (d) In addition to the requirements of s. 408.812, any
 1849 person who owns, operates, or maintains an unlicensed assisted
 1850 living facility after receiving notice from the agency due to a
 1851 change in this part or a modification in rule within 6 months
 1852 after the effective date of such change and who, within 10
 1853 working days after receiving notification from the agency, fails
 1854 to cease operation or apply for a license under this part
 1855 commits a felony of the third degree, punishable as provided in
 1856 s. 775.082, s. 775.083, or s. 775.084. Each day of continued

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1857 operation is a separate offense.

1858 Section 66. Section 429.176, Florida Statutes, is amended
1859 to read:

1860 429.176 Notice of change of administrator.—If, during the
1861 period for which a license is issued, the owner changes
1862 administrators, the owner must notify the agency of the change
1863 within 10 days and provide documentation within 90 days that the
1864 new administrator has completed the applicable core educational
1865 requirements under s. 429.52. A facility may not be operated for
1866 more than 120 consecutive days without an administrator who has
1867 completed the core educational requirements.

1868 Section 67. Paragraph (h) of subsection (1) of section
1869 429.41, Florida Statutes, is amended to read:

1870 429.41 Rules establishing standards.—

1871 (1) It is the intent of the Legislature that rules
1872 published and enforced pursuant to this section shall include
1873 criteria by which a reasonable and consistent quality of
1874 resident care and quality of life may be ensured and the results
1875 of such resident care may be demonstrated. Such rules shall also
1876 ensure a safe and sanitary environment that is residential and
1877 noninstitutional in design or nature. It is further intended
1878 that reasonable efforts be made to accommodate the needs and
1879 preferences of residents to enhance the quality of life in a
1880 facility. Uniform firesafety standards for assisted living
1881 facilities shall be established by the State Fire Marshal
1882 pursuant to s. 633.206. The agency, in consultation with the
1883 department, may adopt rules to administer the requirements of
1884 part II of chapter 408. In order to provide safe and sanitary
1885 facilities and the highest quality of resident care

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1886 accommodating the needs and preferences of residents, the
1887 department, in consultation with the agency, the Department of
1888 Children and Families, and the Department of Health, shall adopt
1889 rules, policies, and procedures to administer this part, which
1890 must include reasonable and fair minimum standards in relation
1891 to:

1892 (h) The care and maintenance of residents, which must
1893 include, but is not limited to:

1894 1. The supervision of residents;

1895 2. The provision of personal services. With the exception
1896 of authorized adult day care services provided within a licensed
1897 assisted living facility, an assisted living facility may not
1898 provide personal services to individuals who are not residents
1899 of the facility;

1900 3. The provision of, or arrangement for, social and leisure
1901 activities;

1902 4. The arrangement for appointments and transportation to
1903 appropriate medical, dental, nursing, or mental health services,
1904 as needed by residents;

1905 5. The management of medication;

1906 6. The nutritional needs of residents;

1907 7. Resident records; and

1908 8. Internal risk management and quality assurance.

1909 Section 68. Subsection (4) of section 456.001, Florida
1910 Statutes, is amended to read:

1911 456.001 Definitions.—As used in this chapter, the term:

1912 (4) "Health care practitioner" means any person licensed
1913 under chapter 457; chapter 458; chapter 459; chapter 460;
1914 chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;

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chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III ~~or part IV~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 69. Paragraphs (h) and (i) of subsection (2) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(2) As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(h) Clinical laboratory personnel licensed under part II ~~III~~ of chapter 483.

(i) Medical physicists licensed under part III ~~IV~~ of chapter 483.

Section 70. Subsection (2) of section 458.307, Florida Statutes, is amended to read:

458.307 Board of Medicine.—

(2) Twelve members of the board must be licensed physicians in good standing in this state who are residents of the state and who have been engaged in the active practice or teaching of medicine for at least 4 years immediately preceding their appointment. One of the physicians must be on the full-time faculty of a medical school in this state, and one of the

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physicians must be in private practice and on the full-time staff of a statutory teaching hospital in this state as defined in s. 408.07. At least one of the physicians must be a graduate of a foreign medical school. The remaining three members must be residents of the state who are not, and never have been, licensed health care practitioners. One member must be a health care risk manager ~~licensed under s. 395.10974~~. At least one member of the board must be 60 years of age or older.

Section 71. Subsection (1) of section 458.345, Florida Statutes, is amended to read:

458.345 Registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.—

(1) Any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07(44) ~~408.07(45)~~ or s. 395.805(2), who does not hold a valid, active license issued under this chapter shall apply to the department to be registered and shall remit a fee not to exceed \$300 as set by the board. The department shall register any applicant the board certifies has met the following requirements:

(a) Is at least 21 years of age.

(b) Has not committed any act or offense within or without the state which would constitute the basis for refusal to

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1973 certify an application for licensure pursuant to s. 458.331.
 1974 (c) Is a graduate of a medical school or college as
 1975 specified in s. 458.311(1)(f).
 1976 Section 72. Part I of chapter 483, Florida Statutes,
 1977 consisting of sections 483.011, 483.021, 483.031, 483.035,
 1978 483.041, 483.051, 483.061, 483.091, 483.101, 483.111, 483.172,
 1979 483.181, 483.191, 483.201, 483.221, 483.23, 483.245, and 483.26,
 1980 is repealed.
 1981 Section 73. Section 483.294, Florida Statutes, is amended
 1982 to read:
 1983 483.294 Inspection of centers.—In accordance with s.
 1984 408.811, the agency shall, ~~at least once annually,~~ inspect the
 1985 premises and operations of all centers subject to licensure
 1986 under this part.
 1987 Section 74. Subsection (3) of section 483.801, Florida
 1988 Statutes, is amended to read:
 1989 483.801 Exemptions.—This part applies to all clinical
 1990 laboratories and clinical laboratory personnel within this
 1991 state, except:
 1992 (3) Persons engaged in testing performed by laboratories
 1993 that are wholly owned and operated by one or more practitioners
 1994 who are licensed under chapter 458, chapter 459, chapter 460,
 1995 chapter 461, chapter 462, chapter 463, or chapter 466 and who
 1996 practice in the same group practice, and in which no clinical
 1997 laboratory work is performed for patients referred by any health
 1998 care provider who is not a member of the same group regulated
 1999 under s. 483.035(1) or exempt from regulation under s.
 2000 483.031(2).
 2001 Section 75. Subsections (2), (3), and (4) of section

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2002 483.803, Florida Statutes, are amended to read:
 2003 483.803 Definitions.—As used in this part, the term:
 2004 ~~(2) "Clinical laboratory" means a clinical laboratory as~~
 2005 ~~defined in s. 483.041.~~
 2006 ~~(3) "Clinical laboratory examination" means a clinical~~
 2007 ~~laboratory examination as defined in s. 483.041.~~
 2008 ~~(2)(4)~~ "Clinical laboratory personnel" includes a clinical
 2009 laboratory director, supervisor, technologist, blood gas
 2010 analyst, or technician who performs or is responsible for
 2011 laboratory test procedures, but the term does not include
 2012 trainees, persons who perform screening for blood banks or
 2013 plasmapheresis centers, phlebotomists, or persons employed by a
 2014 clinical laboratory to perform manual pretesting duties or
 2015 clerical, personnel, or other administrative responsibilities,
 2016 ~~or persons engaged in testing performed by laboratories~~
 2017 ~~regulated under s. 483.035(1) or exempt from regulation under s.~~
 2018 ~~483.031(2).~~
 2019 Section 76. Section 483.813, Florida Statutes, is amended
 2020 to read:
 2021 483.813 Clinical laboratory personnel license.—A person may
 2022 not conduct a clinical laboratory examination or report the
 2023 results of such examination unless such person is licensed under
 2024 this part to perform such procedures. However, this provision
 2025 does not apply to any practitioner of the healing arts
 2026 authorized to practice in this state ~~or to persons engaged in~~
 2027 ~~testing performed by laboratories regulated under s. 483.035(1)~~
 2028 ~~or exempt from regulation under s. 483.031(2).~~ The department
 2029 may grant a temporary license to any candidate it deems properly
 2030 qualified, for a period not to exceed 1 year.

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Section 77. Paragraph (c) of subsection (7), paragraph (c) of subsection (8), and paragraph (c) of subsection (9) of section 491.003, Florida Statutes, are amended to read:

491.003 Definitions.—As used in this chapter:

(7) The “practice of clinical social work” is defined as the use of scientific and applied knowledge, theories, and methods for the purpose of describing, preventing, evaluating, and treating individual, couple, marital, family, or group behavior, based on the person-in-situation perspective of psychosocial development, normal and abnormal behavior, psychopathology, unconscious motivation, interpersonal relationships, environmental stress, differential assessment, differential planning, and data gathering. The purpose of such services is the prevention and treatment of undesired behavior and enhancement of mental health. The practice of clinical social work includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of clinical social work includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy. The practice of clinical social work also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders,

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alcoholism, or substance abuse. The practice of clinical social work may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms “diagnose” and “treat,” as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, shall not be construed to permit the performance of any act which clinical social workers are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483~~, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as “psychological,” except to relate specifically to the definition of practice authorized in this subsection.

(8) The “practice of marriage and family therapy” is defined as the use of scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family systems, including the context of marital formation and dissolution, and is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic

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2089 and marriage and family therapy theories and techniques. The
 2090 practice of marriage and family therapy includes methods of a
 2091 psychological nature used to evaluate, assess, diagnose, treat,
 2092 and prevent emotional and mental disorders or dysfunctions
 2093 (whether cognitive, affective, or behavioral), sexual
 2094 dysfunction, behavioral disorders, alcoholism, and substance
 2095 abuse. The practice of marriage and family therapy includes, but
 2096 is not limited to, marriage and family therapy, psychotherapy,
 2097 including behavioral family therapy, hypnotherapy, and sex
 2098 therapy. The practice of marriage and family therapy also
 2099 includes counseling, behavior modification, consultation,
 2100 client-centered advocacy, crisis intervention, and the provision
 2101 of needed information and education to clients, when using
 2102 methods of a psychological nature to evaluate, assess, diagnose,
 2103 treat, and prevent emotional and mental disorders and
 2104 dysfunctions (whether cognitive, affective, or behavioral),
 2105 sexual dysfunction, behavioral disorders, alcoholism, or
 2106 substance abuse. The practice of marriage and family therapy may
 2107 also include clinical research into more effective
 2108 psychotherapeutic modalities for the treatment and prevention of
 2109 such conditions.

2110 (c) The terms "diagnose" and "treat," as used in this
 2111 chapter, when considered in isolation or in conjunction with any
 2112 provision of the rules of the board, shall not be construed to
 2113 permit the performance of any act which marriage and family
 2114 therapists are not educated and trained to perform, including,
 2115 but not limited to, admitting persons to hospitals for treatment
 2116 of the foregoing conditions, treating persons in hospitals
 2117 without medical supervision, prescribing medicinal drugs as

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2118 defined in chapter 465, authorizing clinical laboratory
 2119 procedures ~~pursuant to chapter 483~~, or radiological procedures,
 2120 or use of electroconvulsive therapy. In addition, this
 2121 definition shall not be construed to permit any person licensed,
 2122 provisionally licensed, registered, or certified pursuant to
 2123 this chapter to describe or label any test, report, or procedure
 2124 as "psychological," except to relate specifically to the
 2125 definition of practice authorized in this subsection.

2126 (9) The "practice of mental health counseling" is defined
 2127 as the use of scientific and applied behavioral science
 2128 theories, methods, and techniques for the purpose of describing,
 2129 preventing, and treating undesired behavior and enhancing mental
 2130 health and human development and is based on the person-in-
 2131 situation perspectives derived from research and theory in
 2132 personality, family, group, and organizational dynamics and
 2133 development, career planning, cultural diversity, human growth
 2134 and development, human sexuality, normal and abnormal behavior,
 2135 psychopathology, psychotherapy, and rehabilitation. The practice
 2136 of mental health counseling includes methods of a psychological
 2137 nature used to evaluate, assess, diagnose, and treat emotional
 2138 and mental dysfunctions or disorders (whether cognitive,
 2139 affective, or behavioral), behavioral disorders, interpersonal
 2140 relationships, sexual dysfunction, alcoholism, and substance
 2141 abuse. The practice of mental health counseling includes, but is
 2142 not limited to, psychotherapy, hypnotherapy, and sex therapy.
 2143 The practice of mental health counseling also includes
 2144 counseling, behavior modification, consultation, client-centered
 2145 advocacy, crisis intervention, and the provision of needed
 2146 information and education to clients, when using methods of a

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psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), behavioral disorders, sexual dysfunction, alcoholism, or substance abuse. The practice of mental health counseling may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, shall not be construed to permit the performance of any act which mental health counselors are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures pursuant to chapter 483, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

Section 78. Paragraph (h) of subsection (4) of section 627.351, Florida Statutes, is amended to read:

627.351 Insurance risk apportionment plans.—

(4) MEDICAL MALPRACTICE RISK APPORTIONMENT.—

(h) As used in this subsection:

1. "Health care provider" means hospitals licensed under

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chapter 395; physicians licensed under chapter 458; osteopathic physicians licensed under chapter 459; podiatric physicians licensed under chapter 461; dentists licensed under chapter 466; chiropractic physicians licensed under chapter 460; naturopaths licensed under chapter 462; nurses licensed under part I of chapter 464; midwives licensed under chapter 467; ~~clinical laboratories registered under chapter 483~~; physician assistants licensed under chapter 458 or chapter 459; physical therapists and physical therapist assistants licensed under chapter 486; health maintenance organizations certificated under part I of chapter 641; ambulatory surgical centers licensed under chapter 395; other medical facilities as defined in subparagraph 2.; blood banks, plasma centers, industrial clinics, and renal dialysis facilities; or professional associations, partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.

2. "Other medical facility" means a facility the primary purpose of which is to provide human medical diagnostic services or a facility providing nonsurgical human medical treatment, to which facility the patient is admitted and from which facility the patient is discharged within the same working day, and which facility is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy or an office maintained by a physician or dentist for the practice of medicine shall not be construed to be an "other medical facility."

3. "Health care facility" means any hospital licensed under chapter 395, health maintenance organization certificated under part I of chapter 641, ambulatory surgical center licensed under

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chapter 395, or other medical facility as defined in subparagraph 2.

Section 79. Paragraph (h) of subsection (1) of section 627.602, Florida Statutes, is amended to read:

627.602 Scope, format of policy.—

(1) Each health insurance policy delivered or issued for delivery to any person in this state must comply with all applicable provisions of this code and all of the following requirements:

(h) 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. This paragraph does not apply to a health insurance policy that is subject to the Subscriber Assistance Program under s. 408.7056 or to the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 80. Paragraphs (b) and (e) of subsection (1) of 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(29) ~~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

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defined in s. 395.002(29) ~~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 81. 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.
- (4) Workers' compensation or similar insurance.
- (5) Automobile medical payment insurance.
- (6) Credit-only insurance.
- (7) Coverage for onsite medical clinics, including prepaid health clinics under part II of chapter 641.
- (8) Other similar insurance coverage, specified in rules adopted by the commission, under which benefits for medical care are secondary or incidental to other insurance benefits. To the extent possible, such rules must be consistent with regulations adopted by the United States Department of Health and Human Services.
- (9) Limited scope dental or vision benefits, if offered

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2263 separately.

2264 (10) Benefits for long-term care, nursing home care, home
2265 health care, or community-based care, or any combination
2266 thereof, if offered separately.

2267 (11) Other similar, limited benefits, if offered
2268 separately, as specified in rules adopted by the commission.

2269 (12) Coverage only for a specified disease or illness, if
2270 offered as independent, noncoordinated benefits.

2271 (13) Hospital indemnity or other fixed indemnity insurance,
2272 if offered as independent, noncoordinated benefits.

2273 (14) Benefits provided through a Medicare supplemental
2274 health insurance policy, as defined under s. 1882(g)(1) of the
2275 Social Security Act, coverage supplemental to the coverage
2276 provided under 10 U.S.C. chapter 55, and similar supplemental
2277 coverage provided to coverage under a group health plan, which
2278 are offered as a separate insurance policy and as independent,
2279 noncoordinated benefits.

2280 Section 82. Effective January 1, 2018, paragraph (j) of
2281 subsection (1) of section 641.185, Florida Statutes, is amended
2282 to read:

2283 641.185 Health maintenance organization subscriber
2284 protections.—

2285 (1) With respect to the provisions of this part and part
2286 III, the principles expressed in the following statements shall
2287 serve as standards to be followed by the commission, the office,
2288 the department, and the Agency for Health Care Administration in
2289 exercising their powers and duties, in exercising administrative
2290 discretion, in administrative interpretations of the law, in
2291 enforcing its provisions, and in adopting rules:

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2292 ~~(j) A health maintenance organization should receive timely~~
2293 ~~and, if necessary, urgent review by an independent state~~
2294 ~~external review organization for unresolved grievances and~~
2295 ~~appeals pursuant to s. 408.7056.~~

2296 Section 83. Effective January 1, 2018, section 641.312,
2297 Florida Statutes, is amended to read:

2298 641.312 Scope.—The Office of Insurance Regulation may adopt
2299 rules to administer the provisions of the National Association
2300 of Insurance Commissioners' Uniform Health Carrier External
2301 Review Model Act, issued by the National Association of
2302 Insurance Commissioners and dated April 2010. This section does
2303 not apply to ~~a health maintenance contract that is subject to~~
2304 ~~the Subscriber Assistance Program under s. 408.7056 or to the~~
2305 types of benefits or coverages provided under s. 627.6513(1)–
2306 (14) issued in any market.

2307 Section 84. Effective January 1, 2018, subsection (4) of
2308 section 641.3154, Florida Statutes, is amended to read:

2309 641.3154 Organization liability; provider billing
2310 prohibited.—

2311 (4) A provider or any representative of a provider,
2312 regardless of whether the provider is under contract with the
2313 health maintenance organization, may not collect or attempt to
2314 collect money from, maintain any action at law against, or
2315 report to a credit agency a subscriber of an organization for
2316 payment of services for which the organization is liable, if the
2317 provider in good faith knows or should know that the
2318 organization is liable. This prohibition applies during the
2319 pendency of any claim for payment made by the provider to the
2320 organization for payment of the services and any legal

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proceedings or dispute resolution process to determine whether the organization is liable for the services if the provider is informed that such proceedings are taking place. It is presumed that a provider does not know and should not know that an organization is liable unless:

(a) The provider is informed by the organization that it accepts liability;

(b) A court of competent jurisdiction determines that the organization is liable; or

~~(c) The office or agency makes a final determination that the organization is required to pay for such services subsequent to a recommendation made by the Subscriber Assistance Panel pursuant to s. 408.7056; or~~

(c) ~~(d)~~ The agency issues a final order that the organization is required to pay for such services subsequent to a recommendation made by a resolution organization pursuant to s. 408.7057.

Section 85. Effective January 1, 2018, paragraph (c) of subsection (5) of section 641.51, Florida Statutes, is amended to read:

641.51 Quality assurance program; second medical opinion requirement.—

(5)

(c) For second opinions provided by contract physicians the organization is prohibited from charging a fee to the subscriber in an amount in excess of the subscriber fees established by contract for referral contract physicians. The organization shall pay the amount of all charges, which are usual, reasonable, and customary in the community, for second opinion

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services performed by a physician not under contract with the organization, but may require the subscriber to be responsible for up to 40 percent of such amount. The organization may require that any tests deemed necessary by a noncontract physician shall be conducted by the organization. The organization may deny reimbursement rights granted under this section in the event the subscriber seeks in excess of three such referrals per year if such subsequent referral costs are deemed by the organization to be evidence that the subscriber has unreasonably overutilized the second opinion privilege. A subscriber thus denied reimbursement under this section shall have recourse to grievance procedures as specified in ss. ~~408.7056~~, 641.495, and 641.511. The organization's physician's professional judgment concerning the treatment of a subscriber derived after review of a second opinion shall be controlling as to the treatment obligations of the health maintenance organization. Treatment not authorized by the health maintenance organization shall be at the subscriber's expense.

Section 86. Effective January 1, 2018, section 641.511, Florida Statutes, is amended to read:

641.511 Subscriber grievance reporting and resolution requirements.—

(1) Every organization must have a grievance procedure available to its subscribers for the purpose of addressing complaints and grievances. ~~Every organization must notify its subscribers that a subscriber must submit a grievance within 1 year after the date of occurrence of the action that initiated the grievance, and may submit the grievance for review to the Subscriber Assistance Program panel as provided in s. 408.7056~~

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~~after receiving a final disposition of the grievance through the organization's grievance process. An organization shall maintain records of all grievances and shall report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievances, and the final disposition of the grievances.~~

(2) When an organization receives an initial complaint from a subscriber, the organization must respond to the complaint within a reasonable time after its submission. At the time of receipt of the initial complaint, the organization shall inform the subscriber that the subscriber has a right to file a written grievance at any time and that assistance in preparing the written grievance shall be provided by the organization.

(3) Each organization's grievance procedure, as required under subsection (1), must include, at a minimum:

(a) An explanation of how to pursue redress of a grievance.

(b) The names of the appropriate employees or a list of grievance departments that are responsible for implementing the organization's grievance procedure. The list must include the address and the toll-free telephone number of each grievance department, the address of the agency and its toll-free telephone hotline number, and the address of the Subscriber Assistance Program and its toll-free telephone number.

(c) The description of the process through which a subscriber may, at any time, contact the toll-free telephone hotline of the agency to inform it of the unresolved grievance.

(d) A procedure for establishing methods for classifying grievances as urgent and for establishing time limits for an expedited review within which such grievances must be resolved.

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(e) A notice that a subscriber may voluntarily pursue binding arbitration in accordance with the terms of the contract if offered by the organization, after completing the organization's grievance procedure ~~and as an alternative to the Subscriber Assistance Program~~. Such notice shall include an explanation that the subscriber may incur some costs if the subscriber pursues binding arbitration, depending upon the terms of the subscriber's contract.

(f) A process whereby the grievance manager acknowledges the grievance and investigates the grievance in order to notify the subscriber of a final decision in writing.

(g) A procedure for providing individuals who are unable to submit a written grievance with access to the grievance process, which shall include assistance by the organization in preparing the grievance and communicating back to the subscriber.

(4) (a) With respect to a grievance concerning an adverse determination, an organization shall make available to the subscriber a review of the grievance by an internal review panel; such review must be requested within 30 days after the organization's transmittal of the final determination notice of an adverse determination. A majority of the panel shall be persons who previously were not involved in the initial adverse determination. A person who previously was involved in the adverse determination may appear before the panel to present information or answer questions. The panel shall have the authority to bind the organization to the panel's decision.

(b) An organization shall ensure that a majority of the persons reviewing a grievance involving an adverse determination are providers who have appropriate expertise. An organization

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shall issue a copy of the written decision of the review panel to the subscriber and to the provider, if any, who submits a grievance on behalf of a subscriber. In cases where there has been a denial of coverage of service, the reviewing provider shall not be a provider previously involved with the adverse determination.

(c) An organization shall establish written procedures for a review of an adverse determination. Review procedures shall be available to the subscriber and to a provider acting on behalf of a subscriber.

~~(d) In any case when the review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber, the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.~~

(5) Except as provided in subsection (6), the organization shall resolve a grievance within 60 days after receipt of the grievance, or within a maximum of 90 days if the grievance involves the collection of information outside the service area. These time limitations are tolled if the organization has notified the subscriber, in writing, that additional information is required for proper review of the grievance and that such time limitations are tolled until such information is provided. After the organization receives the requested information, the time allowed for completion of the grievance process resumes. The Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, is adopted and incorporated by reference as applicable to all organizations

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that administer small and large group health plans that are subject to 29 C.F.R. s. 2560.503-1. The claims procedures of the regulations of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, shall be the minimum standards for grievance processes for claims for benefits for small and large group health plans that are subject to 29 C.F.R. s. 2560.503-1.

(6) (a) An organization shall establish written procedures for the expedited review of an urgent grievance. A request for an expedited review may be submitted orally or in writing and shall be subject to the review procedures of this section, if it meets the criteria of this section. Unless it is submitted in writing, for purposes of the grievance reporting requirements in subsection (1), the request shall be considered an appeal of a utilization review decision and not a grievance. Expedited review procedures shall be available to a subscriber and to the provider acting on behalf of a subscriber. For purposes of this subsection, "subscriber" includes the legal representative of a subscriber.

(b) Expedited reviews shall be evaluated by an appropriate clinical peer or peers. The clinical peer or peers shall not have been involved in the initial adverse determination.

(c) In an expedited review, all necessary information, including the organization's decision, shall be transmitted between the organization and the subscriber, or the provider acting on behalf of the subscriber, by telephone, facsimile, or the most expeditious method available.

(d) In an expedited review, an organization shall make a decision and notify the subscriber, or the provider acting on

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2495 behalf of the subscriber, as expeditiously as the subscriber's
2496 medical condition requires, but in no event more than 72 hours
2497 after receipt of the request for review. If the expedited review
2498 is a concurrent review determination, the service shall be
2499 continued without liability to the subscriber until the
2500 subscriber has been notified of the determination.

2501 (e) An organization shall provide written confirmation of
2502 its decision concerning an expedited review within 2 working
2503 days after providing notification of that decision, if the
2504 initial notification was not in writing.

2505 (f) An organization shall provide reasonable access, not to
2506 exceed 24 hours after receiving a request for an expedited
2507 review, to a clinical peer who can perform the expedited review.

2508 ~~(g) In any case when the expedited review process does not~~
2509 ~~resolve a difference of opinion between the organization and the~~
2510 ~~subscriber or the provider acting on behalf of the subscriber,~~
2511 ~~the subscriber or the provider acting on behalf of the~~
2512 ~~subscriber may submit a written grievance to the Subscriber~~
2513 ~~Assistance Program.~~

2514 (g) (h) An organization shall not provide an expedited
2515 retrospective review of an adverse determination.

2516 ~~(7) Each organization shall send to the agency a copy of~~
2517 ~~its quarterly grievance reports submitted to the office pursuant~~
2518 ~~to s. 408.7056(12).~~

2519 (7) (8) The agency shall investigate all reports of
2520 unresolved quality of care grievances received from

2521 ~~(a)~~ annual and quarterly grievance reports submitted by the
2522 organization to the office.

2523 ~~(b) Review requests of subscribers whose grievances remain~~

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2524 ~~unresolved after the subscriber has followed the full grievance~~
2525 ~~procedure of the organization.~~

2526 ~~(9) (a) The agency shall advise subscribers with grievances~~
2527 ~~to follow their organization's formal grievance process for~~
2528 ~~resolution prior to review by the Subscriber Assistance Program.~~
2529 ~~The subscriber may, however, submit a copy of the grievance to~~
2530 ~~the agency at any time during the process.~~

2531 ~~(b) Requiring completion of the organization's grievance~~
2532 ~~process before the Subscriber Assistance Program panel's review~~
2533 ~~does not preclude the agency from investigating any complaint or~~
2534 ~~grievance before the organization makes its final determination.~~

2535 ~~(10) Each organization must notify the subscriber in a~~
2536 ~~final decision letter that the subscriber may request review of~~
2537 ~~the organization's decision concerning the grievance by the~~
2538 ~~Subscriber Assistance Program, as provided in s. 408.7056, if~~
2539 ~~the grievance is not resolved to the satisfaction of the~~
2540 ~~subscriber. The final decision letter must inform the subscriber~~
2541 ~~that the request for review must be made within 365 days after~~
2542 ~~receipt of the final decision letter, must explain how to~~
2543 ~~initiate such a review, and must include the addresses and toll-~~
2544 ~~free telephone numbers of the agency and the Subscriber~~
2545 ~~Assistance Program.~~

2546 (8) (11) Each organization, as part of its contract with any
2547 provider, must require the provider to post a consumer
2548 assistance notice prominently displayed in the reception area of
2549 the provider and clearly noticeable by all patients. The
2550 consumer assistance notice must state the addresses and toll-
2551 free telephone numbers of the Agency for Health Care
2552 Administration, ~~the Subscriber Assistance Program, and the~~

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Department of Financial Services. The consumer assistance notice must also clearly state that the address and toll-free telephone number of the organization's grievance department shall be provided upon request. The agency may adopt rules to implement this section.

~~(9)(12)~~ The agency may impose administrative sanction, in accordance with s. 641.52, against an organization for noncompliance with this section.

Section 87. Effective January 1, 2018, subsection (1) of section 641.515, Florida Statutes, is amended to read:

641.515 Investigation by the agency.—

(1) The agency shall investigate further any quality of care issue contained in recommendations and reports submitted pursuant to ~~ss. 408.7056 and s.~~ 641.511. The agency shall also investigate further any information that indicates that the organization does not meet accreditation standards or the standards of the review organization performing the external quality assurance assessment pursuant to reports submitted under s. 641.512. Every organization shall submit its books and records and take other appropriate action as may be necessary to facilitate an examination. The agency shall have access to the organization's medical records of individuals and records of employed and contracted physicians, with the consent of the subscriber or by court order, as necessary to carry out the provisions of this part.

Section 88. Effective January 1, 2018, subsection (2) of section 641.55, Florida Statutes, is amended to read:

641.55 Internal risk management program.—

(2) The risk management program shall be the responsibility

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of the governing authority or board of the organization. Every organization which has an annual premium volume of \$10 million or more and which directly provides health care in a building owned or leased by the organization shall hire a risk manager, ~~certified under ss. 395.10971-395.10975,~~ who shall be responsible for implementation of the organization's risk management program required by this section. A part-time risk manager shall not be responsible for risk management programs in more than four organizations or facilities. Every organization which does not directly provide health care in a building owned or leased by the organization and every organization with an annual premium volume of less than \$10 million shall designate an officer or employee of the organization to serve as the risk manager.

The gross data compiled under this section or s. 395.0197 shall be furnished by the agency upon request to organizations to be utilized for risk management purposes. The agency shall adopt rules necessary to carry out the provisions of this section.

Section 89. Section 641.60, Florida Statutes, is repealed.

Section 90. Section 641.70, Florida Statutes, is amended to read:

641.70 Agency duties relating to ~~the Statewide Managed Care Ombudsman Committee and~~ the district managed care ombudsman committees.—

(1) The agency shall adopt rules that specify:

(a) Procedures by which ~~the statewide committee and~~ district committees receive reports of enrollee complaints from the agency.

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(b) Procedures by which enrollee information shall be made available ~~to members of the statewide committee and to the~~ district committees.

(c) Procedures by which recommendations made by the committees shall be considered for incorporation into policies and procedures of the agency.

~~(d) Procedures by which statewide committee members shall be reimbursed for authorized expenditures.~~

~~(d) (e)~~ Any other procedures that are necessary to administer this section and ~~ss. 641.60 and s. 641.65.~~

(2) The Agency for Health Care Administration shall provide a meeting place for district committees in agency offices and shall provide the necessary administrative support to assist ~~the statewide committee and~~ district committees, within available resources.

(3) The secretary of the agency shall ensure the full cooperation and assistance of agency employees with ~~members of the statewide committee and~~ district committees.

Section 91. Subsection (3) of section 641.75, Florida Statutes, is amended to read:

641.75 Immunity from liability; limitation on testimony.—

(3) Members of any state or district ombudsman committee shall not be required to testify in any court with respect to matters held to be confidential except as may be necessary to enforce ss. 641.61-641.75 ~~641.60-641.75~~.

Section 92. Paragraph (b) of subsection (6) of section 766.118, Florida Statutes, is amended to read:

766.118 Determination of noneconomic damages.—

(6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF A

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PRACTITIONER PROVIDING SERVICES AND CARE TO A MEDICAID RECIPIENT.—Notwithstanding subsections (2), (3), and (5), with respect to a cause of action for personal injury or wrongful death arising from medical negligence of a practitioner committed in the course of providing medical services and medical care to a Medicaid recipient, regardless of the number of such practitioner defendants providing the services and care, noneconomic damages may not exceed \$300,000 per claimant, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. A practitioner providing medical services and medical care to a Medicaid recipient is not liable for more than \$200,000 in noneconomic damages, regardless of the number of claimants, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. The fact that a claimant proves that a practitioner acted in a wrongful manner does not preclude the application of the limitation on noneconomic damages prescribed elsewhere in this section. For purposes of this subsection:

(b) The term "practitioner," in addition to the meaning prescribed in subsection (1), includes any hospital or ambulatory surgical center, ~~or mobile surgical facility~~ as defined and licensed under chapter 395.

Section 93. Subsection (4) of section 766.202, Florida Statutes, is amended to read:

766.202 Definitions; ss. 766.201-766.212.—As used in ss. 766.201-766.212, the term:

(4) "Health care provider" means any hospital or ambulatory surgical center, ~~or mobile surgical facility~~ as

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defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; ~~a clinical lab licensed under chapter 483~~; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Section 94. Subsection (1) of section 945.36, Florida Statutes, is amended to read:

945.36 ~~Exemption from health testing regulations for Law enforcement personnel authorized to conduct conducting~~ drug tests on inmates and releasees.—

(1) Any law enforcement officer, state or county probation officer, or employee of the Department of Corrections, who is certified by the Department of Corrections pursuant to subsection (2), may administer ~~is exempt from part I of chapter 483, for the limited purpose of administering~~ a urine screen drug test to:

- (a) Persons during incarceration;
- (b) Persons released as a condition of probation for either a felony or misdemeanor;
- (c) Persons released as a condition of community control;
- (d) Persons released as a condition of conditional release;
- (e) Persons released as a condition of parole;
- (f) Persons released as a condition of provisional release;
- (g) Persons released as a condition of pretrial release; or

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(h) Persons released as a condition of control release.

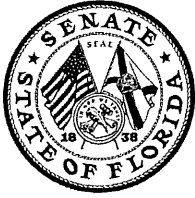
Section 95. Paragraph (b) of subsection (2) of section 1009.65, Florida Statutes, is amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(b) All payments shall be contingent on continued proof of primary care practice in an area defined in s. 395.602 (2) (b) ~~395.602 (2) (e)~~, or an underserved area designated by the Department of Health, provided the practitioner accepts Medicaid reimbursement if eligible for such reimbursement. Correctional facilities, state hospitals, and other state institutions that employ medical personnel shall be designated by the Department of Health as underserved locations. Locations with high incidences of infant mortality, high morbidity, or low Medicaid participation by health care professionals may be designated as underserved.

Section 96. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2017.



The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 14, 2017

I respectfully request that **Senate Bill #916**, relating to Statewide Medicaid Managed Care, and **Senate Bill #1760**, 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
Florida Senate, District 26

THE FLORIDA SENATE
APPEARANCE RECORD

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

3-27-17

Meeting Date

SB 1760

Bill Number (if applicable)

Topic Health Care Facility Regulation

Amendment Barcode (if applicable)

Name Susan Anderson

Job Title V.P. Public Policy

Address 2292 Wednesday St.

Phone 850-708-4971

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Tallahassee

FL

32308

City

State

Zip

Email sanderson@fl.argentum.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Argentum

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)

3/27/17
Meeting Date

1760
Bill Number (if applicable)

Topic Health Care Facility Reg-

Amendment Barcode (if applicable)

Name JACK McRAY

Job Title _____

Address 200 W. COLLEGE ST. #304
Street

Phone 850-577-5187

TLH FL 32301
City State Zip

Email jmcrae@aarp.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing AARP

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/27/17

Meeting Date

1760

Bill Number (if applicable)

Topic

Amendment Barcode (if applicable)

Name Chris Mand

Job Title

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City

State

Zip

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Public Health Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

CourtSmart Tag Report

Room: KN 412

Case No.:

Type:

Caption: Senate Committee on Health Policy

Judge:

Started: 3/27/2017 4:08:32 PM

Ends: 3/27/2017 5:45:28 PM

Length: 01:36:57

4:08:32 PM Meeting Called to order
4:08:41 PM Roll Call
4:08:48 PM Quorum present
4:08:56 PM Chair Young
4:09:17 PM Tab 10 Sb 1324
4:09:24 PM Sen Garcia explains
4:10:00 PM SB A BC 108722
4:10:26 PM Chair calls for questions
4:10:42 PM Chris Nuland, FI society of plastic dematologist, waives in support
4:11:05 PM Chair calls for questions
4:11:11 PM Sen Garcia waives close on the bill
4:11:24 PM Roll call by AA
4:11:34 PM SB 1324 reported favorably
4:11:48 PM Tab 3 SB 588
4:11:53 PM Sen Passidomo explains
4:12:27 PM Amend to BC 436620 explained by Sen Passidomo
4:13:10 PM Chair calls for questions on Strike All
4:13:32 PM Jill Granl, FIA behaviorhal health Assoc., waives in support
4:13:52 PM Sen Passidomo waives in support
4:14:03 PM Chair calls for debate
4:14:13 PM Roll Call for CS SB 588
4:14:20 PM CS/SB 588 reported favorably
4:14:57 PM Tab 7 SB 1124 Sen Book explains
4:15:53 PM Chair AMend BC 77488
4:16:04 PM Sen Book explains amend
4:16:19 PM Chair calls for questions and debate on Amend
4:16:32 PM Chair calls for questions on bill as Amend
4:21:11 PM Cassandra Herring, mother, speaks in support
4:22:12 PM Donna Fogle, mother speaks in support
4:27:31 PM Stephen Winn, FI Osteopathic Medical Assoc., waives i nsupport
4:28:05 PM Kelly MalletteEverday Life Foundation for Rare diseases, waive in support
4:28:24 PM Sen Book waives close
4:28:36 PM Roll CS SB 1124
4:28:52 PM CS/SB 1124 reported favorably
4:29:19 PM Tab 1 SB 414
4:29:24 PM Sen Grimsley explains
4:30:47 PM Chair Calls for questions
4:30:54 PM Tina Braungardt waives in opposition
4:31:09 PM Sean waives in support
4:31:27 PM Allen waives in support
4:31:37 PM Chair calls for debate
4:31:45 PM Amend adopted
4:32:05 PM Sen Grimsley waives close
4:32:15 PM CS/SB 414 reported favorably
4:32:54 PM Sen Grimsley explains strike all amend
4:34:44 PM Chair explains late file amend to the amend
4:35:02 PM Amend to amend 174398
4:35:22 PM Sen Grimsley explains
4:35:29 PM Chair calls for questions on the Amend to the Amend
4:35:44 PM Amend adopted
4:35:49 PM Chair calls for questions to the strike all amend
4:35:57 PM Sen Montford question

4:36:59 PM Chair calls for further questions
 4:37:24 PM Michael McQuone Associate Director for Health, speaks to inform
 4:38:29 PM Tina Braunggardt, Vitas healthcare, waives in support
 4:39:27 PM Paul Ledford, Florida Hospice Care, speaks in support
 4:41:08 PM Sen Montford question
 4:41:38 PM Mr. Ledford comments
 4:42:00 PM Dr. Stephen Leeds, Hospice physician waives in support
 4:42:37 PM Dr. Diane Gowski, FI Guilds of Catholic Medical Association, speaks in opposition
 4:45:59 PM Chair Young comments
 4:46:15 PM Dr. Gowski response
 4:46:22 PM Tab 2 SB 474 Sen Grimsley
 4:46:27 PM Heather Youmans, American Cancer Society, waives in support
 4:47:06 PM Chair Young calls for debate on the Amend
 4:47:16 PM Sen Grimsely waives to close on the Amend
 4:47:29 PM Chair Young calls for vote on SB as Amend
 4:47:40 PM Roll Call by AA
 4:47:48 PM CS/SB 474 reported favorably
 4:48:02 PM Tab 6 SB 916
 4:48:15 PM Sen Grimsley explains the bill
 4:49:52 PM Chair calls for questions
 4:50:06 PM Sen Grinsley waives close
 4:50:11 PM roll Call SB 916
 4:50:21 PM SB 916 reported favorably
 4:50:29 PM Tab 12 SB 1760 BC 527966
 4:50:34 PM Sen Grimsley explains strike all amend
 4:58:16 PM Chair calls for questions
 4:59:21 PM Sen Grimsley
 4:59:40 PM Sen Benaquisto question
 5:00:10 PM Sen Book comment
 5:00:21 PM Amend withdrawn
 5:00:44 PM Susan Anderson, Florida Argentum, waives in support
 5:00:52 PM Jack McCray, AARP, waives in support
 5:01:00 PM Chris Nuland, Florida Public Health, waives in support
 5:01:12 PM Sen Grimsley waives to close
 5:01:26 PM Roll Call SB 1760
 5:01:39 PM SB 1760 reported favorably
 5:01:56 PM SB 682
 5:02:07 PM Sen Stargel explains
 5:02:46 PM Amend BC 716712
 5:02:58 PM Sen Stargel explains Amend
 5:03:58 PM Chair calls for questions on Sen Stargels strike all
 5:04:13 PM Sen Passidomo question
 5:04:38 PM Sen Stargel responds
 5:06:03 PM Bc 204196
 5:06:20 PM Sen Young explains and withdraws her amend
 5:08:26 PM Chair calls for questions on strike all amend
 5:08:37 PM A BC 370222
 5:08:50 PM Sen Stargel explains
 5:09:24 PM Sen Powell question
 5:09:54 PM Sen Stargel
 5:10:16 PM Sen Stargel explains
 5:10:22 PM Amend to Amend adopted
 5:10:39 PM Chair calls for question
 5:10:50 PM Sen Stargel comments
 5:13:02 PM Debra Franklin, Sr. Director of Quality affairs, speaking in favor of Amend 204196
 5:17:30 PM Tom Parker, Florida Health Care Association, speaking in favor
 5:18:52 PM Julie Ann Kemman, Florida Nursing Homes, Speakign in favor
 5:22:28 PM Audrey Brown, , Florida Assoc. of Health Plans, speaking in opposition
 5:25:19 PM Tammy Perdue, Sunshine Health, speaking in opposition
 5:27:02 PM Strike All Amend adopted
 5:27:19 PM Chair calls for questions for Sen Stargel
 5:27:34 PM Sen Passidomo question

5:29:21 PM	Chair Young comments
5:32:22 PM	Sen Stargel closes
5:33:23 PM	Roll Call CS/SB 682 by AA
5:33:44 PM	CS/SB 682 reported favorably
5:34:04 PM	TA SB 694
5:34:19 PM	Sen Hutston explains
5:34:27 PM	Sen Hutson explains the amend
5:34:48 PM	Amend adopted
5:35:06 PM	David Poole, AIDS Healthcare Foundation, waives in opposition
5:35:29 PM	Sen Hutson waives close
5:35:37 PM	Roll Call SB 694 by AA
5:35:48 PM	CS/SB 694 reported favorably
5:36:02 PM	Tab 8 SB 1144
5:36:09 PM	Sen Montford explains
5:37:36 PM	A BC 682720
5:37:57 PM	Sen Montford explains
5:38:18 PM	David Cullen, waives in support
5:38:31 PM	Tom Juice, waives in support
5:38:41 PM	Chris Nuland, waives in support
5:39:03 PM	
5:39:11 PM	Aimee diaz, Aids Inst., waives in support
5:39:21 PM	roll call SB 1144
5:39:29 PM	CS/SB144 reported favorably
5:39:57 PM	Tab 9 SB 1206
5:40:14 PM	Sen Montford explains
5:40:30 PM	Amend BC 312436
5:40:41 PM	Sen Montford explains the amend
5:41:28 PM	Chair calls for questions
5:41:37 PM	Cynthia Henderson, waives in support
5:41:57 PM	roll call SB 1206
5:42:07 PM	CS/SB 1206 reported favorably
5:42:23 PM	SB 1406
5:42:28 PM	Sen Powell explains
5:42:49 PM	A 169250
5:42:55 PM	Amen adopted
5:43:30 PM	Fely Curvo, waives in support
5:43:46 PM	Mark Landree waives in support
5:44:02 PM	Riers Buford, waives in support
5:44:12 PM	Sen Powell waives in support
5:44:22 PM	Roll Call
5:44:28 PM	CS/SB 1406 reported favorably
5:44:50 PM	Sen Hutson votes in affirmitive for bills
5:45:07 PM	Sen Powell voting n the affirmative