The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Tuesday, January 23, 2018
TIME: 3:30—5:30 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 112** Campbell (Identical H 573)	Involuntary Examinations Under the Baker Act; Authorizing physician assistants and advanced registered nurse practitioners to execute a certificate under certain conditions stating that they have examined a person and find the person appears to meet the criteria for involuntary examination, etc. HP 01/23/2018 Favorable CF JU RC	Favorable Yeas 7 Nays 1
2	**SB 162** Steube (Similar H 217)	Payment of Health Care Claims; Prohibiting a health insurer or a health maintenance organization from retroactively denying a claim under specified circumstances, etc. BI 12/05/2017 Favorable HP 01/23/2018 Favorable RC	Favorable Yeas 8 Nays 0
3	**SB 164** Grimsley (Similar H 735)	Mammography; Requiring facilities performing mammography to include certain information in a summary of the mammography report which must be provided to each patient, etc. HP 01/23/2018 Fav/CS RC	Fav/CS Yeas 8 Nays 0
4	**SB 954** Passidomo (Similar H 517)	State Employees' Prescription Drug Program; Requiring the Department of Management Services to implement formulary management cost-saving measures; removing a provision that prohibits the department from implementing a restricted prescription drug formulary or prior authorization program in the state employees' prescription drug program, etc. HP 01/23/2018 Favorable AGG AP	Favorable Yeas 8 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
5	**SB 1252** Passidomo (Similar H 513)	Home Renal Dialysis; Revising conditions under which manufacturers, or agents thereof, who distribute home dialysis supplies are exempt from the requirements of the Florida Pharmacy Act, etc. HP 01/23/2018 Fav/CS AHS AP	Fav/CS Yeas 8 Nays 0
6	**SB 1680** Montford (Similar H 1045)	Immunization Registry; Revising provisions relating to the communicable disease prevention and control programs under the Department of Health; deleting a provision that allows the parent or guardian of a child to refuse to have the child included in the immunization registry; revising school-entry health requirements to require that students have a certificate of immunization on file with the department's immunization registry, etc. HP 01/23/2018 Fav/CS ED RC	Fav/CS Yeas 6 Nays 2
7	**SB 514** Young	Transplant of Human Tissue; Requiring an institution or physician responsible for transplanting an organ or an allograft, or for artificial insemination, to warn the recipient as to the risks of contracting Zika virus; providing an exception to the warning requirement for an organ or allograft that has been virally inactivated, etc. HP 01/23/2018 Fav/CS JU RC	Fav/CS Yeas 8 Nays 0
8	**SB 1876** Young (Compare H 1165)	Trauma Services; Revising the trauma service areas and provisions relating to the number and location of trauma centers; requiring the Department of Health to establish the Florida Trauma System Advisory Council by a specified date, etc. HP 01/23/2018 Fav/CS AHS AP RC	Fav/CS Yeas 8 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:	SB 112
INTRODUCER:	Senator Campbell
SUBJECT:	Involuntary Examinations Under the Baker Act
DATE:	January 22, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Favorable**
2.			CF	
3.			JU	
4.			RC	

I. Summary:

SB 112 adds advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) to the list of health care practitioners who may initiate an involuntary examination of a person under the Florida Mental Health Act, also known as the Baker Act.

When an involuntary examination is initiated, the person to be examined may be taken into custody by a law enforcement officer and delivered to a receiving facility. The person must be examined by a physician, clinical psychologist, or psychiatric nurse at the facility within 72 hours. The facility generally must release the person within that time period, but the person may be detained longer if a petition for involuntary inpatient placement is filed with a court.

The bill takes effect July 1, 2018.

II. Present Situation:

Involuntary Examination Under the Baker Act

Overview

In 1971, the Legislature passed the Florida Mental Health Act, also known as the Baker Act, to address mental health needs in the state.[1] The Baker Act provides the authority and process for the voluntary and involuntary examination of persons who meet certain criteria, and the subsequent inpatient or outpatient placement of those individuals for treatment.

The Department of Children and Families (DCF) administers the Baker Act through receiving facilities, which are designated by DCF. The facilities that provide the examination and short-

[1] Chapter 71-131, s. 1, Laws of Fla. This is codified in part I of ch. 394, F.S.

term treatment of persons who meet the criteria under the Baker Act may be public or private.[2] If, after an examination at a receiving facility,[3] a person requires further treatment he or she may be transported to a treatment facility. Treatment facilities are state hospitals that provide extended treatment and hospitalization beyond what is provided in a receiving facility.[4]

A person who is subject to an involuntary examination generally may not be held longer than 72 hours in a receiving facility.[5]

Criteria

A person may be subjected to an involuntary examination if there is reason to believe he or she has a mental illness, and because of the illness, that person:

- Has refused a voluntary examination after the purpose of the exam has been explained, or
- Is unable to determine for himself or herself that an examination is needed; and
- Without care or treatment, the person is likely to suffer from neglect or refuse to care for himself or herself; such neglect or refusal poses a real and present threat of substantial harm to his or her well-being; and it is not apparent that the harm may be avoided through the help of willing family members or friends or the provision of other services; or
- There is a substantial likelihood that without care or treatment, the person will cause serious bodily harm to himself, herself, or others in the near future, as evidenced by recent behavior.[6]

Who May Initiate an Involuntary Exam?

A circuit or county court, law enforcement officers, and certain health care practitioners may initiate an involuntary examination of a person.[7]

A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination. A law enforcement officer must take into custody a person who appears to meet the criteria for involuntary examination and transport that person to a receiving facility for examination.

Health care practitioners may initiate an involuntary examination if the health care practitioner has examined the person within the last 48 hours and finds that the person meets the criteria for an involuntary examination. The practitioner must state on a DCF form,[8] the observations upon which that conclusion is based.[9] The form contains information related to the person's diagnosis and the health care practitioner's personal observations of statements and behaviors that support the involuntary examination of the person.[10]

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[2] Section 394.455(39), F.S.
[3] Section 394.455(47), F.S.
[4] Section 394.55(47), F.S.
[5] Section 394.463(2)(g), F.S.
[6] Section 394.463(1), F.S.
[7] Section 394.463(2), F.S.
[8] The form is a Certificate of Professional Initiating Involuntary Examination. *See* Department of Children and Families, *CF-MH 3052b*, incorporated by reference in Rule 65E-5.280, F.A.C. http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/3052b.pdf. (last visited Sept. 18, 2017).
[9] Section 394.463(2)(a), F.S.
[10] *See* supra note 8.

The Baker Act currently authorizes the following health care practitioners to initiate an involuntary examination:

- A physician licensed under chs. 458 or 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders;
- A physician employed by a facility operated by the U.S. Department of Veterans Affairs or the United States Department of Defense;
- A clinical psychologist, as defined in s. 490.003(7), F.S., who has three years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure;
- A psychologist employed by a facility operated by the U.S. Department of Veterans Affairs or the U.S. Department of Defense that qualifies as a receiving or treatment facility;
- A psychiatric nurse, who is an ARNP, with a master's degree or doctoral degree in psychiatric nursing, who holds a national advanced practice certification as a psychiatric mental health advanced practice nurse, and who has two years of post-master's clinical experience under the supervision of a physician;
- A mental health counselor licensed under ch. 491, F.S.;
- A marriage and family therapist licensed under ch. 491, F.S.; and
- A clinical social worker licensed under ch. 491, F.S.[11]

Detention and Delivery of a Person for an Involuntary Examination

Once an involuntary examination is initiated by a court or health care practitioner, a law enforcement officer "shall" take the person into custody and deliver or have the person delivered to the appropriate or nearest facility for the examination.[12] A law enforcement officer executing an ex parte order for an involuntary examination, issued by a court, may take the person into custody "on any day of the week, at any time of day or night."[13] The law enforcement officer is further authorized to use "reasonable physical force as is necessary to gain entry to the premises, and any dwellings, buildings, or other structures located on the premises, and to take custody of the person who is the subject of the ex parte order."[14]

Physician Assistants

Overview

The Department of Health (DOH) licenses physician assistants in Florida, either under s. 458.347(7), F.S., if the physician assistant works with a physician, or s. 459.022(7), F.S., if he or she works with an osteopathic physician. PAs are regulated by the Florida Board of Medicine if licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine if licensed under ch. 459, F.S., and the Florida Council on Physician Assistants. The board makes disciplinary decisions as to whether a doctor or PA has violated the provisions of his or her practice act. In 2017, there were 7,730 PAs holding active licenses in Florida.[15]

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[11] Sections 394.463(2)(a)3., and 394.455, F.S.
[12] Section 394.463(2), F.S.
[13] Section 394.463(2)(c), F.S.
[14] Section 394.463(2)(d), F.S.
[15] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2016-2017*, http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html, (last visited Jan. 18, 2018).

Scope of Practice

Physician Assistants may practice only under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[16] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[17] The supervising physician is responsible and liable for any acts or omissions of the PA[18] and may not supervise more than four PAs at a time.[19]

Licensure

To be licensed as a PA in Florida, an applicant must:

- Pass the exam established by the National Commission on Certification of Physician Assistants;
- Complete the application and submit the application fee;[20]
- Complete an approved PA training program;
- Acknowledge any prior felony convictions;
- Acknowledge any previous revocation or denial of licensure in any state; and
- If the applicant wishes to apply for prescribing authority, submit a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.[21]

Licenses are renewed biennially.[22] At the time of renewal, a PA must demonstrate that he or she has met the continuing education requirements and must submit an acknowledgement that he or she has not been convicted of any felony in the previous two years.[23]

Authorization

Current Florida law does not expressly allow PAs to refer for, or initiate, an involuntary examination of a person under the Baker Act; however, in 2008, Attorney General Bill McCollum issued an opinion stating:

> . . . [A] physician assistant licensed pursuant to Chapter 458 or 459, Florida Statutes, may refer a patient for involuntary evaluation pursuant to section 394.463, Florida Statutes, provided that the physician assistant has experience regarding the diagnosis and treatment of mental and nervous

[16] Sections 458.347(2)(f) and 459.022(2)(f), F.S., are identical and define "supervision" as "responsible supervision" and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[17] Sections 458.347(12) and 459.022(12), F.S.
[18] Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C.
[19] Section 458.347(3) and 459.022(3), F.S.
[20] The application fee is $100 and the initial license fee is $205. *See* http://flboardofmedicine.gov/licensing/physician-assistant-licensure/ (last visited Sept. 18, 2017).
[21] Sections 458.347(7) and 459.022(7), F.S.
[22] For timely renewed licenses, the renewal fee is $280 and the prescribing registration is $150. An applicant may be charged an additional fee if the license is renewed after expiration or is more than 120 days delinquent. Florida Board of Medicine, *Renewals, Physician Assistants*, http://flboardofmedicine.gov/renewals/physician-assistants/ (last visited Sept. 18, 2017).
[23] Sections 458.347(7)(b)-(c) and 459.022(7)(b)-(c), F.S.

disorders and such tasks are within the supervising physician's scope of practice.[24]

Legislation was enacted in 2016 that authorizes a licensed PA to perform services delegated by the supervising physician. The service must be in the physician assistant's practice in accordance with his or her education and training unless expressly prohibited under chs. 458 or 459, F.S., or rules adopted under those chapters.[25]

Curriculum

According to the American Academy of Physician Assistants, most PA programs last approximately 26 months, or three academic years, and award master's degrees. They include classroom instruction and clinical rotations.

Physician Assistant students complete more than 2,000 hours of clinical rotations, with an emphasis on primary care in ambulatory clinics, physician offices and acute or long-term care facilities. PA rotations can include:

- Family medicine;
- Internal medicine;
- Obstetrics and gynecology;
- Pediatrics;
- General surgery;
- Emergency medicine; and
- Psychiatry.[26]

Additional Requirements

Physician Assistants are not currently required under Florida law to have any specific education, training, or experience in the diagnosis or treatment of mental health or nervous disorders for licensure or renewal. However, a PA working under the supervision of a physician who has experience in the diagnosis and treatment of mental and nervous disorders, or a physician employed by a facility operated by the U.S. Department of Veterans Affairs or the United States Department of Defense might obtain training or experience in these areas.

Advanced Registered Nurse Practitioners

Licensure

Nurses are licensed by the DOH and regulated by the Board of Nursing.[27] To be licensed, a nurse must complete an approved educational program, pass a DOH approved exam, pass a criminal

[24] Op. Att'y Gen. Fla. 08-31 (2008) at p. 4 http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/agopinion.pdf (last visited Sept. 18, 2017).
[25] Chapter 2016-125, Laws of Fla. (codified as ss. 458.347(4)(h) and 459.022(4)(g), F.S.).
[26] American Association of Physician Assistants, *Attend a PA Program*, https://www.aapa.org/career-central/become-a-pa/ (last visited Sept. 18, 2017).
[27] See Part I, Chapter 464, F.S.

background screening, and pay the applicable fees.[28] In 2017, there were 22,672 advanced registered nurse practitioners with active licenses in Florida.[29]

A licensed nurse may apply to be certified as an Advanced Registered Nurse Practitioner (ARNP) if the nurse meets one or more of the following requirements:

- Satisfactory completion of a formal post-basic educational program of at least one academic year that prepares nurses for advanced or specialized practice;
- Certification by a specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.[30]

Categories of ARNPs and Scope of Practice

Current law defines four categories of ARNPs: certified registered nurse anesthetists; certified nurse midwives; a nurse practitioner,[31] and a psychiatric nurse.[32] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of someone licensed as a physician under ch. 458, F.S., an osteopathic physician licensed under ch. 459, F.S., or a dentist licensed under ch. 466, F.S.[33] ARNPs may carry out treatments as specified in statute, including:[34]

- Prescribing, dispensing, administering, or ordering any drug;[35]
- Initiating appropriate therapies for certain conditions;
- Ordering diagnostic tests and physical and occupational therapy;
- Ordering any medication for administration to patients in certain facilities; and
- Performing additional functions as maybe determined by rule in accordance with s. 464.003(2), F.S.[36]

In addition to these acts, an ARNP may also perform other acts as authorized by statute and within his or her specialty.[37] Further, if it is within an ARNP's established protocol, the ARNP may establish behavioral problems and diagnosis and make treatment recommendations.[38]

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[28] Sections 464.008 and 464.009, F.S. As an alternative to licensure by examination, a nurse may also be eligible for licensure by endorsement.
[29] *See supra* note 15.
[30] Section 464.012, F.S.
[31] Sections 464.003(3) and 464.012(2), F.S.
[32] Section 394.455(35), F.S., defines a "psychiatric nurse" as an ARNP certified under s. 464.012, F.S., who has a master's or doctoral degree in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advanced practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.
[33] Section 464.012(3), F.S.
[34] *Id*.
[35] An ARNP may only prescribe controlled substances 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. An ARNP is limited to prescribing a seven-day supply of Schedule II controlled substances. Only a psychiatric nurse may prescribe psychotropic controlled substances for the treatment of mental disorders and psychiatric mental health controlled substances for children younger than 18. See s. 464.012(3)(a) and (7)(a), F.S.
[36] Section 464.003(2), F.S., defines an "advanced or specialized nursing practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[37] Section 464.012(4), F.S.
[38] Section 464.012(4)(c)5., F.S.

Currently, only ARNPs who are "psychiatric nurses" may initiate involuntary examinations under the Baker Act.[39] To qualify as a psychiatric nurse, an ARNP must have a master's or doctoral degree in psychiatric nursing, hold a national advance practice certification as a psychiatric mental health advanced practice nurse, and two years post-master's clinical experience.[40]

III. Effect of Proposed Changes:

The bill specifically authorizes PAs and ARNPs to initiate involuntary examinations under the Baker Act. The PA or ARNP must execute a certificate stating that a person he or she examined within the preceding 48 hours appears to meet the criteria for an involuntary examination for mental illness. Under current law, only a physician with experience in the diagnosis and treatment of mental and nervous disorders, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, or clinical social worker may initiate an involuntary examination by executing the certificate.

When an involuntary examination is initiated, the person to be examined may be taken into custody by a law enforcement officer and delivered to a receiving facility for the examination. The receiving facility generally may not detain the person for longer than 72 hours.

The bill also makes necessary conforming changes due to the substantive changes made by the bill.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[39] Section 394.463(2)(a), F.S.
[40] Section 394.455(35), F.S.

B. Private Sector Impact:

None

C. Government Sector Impact:

None

VI. Technical Deficiencies:

None.

VII. Related Issues:

SB 112 defines a "physician assistant" and an "advanced registered nurse practitioner" in the same manner as their respective practice acts.[41] The bill does not direct any additional training, clinical or continuing education requirements for either the PA or the ARNP to be qualified to perform the examination and execute the certificate in order to subject a person to an involuntary mental health examination. All others health care providers authorized to initiate an involuntary examination have additional professional specialized training in psychiatric mental health.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 394.455, 394.463, 39.407, 394.495, 394.496, 394.9085, 409.972, and 744.2007.

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.

[41] See ss. 458.347, 459.022, and 464.003, F.S.

By Senator Campbell

38-00156-18 2018112__

A bill to be entitled

An act relating to involuntary examinations under the Baker Act; amending s. 394.455, F.S.; defining terms; amending s. 394.463, F.S.; authorizing physician assistants and advanced registered nurse practitioners to execute a certificate under certain conditions stating that they have examined a person and find the person appears to meet the criteria for involuntary examination; amending ss. 39.407, 394.495, 394.496, 394.9085, 409.972, and 744.2007, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Present subsections (5) through (48) of section 394.455, Florida Statutes, are redesignated as subsections (6) through (49), respectively, a new subsection (5) is added to that section, and present subsection (33) is amended, to read:

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

(5) "Advanced registered nurse practitioner" means a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

(34)~~(33)~~ "Physician assistant" has the same meaning as provided in s. 458.347(2) ~~means a person licensed under chapter 458 or chapter 459 who has experience in the diagnosis and treatment of mental disorders~~.

Section 2. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A circuit or county court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination and specifying the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on written or oral sworn testimony that includes specific facts that support the findings. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The order of the court shall be made a part of the patient's clinical record. A fee may not be charged for the filing of an order under this subsection. A facility accepting the patient based on this order must send a copy of the order to the department the next working day. The order may be submitted electronically through existing data systems, if available. The order shall be valid only until the person is delivered to the facility or for the period specified in the order itself, whichever comes first. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to

an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, which must be made a part of the patient's clinical record. Any facility accepting the patient based on this report must send a copy of the report to the department the next working day.

3. A physician, physician assistant, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, ~~or~~ clinical social worker, or an advanced registered nurse practitioner may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means, such as voluntary appearance for outpatient evaluation, are not available, a law enforcement officer shall take into custody the person named in the certificate and deliver him or her to the appropriate, or nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any facility accepting the patient based on this certificate must send a copy of the certificate to the department the next working day. The document may be submitted electronically through existing data systems, if applicable.

Section 3. Paragraph (a) of subsection (3) of section

39.407, Florida Statutes, is amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the prescribing physician shall attempt to obtain express and informed consent, as defined in s. 394.455 ~~s. 394.455(15)~~ and as described in s. 394.459(3)(a), from the child's parent or legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician. However, if the parental rights of the parent have been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic

medication for a child, the department must provide to the evaluating physician all pertinent medical information known to the department concerning that child.

Section 4. Subsection (3) of section 394.495, Florida Statutes, is amended to read:

394.495 Child and adolescent mental health system of care; programs and services.—

(3) Assessments must be performed by:

(a) A professional as defined in s. 394.455(6), (8), (33), (36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~;

(b) A professional licensed under chapter 491; or

(c) A person who is under the direct supervision of a qualified professional as defined in s. 394.455(6), (8), (33), (36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~ or a professional licensed under chapter 491.

Section 5. Subsection (5) of section 394.496, Florida Statutes, is amended to read:

394.496 Service planning.—

(5) A professional as defined in s. 394.455(6), (8), (33), (36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~ or a professional licensed under chapter 491 must be included among those persons developing the services plan.

Section 6. Subsection (6) of section 394.9085, Florida Statutes, is amended to read:

394.9085 Behavioral provider liability.—

(6) For purposes of this section, the terms "detoxification services," "addictions receiving facility," and "receiving facility" have the same meanings as those provided in ss. 397.311(26)(a)4., 397.311(26)(a)1., and 394.455(40) ~~394.455(39)~~,

respectively.

Section 7. Paragraph (b) of subsection (1) of section 409.972, Florida Statutes, is amended to read:

409.972 Mandatory and voluntary enrollment.—

(1) The following Medicaid-eligible persons are exempt from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program:

(b) Medicaid recipients residing in residential commitment facilities operated through the Department of Juvenile Justice or a treatment facility as defined in s. 394.455(48) ~~s. 394.455(47)~~.

Section 8. Subsection (7) of section 744.2007, Florida Statutes, is amended to read:

744.2007 Powers and duties.—

(7) A public guardian may not commit a ward to a treatment facility, as defined in s. 394.455(48) ~~s. 394.455(47)~~, without an involuntary placement proceeding as provided by law.

Section 9. This act shall take effect July 1, 2018.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Finance and Tax
Appropriations Subcommittee on General Government
Children, Families, and Elder Affairs
Communications, Energy, and Public Utilities
Community Affairs

JOINT COMMITTEE:
Joint Administrative Procedures Committee

SENATOR DAPHNE CAMPBELL
38th District

October 30, 2017

Chair Dana Young
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chair Young,

I respectfully request that SB 112 Involuntary Examinations under the Baker Act be placed on the next available committee agenda. The purpose of this bill is to add advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) to the list of health care practitioners who may initiate an involuntary mental examination of a person under the Florida Mental Health Act, also known as the Baker Act. During the 2017 session, this bill passed this committee and the floor of the House however, it died in Rules.

Sincerely,

Campbell

REPLY TO:
❒ 633 N.E. 167th Street, Suite 1101, North Miami Beach, Florida 33162 (305) 493-6009
❒ 218 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5038

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)

1/23/2018
Meeting Date

SB 112
Bill Number (if applicable)

Topic Incidentary Exam Under the Baker Act

Amendment Barcode (if applicable)

Name Chris Floyd

Job Title Consultant

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Street

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City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Association of Nurse Practitioners

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)

January 23, 2018
Meeting Date

112
Bill Number (if applicable)

Topic Baker Act

Amendment Barcode (if applicable)

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Academy of Physician Assistants

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)

1-23-18
Meeting Date

1112
Bill Number (if applicable)

Topic SB 112 Baker Act / Parent Involvement

Amendment Barcode (if applicable)

Name Wendy Birket

Job Title Legislative Chair, Orange County Council of PTAs

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Orlando FL 32835
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Speaking: ☑ For ☐ Against ☐ Information

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

Representing Orange County Council of PTA / PTSAs

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)

1-23-18
Meeting Date

SB 112
Bill Number (if applicable)

Topic BAKER ACT Initiate

Amendment Barcode (if applicable)

Name ALLISON CARVAJAL

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Nurse Practitioner Network

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)

1-23-18
Meeting Date

SB 112
Bill Number (if applicable)

Topic Involuntary Examinations - Baker Act

Amendment Barcode (if applicable)

Name John Bryant

Job Title Asst. Secretary DCF

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Tallahassee
City *State* *Zip*

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Email John.Bryant@myFLFamilies.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

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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)

1.23.18
Meeting Date

112
Bill Number (if applicable)

Topic Involuntary Examinations under the Baker Act

Amendment Barcode (if applicable)

Name Barney Bishop

Job Title CEO

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Street

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City *State* *Zip*

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Smart Justice Alliance

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:	SB 162
INTRODUCER:	Senators Steube and Mayfield
SUBJECT:	Payment of Health Care Claims
DATE:	January 22, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Favorable**
2.	Lloyd	Stovall	HP	**Favorable**
3.			RC	

I. Summary:

SB 162 prohibits health insurers and health maintenance organizations (HMOs) from retroactively denying a claim at any time if the insurer or HMO verified the eligibility of an insured or subscriber at the time of treatment and provided an authorization number. The provisions of the bill apply to policies or contracts issued or renewed on or after January 1, 2019. Medicaid managed care plans are exempt from the provisions of the bill. Currently, a health insurer or HMO may retroactively deny a claim because of an insured's ineligibility up to 1 year after the payment of the claim. Under existing law, the patient is responsible for those claims, which potentially exposes the physician to financial risk if the patient does not pay the claims.

The bill has an estimated negative fiscal impact of $166,347 on the fully-insured HMO plan in the State Group Insurance.

II. Present Situation:

Denial of Health Insurance Claims

According to the American Medical Association (AMA), health care providers lose a significant amount of administrative time and revenue due to denied claims. In 2013, the AMA estimated that more than $43 billion in savings could have been realized since 2010 if commercial insurers had consistently paid claims correctly.[1]

Coverage for medical services can be denied before or after the service has been provided, through denial of preauthorization requests, through denial of claims for payment, or a retroactive denial of payment. As a condition for coverage of some services, providers or insureds are required to request authorization prior to providing or receiving the service. The full

[1] Amednews.com, *Claims Analysis Shows Doctors the Way to Fight Insurer Denials* (July 15, 2013), http://www.amednews.com/article/20130715/business/130719992/5/ (last visited Jan. 17, 2018).

claim or certain lines of the claim may be denied, such as a surgery with charges for multiple procedures and supplies.

There are many possible reasons for claim denials. Claims may be denied due to an incorrect diagnosis code, incomplete claim submission, or the submission of a duplicate claim. Eligibility issues can cause claims to be denied. For example, a claim may be submitted for a service provided prior to an individual's effective date of coverage or after it has been terminated. Finally, claim denials can occur when a determination is made that the service provided was not covered or it was not medically necessary. Under state and federal laws, denied claims may be appealed.

After an insurer or HMO pays a claim, the insurer or HMO may conduct a claims audit to verify claims were paid appropriately and accurately. Such an audit can be triggered by a variety of reasons. Some of these situations include regulators establishing new billing guidelines; the provider making significant changes to the original bill, such as the diagnosis of the patient; the plan is notified that the enrollee's coverage is terminated due to non-payment of premiums; or the plan is notified that the enrollee has other health insurance coverage. After the audit, an insurer or HMO may retrospectively deny a claim for a preauthorized service and try to recoup the payment from the provider. Reasons for the retroactive denial may include fraud, submission of incomplete or inaccurate information; nonpayment of premiums; exhaustion of benefits; coordination of benefits; or if the individual was not enrolled or eligible for coverage at the time services were rendered. As a result, an insurer or HMO may try to recoup payment from a provider by retroactively denying a previously paid claim.

Group Health Plans Retroactive Termination of Coverage

Retroactive termination of insurance coverage to an earlier date due to an employee's discharge is an increasing problem for some providers and consumers. Some plans may allow an employer to cancel coverage of an employee retroactively more than 90 days post termination. Other plans will accept retroactive terminations for up to the preceding 3 months, if the plan has not paid any claims for the enrollee during that period. If claims have been paid within the previous 60 days, the coverage termination date may be established as of the end of the month in which services were rendered.

When a provider is notified of a retroactive termination, the provider may have already verified that the patient was covered, rendered services in reliance and expectation of payment, and even received payment. Retroactive terminations often result in the provider or the consumer bearing the loss, despite the verified eligibility.

Federal Subsidized Individual Policies or Contracts and Grace Periods

The federal Patient Protection and Affordable Care Act (PPACA)[2] guarantees access to coverage and mandates certain essential health benefits and other requirements. To address affordability issues, federal premium tax credits and cost-sharing subsidies are available to assist eligible low and moderate-income individuals to purchase qualified health plans (QHPs) on a state or federal

[2] The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended several provisions of the PPACA, was enacted on March 30, 2010.

exchange.[3] A QHP is a health plan that has been certified by the federal Health Insurance Marketplace, provides essential health benefits, follows established limits on cost sharing (such as deductibles, copayments, and out of pocket maximums), and meets other requirements of the PPACA known as "minimum essential coverage."[4] QHPs can be a health plan bought in the federal Health Insurance Marketplace, but it can also be an individual health plan purchased outside of the marketplace, an employer-based plan, a Medicare Part A or C plan, a Children's Health Insurance Plan (CHIP), and most student health plans.[5]

During the open enrollment period which ended January 31, 2018, 1,588,736 Floridians (or 90 percent of the state's total) who enrolled through the federal exchange received premium tax credits, cost sharing reductions or both.[6] The average premium rate during the 2017 Open Enrollment Period averaged $442 per member per month with advance premium tax credits and cost sharing reductions per person close to $360 per individual leaving a remaining premium responsibility to the enrollee of approximately $84 per month.[7]

Under PPACA, insurers and HMOs must provide a grace period[8] of at least three consecutive months[9] before cancelling the policy or contract of a federally subsidized enrollee who is delinquent if the enrollee previously paid one-month's premium. During the grace period, the insurer must pay all appropriate claims for services provided during the first month of the grace period. For the second and third months, an insurer may pend claims. Issuers must notify providers that may be affected that an enrollee has lapsed in his or her payment of premiums and there is a possibility the issuer may deny the payment of claims incurred during the second and third months.[10]

If the enrollee resolves all outstanding premium payments by the end of the grace period, then the pended claims would be paid as appropriate. If not, the claims for the second and third month would be denied. If coverage is terminated, the termination date is the last day of the first month of the grace period and the insurer may not recoup any payment for claims made during the first

[3] In general, individuals and families may be eligible for the premium tax credit if their household income for the year is at least 100 percent but no more than 400 percent of the federal poverty line for their family size. For residents of one of the 48 contiguous states or Washington, D.C., the following illustrates when household income would be at least 100 percent but no more than 400 percent of the federal poverty line in computing your premium tax credit for 2016: $11,770 (100 percent) up to $47,080 (400 percent) for one individual; $15,930 (100 percent) up to $63,720 (400 percent) for a family of two; and $24,250 (100 percent) up to $97,000 (400 percent) for a family of four. ASPE Research Brief, *Health Plan Choice and Premiums in the 2017 Health Insurance Marketplace*, (Oct. 24, 2016), https://www.irs.gov/affordable-care-act/individuals-and-families/questions-and-answers-on-the-premium-tax-credit (last viewed Jan. 17, 2018).

[4] U.S. Department of Health and Human Services, Healthcare.gov, *Qualified Health Plan*, https://www.healthcare.gov/glossary/qualified-health-plan/ (last visited Jan. 17, 2018).

[5] U.S. Department of Health and Human Services, Healthcare.gov, *Types of health insurance that count as coverage*, https://www.healthcare.gov/fees/plans-that-count-as-coverage/ (last visited Jan. 17, 2018).

[6] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *2017 Marketplace Open Enrollment Public Use Files – 2017 OEP State-Level Public Use File* (May 11, 2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Marketplace-Products/Plan_Selection_ZIP.html (last visited Jan. 17, 2018).

[7] Id.

[8] Example of grace period: Premium is not paid in May. Premium payments are made in June and July. Grace period would end July 31. Coverage would be cancelled retroactively to the last day of May. See https://www.healthcare.gov/apply-and-enroll/health-insurance-grace-period/ (last viewed Jan. 17, 2018).

[9] 45 C.F.R. s. 155.430.

[10] 45 C.F.R. s. 156.270.

month of the grace period. At the end of the grace period, the provider may seek payment for the medical services the insurer denied for months two and three. Providers note that it will be extremely difficult to obtain direct payment from patients receiving federal subsidies given their low or moderate income.[11] According to a 2014 survey, 48 percent of the providers not participating with any PPACA exchange products cited concerns about assuming financial liability during the grace period as a reason for their decision.[12]

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[13] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.[14]

Florida's Prompt Payment Laws

Florida's prompt payment laws govern payment of provider claims submitted to insurers and HMOs, including Medicaid managed care plans in accordance with ss. 627.6131 and 641.3155, F.S., respectively.[15] These provisions delineate the rights and responsibilities of insurers, HMOs, and providers for the payment of claims. An insurer or HMO 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., (physicians), ch. 459, F.S., (osteopaths), 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.[16] 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.

Grace Periods

The federal regulation governing grace periods for federally subsidized policies or contracts does not affect policies or contracts of individuals who are not enrolled in an exchange QHP or who are enrolled in an exchange QHP and do not receive a subsidy. The grace period for these individual policies or contracts remains at the duration required under Florida law,[17] which varies

[11] American Hospital Association, *et al*, Letter to Ms. Tavenner, Centers for Medicare and Medicaid Services (Aug. 15, 2013), https://www.aamc.org/download/352602/data/coalitionletteronnonpaymentofpremiums-noncoverageissue.pdf (last visited Jan. 17, 2018).
[12] Tracy Gnadinger, *Health Policy Brief: The Ninety-Day Grace Period*, (Oct. 16, 2014) http://healthaffairs.org/blog/2014/10/17/health-policy-brief-the-ninety-day-grace-period/ (last viewed Jan. 17, 2018).
[13] Section 20.121(3), F.S.
[14] Section 641.21(1), F.S.
[15] 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.
[16] Section 627.6131, F.S., and 641.3155, F.S., provide exceptions to this time limit in cases relating to fraud.
[17] Sections 627.608 and 641.31(15), F.S. The grace period of an individual policy must be a minimum of 7 days for weekly premium; 10 days for a monthly premium; and 31 days for all other periods. The grace period of a HMO contract must be at least 10 days. For group policies, s. 627.6645, F.S., requires that if cancellation is due to nonpayment of premium, the insurer may not retroactively cancel the policy to a date prior to the date that notice of cancellation was provided to the policyholder

by the duration of the premium payment interval. During the grace period, the policy or contract stays in force, thus the insurer or HMO must affirm that an individual is insured, even when the payment is late and remains unpaid during the grace period. If the insurer or HMO does not receive the full payment of the premium by the end of the grace period, coverage terminates as of the grace period start date and the insurer or HMO may retroactively deny any claims incurred during the grace period.

Division of State Group Insurance

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group health insurance program under a cafeteria plan consistent with section 125, Internal Revenue Code. To administer the state group health insurance program, DMS contracts with third party administrators for self-insured health plans and insured health maintenance organizations (HMOs), as well as a pharmacy benefits manager for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.

Florida's Statewide Medicaid Managed Care Program

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, the Agency for Health Care Administration (AHCA) oversees the Medicaid program. The Department of Children and Families (DCF) conducts Medicaid eligibility determinations.[18] The Statewide Medicaid Managed Care (SMMC) program[19] has two components: the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) program. The AHCA contracts with managed care plans to provide services to eligible recipients. The MMA program covers medical and acute care services for plan enrollees. Most Florida Medicaid recipients who are eligible for the full array of Florida Medicaid benefits are enrolled in an MMA plan. The LTC program covers nursing facility and home and community-based services to eligible adults.

Medicaid managed care plans are responsible for paying claims in accordance with federal and state law and contractual requirements. Florida Medicaid managed care plans are required to comply with s. 641.3155, F.S.,[20] which allows HMOs to deny a claim retroactively because of an insured or subscriber ineligibility up to one year after the date of payment of the claim. After paying claims pursuant with the deadlines in s. 641.3155, F.S., an HMO may audit claims to verify payment was appropriate and accurate. As a result, an HMO may try to recoup payment from a provider for claims paid in error. It may do this by reducing payments currently owed the provider, withholding future payments, or otherwise requiring a refund from the provider.

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unless the insurer mails notice of cancellation to the policyholder prior to 45 days after the date the premium was due. Such notice must be mailed to the policyholder's last address as shown by the records of the insurer and may provide for a retroactive date of cancellation no earlier than midnight of the date that the premium was due. See 45 C.F.R. s. 155.735 for provisions relating to the termination of Small Business Health Options Program (SHOP) enrollment or coverage obtained through an exchange.

[18]The Social Security Administration makes determination for recipients of Supplemental Security Income. See http://www.myflfamilies.com/service-programs/access-florida-food-medical-assistance-cash/medicaid (last viewed Jan. 17, 2018).

[19] Part IV of ch. 409, F.S.

[20] Section 409.967(2)(j), F.S.

III. Effect of Proposed Changes:

Sections 1 and 2 of the bill amend ss. 627.6131 and 641.3155, F.S., respectively, to prohibit a health insurer or an HMO from retroactively denying a claim because of an insured's ineligibility at any time if the health insurer or HMO verified the eligibility of an insured at the time of treatment and provided an authorization for payment. The provisions of Sections 1 and 2 apply to policies or contracts issued or renewed on or after January 1, 2019. Section 2 provides that the provisions of the bill do not apply to Medicaid managed care plans.

Currently, ss. 627.608, F.S., and 641.31(15), F.S., require individual health insurance policies and all HMO contracts, excluding federally subsidized policies or contracts, to have a grace period of not less than 7 days and up to 31 days. If any required premium is not paid on or before the due date, it may be paid during the following grace period. During the grace period, the contract stays in force. If full payment of the premium is not received by the end of the grace period, coverage terminates as of the grace period start date, and the insurer or HMO will retroactively deny any claims incurred during the grace period. For a group policy, if cancellation is due to nonpayment of premium, the insurer may not retroactively cancel the policy to a date prior to the date that notice of cancellation was provided to the policyholder unless the insurer mails notice of cancellation to the policyholder prior to 45 days after the date the premium was due. Such notice must be mailed to the policyholder's last address as shown by the records of the insurer and may provide for a retroactive date of cancellation no earlier than midnight of the date that the premium was due. [21]

The bill requires HMOs and insurers to pay claims incurred during the grace period and any other time for policies or contracts that were not eligible for the federal premium tax credit, if the provider verified the insured as eligible at the time of treatment and was provided an authorization number by the insurer or HMO. Currently ss. 627.6131, F.S., and 641.3155, F.S., limit the ability of a HMO or insurer to deny a claim retroactively because of insured ineligibility to one year after the date of payment of the claim.

Section 3 provides this act takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[21] Section 627.6645, F.S.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Eliminating the ability of a health insurer or HMO to recoup the payment of a claim for an authorized treatment for an individual previously deemed eligible will prevent unanticipated additional financial obligations to a patient and potential unexpected loss of revenues to a provider. This will simultaneously impose additional financial liability on a health insurer or HMO that provides authorization for an individual who is later deemed ineligible for coverage.

Federal regulations govern the grace period and payment of claims of individuals receiving federally subsidized products on the exchange. This bill would not apply to such claims.

The provisions of the bill would not apply to ERISA (Federal Employee Retirement Income Security Act of 1974)[22] self-insured plans. ERISA preempts the regulation of such plans by the state.

C. Government Sector Impact:

DMS/Division of State Group Insurance. According to DMS, Capital Health Plan, the only fully insured plan, would incur an estimated negative fiscal impact of $166,347 on an annual basis. The department's calculation was based on a fiscal impact of $0.23 per member. The bill would not affect the self-funded insurance plans.[23]

Florida's Medicaid Program. Medicaid managed care plans are exempt from the provisions of the bill.

Office of Insurance Regulation. None.[24]

VI. Technical Deficiencies:

None.

VII. Related Issues:

Internally, an insurer may understand an authorization to be a pre-service approval for certain benefits or services, a voluntary pre-certification request, or a pre-admission certification. Not all

[22] 29 U.S.C. 1001 et seq. (1974).
[23] Department of Management Services, *Senate Bill 162 Analysis* (Nov. 13, 2017) (on file with the Senate Committee on Health Policy).
[24] Office of Insurance Regulation, *Senate Bill 162 Analysis* (Sep. 29, 2017) (on file with the Senate Committee on Health Policy).

benefits or procedures require prior authorization. A plan may offer a reference number for the call. An insured, member, or provider may consider this their authorization number.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 627.6131, and 641.3155.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Steube

23-00002-18 2018162__

A bill to be entitled

An act relating to the payment of health care claims; amending s. 627.6131, F.S.; prohibiting a health insurer from retroactively denying a claim under specified circumstances; providing applicability; amending s. 641.3155, F.S.; prohibiting a health maintenance organization from retroactively denying a claim under specified circumstances; providing applicability; providing an effective date.

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

Section 1. Subsection (11) of section 627.6131, Florida Statutes, is amended to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim because of insured ineligibility:

(a) At any time, if the health insurer verified the eligibility of an insured at the time of treatment and provided an authorization number. This paragraph applies to policies entered into or renewed on or after January 1, 2019.

(b) More than 1 year after the date of payment of the claim.

Section 2. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) At any time, if the health maintenance organization

verified the eligibility of a subscriber at the time of treatment and provided an authorization number. This paragraph applies to contracts entered into or renewed on or after January 1, 2019. This paragraph does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

(b) More than 1 year after the date of payment of the claim.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

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

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GREG STEUBE
23rd District

December 5, 2017

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

Dear Senator Young,

I am writing this letter because my bill, SB 162 – Payment of Health Care Claims, has been referred to the Senate Health Policy Committee. I am respectfully requesting that you place the bill on your committee's calendar for the next committee week.

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

Very respectfully yours,

W. Gregory Steube, District 23

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

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

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

SB 162
Bill Number (if applicable)

Topic Payment of Healthcare Claims

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing American College of Physicians

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

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1/23/18
Meeting Date

162
Bill Number (if applicable)

Topic Payment of HC Claims

Amendment Barcode (if applicable)

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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 ASSOC.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

9/2 Knott Health Policy

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

SB 162
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Payment of Health Care Claims

Name Dorene Barker

Job Title Associate ~~State~~ Director

Address 200 W. College Ave, Suite 304
Street

Phone 850 228-6387

City *State* *Zip*

Email dobarker@aarp.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP FL

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)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-23-2018
Meeting Date

SB 162
Bill Number (if applicable)

Topic Retroactive Denial

Amendment Barcode (if applicable)

Name Marnie George

Job Title Sr. Advisor, Buchanan Ingersoll & Rooney

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Street

Phone 850 510-8866

Tallahassee FL 32303
City *State* *Zip*

Email marnie.george@bipc.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Chapter, American College of Cardiology

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)

1/23
Meeting Date

162
Bill Number (if applicable)

Topic Payment of HealthCare Claims

Amendment Barcode (if applicable)

Name Chris Hansen

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Email chansen@ballardfl.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Podiatric Medical Assoc.

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)

1/23/18
Meeting Date

SB 162
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Payment of Health Care Claims

Name JoeAnne Hart

Job Title Chief Legislative Officer

Address 118 East Jefferson St
Street

Tall, FL 32301
City *State* *Zip*

Phone (850) 224-1089

Email jahart@floridadentalorg

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

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

Representing Florida Dental Association

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

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

SB 162
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title _____

Address 1430 Piedmont Dr. E.
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850 251-2439

Email jscott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida 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.

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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)

1-23-18
Meeting Date

SB162
Bill Number (if applicable)

Topic PAYMENT OF HEALTH CLAIMS

Amendment Barcode (if applicable)

Name JACK HEBERT

Job Title

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Street

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CLEARWATER FL 33762
City *State* *Zip*

Email JACK@FCACHIRO.ORG

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FLORIDA CHIROPRACTIC ASSN

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

SB 162
SB 162
Bill Number (if applicable)

Topic Health Care Claims

Amendment Barcode (if applicable)

Name Brewster Bevis

Job Title Senior VP

Address 516 W Adams St
Street

Phone 224-7173

TLH FL 32301
City *State* *Zip*

Email bbevis@aif.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Associated Industries of Florida

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 164
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Mammography
DATE:	January 23, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 162 requires facilities that perform mammography to send a patient a summary report that includes specific information describing the patient's mammogram and to include a statutorily prescribed notice if the patient has heterogeneously or extremely dense breasts. The prescribed notice must inform the patient that dense breast tissue can make it more difficult to determine some abnormalities and may be associated with an increased risk of breast cancer. The notice must also include a statement that puts the patient on notice that additional screenings may not be covered by insurance.

The bill provides that a standard of care or duty has not been created beyond the duty to provide the notice and that the notice is not inconsistent with federal law. These mammography notice provisions sunset June 30, 2023.

The bill is effective July 1, 2018.

II. Present Situation:

Breast cancer is one of the most common cancers in women, second only to skin cancer.[1] Although breast cancer can occur in both men and women, it is rare in men. In 2014, Florida

[1] National Cancer Institute, *Breast Cancer-Patient Version (Overview)*, https://www.cancer.gov/types/breast (last visited Jan. 18, 2018).

recorded 2,845 breast cancer deaths out of 42,551 total cancer deaths.[2] Additionally, 15,570 new breast cancer cases were reported out of 110,602 total new cancer cases.[3] No cases for men are recorded in the Florida Cancer Statewide Registry.

Some risk factors for breast cancer are related to life-style and others may include factors that individuals have no control over. Lifestyle or behavioral risk factors that may increase an individual's chances of developing breast cancer include:

- Drinking alcohol: Compared with non-drinkers, women who have two to five drinks daily, have about 1.5 times the risk of women who do not drink alcohol;
- Being overweight or obese after menopause: Having more fat tissue after menopause can raise estrogen levels and increase a woman's chances of getting breast cancer;
- Lacking physical activity: To reduce the risk, adults should get at least 150 minutes of moderate intensity or 75 minutes of vigorous intensity activity per week;
- Not having children: Women who have not had children or who had their first child after age 30 have a slightly higher breast cancer risk overall;
- Using birth control: Women using oral contraceptives have a slightly higher risk than women that never used them;
- Using hormone therapy after menopause: Use of combined hormone therapy after menopause increases the risk of breast cancer while the use of estrogen alone does not seem to increase the risk much; but if used long-term (more than 10 years), estrogen therapy has been found in some studies to increase the risk of ovarian and breast cancer; and
- Breastfeeding: May slightly lower breast cancer risk, especially if it is continued for one and a half years to two years.[4]

Along with these lifestyle or behavioral risk factors, there are some risk factors that are out of a person's control, such as:

- Being a woman;
- Getting older;
- Inheriting certain genes, BRCA1 and BRCA2;
- Having changes in other genes;
- Having a family history of breast cancer;
- Having a personal history of breast cancer;
- Being certain races and ethnicities;
- Having dense breast tissue;
- Having certain benign breast conditions;
- Starting menstruation before age 12;

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[2] Department of Health, Florida Cancer Statewide Registry, *Florida Annual Cancer Report: 2014 Incidence and Mortality (Table 16 – Number of Cancer Death by County, Florida 2014)*, https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2014/Table_No_T16_(2014).pdf, (last visited Jan. 18. 2018

[3] Department of Health, Florida Cancer Statewide Registry, *Florida Annual Cancer Report: 2014 Incidence and Mortality (Table 2 – Number of New Cancer Cases by County, Florida 2014)*, https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2014/Table_No_T2_(2014).pdf, (last visited Jan. 18, 2018).

[4] American Cancer Society, *Lifestyle-related Breast Cancer Risk Factors*, https://www.cancer.org/cancer/breast-cancer/risk-and-prevention/lifestyle-related-breast-cancer-risk-factors.html, (last visited Jan. 18, 2018).

- Going through menopause after age 55;
- Having radiation to your chest; and
- Having exposure to diethylstilbestrol (DES).[5]

As to the risk factor for dense breasts, almost half of all women between the ages of 40 and 74 (about 25 million nationally) are identified as having dense breasts.[6] Having "dense" breasts makes it more difficult to find and accurately identify breast cancers on a mammogram.[7] Breast density refers to ratio of fatty tissue to glandular tissue (milk ducts, milk glands, and supportive tissue) on a mammogram.[8] A dense breast has less fat than glandular and connective tissue.

Besides making a mammogram hard to read, dense breasts are also a risk factor for breast cancer.[9]

Mammography

A mammogram is an X-ray picture of the breast. Federal law and regulations specifically define mammography as a radiographic image of the breast produced through mammography.[10,11] Mammography serves as an important screening tool in the early detection of breast cancer and has the potential benefit to reduce the chance that a woman will die from breast cancer.

The United States Preventive Services Task Force (USPSTF)[12] recommends that women age 50 to 74 with no signs of breast cancer have a screening mammogram every two years and that women prior to age 50 should talk with their health care providers about the risks and benefits of whether to have mammograms and when to have them.[13] Approximately 74 percent of female Floridians age 40-plus and 78 percent from age 50 to 74 report having had a mammogram within the past two years, both percentages that either meet or exceed the national averages.[14] Current

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[5] American Cancer Society, *Breast Cancer Risk Factors You Cannot Change*, https://www.cancer.org/cancer/breast-cancer/risk-and-prevention/breast-cancer-risk-factors-you-cannot-change.html, (last visited Jan. 18, 2018).
[6] U.S. Preventive Services Task Force, *U.S. Preventive Services Task Force Issues Final Recommendations on Screening for Breast Cancer* (January 12, 2016), www.uspreventiveservicestaskforce.org/Home/GetFile/6/250/breastcanfinalrsbulletin/pdf, (last visited Jan. 18, 2018).
[7] *Id.*
[8] The American Society of Breast Surgeons Foundation, *Breast Density Legislation*, https://breast360.org/en/topics/2017/01/01/breast-density-legislation/ (last visited Jan. 19, 2018).
[9] *Supra* note 5.
[10] 42 U.S.C. §263b(5) and (6).
[11] 21 CFR 900.2(y).
[12] The United States Preventive Services Task Force (USPSTF) is an independent, volunteer group of national experts in prevention and evidence-based medicine. The Task Force makes evidence-based recommendations about clinical preventive services, such as screenings, counseling services, and preventive medicines. Each recommendation receives a letter grade (A, B, C, or D or an I statement) based on the strength of the evidence and the balance of the benefits and harms of the preventive service. The recommendation applies only to people who have no signs or symptoms of the specific disease or condition, and address only services offered in the primary care setting or services referred by a primary care physician. The USPSTF is administratively supported by the Agency for Healthcare Research and Quality (AHRQ) and must make an annual report to Congress. *See* https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf, (last visited Jan. 18, 2018).
[13] U.S. Preventive Services Task Force, *U.S. Preventive Services Task Force Issues Final Recommendations on Screening for Breast Cancer (January 12, 2016)*, www.uspreventiveservicestaskforce.org/Home/GetFile/6/250/breastcanfinalrsbulletin/pdf, (last visited Jan. 18, 2018).
[14] National Cancer Institute, Florida State Profile, https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=florida#t=1, (last visited Jan. 18, 2018).

evidence is insufficient to assess the benefits and harms of mammograms for women age 75 and older.[15]

The most serious harms to having a mammogram are either an over-diagnosis or a false diagnosis. With an over-diagnosis, a woman is diagnosed with a breast cancer that would not have been a harm to her health during her lifetime.[16] The over-diagnosed patient is still treated and may receive over-treatment, including surgery, chemotherapy, and radiation which can have serious side effects.[17] A false diagnosis of breast cancer can have a similar result to an over-diagnosis with unnecessary tests, follow-up procedures, anxiety, and the side effects of any treatments.[18]

Types of Mammograms

There are two types of mammograms. A screening mammogram is used to check for breast cancer in individuals who have no signs of cancer or symptoms of the disease.[19] With a screening mammogram, usually two or more X-ray pictures are taken of each breast. The second type of mammogram is a diagnostic mammogram which is used to check for breast cancer after a lump or another sign or symptom of cancer has been identified.[20] Besides a lump, other signs of breast cancer can include breast pain, thickening of the skin of the breast, nipple discharge, or a change in breast size or shape; however, these may also be signs of benign conditions.[21] Early detection of breast cancer with screening mammography means that treatment can be started earlier in the course of the disease, possibly before it has spread.

Other Detection Methods

Magnetic Resonance Imaging (MRI) is technology that uses magnets and radio waves to produce detailed cross-sectional images of breast tissue and other internal body structure. For breast MRIs, a special MRI machine is required which uses dedicated breast coils. Finding a facility with a dedicated breast MRI equipment may be difficult and if a biopsy is needed later, the patient may be required to find a different facility for that procedure.

The American Cancer Society (ACS) does not recommend the use of an MRI for routine breast cancer screenings, but if one is used it should be used in addition to, not instead of a screening mammogram.[22] The ACS suggests that women who are at high risk for breast cancer based on certain factors get both an MRI and a mammogram every year, including women who:

- Have a lifetime risk of breast cancer of about 20 to 25 percent greater, according to risk assessment tools that are based primarily on family history;
- Have a known BRCA1 or BRCA2 gene mutation;

[15] *Supra* note 13, at 4.
[16] *Id*.
[17] *Id*.
[18] *Id*.
[19] National Cancer Institute, *Breast Cancer Screening (Patient Version)*, https://www.cancer.gov/types/breast/patient/breast-screening-pdq, (last visited Jan. 18, 2018).
[20] *Id*.
[21] *Id*.
[22] American Cancer Society, *Breast Cancer Early Detection and Diagnosis*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html, (last visited Jan. 19, 2018).

- Have a first degree relative (parent, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves;
- Had radiation therapy to the chest when they were between the ages of 10 and 30 years; or
- Have Li-Fraumeni Syndrome, Cowden Syndrome, or Bannayan-Riley-Ruvalcaba Syndrome, or have first-degree relatives with one of these syndromes.[23]

A breast ultrasound is often used to examine a breast change that has been viewed on a mammogram. It is also useful for viewing breast changes that cannot be seen on a mammogram, but can be felt; or for changes in women with dense breast tissue.[24] Breast ultrasound uses soundwaves to make a computer picture of the inside of the breast. A gel that is put on the skin and a transducer which is moved across the skin is used to show the underlying tissue structure. The sound waves and echoes make a black and white picture on the screen.[25] An automated ultrasound is also an option as is the use of a second handheld transducer in order to get more pictures.

A newer technology for mammography are 3D screenings. The USPSTF has not made a recommendation on the use of 3D screening as a primary tool saying that it is not clear whether the technology will result in improved health, quality of life, or fewer deaths among women screened.[26]

The other methods, ultrasound and MRI, were also reviewed specifically by the USPSTF for how they could assist with screening women with dense breasts.[27] For all three alternative methods, the USPSTF graded the practices an "I" which means the Task Force concluded that the current evidence is inconclusive to assess the balance of benefits and harms of the service. The evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.[28]

Federal Regulations

The federal Mammography Quality Standards Act (MQSA)[29] contains requirements related to the accreditation and operation of mammography facilities. Such a facility is defined as a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including operating equipment to produce a mammogram, processing the mammogram, interpreting the initial mammogram, and maintaining the viewing conditions for that mammogram. The term does not include any facilities of the Department of Veteran Affairs.[30]

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[23] American Cancer Society. *Breast MRI Scans*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/breast-mri-scans.html (last visited Jan. 19, 2018).
[24] American Cancer Society, *Breast Ultrasound*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/breast-ultrasound.html (last viewed Jan. 19, 2018).
[25] *Id.*
[26] *Supra* note 13, at 3.
[27] *Supra* note 13, at 3.
[28] U.S. Preventive Services Task Force, *Grade Definitions* https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions, (Jan. 18, 2018).
[29] 42 U.S.C. § 263b.
[30] 21 C.F.R. § 900.1.

A certificate issued by the Food and Drug Administration is required for all mammography facilities, subject to the provisions of the MQSA. To obtain a certificate, facilities must meet various quality standards set forth in federal law and regulations, including the requirement to communicate mammography results to patients and health care providers.[31]

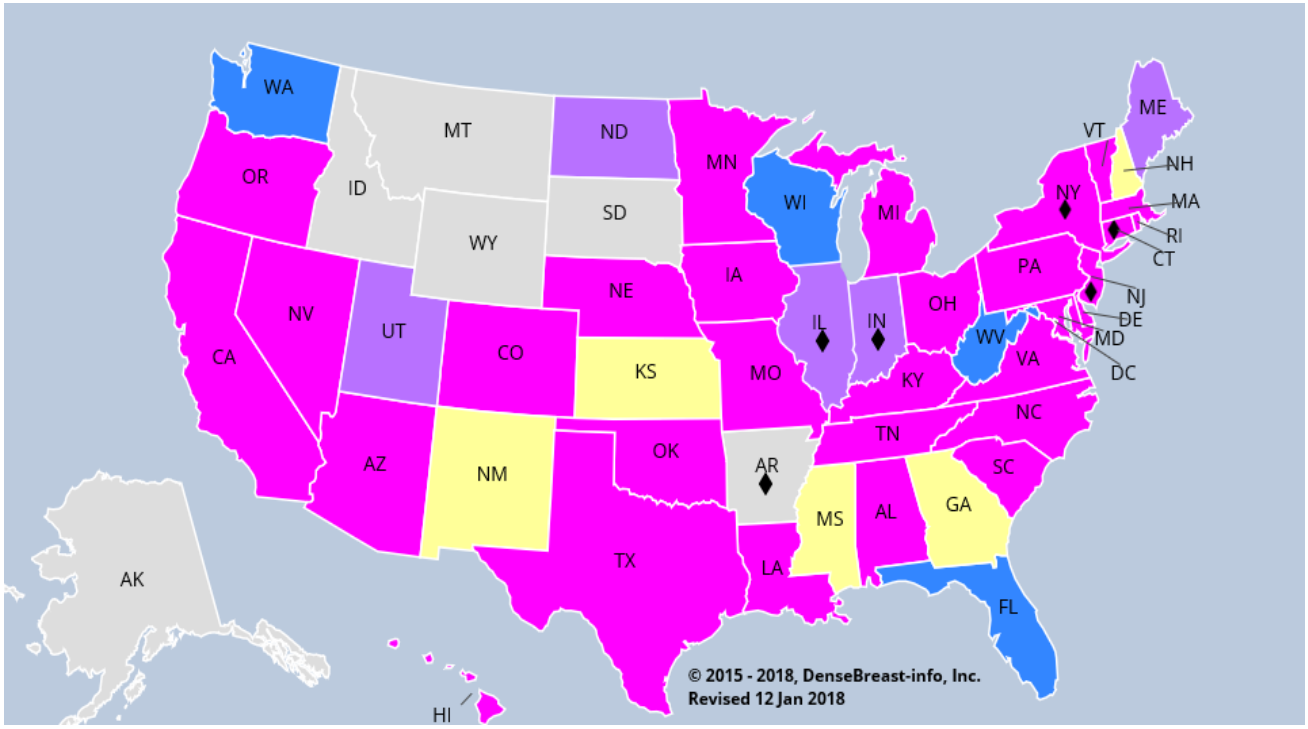
Mammogram facilities are required to send each patient a summary of the mammogram report written in lay term within 30 days of the mammographic examination. However, if the assessment is found to be "suspicious" or "highly suggestive" of malignancy, the facility is required to make reasonable attempts to reach the patient and the referring physician, if there is one, as soon as possible.[32] Neither the federal law nor the regulation requires the facility to include specific information about breast tissue density in the report summary sent to the patient or the referring physician.

Breast Density Notification in Other States

As of January 2018, there are 31 states with laws requiring that women be notified of their breast density and there are four additional states that recommend but do not require notification.[33] The components of those notification laws vary, but the intent of the notification is to give women who have dense breasts the necessary information to assist them with further action.[34] Most states' prescribed notices encourage women to talk with their health care providers about their results and to discuss the possible options available. Six states also require insurance coverage for comprehensive ultrasound screenings or other supplemental screenings for women identified with dense breasts.[35]

The map below shows which states currently require some density notification to patients and which states also require insurance coverage for supplemental screenings for dense breasts.[36]

[31] 21 C.F.R. § 900.12(c)(2) and (3).
[32] *Id.*
[33] *Supra* note 8.
[34] Marijke Vroomen Durning, Diagnostic Imaging, *Breast Density Notification Laws by State – Interactive Map* (June 12, 2017), http://www.diagnosticimaging.com/breast-imaging/breast-density-notification-laws-state-interactive-map, (last visited Jan. 19, 2018).
[35] Dense-breasts-info.org, *Legislation and Regulations – What is required*, http://densebreast-info.org/legislation.aspx, (Jan. 19, 2018).
[36] *Id.*



Map Legend

Some density notification required (30 states)

Effort for inform/education; notification not required

Active bill Inactive bill/no notification enacted

♦ State with insurance coverage (6 states)

Florida Insurance Mandates

Sections 627.6418, 627.6613, and 641.31095, F.S., contain mandates for accident or health insurance policies, group, blanket, or franchise accident or health insurance policies, and HMOs, respectively, to cover mammograms under certain parameters and requirements. Those parameters and requirements include coverage of a baseline mammogram and coverage of mammograms performed annually, biennially, or on a more frequent basis, depending on the age of the patient, recommendation of the patient's physician, and the patient's risk of breast cancer as determined by personal or family history.

These statutes also allow copayments and deductibles to be applied to mammogram services while requiring health insurers and HMOs to make mammogram coverage available, as part of the application for coverage and for an appropriate additional premium, without mammogram services being subject to copayments and deductibles.

All plans offered under the federal Marketplace and many other plans must offer breast cancer mammography screenings every one to two years for women over to age of 40 without charging a copayment or coinsurance, even if the patient has not met her yearly deductible.[37]

[37] *See* 45 C.F.R. §147.130, for the definition of coverage of preventive services by a group health plan, or a health insurance issuer offering group health insurance or individual insurance under the federal Patient Protection and Affordable Care Act

III. Effect of Proposed Changes:

Sections 1 and 2 re-locate the definition of mammography from s. 404.22, F.S., to s. 404.031, F.S.

Section 3 creates s. 402.221, F.S., to require each facility that performs mammography to send a summary of a patient's mammography report which meets federal requirements to each patient. The patient report must also include the following specific notice if the patient has heterogeneously or extremely dense breasts:

> Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in approximately 50 percent of women. The presence of dense breast tissue can make it more difficult to detect some abnormalities in the breast and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness. A report of your results was sent to your health care provider. Further recommendations may be added at the discretion of the interpreting radiologist. Please be aware that additional screening studies may not be covered by your insurance.

The bill specifies that no specific duty, standard of care, or other legal obligation is created beyond the duty to provide the notice required under this section. The notice that is required under this section is not inconsistent with the notice requirements of the federal Mammography Quality Standards Act or any regulations that are promulgated pursuant to that act.

If enacted, the provisions of this section of law are repealed effective June 30, 2023.

Section 4 provides an effective date of the act of July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

(Act). The Act requires coverage of those preventive services rated as an A or B in the current recommendations of the United States Preventive Services Task Force and that those services be covered without any cost sharing requirements (such as copayments, coinsurance, or deductibles).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The health care providers and screening facilities would likely incur one-time costs to modify the format of existing mammography reports to comply with the new requirements.

The demand for additional screenings may also put pressure on the health care delivery system for expanded access by those patients who receive a notice which alerts them to seek additional services or to contact their provider.[38]

C. Government Sector Impact:

Women with dense breast tissue who were unaware of this fact until receiving the proposed notice may seek additional health care screenings. To the extent that such patients are in the Medicaid program, these additional screenings could have a state and federal fiscal impact for the cost of the additional mammograms, the reading of those mammograms, and the follow-up health care visits, including biopsies and surgery.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 404.031 of the Florida Statutes
This bill creates section 402.221 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 January 23, 2018:
The CS deletes the requirement for the patient's summary report to include information describing the Breast Imaging-Reporting and Data System (BI-RADS) categories and the patient's individual BI-RADS score. The CS modifies the patient notice for dense breasts,

[38] The bill does not require insurers and health plans to pay for any follow-up screenings or services from the mammogram screenings.

including informing the patient that additional screenings may not be covered by the patient's insurance. The CS also specifies that the bill creates no additional standards, duties of care, or legal obligations beyond the required notice and finds the state notice is not inconsistent with a specific federal law. The CS adds a sunset date for these provisions of June 30, 2023.

B. Amendments:

None.

868704

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/23/2018	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 25 - 62

and insert:

(6) ~~(a) For purposes of this subsection, "mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.~~

~~(b)~~ All radiation machines used for mammography must:

(a) ~~shall~~ Meet the accreditation criteria of the American

868704

College of Radiology or similar criteria established by the department.

(b) ~~(c) All radiation machines used for mammography shall~~ Be specifically designed to perform mammography.

(c) ~~(d) All radiation machines used for mammography shall~~ Be used exclusively to perform mammography.

The department shall adopt rules to implement ~~the provisions of~~ this subsection.

Section 3. Section 402.221, Florida Statutes, is created to read:

402.221 Mammography reports.—Each facility that performs mammography shall send a summary of a patient's mammography report to each patient in accordance with 21 C.F.R. s. 900.12(c). If a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include the following notice:

"Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in approximately 50 percent of women. The presence of dense breast tissue can make it more difficult to detect some abnormalities in the breast and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness. A report of your results was sent to your health care provider. Further recommendations may be added at the discretion of the interpreting radiologist. Please be aware that additional screening studies may not be covered by your insurance."

868704

(1) This section does not create a duty, a standard of care, or another legal obligation beyond the duty to provide notice as required in this section.

(2) This section does not require a notice that is inconsistent with the federal Mammography Quality Standards Act or any regulation promulgated pursuant to that act.

(3) This section is repealed June 30, 2023.

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

And the title is amended as follows:

Delete line 8

and insert:

provided to each patient; providing applicability; providing for future repeal; providing an effective date.

By Senator Grimsley

26-00295-18 2018164__

A bill to be entitled

An act relating to mammography; amending s. 404.031, F.S.; defining the term "mammography"; amending s. 404.22, F.S.; conforming a change made by the act; creating s. 402.221, F.S.; requiring facilities performing mammography to include certain information in a summary of the mammography report which must be provided to each patient; providing an effective date.

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

Section 1. Present subsections (10) through (20) of section 404.031, Florida Statutes, are redesignated as subsections (11) through (21), respectively, and a new subsection (10) is added to that section, to read:

404.031 Definitions.—As used in this chapter, unless the context clearly indicates otherwise, the term:

(10) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.

Section 2. Subsection (6) of section 404.22, Florida Statutes, is amended to read:

404.22 Radiation machines and components; inspection.—

(6)(a) ~~For purposes of this subsection, "mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.~~

~~(b)~~ All radiation machines used for mammography shall meet

the accreditation criteria of the American College of Radiology or similar criteria established by the department.

(b) ~~(c)~~ All radiation machines used for mammography shall be specifically designed to perform mammography.

(c) ~~(d)~~ All radiation machines used for mammography shall be used exclusively to perform mammography.

The department shall adopt rules to implement ~~the provisions of~~ this subsection.

Section 3. Section 402.221, Florida Statutes, is created to read:

402.221 Mammography reports.—Each facility that performs mammography shall send a summary of a patient's mammography report to each patient in accordance with 21 C.F.R. s. 900.12(c).

(1) The summary must include information describing the Breast Imaging-Reporting and Data System (BI-RADS) categories established by the American College of Radiology and the patient's individual BI-RADS categorical score.

(2) If a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include the following notice:

"Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in 40 percent of women. The presence of dense breast tissue makes it more difficult to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information is given to you so that you will be informed when

you discuss your dense breast tissue and other breast cancer risk factors with your health care providers. Together, you can decide which screening options are right for you. A report of your results was sent to your primary physician."

Section 4. This act shall take effect July 1, 2018.

The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: December 11, 2017

I respectfully request that **Senate Bill #164**, relating to Mammography, and **Senate Bill #848**, relating to Remote Dispensing Site Pharmacies, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Denise Grimsley

Senator Denise Grimsley
Florida Senate, District 26

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/2018
Meeting Date

164
Bill Number (if applicable)

Topic MAMMOGRAPHY

Amendment Barcode (if applicable)

Name SLATER BAILISS

Job Title

Address 204 S. MONROE ST
Street

Phone 222 8900

TALLAHASSEE FL 32312
City *State* *Zip*

Email swb@cardenaspann.

Speaking: ☐ For ☐ Against ☐ Information

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

Representing HOLOGIC

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 954
INTRODUCER:	Senator Passidomo
SUBJECT:	State Employees' Prescription Drug Program
DATE:	January 22, 2018
REVISED:	01/23/18

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.			AGG	
3.			AP	

I. Summary:

SB 954 directs the Department of Management Services to implement formulary management cost-saving measures in the state employees' prescription drug program, including the inclusion and exclusion of prescription drugs. The cost-saving measures may not restrict access to the most clinically appropriate, clinically effective, lowest net-cost prescription drugs. The measures must also permit a specified prescribing practitioner to indicate when an excluded drug is medically necessary and cannot be substituted.

The bill removes a provision authorized in Chapter 99-255, Laws of Florida, which prohibits the implementation of a prior authorization program or a restricted formulary program on a non-HMO enrollee's access to certain prescription drugs.

Based on a January 1, 2019 implementation date, the bill has a projected positive fiscal impact to the state of $15.3 million in General Revenue and $11.7 million in trust funds in fiscal year 2018-2019. The annualized savings are projected at a total $54.1 million.

The effective date of the bill is January 1, 2019.

II. Present Situation:

Cafeteria Plans

A cafeteria plan is a separate written plan maintained by an employer for employees that allows participants to receive certain benefits on a pre-tax basis. Participants must be permitted to

choose among at least one taxable benefit (cash) and one qualified benefit.[1] Employer contributions are usually made through a salary reduction agreement between the employer and employee on a pre-tax basis.

A qualified benefit does not confer compensation and it is excluded from an employee's gross income. Qualified benefits include benefits such as:

- Accident and health benefits;
- Adoption assistance;
- Dependent care assistance;
- Group life insurance coverage; and
- Health savings account, including distributions to pay long-term care services.[2]

In general, to qualify for the cafeteria plan as an employee, the employee must have had at least 1,000 hours of service in the prior year.[3] An employer may elect to exclude employees under the age of 21, those who have been in service for less than one year, those covered under a collective bargaining agreement with a cafeteria plan, or who are non-resident aliens working inside the United States.[4]

State Group Health Insurance Program Background

The State Group Health Insurance Program (SGI) is created by s. 110.123, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services. (DMS). The state group health insurance plan is administered as a cafeteria plan consistent with Section 125, Internal Revenue Code.[5]

The SGI program is an optional benefit for all state employees, including all state agencies, state universities, the court system, and the Legislature. The program includes health, life, dental, vision, disability, and other supplemental insurance benefits. The SGI program typically makes program changes on a plan year basis, January 1 through December 31. Benefit changes are subject to approval of the Legislature.

The health insurance benefit for active employees has premium rates for single, spouse program,[6] or family coverage regardless of plan selection. The state contributes approximately 92 percent of the total annual premium for active employees, $1.87 billion out of a total premium of $2.04 billion for active employees during fiscal year 2017-2018.[7]

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[1] Internal Revenue Service, *FAQs for Government Entities regarding Cafeteria Plans* (last updated Nov. 11, 2017) https://www.irs.gov/government-entities/federal-state-local-governments/faqs-for-government-entities-regarding-cafeteria-plans (last visited Jan. 18, 2018).
[2] *Id*.
[3] 26 U.S.C. §125(4)(A).
[4] 26 U.S.C. §125(4)(B).
[5] Department of Management Services, *2018 Plan Year Benefits Guide*, pg. 9, https://www.mybenefits.myflorida.com/content/download/132894/826709/2018_102417_Benefits_Guide.pdf (last visited Jan. 19, 2018).
[6] The Spouse program provides discounted rates for family coverage when both spouses work for the state.
[7] Florida Legislature, Office of Economic and Demographic Research, Self-Insurance Estimating Conference, *State Employees' Group Health Self-Insurance Trust Fund – Report on the Financial Outlook for Fiscal Years Ending June 30,*

Health Plan Options

The SGI provides employees with two types of health plans: health maintenance organizations (HMOs) and preferred provider organizations (PPOs). The PPO is the statewide, self-insured health plan administered by Florida Blue, whose current contract is effective from the 2015 through 2018 plan years. The administrator is responsible for processing health claims, providing access to a Preferred Provider Care Network, managing customer service, utilization review, and case management functions. The standard health maintenance organization (HMO) plan is an insurance arrangement in which the state has contracted with multiple statewide and regional HMOs.[8]

Prior to the 2011 plan year, the participating HMOs were fully insured, meaning the HMOs assumed all financial risk for the covered benefits. During the 2010 session, the Legislature enacted s. 110.12302, F.S., which directed DMS to require costing options for both fully insured and self-insured plan designs for the 2012 plan year and beyond for HMOs.[9] The department included these costing options in its *Invitation to Negotiate* to HMOs for plan years beginning January 1, 2012.[10]

Currently, there are four vendors participating who were awarded contracts with initial terms of three years (January 1, 2018 through December 2020) with annual renewal options for up to three additional years.[11] The number of HMO vendors per county was limited to one. Three of the HMOs vendors were contracted under a self-insured financial model and two HMOs were contracted under a fully-insured model.[12] Approximately 52 percent of all participants in the plan are enrolled in HMO plans.[13]

The SGI program also includes two high deductible health plans (HDHPs) with health savings accounts (HSAs). The Health Investor PPO is the statewide HDHP with the integrated HSA. The plan is administered by Florida Blue.[14] The Health Investor HMO Plan is an HDHP with an integrated HSA for which employees can combine with one of several state or regional HMOs.[15]

2018 through June 30, 2023, adopted December 13, 2017, p 6, *available at* http://edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf (last visited Jan. 19, 2018).

[8] Department of Management Services, MyBenefits, *2018 Health Plan Options,* https://www.mybenefits.myflorida.com/health/2018_benefit_options/2018_health_plan_options (last visited Jan 22, 2018). The current contracted HMOs are: Aetna, AvMed, Capital Health Plan, and United Healthcare.

[9] *See* Chapter 2010-150, s. 3, Laws of Fla.

[10] Department of Management Services, *Invitation to Negotiate, No.: DMS 10/11-011*, pg. 7, http://www.myflorida.com/apps/vbs/adoc/F4568_HMORFPWordWrap_Final.pdf (last visited Jan. 19, 2018).

[11] State Employees' Group Health Self-Insurance Trust Fund, *Report on Financial Outlook for the Fiscal Years Ending June 30, 2018 through June 30, 2023,* Adopted at the August 3, 2017 Self-Insurance Estimating Conference, pg. 1, http://edr.state.fl.us/Content/conferences/healthinsurance/archives/170803healthins.pdf (last visited Jan. 19, 2018).

[12] *Id.*

[13] *Id.*

[14] Department of Management Services, *MyBenefits, Health Insurance Plans,* https://www.mybenefits.myflorida.com/health/health_insurance_plans (last visited Jan. 19, 2018).

[15] Department of Management Services, State Group Insurance, *2018 Plan Year – 2018 Benefits Guide,* https://www.mybenefits.myflorida.com/content/download/132894/826709/2018_102417_Benefits_Guide.pdf (last visited Jan. 19, 2018).

Flexible Spending and Savings Accounts

A flexible spending account (FSA) is also a form of a cafeteria plan benefit funded through salary reductions that reimburses employees for qualified expenses. An FSA may be created for dependent care assistance, adoption assistance, and medical care reimbursement.[16] Pre-tax dollars are deposited into an FSA account through payroll deduction. The employee uses either a prepaid card or submits claims for reimbursement for eligible expenses.
Florida offers its employees four types of accounts:

- Health Care Flexible Spending Accounts (FSA);
- Limited Purpose Flexible Spending Accounts (FSA);
- Dependent Care Flexible Spending Accounts; and
- Health Savings Accounts (HSAs).

The limited purpose flexible spending account and health savings account (HSA) require the employee to pair the account with a high deductible/health savings account plan (HDHP/HSA).[17]

Three of these four savings and spending accounts (Healthcare FSA, Limited purpose FAS, and Health Savings Account) allow the employee to use pre-tax dollars for eligible medical, prescription, dental, or vision care services that are not otherwise covered by the employee's insurance plan.[18] The chart below compares the different savings and spending accounts for health benefits with the High Deductible Health Plans.

The high deductible health plan HMO has the same in-network requirements as the standard HMO; however, the member must meet a higher deductible before anything except certain preventive services are covered. Once the member has met the deductible, the member is responsible for coinsurance for all services and prescription drugs which is 20 percent in-network and 40 percent out-of-network, plus the cost difference between the charge and out-of-network allowance.[19]

Additionally, employers are permitted, at their option, to amend their cafeteria plans, to allow employees to carryover up to $500 of any unused amount under a Healthcare Flexible Spending Account (FSA) to the following plan year. Healthcare FSA funds can be used to pay for healthcare expenses not covered by insurance such as contact lenses, deductibles, dental treatment, or a private hospital room.[20] The carry-over amount does not count against the annual

[16] *Id.*
[17] Department of Management Services, MyBenefits, *Savings and Spending Accounts,* https://www.mybenefits.myflorida.com/health/savings_and_spending_accounts (last visited Jan. 19, 2018).
[18] Department of Management Services, *My Benefits – Savings and Spending Accounts,* https://www.mybenefits.myflorida.com/health/savings_and_spending_accounts (last visited Jan. 19, 2018).
[19] Department of Management Services, *Health Plan Summary Comparison Chart,* p 19, https://www.mybenefits.myflorida.com/content/download/132894/826709/2018_102417_Benefits_Guide.pdf (last visited Jan 19, 2018).
[20] Chard Snyder Benefit Solutions, *2018 Savings and Spending Accounts Guide,* https://www.mybenefits.myflorida.com/content/download/134963/849052/SOF_2018_S&SA_Guide_FINAL_VERSION_-_APPROVED_10-6.pdf (last visited Jan. 19, 2018).

salary reduction limit.[21] For those age 55 and over, participants are permitted to make annual "catch up" contributions of up to $1,000.[22]

State Employee Health Care Options- 2018[23]					
	HDHP (HMO or PPO)		Health Savings Account (HSA	Limited Purpose FSA	Healthcare FSA
	Deductible (Minimum)	Out of Pocket (Maximum)	Contribution (Maximum)	Contribution (Maximum)	Contribution (Maximum)
Self	$1,350	$3,000 (HMO) $4,350 (PPO)	$3,450	$2,650	$2,650
Family	$2,700	$6,000 (HMO) $8,700 (PPO)	$6,900	$2,650	$2,650
Other Plan Required?	Pair with HSA	Pair with HSA	Pair with HDHP	Pair with HDHP	NA
Catch-Up for 55+?	No	No	$1,000/year	No	No
Carryover?	NA	NA	Rolls over every year; can take with you when you leave	$500	$500

Current State Prescription Drug Plan

The DMS contracts with third party administrators for self-insured health plans, insured health maintenance organizations (HMOs), and a pharmacy benefits manager (PBM) for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.[24] In fiscal year 2016-2017, the total pharmacy claims expenses were $611.7 million.[25]

The pharmacy benefits manager for the State Employees' Prescription Drug Plan is CVS/caremark. The cost to a member for a drug varies depending on which health plan a member is enrolled in and whether the prescription is generic, a preferred brand-name, or a non-preferred brand-name.[26] The following chart depicts the member's cost.

[21] Department of Treasury, Internal Revenue Service, *Notice 2013-71: Modification of "Use or Lose" Rule for Health Flexible Spending Arrangements (FSAs) and Clarification Regarding 2013-2014 Non-Calendar Year Salary Reduction Elections Under §125 Cafeteria Plans*, https://www.irs.gov/pub/irs-drop/n-13-71.pdf (last visited Jan. 19, 2018).
[22] Department of Management Services, *Health Savings Account*, https://www.mybenefits.myflorida.com/health/savings_and_spending_accounts/health_savings_account (last visited Jan. 18, 2018.)
[23] *Supra* note 19.
[24] Department of Management Services, *House Bill 517 Analysis* (November 27, 2017) (on file with the Senate Committee on Health Policy).
[25] *Supra* note 13, at 5.
[26] Department of Management Services, *MyBenefits, Prescription Drug Plan*, https://www.mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited Jan. 18, 2018).

Copayments or Coinsurance for State Employee Prescriptions and 90-Day Maintenance Medications[27]						
	Standard PPO[28] Standard HMO			High Deductible HMO High Deductible PPO		
	Retail (30 day)	***Mail Order (90 days)***	***Retail (90 days)***	***Retail 30 day***	***Mail Order 90 day***	***Retail 90 day***
Generic						
Preferred Brand Name[29]	$7	$14		30%		
Non-Preferred Brand Name	$30	$60		30%		
	$50	$100		30%		

The plan currently covers all federal legend drugs[30] (open formulary) for covered medical conditions, and provides very limited utilization review and clinical review for traditional or specialty prescription drugs.[31] However, the PBM announces each July the therapeutic classes of drugs that will be excluded from the next plan year.

The current plan also covers compounded medications. Compounded medications combine, mix, or alter the ingredients of one or more drugs or products to create another drug or product. The plan only covers the federal legend drug ingredient of a compounded medication when all of the following criteria are met:

- The compounded medication is not used in place of a commercially available federal legend drug in the same strength and formulation, unless medically necessary;
- The compounded medication is specifically produced for use by a covered person to treat a covered condition; and
- The compounded medication, including all sterile compounded products, is made in compliance with ch. 465, F.S., the Florida Pharmacy Act.[32]

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[27] Maintenance medications are considered those prescriptions commonly used to treat conditions that are considered chronic or long-term. These conditions require regular or on-going use of the drugs. Some examples include those medications that treat heart disease, diabetes, asthma, or heart disease.

[28] Members enrolled in a state employee PPO plan must fill their maintenance medications through the mail order pharmacy or a participating 90-day retail pharmacy after three fills at a 30-day retail pharmacy. *See* Department of Management Services, Prescription Drug Plan https://www.mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited Jan. 18, 2018).

[29] Members who request a preferred brand-name drug when a generic is available, must pay the difference between the generic cost and the preferred name-brand cost, plus the appropriate copayment or coinsurance. If the prescribing physician writes on the prescription that the preferred brand is medically necessary or to "dispense as written" and the reason, the member pays only the appropriate brand copayment or coinsurance. *See* Department of Management Services, *Frequently Asked Questions*, https://www.mybenefits.myflorida.com/health/resources/faq_s/frequently_asked_questions_prescription_drug_plan (last visited Jan. 19, 2018).

[30] A legend drug is defined as any drug approved by the U.S. Food and Drug Administration and that are required by federal or state law to be dispensed to the public only on prescription of a licensed physician or other licensed provider.

[31] *Supra*, note 19 at 19.

[32] Department of Management Services, *My Benefits, Frequently Asked Questions – Prescription Drug Plan*, https://www.mybenefits.myflorida.com/health/resources/faq_s/frequently_asked_questions_prescription_drug_plan (last visited Jan. 19, 2018).

Currently, the law prohibits the program from implementing a restricted formulary or prior authorization process on the non-HMO component of the state employees' prescription drug program.[33] In August 2017, the state's Revenue Estimating Conference (REC) projected gross costs related to prescription drug coverage to increase by 55 percent over the next three years or nearly $693 billion for fiscal year 2017-2018 to $1.1 billion in fiscal year 2020-2021.[34] These estimates were reduced slightly in December, 2017, with reductions in enrollment and projected claims experience; however, the Self-Insurance Estimating Conference revised upwards the HMO pharmacy growth factor slightly from 15.9 percent to 16 percent for fiscal year 2018-2019 through 2022-2023.[35] This adjustment in the growth factor indicates a forecast for continued increases year after year in pharmacy costs beyond what had been predicted in December 2017.

National health spending on prescription drugs is projected to peak in 2018 at 7.6 percent, as fewer brand-name drugs are expected to lose patent protection and is expected to grow at an average of 6.3 percent a year in the private marketplace for 2016 through 2025.[36]

Formulary Development

Formularies are developed by a pharmacy and therapeutics (P&T) committee or an equivalent entity within health plans, PBMs, hospitals, government agencies, and Medicare and Medicaid programs. The P&T committee determines which medications and related products should be listed on the formulary. The committee is composed of primary care and specialty care physicians, pharmacists and other professionals in the health care field and can also include nurses, legal experts, and administrators.[37] In order to keep up to date on newly approved medications from the United States Food and Drug Administration the P&T committee should meet regularly to review newly released drugs and classes of drugs. As part of that review process, the P&T committee reviews some or all of the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information including safety data;
- Relevant information on use of medications by patients and experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data (not all P&T committees review drug specific economic data); and

[33] Ch. 99-255, s. 8, Laws of Fla.
[34] Department of Management Services, *Executive Briefing Paper – Formulary Management* (on file with the Senate Health Policy Committee).
[35] State Employee's Group Health Self-Insurance Trust Fund, *Report on Financial Outlook (For the Fiscal Years Ending June 30, 2018 through June 30, 2023)*, pg. 3, Adopted at the December 13, 2017 Self-Insurance Estimating Conference, http://edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf (last visited Jan. 19, 2018).
[36] Centers for Medicare and Medicaid Services, National Health Expenditure Projections 2016-2025, *Forecast Summary*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf (last visited Jan. 19, 2018).
[37] Academy of Managed Care Pharmacy, *Formulary Management*, http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last visited Jan. 19, 2018).

- Health care provider recommendations.[38]

Florida uses a P&T committee in its Medicaid program.[39] Membership on its committee includes physicians, pharmacists, and a consumer. The Medicaid preferred drug list is a listing of cost-effective, safe, and clinically efficient medications for each of the therapeutic classes on the list and is posted on the Agency for Health Care Administration's website.[40] Medicaid recipients may appeal any drug formulary decisions using the Medicaid fair hearing process.[41]

III. Effect of Proposed Changes:

Section 1 directs the Department of Management Services to implement formulary management cost saving measures in the state employees' prescription drug program as established in s. 110.12315, F.S. The measures must require that the prescription drugs be subject to formulary inclusion or exclusion, but may not restrict access to the most clinically appropriate, clinically effective, and lowest net-cost prescription drugs.

The formulary program must allow for an excluded drug to be included if a physician, an advanced registered nurse practitioner, or a physician assistant prescribing a pharmaceutical clearly states that the excluded drug is medically necessary and cannot be substituted.

According to the DMS, the CVS/caremark[42] formulary for 2018 covers the majority of generic drugs on the market as well as approximately 5,400 brand name drugs (preferred, non-preferred, and specialty). The 2019 formulary also excludes 159 drugs, test strips, insulin syringes, and pen needles which, as exclusions, require prior authorization or clinical review for members to receive.[43]

By October of each year, CVS/caremark would announces the therapeutic classes and the specific drugs that will be impacted by formulary changes.

Section 2 deletes Section 8 of Chapter 99-255, Laws of Florida, to remove a provision that prohibits the DMS from implementing a restricted prescription drug formulary or prior authorization program in the state employees' prescription drug program.

Section 3 provides an effective date of January 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[38] *Id.*
[39] Section 409.9119(1), F.S.
[40] *See Florida Medicaid Preferred Drug List (PDL),* http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/fmpdl.shtml (last visited Jan. 19, 2018).
[41] Section 409.9119(11), F.S.
[42] CVS/caremark is the state's contracted PBM for the state employee prescription drug program.
[43] *Supra* note 29, at 6.

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:

If CVS/caremark's 2018 Standard Control Formulary[44] were implemented, the projected impacts on current prescriptions filled and members are:

Non-Specialty Prescriptions:	84,043
Specialty Prescriptions:	513
Total:	84,556 or 1.9% of all prescriptions
Non-Specialty Members:	30,917
Specialty Members:	130
Total:	31,047 or 8.6% of all members

With a restricted formulary or prior authorization process, prescribers in the private sector or public sector need to indicate that a drug is "medically necessary" or to engage in a prior authorization process if a member needs an excluded drugs. This may create an administrative burden on the health care community, depending on the volume of members who seek exceptions.

Taxpayers may experience savings from the implementation of a restricted formulary and prior authorization process as the bill is projected to reduce state expenditures by $54 million on an annual basis.

C. Government Sector Impact:

The DMS estimates that the implementation of a standard formulary would result in a cost avoidance to the state of approximately $27 million in the first half of the fiscal year and $54 million annually thereafter.[45] The estimate is based on 2017 member utilization, the program's current Preferred Drug list, and the 2018 CVS/caremark Standard Control Formulary.

[44] CVS/caremark, *Prescribing Guide – Standard Control 2018* (January 2018) https://www.caremark.com/portal/asset/prescribing_guide.pdf (last visited Jan. 19, 2018).
[45] *Supra* note 33.

The DMS projects the annual fiscal year savings from the proposed changes in SB 954 at $55.6 million or a net plan savings of $54 million. The net savings projected to the SGI members is $1.5 million.[46]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 110.12315 of the Florida Statutes and Chapter 99-255, Laws of Florida.

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.

[46] *Supra*, note 24 at 6.

By Senator Passidomo

28-00994A-18 2018954__

A bill to be entitled

An act relating to the state employees' prescription drug program; amending s. 110.12315, F.S.; requiring the Department of Management Services to implement formulary management cost-saving measures; providing requirements for such measures; amending ch. 99-255, Laws of Florida; removing a provision that prohibits the department from implementing a restricted prescription drug formulary or prior authorization program in the state employees' prescription drug program; providing an effective date.

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

Section 1. Subsection (9) is added to section 110.12315, Florida Statutes, to read:

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

(9) The department shall implement formulary management cost-saving measures. Such measures must require prescription drugs to be subject to formulary inclusion or exclusion and may not restrict access to the most clinically appropriate, clinically effective, and lowest net-cost prescription drugs. However, excluded drugs may be available for inclusion if a physician, an advanced registered nurse practitioner, or a

physician assistant prescribing a pharmaceutical clearly states that the excluded drug is medically necessary and cannot be substituted.

Section 2. Section 8 of Chapter 99-255, Laws of Florida, is amended to read:

~~Section 8. The Department of Management Services shall not implement a prior authorization program or a restricted formulary program that restricts a non-HMO enrollee's access to prescription drugs beyond the provisions of paragraph (b) related specifically to generic equivalents for prescriptions and the provisions in paragraph (d) related specifically to starter dose programs or the dispensing of long-term maintenance medications. The prior authorization program expanded pursuant to section 8 of the 1998-1999 General Appropriations Act is hereby terminated. If this section conflicts with any General Appropriations Act or any act implementing a General Appropriations Act, the Legislature intends that the provisions of this section shall prevail. This section shall take effect upon becoming law.~~

Section 3. This act shall take effect January 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: December 5, 2017

I respectfully request that **Senate Bill #954**, relating to Formulary Management, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Kathleen Passidomo
Florida Senate, District 28

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

1-23-18
Meeting Date

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

SB 954
Bill Number (if applicable)

Topic SB 954

Amendment Barcode (if applicable)

Name Meredith Stanfield

Job Title Legislative Affairs Director

Address 4050 Esplanade Way
Street
Tallahassee FL 32399
City *State* *Zip*

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Email meredith.stanfield@dms.myflorida.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Department of Management 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

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 1252
INTRODUCER:	Health Policy Committee and Senator Passidomo
SUBJECT:	Home Renal Dialysis
DATE:	January 23, 2018
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1252 exempts any manufacturer holding a manufacturer permit, or its agent that holds a manufacturer or third party logistics provider permit, under the Florida Drugs and Cosmetics Act, from the requirements of the Florida Pharmacy Act for the distribution of dialysate, drugs, or devices that are necessary to perform home renal dialysis under certain circumstances.

The bill takes effect upon becoming law.

II. Present Situation:

Kidney Disease and Renal Dialysis

Chronic kidney disease is a condition in which a person gradually loses kidney function over time, and includes conditions that damage the kidneys and decrease their ability to process waste.[1] Renal dialysis is a common treatment for individuals with chronic kidney failure, and is used to:[2]

- Remove waste, salt, and extra water to prevent build up in the body;
- Maintain a safe level of certain chemicals in the blood, such as potassium, sodium, and bicarbonate; and

[1] National Kidney Foundation, *About Chronic Kidney Disease*, (February 15, 2017) https://www.kidney.org/kidneydisease/aboutckd (last visited Jan. 18, 2018).
[2] National Kidney Foundation, *Dialysis* https://www.kidney.org/atoz/content/dialysisinfo(last visited Jan. 18, 2018).

- Control blood pressure.

Renal dialysis can be performed in a hospital, in a dialysis unit that is not part of a hospital, or in a person's home.[3] Additionally, there are two types of dialysis, hemodialysis and peritoneal dialysis.

In hemodialysis, an artificial kidney, called a hemodialyzer, is used to remove waste and extra chemicals and fluid from the blood.[4] Blood is pumped out of the body and into the hemodialyzer to be cleaned. The dialyzer, or filter, has two parts, separated by a thin membrane: one for blood and one for a washing fluid, called dialysate.[5] Blood cells and proteins remain in the blood because they are too large to pass through the membrane; however, smaller waste products, such as urea, creatinine, potassium and extra fluid pass through the membrane and are washed away.[6] The filtered blood is returned to the body when the process is complete.[7]

In peritoneal dialysis the inside lining of the abdominal cavity acts as a natural filter and wastes are taken out with dialysate, which is washed in and out of the abdominal cavity in cycles.[8] A catheter is surgically inserted into the abdominal cavity and is used to transfer the dialysate into and out of the abdominal cavity.[9] There are two kinds of peritoneal dialysis, continuous ambulatory peritoneal dialysis and automated peritoneal dialysis.[10] The former is manual and done while the person receiving treatment goes about normal daily activities, and the latter is a machine cycler that is usually done overnight, while the person is asleep.[11]

Regulation of Pharmacies and Pharmacists

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy, within the Department of Health (DOH), licenses and regulates the practice of pharmacy including community pharmacies,[12] institutional pharmacies,[13] nuclear pharmacies,[14] special pharmacies,[15] and internet pharmacies.[16]

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[3] Id.
[4] National Kidney Foundation, *Hemodialysis*, https://www.kidney.org/atoz/content/hemodialysis (last visited Jan. 18, 2018).
[5] National Kidney Foundation, *Peritoneal Dialysis: What You Need to Know*, https://www.kidney.org/atoz/content/peritoneal (last visited Jan. 18, 2018).
[6] Supra note 4.
[7] Supra note 5.
[8] Id.
[9] Id.
[10] Id.
[11] Id.
[12] A community pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, or where prescriptions are filled or dispensed on an outpatient basis. Section 465.003(11)(a)1., F.S.
[13] An institutional pharmacy includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. Section 465.003(11)(a)2., F.S.
[14] A nuclear pharmacy includes every location were radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals or the nuclear medicine facilities of hospitals. Section 465.003(11)(a)3., F.S.
[15] A special pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, if not otherwise classified as a community pharmacy, institutional pharmacy, nuclear pharmacy, or internet pharmacy. Section 465.003(11)(a)4., F.S.
[16] An internet pharmacy includes locations not otherwise licensed or issued a permit pursuant to statute, within or outside of this state, which use the Internet to communicate with or obtain information from consumers in this state and use such

The board regulates the operation of pharmacies and disciplines pharmacies for failure to comply with state and federal regulations.[17] One aspect of the practice of pharmacy involves the dispensing of prescription drugs pursuant to a physician's prescription or order.[18]

Special Pharmacy – End Stage Renal Dialysis Permit

The Board of Pharmacy recognizes six types of special pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD).[19] An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.[20] To obtain an ESRD permit, an applicant must:[21]

- Complete an application and pay a $250 initial payment fee;
- Submit a legible set of fingerprint cards and $48 fee for each person having an ownership interest of at least 5 percent and any person who, directly or indirectly, manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors, if the applicant is a corporation;
- Pass an on-site inspection;
- Provide written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships; and
- Designate a prescription department manager or consultant pharmacist of record.

Florida law provides an exemption to pharmacy permitting requirements, including ESRD permits, under limited circumstances. Specifically, s. 465.027(2), F.S., exempts a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting and regulatory requirements if the dialysate, drugs, or devices are:

- Approved by the federal Food and Drug Administration, and
- Delivered in the original, sealed packaging to the patient for self-administration after receipt of a physician's order to dispense, to a health care practitioner, or to an institution.[22]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[23] Most of the regulations relate to the distribution of prescription drugs into and within Florida. The chapter also regulates manufacturing and distributing medical devices. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and

communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy. Section 465.003(11)(a)5., F.S.

[17] See ss. 465.022 and 465.023, F.S.

[18] See s. 465.003(6) and (14), F.S.

[19] Rule 64B16-28.100(5)(d), F.A.C.

[20] Rule 64B16-28.850(1), F.A.C.

[21] Rule 64B16-28.100(1) and (5), F.A.C.

[22] This exemption was enacted in ch. 2016-230, Laws of Fla.

[23] Section 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the DOH to the DBPR.

prescription drug wholesale distributors, to obtain permits. Florida has 18 distinct permits for these entities.[24]

Manufacturer Permits

The DBPR offers nine different manufacturer and repackager permits for prescription drugs, over-the-counter drugs, cosmetics, and medical devices.

Prescription drug manufacturer permits are required for anyone that manufactures a prescription drug and manufactures or distributes that prescription drugs in Florida.[25] If someone manufactures prescription drugs outside of Florida, but distributes their prescription drugs into Florida, a nonresident prescription drug manufacturer permit is required, unless that person is permitted as a third party logistics provider.[26] Virtual permits are available for those who manufacture prescription drugs but do not make or take physical possession of any prescription drugs.[27] An over-the-counter drug manufacturer permit is required for anyone manufacturing or repackaging over-the-counter drugs[28] and a cosmetic manufacturer permit is required for anyone manufacturing or repackaging cosmetics in Florida.[29]

A device manufacturer permit is required for anyone manufacturing, repackaging, or assembling medical devices for human use unless the person only manufactures, repackages, or assembles medical devices or components: [30]

- Pursuant to a practitioner's order for a specific patient; or,
- That are registered with the federal Food and Drug Administration and satisfy specified statutory requirements.

Regulation of Third-Party Logistics Providers

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. A third party logistics provider contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf a manufacturer, wholesale distributor, or dispenser, but does not take title to or have responsibility to direct the sale or disposition of the prescription drug.[31]

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[24] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. Section 499.01(1), F.S.
[25] Section 499.01(2)(a), F.S.
[26] Section 499.01(2)(c), F.S.
[27] Section 499.01(2)(a)1., F.S. and S. 499.01(2)(c), F.S.
[28] Section 499.01(2)(n), F.S.
[29] Section 499.01(2)(p), F.S. Someone that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a cosmetic manufacturer permit.
[30] Section 499.01(2)(o), F.S.
[31] Section 499.01(2)(q), F.S.

Third-party logistic providers must obtain a DBPR permit before operating in Florida and out-of-state third-party logistics providers must also be licensed in the state or territory from where it distributes the prescription drug.[32] Third-party logistics providers that provide dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit from the Board of Pharmacy.[33]

III. Effect of Proposed Changes:

CS/SB 1252 amends s. 465.027, F.S., to expand and clarify the exemption from the Florida Pharmacy Act for the distribution of certain drugs and devices directly to the patient by a manufacturer's third party logistics provider. The bill exempts a manufacturer's agent if the agent holds a third party logistics provider permit under ch. 499, F.S., related to the regulation of drugs, devices, and cosmetics, from the requirements of ch. 465, F.S., related to the regulation of pharmacies, to the extent that the manufacturer's agent is engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

- Approved by the United States Food and Drug Administration; and
- Delivered in the original, sealed packaging after receipt of a physician's order to dispense to a patient or the patient's designee for the patient's self-administration or to a health care practitioner or institution for administration or delivery of dialysis therapy.

The bill is effective upon becoming law.

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.

[32] If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required under federal law.
[33] Rule 64B16-28.100(5)(d)4., F.A.C.

B. Private Sector Impact:

Third party logistics provider permit holders made exempt under the bill may see a positive fiscal impact due to no longer being required to pay any permitting fees required by ch. 465, F.S.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.027 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on January 23, 2018:
The CS specifies that the exemption from the Florida Pharmacy Act also applies to the manufacturer's agent if the agent is a third party logistics provider permit holder, or the agent of the manufacturer or third party logistics provider permit holder is engaged in providing dialysate, drugs, or devices related to renal dialysis as detailed in the bill.

The CS changes the effective date to upon becoming law..

B. Amendments:

None.

927006

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/23/2018	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (2) of section 465.027, Florida Statutes, is amended to read:

465.027 Exceptions.—

(2) This chapter does ~~shall~~ not apply to a manufacturer, or its agent, holding an active manufacturer or third-party logistics provider permit ~~as a manufacturer~~ under chapter 499,

927006

to the extent the manufacturer, or its agent, is ~~and~~ engaged ~~solely~~ in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician's order to dispense to:

1. A patient with chronic kidney failure, or the patient's designee, for the patient's self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

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

========== 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 distributing pharmaceutical drugs and devices; amending s. 465.027, F.S.; revising an exception to pharmacy regulations for certain manufacturers and distributors of dialysis drugs or supplies; providing an effective date.

By Senator Passidomo

28-01376-18 20181252__

A bill to be entitled

An act relating to home renal dialysis; amending s. 465.027, F.S.; revising conditions under which manufacturers, or agents thereof, who distribute home dialysis supplies are exempt from the requirements of the Florida Pharmacy Act; providing an effective date.

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

Section 1. Subsection (2) of section 465.027, Florida Statutes, is amended to read:

465.027 Exceptions.—

(2) This chapter does ~~shall~~ not apply to a manufacturer, or its agent, holding an active manufacturer or third party logistics permit ~~as a manufacturer~~ under chapter 499 who is ~~and~~ engaged ~~solely~~ in the ~~manufacture or~~ distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician’s order to dispense to:

1. A patient with chronic kidney failure, or the patient’s designee, for the patient’s self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

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

The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: January 12, 2018

I respectfully request that **Senate Bill #1252**, relating to Home Renal Dialysis, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Kathleen Passidomo
Florida Senate, District 28

File signed original with committee office

S-020 (03/2004)

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 1680
INTRODUCER:	Health Policy Committee and Senator Montford
SUBJECT:	Immunization Registry
DATE:	January 23, 2018
REVISED:	1/23/18

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1680 requires certain health care practitioners to report vaccination administration data to the Department of Health (DOH) immunization registry when vaccinating children, or college or university students, 18 to 23 years of age, at a college or university student health care facility. Mandatory reporting to the registry will eliminate the use of a paper-based certification of immunization. The bill removes a parent's or guardian's ability to opt a child out of the immunization registry.

The reporting of the vaccination data to the registry for other persons is permitted, but not required.

The bill also requires school boards, and private school governing bodies, to establish and enforce a policy requiring that, before a child may attend a public or private school, the child must have on file a Florida Certification of Immunization (FCI) with the DOH immunization registry. Currently the policy allows submission of an FCI in paper form.

The effective date of the bill is January 1, 2020.

II. Present Situation:

Communicable Disease Prevention and Control

The DOH is responsible for the state's public health system which must promote, protect, and improve the health of all people in the state.[1] As part of fulfilling this public health mission the DOH is responsible for conducting a communicable disease prevention and control program. A communicable disease is any disease caused by the transmission of a specific infectious agent, or its toxic products, from an infected person, animal, or the environment to a susceptible host, either directly or indirectly.[2]

The DOH communicable disease program includes, but need not be limited to, programs for the prevention and control of:

- Tuberculosis;
- Human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS);
- Sexually transmissible diseases;
- Communicable diseases of public health significance; and
- Vaccine-preventable diseases[3], including programs to immunize school children[4] and the development of an automated, electronic, and centralized database or registry for immunization records.[5]

The DOH may adopt rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for:

- Investigating disease;
- Timeframes for reporting disease;
- Definitions;
- Procedures for managing specific diseases;
- Requirements for follow-up reports on disease exposure; and
- Procedures for providing access to confidential information necessary for disease investigations.[6]

The DOH Immunization Registry (Florida SHOTS)

The DOH must ensure that all children are immunized against vaccine-preventable diseases, and be included in the immunization registry, to enhance the department's current immunization activities and improve immunization for all children. The Florida State Health Online Tracking System (SHOTS) is the free, statewide, centralized online immunization registry that assists

[1] Section 381.001, F.S.
[2] Section 381.003(1), F.S.
[3] Measles, mumps, rubella, pertussis, diphtheria, tetanus, polio, varicella, pneumococcal disease, hepatitis A, hepatitis B, influenza, meningococcal and Haemophilus influenza type b (Hib) are all preventable by vaccine. *See* Department of Health, *Vaccine Preventable Diseases*, http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html (last visited Jan. 18, 2018).
[4] *See* s. 1003.22(3)-(11), F.S.
[5] Section 381.003(1), F.S.
[6] Section 381.003(2), F.S.

healthcare providers, schools, and parents with keeping track of immunization records.[7] The program ensures a cause and effect response by monitoring immunization levels in vulnerable populations throughout the state, thereby contributing to strategies to attain, and sustain, high immunization levels. This has the effect of increasing herd immunity and lowering vaccine-preventable disease rates.[8]

The DOH may make rules for the immunization registry, to include:
- Procedures for a health care practitioner to obtain authorization to use the registry;
- Methods for a parent or guardian to elect not to participate in the registry; and
- Procedures for health care practitioners licensed under chs. 458, 459, or 464, F.S., to access and share electronic immunization records with other entities allowed by law to have access to the records.[9]

The DOH includes all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics; and then adds other children to the registry as immunizations are given. The DOH documents in the registry the child's:
- Name;
- Date of birth;
- Address;
- Other unique information to identify the child;
- The immunization administered, including:
  - Type of vaccine administered;
  - The date the vaccine was administered;,
  - The vaccine lot number; and
  - The presence or absence of any adverse reaction or contraindication to the immunization.[10]

A parent or guardian may refuse to have a child included in the immunization registry. In that case a parent or guardian must sign a DOH approved form which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the registry must also be noted in the registry.[11]

The DOH immunization registry allows for immunization records to be electronically transferred to entities that are required by law to have such records, including schools, licensed child care facilities, and any other entities required by law to obtain proof of a child's immunizations. Any health care practitioner licensed under chs. 458, 459, or 464, F.S., who complies with the DOH rules to access the immunization registry, may:
- Directly access a child's immunization records;
- Update a child's immunization history; or

[7] Department of Health, Providing Records to Patients, *Deliver Accurate, Timely Records,* http://www.floridahealth.gov/programs-and-services/immunization/information-for-healthcare-providers/providing-records-to-patients/index.html (last visited Jan. 18, 2018).
[8] *See* Department of Health, *Vaccine Preventable Diseases,* http://www.floridahealth.gov/diseases-and-conditions/vaccine-preventable-disease/index.html (last visited Jan. 18, 2018).
[9] Section 381.003(1)(e), F.S.
[10] Section 381.003(1)(e)4., F.S.
[11] Section 381.003 (1)(e)2., F.S.

- Exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.[12]

The SHOTS also helps prevent needless revaccinations for entry into daycare and schools because of lost or unavailable paper vaccination and medical records. Currently over 15,000 health care practitioners licensed under chs. 458, 459, or 464, F.S., voluntarily provide data to the registry; but because reporting is currently voluntary, some individuals' immunization records in the data base have been incomplete. As a result, the immunization program has received many complaints with respect to incomplete records. This has resulted in unnecessary revaccinations and the scrambling of parents and schools to obtain a paper record.[13]

The information included in the DOH immunization registry retains its status as confidential medical information; and the DOH must maintain the confidentiality of that information as required by law. A health care practitioner, or other agency, that obtains information from the immunization registry must also maintain the confidentiality of the records as required by law.[14]

DOH Required Immunizations

Each school district board, and private school governing body, is required to ensure that every child entering school in kindergarten through grade 12, present, or have on file, an FCI before entering or enrolling in school.[15] Children entering, attending or transferring to Florida public or private schools, kindergarten through grade 12, must have on file as part of their permanent school record[16] an FCI documenting that they have had the following immunizations:

- Four or five doses of DTaP (Diphtheria-tetanus-acellular pertussis);
- Four or five doses of IPV (Inactivated polio vaccine);
- Two doses of MMR (Measles-mumps-rubella);
- Three doses of Hep B (Hepatitis B);
- One Tdap (Tetanus-diphtheria-acellular pertussis);
- Two doses of Varicella (unless there is a history of varicella disease documented by a health care provider); and
- If entering a public or private school in seventh grade or later, an additional dose of Tdap (Tetanus-diphtheria-acellular pertussis).[17]

Private healthcare providers may grant a temporary medical exemption (TME), documented on the FCI form,[18] for those who are in the process of completing any necessary immunizations. The TME requires an expiration date after which the exemption is no longer valid, and the

[12] Section 381.003(1)(e), F.S.
[13] Department of Health, *Senate Bill 1680 Analysis* (Dec. 20, 2017) (on file with the Senate Committee on Health Policy).
[14] Section 381.003(1)(e)4., F.S.
[15] Section 1003.22(4), F.S.
[16] *Id*.
[17] *See also* Department of Health, *School Immunization Requirements* http://www.floridahealth.gov/%5C/programs-and-services/immunization/children-and-adolescents/school-immunization-requirements/index.html#childcare (last visited Jan. 18, 2018). *See also* the DOH Form DH 680, 07/2010, http://www.floridahealth.gov/%5C/programs-and-services/immunization/_documents/dh-680-sample.pdf (last visited Jan.18, 2018).
[18] Department of Health, Form DH 680, 07/2010, http://www.floridahealth.gov/%5C/programs-and-services/immunization/_documents/dh-680-sample.pdf (last visited Jan. 18, 2018).

immunizations must be completed before or at that time. A permanent medical exemption, may be granted if a child cannot be fully immunized due to medical reasons. In this case, the child's physician must state in writing, the reasons for exemption based on valid clinical reasoning or evidence on the ECI form.[19]

A request for a religious exemption from immunizations requires the parent or guardian to provide the school or facility with a *Religious Exemption From Immunization* form.[20] The form is issued only by county health departments, and only for children who are not immunized because of the family's religious tenets or practices. Exemptions for personal or philosophical reasons are not permitted under Florida law.[21]

III. Effect of Proposed Changes:

The bill requires health care practitioners licensed under chs. 458, 459, or 464, F.S., who administer vaccinations, or cause vaccinations to be administered, to children, or to college or university students, 18 to 23 years of age, at a college or university student health care facility, to report the following patient vaccination administration information to the DOH immunization registry (SHOTS):

- Patient's name;
- Date of birth;
- Address;
- Other unique information to identify the child;
- The immunization administered, including:
  - Type of vaccine administered;
  - The date the vaccine was administered;,
  - The vaccine lot number; and
  - The presence or absence of any adverse reaction or contraindication to the immunization.

Mandatory reporting to the registry will eliminate the use of a paper-based certificate of immunization.

The bill specifies that the reporting of the above vaccination administration data to the DOH registry for other persons is permitted, but not required. Health care practitioners may use an existing automated data system for updating immunization information in the immunization registry.

The bill removes a parent's or guardian's ability to opt a child out of the immunization registry.

---

[19] Department of Health, *Exemptions from Immunizations*, http://www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/immunization-exemptions/index.html (last visited Jan. 18, 2018).
[20] Department of Health, *Religious Exemption From Immunization, DH 681 Form*, http://www.floridahealth.gov/%5C/programs-and-services/immunization/_documents/dh-681-sample.pdf (last visited Jan. 18, 2018). The DH 681 Form, *Religious Exemption From Immunization* form, puts a parent or guardian on notice that any child not immunized against a communicable disease that has been declared a communicable disease emergency.
[21] Department of Health, Immunization Section, Bureau of Communicable Diseases, *Immunization Guidelines, Florida Schools, Childcare Facilities and Family Daycare Homes* (March 2013), http://www.floridahealth.gov/%5C/programs-and-services/immunization/schoolguide.pdf (last visited Jan. 18, 2018).

The bill requires that the immunization registry make electronically available the immunization records to entities required by law to have such records, including, but not limited to, schools and licensed child care facilities.

Detailed rulemaking authority relating to the DOH's responsibilities to conduct a communicable disease prevention and control program is condensed into a general grant of rulemaking authority.

The bill requires school boards, and private school governing bodies, to establish and enforce a policy requiring that before a child may attend a public or private school, the child must have on file an FCI with the DOH immunization registry. The FCI becomes a part of each student's permanent school record.

The bill takes effect January 1, 2020.

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:

The mandatory registry for children and college students' immunization data records may reduce a parent's or individual's cost in locating and obtaining lost, destroyed or misplaced immunization records. Housing the vaccination data in the registry may also avoid the cost of needless revaccination.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.003, 1003.22.

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 January 23, 2018:
Sets an age limit of up to 23 for required reporting on college or university students who are vaccinated at a student health center.

- Removes the delayed effective date of July 1, 2021, for updating the district school board and private school governing authority policies.
- Changes the effective date of the entire bill to January 1, 2020.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/24/2018	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public

663502

health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly. The communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of communicable diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and ~~or~~ registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry shall allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. ~~Except as provided in subparagraph 2.,~~ The department shall include all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to

663502

the registry as immunization services are provided.

~~2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the immunization registry must be noted in the registry.~~

2.~~3.~~ The immunization registry must ~~shall~~ allow for immunization records to be electronically available to ~~transferred to~~ entities that are required by law to have such records, including, but not limited to, schools and~~,~~ licensed child care facilities~~, and any other entity that is required by law to obtain proof of a child's immunizations~~.

3.~~4.~~ A ~~Any~~ health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to children at any time from their birth to 18 years of age is required to report vaccination data to the immunization registry. A health care practitioner licensed under chapter 458, chapter 459, or chapter 464 who administers vaccinations or causes vaccinations to be administered to college or university students who are 18 years of age up to 23 years of age at a college or university student health care facility in this state is required to report vaccination data to the immunization registry. Vaccination data for other age ranges may be submitted to the immunization registry on an optional basis. Automated data upload from existing automated systems is an acceptable

663502

method for updating immunization information in the immunization registry. ~~complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.~~ The information ~~included~~ in the immunization registry must include the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical records in accordance with s. 456.057 or as otherwise required by law.

(2) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section~~, repeal, and amend rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for followup reports of known or suspected exposure to disease, and~~


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~~procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic immunization records with other entities allowed by law to have access to the records~~.

Section 2. Subsection (4) of section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.—

(4) Each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each child ~~present or~~ have on file with the state registry of immunizations ~~school~~ a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age. Such certification becomes ~~shall be made on forms approved and provided by the Department of Health and shall become~~ a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes

663502

schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

Section 3. This act shall take effect January 1, 2020.

========== 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 immunization registry; amending s. 381.003, F.S.; revising provisions relating to the communicable disease prevention and control programs under the Department of Health; deleting a provision that allows the parent or guardian of a child to refuse to have the child included in the immunization registry; providing requirements for electronic availability of, rather than transfer of, immunization records; requiring certain health care practitioners to report vaccination data to the immunization registry; authorizing the department to adopt rules; amending s. 1003.22, F.S.; revising school-entry health requirements to require that students have a certificate of immunization on file with the department’s immunization registry; providing an effective date.

By Senator Montford

3-00954B-18 20181680__

A bill to be entitled

An act relating to immunization registry; amending s. 381.003, F.S.; revising provisions relating to the communicable disease prevention and control programs under the Department of Health; deleting a provision that allows the parent or guardian of a child to refuse to have the child included in the immunization registry; providing requirements for electronic availability of, rather than transfer of, immunization records; requiring certain health care practitioners to submit and update vaccination data in the immunization registry; authorizing the department to adopt rules; amending s. 1003.22, F.S.; revising school-entry health requirements to require that students have a certificate of immunization on file with the department's immunization registry; providing effective dates.

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

Section 1. Section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the

environment to a susceptible host, either directly or indirectly. The communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of communicable diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and ~~or~~ registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry shall allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. ~~Except as provided in subparagraph 2.,~~ The department shall include all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

~~2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form~~

~~obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the child included in the immunization registry. The decision to not participate in the immunization registry must be noted in the registry.~~

2.~~3.~~ The immunization registry must ~~shall~~ allow for immunization records to be electronically available to ~~transferred to~~ entities that are required by law to have such records, including, but not limited to, schools and~~,~~ licensed child care facilities~~, and any other entity that is required by law to obtain proof of a child's immunizations~~.

3.~~4.~~ A ~~Any~~ health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to children from birth to 18 years of age or to students at a student health care facility of a Florida College System institution or a state university shall report vaccination data to the immunization registry. Vaccination data for other age ranges may be submitted to the immunization registry on an optional basis. Automated data upload from existing automated systems is an acceptable method for updating immunization information in the immunization registry. ~~complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care.~~ The information ~~included~~ in the immunization registry must include

the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical records in accordance with s. 456.057 or as otherwise required by law.

(2) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section~~, repeal, and amend rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for followup reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic~~

~~immunization records with other entities allowed by law to have access to the records~~.

Section 2. Effective July 1, 2021, subsection (4) of section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.—

(4) Each district school board and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each child ~~present or~~ have on file with the state registry of immunizations ~~school~~ a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age. Such certification becomes s~~hall be made on forms approved and provided by the Department of Health and shall become~~ a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

Section 3. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2018.

The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Senate Committee on Health Policy

Subject: Committee Agenda Request

Date: January 12, 2018

I respectfully request that SB 1680 Immunizations Registry be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Bill Montford

Senator Bill Montford
Florida Senate, District 3

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

1680
Bill Number (if applicable)

Topic Immunization Registry

Amendment Barcode (if applicable)

Name Stephen R. Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Drive
Street

Phone 850-878-3056

Tall. Fla. 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 Assoc.

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-23-18
Meeting Date

1680
Bill Number (if applicable)

Topic Immunization Registry

Amendment Barcode (if applicable)

Name Paul Rundle

Job Title Legislative Affairs Director

Address 3402 Bald Cypress Way
Street

Tallahassee FL 32399
City *State* *Zip*

Phone

Email 850-245-4444

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)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

01/23/2018
Meeting Date

SB1680
Bill Number (if applicable)

Topic Immunization Registry

Amendment Barcode (if applicable)

Name Susan Callahan

Job Title Registered Nurse

Address 3620 Shinnecock Lane
Street

Phone (904)504-1334

Green Cove Springs — *City* | Fl — *State* | 32043 — *Zip*

Email SusanRN@Bellsouth.net

Speaking: ☐ For ☑ Against ☐ Information

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

Representing

Appearing at request of Chair: ☑ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-23-18
Meeting Date

SB 1680
Bill Number (if applicable)

Topic Immunization Registry

Amendment Barcode (if applicable)

Name Toni Krebel

Job Title

Address 372 San Juan Drive
Street
Ponte Vedra Beach FL 32082
City *State* *Zip*

Phone 904-631-6054

Email tkrebel@comcast.net

Speaking: ☐ For ☒ Against ☐ Information

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

Representing National Vaccine Information 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)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

01/23/2018 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 1680

Meeting Date *Bill Number (if applicable)*

Topic SB 1680 Immunization Registry *Amendment Barcode (if applicable)*

Name Claire Friedman, RN

Job Title Florida Advocacy Director NVIC

Address 111 Baltic Circle Phone 813 230 8589

Street

Tampa FL 33606 Email ClaireNVIC@icloud.com

City *State* *Zip*

Speaking: ☐ For ☒ Against ☐ Information Waive Speaking: ☐ In Support ☐ Against

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

Representing The National Vaccine Information 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

APPEARANCE RECORD

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

11/23/18
Meeting Date

1680
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Angie Gaillo

Job Title Legislation Chair

Address 1747 Orlando Central Pkwy
Street

Phone _____

Ofn FL 32824
City *State* *Zip*

Email _____

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida PTA

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)

1/23/2018
Meeting Date

SB 1680
Bill Number (if applicable)

Topic Improve Vaccination Reporting System

Amendment Barcode (if applicable)

Name Madeline Joseph, M.D.

Job Title President

Address 700 Queens Harbor BLVD
Street

Phone (904) 705-2746

Jacksonville. FL 32225
City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Chapter of the American Academy of Pediatrics

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 514
INTRODUCER:	Health Policy Committee and Senator Young
SUBJECT:	Transplant of Human Tissue
DATE:	January 23, 2018
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 514 requires the Department of Health (DOH) to develop a pamphlet that contains certain information on the risks and benefits of human cell and tissue transplants. The DOH must publish the pamphlet on its website, and electronically notify physicians when it is available.

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

II. Present Situation:

Tissue Donation and Transplantation

Organ and tissue donation and transplantation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation may be necessary because the recipient's organ or tissue has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas and intestine.[1] Transplantable tissue includes skin used as a temporary dressing for burns, serious abrasions and other exposed areas; heart valves used to replace defective valves; tendons used to repair torn ligaments on knees or other joints; veins used in cardiac by-pass

[1] Donate Life Florida, *Frequently Asked Questions* https://www.donatelifeflorida.org/categories/donation/ (last visited Jan. 17, 2018).

surgery; corneas used to restore sight; and bone used in orthopedic surgery to facilitate healing of fractures or to prevent amputation.[2]

The Organ Procurement and Transplantation Network (OPTN) regulates how donor organs are matched and allocated to patients on the waiting list.[3] Non-profit, federally designated organ procurement organizations (OPOs) work closely with OPTN, hospitals, and transplant centers to facilitate the organ donation and transplantation process,[4] including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.[5]

The Department of Health (DOH) is responsible for the state's public health system to promote, protect, and improve the health of all people in the state. This includes regulating human tissue donation and transplantation.[6] Absent limited exceptions, every donation of human tissue, cells, skin, organs, blood, or plasma for transfusion or transplantation to another person must be tested for human immunodeficiency virus (HIV) infection[7] and any other communicable diseases specified by rule of the DOH or undergo a DOH approved process capable of killing the causative agent of those diseases.[8].[9] The DOH, by rule,[10] has required that blood, organs, and tissue be tested for the following additional infectious disease agents, as identified by the federal regulation:

- Hepatitis B virus;
- Hepatitis C virus;
- Human T-lymphotropic virus, type I; and
- Human T-lymphotropic virus, type II.[11]

The Zika Virus (ZIKV) and Transplant Tissue Testing

In March 2016, U.S. Department of Health and Human Services, Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, issued non-binding recommendations on donor screening to reduce the risk of the ZIKV transmission to human cells, tissues, and cellular products. The recommendations included the review of a potential donor's medical records for any clinical evidence of the ZIKV; and the donor was considered ineligible if he or she had any of the following:

- A medical diagnose of a ZIKV infection in the past six months;
- Was a resident of, or traveled to, an area with active ZIKV transmission within the past six months; or

---

[2] Id.
[3] U.S. Government Information on Organ Donation and Transplantation, U.S. Department of Health & Human Services, *The Organ Transplant Process* https://organdonor.gov/about/process/transplant-process.html (last visited Jan. 17, 2018).
[4] Donate Life Florida, *Organ Procurement Organizations and Transplant Centers* https://www.donatelifeflorida.org/local-resources/transplant-centers/ (last visited Jan. 17, 2018).
[5] Organ Procurement and Transplantation Network, U.S. Department of Health and Human Services, *The Basic Path of Donation* https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/ (last visited Jan. 17, 2018).
[6] Section 381.001, F.S.
[7] Testing for HIV infection is required for both type 1and type 2 HIV. See 21 C.F.R. ss. 610.40 and 1270.21 (2013).
[8] Section 381.0041(3), F.S.
[9] Section 381.0041(1) and 3, F.S.
[10] Rule 64D-2.005, F.A.C.
[11] See 21 C.F.R. ss. 610.40 and 1270.21 (2013).

- Had sex with a male diagnosed with a ZIKV infection in the past six months who had resided in, or traveled to, an area with active ZIKV transmission within the past six months. [12]

The CDC further recommended that cadaveric donors be ineligible for donation if the cadaver has had a medical diagnosis of the ZIKV in the past six months.[13]

III. Effect of Proposed Changes:

CS/SB 514 requires the DOH to develop a pamphlet on the risks and benefits of human cells and tissue transplants. The DOH must publish the pamphlet on its website, and electronically notify physicians when it is available. The pamphlet must include the following:

- An overview of transplant infectious disease risks;
- A summary of testing and screening standards for donors;
- A summary of processing methods used to reduce the risk of disease transmission;
- A statement acknowledging the importance of limiting information provided to the supplier about the recipient; and
- A statement acknowledging the generosity of donors.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

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[12] The FDA has authority to issue Guidance to Industry in accordance with 21 CFR 10.115(g)(2). See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products - Guidance for Industry*, https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm488582.pdf (last visited Jan. 17, 2018).

[13] *See* note 31.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH will incur a cost in developing the educational pamphlet, in publishing it on the website, and in notifying physicians of the pamphlet's availability. The cost is undeterminable at this time.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0041 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/SB 514 by Health Policy on January 23, 2018:
The CS removed the requirement for health care providers to warn potential transplant recipients of the risks of contracting ZIKV. Instead, the DOH must develop a pamphlet addressing the risks and benefits of human cells and tissue transplants; publish the pamphlet on its website; and electronically notify physicians when the pamphlet is available.

B. Amendments:

None.

659780

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/23/2018	.	
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The Committee on Health Policy (Young) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (13) is added to section 381.0041, Florida Statutes, to read:

381.0041 Donation and transfer of human tissue; testing requirements.—

(13) The department shall develop an educational pamphlet that contains information on the risks and benefits of human

659780

cell, tissue, and cellular- and tissue-based product transplants. The department shall publish the pamphlet on its website and shall electronically notify physicians when the pamphlet becomes available. At a minimum, the pamphlet must include all of the following:

(a) An overview of the infectious disease transmission risks associated with a transplant.

(b) A summary of the standards for the testing and screening of donors.

(c) A summary of processing methods that are used to reduce the risk of transmission of bacteria and infectious diseases in donated human cells, tissues, and cellular- and tissue-based products before transplantation.

(d) A statement acknowledging the importance of limiting information provided to the supplier of the human cells, tissue, or cellular- or tissue-based product on the recipient of the transplant.

(e) A statement acknowledging the generosity of donors of human cells, tissues, and cellular- and tissue-based products.

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

========== 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 transplant of human tissue; amending s. 381.0041, F.S.; requiring the Department of Health to develop and publish an educational

659780

pamphlet which contains certain information on the risks and benefits of transplants; requiring the department to notify physicians of the availability of the pamphlet; providing an effective date.

By Senator Young

18-00552-18 2018514__

A bill to be entitled

An act relating to transplant of human tissue; amending s. 381.0041, F.S.; requiring an institution or physician responsible for transplanting an organ or an allograft, or for artificial insemination, to warn the recipient as to the risks of contracting Zika virus; providing an exception to the warning requirement for an organ or allograft that has been virally inactivated; defining the term "virally inactivated"; providing an effective date.

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

Section 1. Subsection (12) of section 381.0041, Florida Statutes, is amended to read:

381.0041 Donation and transfer of human tissue; testing requirements.—

(12) Before ~~Prior to~~ the transplant of an organ or allograft, or artificial insemination, the institution or physician responsible for overseeing the procedure must provide the prospective recipient a warning as to the risks of contracting human immunodeficiency virus and Zika virus. The Zika virus warning is not required for an organ or an allograft that has been virally inactivated. For purposes of this subsection, the term "virally inactivated" means an organ or allograft that has undergone a validated process to eliminate viral contamination.

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-23-18
Meeting Date

514
Bill Number (if applicable)

659780
Amendment Barcode (if applicable)

Topic _____

Name Ron LaFace

Job Title _____

Address 101 E College Ave
Street

Phone 222-9075

Tall FL 32301
City *State* *Zip*

Email _____

Speaking: ☑ For ☐ Against ☐ Information

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

Representing MiMedx

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 1876
INTRODUCER:	Health Policy Committee and Senator Young
SUBJECT:	Trauma Services
DATE:	January 23, 2018
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1876 amends various sections of law related to the selection and licensure of trauma centers and the reporting of trauma center data. The bill:

- Eliminates outdated language related to a Department of Health (DOH) assessment of the trauma system and continuing annual reviews of the assignment of counties to trauma service areas (TSA).
- Eliminates TSA 19 and revises the county make up of certain TSAs.
- Restricts the DOH from designating additional Level I trauma centers in the same TSA where a Level I trauma center currently exists.
- Restricts the DOH from designating a Level II trauma center as a pediatric or a Level I trauma center.
- Designates the number of trauma centers allowed in each TSA for a total of 35 trauma centers statewide.
- Requires the DOH to establish the Florida Trauma System Advisory Council (FTSAC) by October 1, 2018. The bill specifies the makeup of the FTSAC and requires the FTSAC to submit a biennial report, beginning January 5, 2020, to the Governor and the Legislature on whether an increase of the number of trauma centers within each TSA is recommended.
- Revises the procedure for the DOH to choose and license new trauma centers if there is statutory capacity within a TSA.

- Provides grandfathering language for currently verified trauma centers and for certain provisionally approved trauma centers.
- Requires the DOH to designate any hospital as a Level II trauma center if the hospital receives a final recommended order from the Division of Administrative Hearings or a final determination from the DOH or a court that it was entitled to be a Level II trauma center and was provisionally approved and operating within specified dates.
- Eliminates the trauma registry under the DOH in favor of requiring trauma centers to participate in the National Trauma Data Bank. Trauma centers and acute care hospitals are still required to report all transfers and outcomes of trauma patients to the DOH.

II. Present Situation:

The regulation of trauma centers in Florida is established under part II of ch. 395, F.S. Trauma centers treat individuals who have incurred single or multiple injuries because of blunt or penetrating means or burns, and who require immediate medical intervention or treatment. Currently, there are 36 verified and provisional trauma centers in the state.[1]

Trauma centers in Florida are divided into several categories including Level I, Level II, and Pediatric trauma centers.

- A Level I trauma center is defined as a trauma center that:
  - Has formal research and education programs for the enhancement of trauma care; is verified by the DOH to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the DOH to operate as a Level I trauma center;
  - Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.[2]
- A Level II trauma center is defined as a trauma center that:
  - Is verified by the DOH to be in substantial compliance with Level II trauma center standards and has been approved by the DOH to operate as a Level II trauma center or is designated pursuant to s. 395.4025(14), F.S.;
  - Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care.[3]
- A Pediatric trauma center is defined as a hospital that is verified by the DOH to be in substantial compliance with pediatric trauma center standards and has been approved by the DOH to operate as a pediatric trauma center.[4,5]

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[1] Department of Health, *Senate Bill 1876 Analysis* (January 17, 2018) (on file with the Senate Committee on Health Policy).
[2] Section 395.4001(6), F.S.
[3] Section 395.4001(7), F.S.
[4] Section 395.4001(9), F.S.
[5] For Level I, Level II, and pediatric trauma center standards *see* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf, (last visited on Jan. 19, 2018).

Trauma Center Apportionment

Pursuant to s. 395.402, F.S., Florida is divided into 19 "trauma service areas." A trauma service area is determined based on population density and an ability to respond to a specified number of patients in a trauma center environment. For purposes of medical response time, the trauma service area should have at least one Level I or Level II trauma center, and the DOH is required to allocate, by rule, the number of trauma centers for each trauma service area. There cannot be more than 44 trauma centers in the state.

Rule Litigation

Since 2011, the DOH has been involved in constant litigation involving its annual assessment of need for trauma centers. The majority of this litigation is based on the state's TSA allocation methodology which imposes limitations on hospitals seeking trauma center verification. Protests have been levied regarding the validity of the DOH's allocation of new trauma centers in specific geographic areas. Despite prevailing in an administrative rule challenge in 2014 that validated the DOH's allocation methodology, the DOH has been unable to promulgate the required annual rule change since 2014 due to litigation.

In 2016, the DOH attempted to promulgate an apportionment rule that interpreted need to mean the "minimum" number of trauma centers in a TSA. The proposed rule was subsequently challenged by seven existing trauma centers. The Division of Administrative Hearings issued an order that invalidated the proposed rule in March of 2017. The administrative law judge recognized the challenges faced by the DOH and Florida's trauma system in his final order by stating, "After considering all of the evidence and testimony, the undersigned is of the opinion that it would be impossible to draft a set of rules that would satisfy the concerns/interests of all the relevant stakeholders." Since the invalidation of the rule, the DOH has been unable to promulgate a new rule.

In 2015, an Administrative Law Judge outlined in a recommended order that the DOH must grant provisional trauma center status to all applicants that demonstrate compliance with the critical elements of the trauma center standards, regardless if there is an allocated slot in the TSA. In addition, he indicated the DOH's determination of need happens at the point in which a trauma center is granted verification. This point was upheld in December 2017 per a ruling from the 1st District Court of Appeals. In a separate ruling, the first DCA also stated that a hospital may apply over multiple years without jeopardizing the previous application. In combination, a hospital may essentially operate indefinitely as a provisional trauma center so long as they submit and receive approval of their application annually.

The DOH has been unable to promulgate a valid allocation rule since July, 2014.[6]

Trauma Center Approval

Section 395.4025, F.S., provides a scheduled application process and specific trauma center selection criteria. Standards for verification and approval are based on national guidelines

[6] Supra note 1

established by the American College of Surgeons.[7] Standards for verification and approval as a pediatric trauma center are developed in conjunction with the DOH Children's Medical Services.

Acute care hospitals that submit a Letter of Intent to the DOH by October 1 are eligible to submit a trauma center application by April 1.[8] Once an applicant hospital receives the DOH's notification letter of provisional status designation, the hospital may begin operation as a provisional trauma center. During the provisional phase, the DOH conducts an in-depth review of the hospital's application. An onsite visit is conducted by an out-of-state survey team to verify compliance with the *Trauma Center Standards, DH Pamphlet 150-9*.[9] Based on the recommendations from the out-of-state survey team, the DOH makes the decision to approve or deny the hospital to operate as a verified trauma center.[10]

Hospitals verified by the DOH receive a seven year certificate. A verified trauma center that intends to renew its verification must submit a renewal application form to the DOH at least 14 months prior to the expiration of the certificate. All renewing verified trauma centers receive an onsite visit by an out-of-state survey team after the DOH's receipt of the completed renewal form. Hospitals that have been verified by the DOH to be in compliance with the requirements of s. 395.4025, F.S., are approved to operate as a verified trauma center.[11]

Florida's current trauma center verification process has experienced a number of challenges. Section 395.4025(7), F.S., allows any hospital in the state to protest verification decisions by the DOH. Hypothetically, under this subsection, a 25-bed acute care hospital in northwest Florida can protest the verification of a trauma center in Miami-Dade County. In actual application, the DOH has been involved in litigation numerous times where one or more parties operating a trauma center in one geographic area of the state have challenged trauma center verification in another area of the state.[12]

Florida Trauma Registry

The DOH has maintained a trauma registry since at least 2000. Currently, only a small number of states nationwide do not have a state trauma registry. In 2014, the DOH upgraded the trauma registry and receives patient data from every verified trauma center in the state. Changes made to the registry in 2016, based on feedback received from trauma stakeholders, allow a Florida trauma center to submit the same data elements as those required by the National Trauma Data Bank (NTDB).

The trauma registry serves two critical functions. First, the DOH is able to perform statewide, local and regional data analysis much faster than the NTDB. The NTDB does not perform local and regional analysis and due to the reporting requirements of the NTDB, data analysis is not

[7] The ACS requirements for Level I, Level II, and pediatric trauma centers are available at: http://www.facs.org/trauma/verifivisitoutcomes.html, (last visited on Jan. 19, 2018).
[8] The required criteria included in the application package is outlined in the department's *Trauma Center Standards, DH Pamphlet 150-9*, in accordance with s. 395.401(2), F.S., and is incorporated by reference in Rule 64J-2.011, F.A.C.
[9] Section 395.4025(5), F.S.
[10] Section 395.4025(6), F.S.
[11] Id.
[12] Supra note 1. A list of current litigation is on file with Senate Health Policy Committee staff.

available for 18 months after the initial reporting period and is limited to standardized reports provided to all participants. In contrast, the DOH is able to provide information as quickly as six months after the end of the reporting period. The Department is also able to create customized, analytical reports not currently available from the NTDB. Second, s. 305.4036, F.S. requires that patient volumes from the Florida Trauma Registry be used as part of the formula to calculate the distribution of traffic fine revenues.[13]

III. Effect of Proposed Changes:

Section 1 amends s. 395.402, F.S., to:

- Strike language requiring Level I and Level II trauma centers to be capable of annually treating a minimum of 1,000 and 500 (or 1,000 in a county with 500,000 or more population) patients with an injury severity score (ISS) of 9 or greater, respectively. These requirements are republished as part of the report that the FTSAC must present to the Governor and the Legislature biennially.
- Strike outdated language requiring the DOH to conduct a one-time assessment of the trauma system.
- Strike a requirement that the DOH conduct annual assessments of the assignment of the counties in TSAs.
- Rework the make-up of the TSAs as follows:
  - Eliminate TSA 19 and place Miami-Dade and Monroe Counties into TSA 18;
  - Move Broward County from TSA 18 to TSA 17;
  - Move Collier County from TSA 17 to TSA 15; and
  - Move Charlotte County from TSA 15 to TSA 13.
- Restrict the DOH from designating an additional Level I trauma center in a TSA where a Level I trauma center already exists or from designating a Level II trauma center as a Level I or pediatric trauma center.
- Eliminate the DOH's responsibility to allocate trauma centers by TSA and, instead, specify the number of trauma centers allowed in each TSA as follows:
  - TSAs 2, 3, 4, 6, 7, 11, 12, 14, and 15 are allocated one trauma center;
  - TSAs 10, 13, and 16 are allocated two trauma centers;
  - TSAs 1, 5, 8, 9, and 17 are allocated three trauma centers; and
  - TSA 18 is allocated five trauma centers.
- By October 1, 2018, the DOH is required to establish the FTSAC. The FSTAC will consist of the following 15 Governor-appointed members:
  - The State Surgeon General;
  - A representative from the Agency for Health Care Administration;
  - A representative from an emergency medical services organization;
  - A representative of a local or regional trauma agency;
  - A trauma program manager or trauma medical director representing an investor-owned hospital with a trauma center;
  - A trauma program manager recommended by the Teaching Hospital Council of Florida;
  - A representative of the Florida Hospital Association;
  - A trauma program manager or trauma medical director representing a public hospital;

[13] Supra note 1.

  - A trauma program manager or trauma medical director representing a nonprofit hospital with a trauma center;
  - A trauma surgeon representing an investor-owned hospital with a trauma center;
  - A trauma surgeon recommended by the Teaching Hospital Council of Florida;
  - A trauma surgeon representing a not-for-profit hospital with a trauma center;
  - A representative of the American College of Surgeons Committee on Trauma;
  - A representative of Associated Industries of Florida; and
  - A representative of the Safety Net Hospital Alliance of Florida.
- The FTSAC is required to conduct its first meeting no later than January 5, 2019. By January 5, 2020, and biennially thereafter, it must submit a report to the Governor and the Legislature which assess whether an increase in the number of trauma centers within each TSA is recommended. Additionally, the report must state whether each Level I and II trauma center is capable of annually treating at least 1,000 and 500 (or 1,000 in counties with a population of greater than 500,000) patients with an ISS of 9 or greater, respectively.
- The FTSAC may also submit recommendations to the DOH on the adequacy and continuing development of the state's trauma system.
- In order to make recommendations required by the section, the FTSAC must review and consider materials submitted by the DOH and stakeholders, materials published by the American College of Surgeons Committee on Trauma (ACS), and other relevant materials as the FTSAC deems appropriate. The FTSAC must base its recommendation to the Governor and the Legislature on the following factors:
  - Population changes within a trauma service area;
  - The impact of tourism on a trauma service area;
  - The number of patients with an injury severity score of less than 0.9 who are treated in hospitals that are not trauma centers;
  - Ground and air transport times to a trauma center within each service area;
  - The number of patients treated in existing trauma centers;
  - The capacity of existing trauma centers to treat additional trauma patients;
  - The potential financial impact on existing trauma centers of the designation of additional trauma centers;
  - The financial impact on commercial and government payors of health care insurance and on Florida taxpayers caused by the designation of additional trauma centers;
  - A cost comparison of the charges of existing trauma centers as contrasted with the charges of any prospective trauma centers;
  - Any impacts on graduate medical education programs and resident training for trauma and surgical specialties in the state;
  - The negative impacts, if any, of the designation of new trauma centers on the ability of existing centers to meet standards established by the American College of Surgeons Committee on Trauma;
  - A survey of literature relating to trauma center allocation, including peer-reviewed and academic publications; and
  - Any other factor the advisory council deems appropriate.

Section 2 amends s. 395.4025, F.S., to rework how the DOH selects and licenses trauma centers.[14] The process under the bill will proceed under the following steps:

Letter of Intent

The bill requires the DOH to notify hospitals that the DOH is accepting letters of intent from applicants when there is statutory capacity for an additional trauma center based on the limits established in section one of the bill. The DOH may not accept a letter of intent from a hospital if there is not statutory capacity or if the hospital is located in a TSA or a contiguous TSA where a current Level I trauma center is located that has failed to exceed 1,000 patients annually.

Letters of Intent must be postmarked by October 1 of year one.

Application

By October 15 of year one[15] the DOH must send each hospital that provided a letter of intent an application package. Completed applications must be received by the DOH by April 1 of year two. Between April 1 and April 30 of year two, the DOH will conduct an initial review of the application packages it received to determine if each application shows that the hospital will be capable of attaining and operating with specified criteria by April 30 of year three. The operating criteria include:

- Equipment and physical facilities necessary to provide trauma services.
- Personnel in sufficient numbers and with proper qualifications to provide trauma services.
- An effective quality assurance process.
- A submitted written confirmation by the local or regional trauma agency that the hospital applying to become a trauma center is consistent with the plan of the local or regional trauma agency, as approved by the DOH, if such agency exists.

After April 30 of year two, the DOH must select one or more hospitals that meet the criteria detailed above, up to the statutory capacity designated in s. 395.402, F.S., for each TSA. If the DOH receives more applications than available capacity, the DOH must select one or more applicants, as necessary, that the DOH determines will provide the highest quality patient care using the most recent technological, medical, and staffing resources available as well as any other criteria as determined by the DOH in rule. At this point, the applicant may begin preparing to operate, but the bill restricts an applicant from operating until the DOH completes its final evaluation. A hospital that is not ready to operate by April 30 of year three may not be designated as trauma center.

In-Depth Evaluation

Between May 1 of year two and April 30 of year three the DOH must conduct an in-depth evaluation of each application against the criteria enumerated in the application packages. Also during this time frame the DOH must assemble a review team of out of state experts to make

[14] Note: Some of what is described in this section is current law. However, for the sake of providing a timeline for how the process will work after changes made by SB 1876, the portions that are current law are integrated into the changes made by the bill.

[15] The timeframes in the bill use dates over multiple years. In order to simplify the timeline, the timeframes will be referred to as happening in year one, year two, or year three.

onsite visits to all existing trauma centers. The bill maintains current law regarding the survey instrument that the out of state experts must use.

Designation as a Trauma Center

Based on the recommendations from the review team, the DOH may designate a trauma center that is in compliance with trauma center standards and the requirements in s. 395.4025, F.S. An applicant may not operate as a trauma center until it is designated and it must maintain the operating requirements detailed above. A trauma center is designated for a seven year approval period after which it must apply for renewal of its designation.

Under changes made by the bill, the DOH will no longer provisionally approve trauma centers prior to fully verifying them. The bill also restricts protests against any decision made by the DOH unless the protest is made by a hospital in the same or contiguous TSA.

Grandfathering

The bill deems certain currently operational trauma centers to be compliant with trauma center application and operational standards as follows::

- A trauma center that was verified by the DOH before December 15, 2017, is deemed to have met the trauma center application and operational requirements of this section.
- A trauma center that was not verified by the DOH before December 15, 2017, but that was provisionally approved by the DOH to be in substantial compliance with Level II trauma standards before January 1, 2017, and is operating as a Level II trauma center is deemed to have met the application and operational requirements of this section for a trauma center.
- A trauma center that was not verified by the DOH before December 15, 2017, as a Level I trauma center but that was provisionally approved by the DOH as a Level I trauma center in calendar year 2016 is deemed to have met the application and operational requirements for a Level I trauma center, if the trauma center complies with the American College of Surgeons Committee on Trauma standards for adult Level I trauma centers and does not treat pediatric trauma patients.
- A trauma center that was not verified by the DOH before December 15, 2017, as a pediatric trauma center but that was provisionally approved by the DOH to be in substantial compliance with the pediatric trauma standards established by rule before January 1, 2018, and is operating as a pediatric trauma center is deemed to have met the application and operational requirements of this section for a pediatric trauma center.
- Notwithstanding the statutory capacity limits established in s. 395.402(1), F.S., a trauma center is eligible for designation if all of the following apply:
    - The trauma center was not verified by the DOH before December 15, 2017;
    - The DOH initially provisionally approved the trauma center to begin operations in May 2017;
    - The trauma center is currently operating as a provisional Level II trauma center;
    - The DOH determines that the trauma center has met the application and operational requirements of this section for a Level II trauma center; and
    - The DOH's decision to provisionally approve the trauma center is:
        - Supported by a recommended order from the Division of Administrative Hearings and, if the order is appealed, the DOH's decision is upheld on appeal; or

- Not supported by a recommended order from the Division of Administrative Hearings, but the department's decision is upheld on appeal.

Section 3 of the bill amends s. 395.404, F.S., to eliminate the trauma registry under the DOH in favor of requiring trauma centers to participate in the National Trauma Data Bank. Trauma centers and acute care hospitals are still required to report all transfers and outcomes of trauma patients to the DOH.

The bill also eliminates a public records exemption for the DOH's trauma registry and eliminates the requirement that pediatric trauma centers report certain data to the DOH's brain and spinal cord injury central registry.

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 1876 may have an indeterminate positive fiscal impact on hospitals that do not currently have verified trauma centers but that become designated as a trauma center due to changes made by the bill.

Hospitals that have currently verified trauma centers in TSAs where new trauma centers are designated under the provisions of the bill may see an indeterminate negative fiscal impact due to the potential loss in volume of trauma patients and other economic impacts of competition.

C. Government Sector Impact:

The bill requires the DOH to make on-site visits to "all existing trauma centers." This provision could be interpreted to mean that the DOH is required to conduct on-site visits

to all 36 trauma centers every time it designates a new hospital as a trauma center. The estimated cost to visit all existing trauma centers is $500,000.[16]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The timing on when the DOH must engage out-of-state surveyors to conduct an on-site visit of a trauma center applicant is unclear. The bill seems to require that such a visit be conducted before the trauma center is operational. If this is the case, it is unclear how the on-site visit would be completed without being able to survey the trauma center's actual operations. The timing in the bill should be clarified so that the on-site visit by the out-of-state surveyors occurs while the trauma center is operational.

The bill creates specific, date-based timeframes for the DOH and trauma center applicants to complete certain aspects of the application and approval process for new trauma centers. The bill also provides that applicants that are not ready to operate by April 30 of year three may not be designated as a trauma center. The bill does not provide any exception to this requirement for applicants that are in litigation over the DOH's selection process or that are otherwise delayed through no fault of their own.

The bill establishes grandfathering provisions for currently verified trauma centers and certain provisionally approved trauma centers on lines 496-538. However, the bill does not automatically designate such trauma centers as trauma centers under the requirements established by the bill. Rather, the bill deems such trauma centers to be compliant with trauma center application and operational standards. It is possible that the grandfathering provisions may be interpreted to require the DOH to perform a ministerial task to officially designate such trauma centers after the bill becomes effective. Additionally, the bill restricts any trauma center from operating if it has not been designated as a trauma center by the DOH. These two provisions, when taken together, may require all currently operating trauma centers to cease operations for the period of time between when the bill takes effect and when the DOH is able to officially designate them as trauma centers.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.402, 395.4025, and 395.404.

[16] Supra note 1

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 January 23, 2018:
The CS replaces grandfathering language related to Level II trauma centers in ongoing court proceedings to clarify that it is the DOH, and not a court, that must determine that the trauma center has met application and operational requirements, to specify the required court actions that qualify a trauma center under the paragraph, and to conform the title of the bill to changes made by the amendment.

B. Amendments:

None.

735918

LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
01/24/2018	.	
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	.	

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

Senate Amendment (with title amendment)

Delete lines 522 - 538

and insert:

established in s. 395.402(1), the determination of whether a trauma center that was not verified by the department before December 15, 2017, but was initially approved by the department in May 2017 to begin operations and is currently operating as a provisional Level II trauma center meets the application and operational requirements for a trauma center shall be governed

735918

by a final order from the department or, if appealed, an order from a court of competent jurisdiction.

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

And the title is amended as follows:

Delete lines 60 - 62

and insert:

requirements; providing that a certain order governs the determination of certain trauma centers;

647210

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
01/24/2018	.	
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	.	

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

Senate Substitute for Amendment (735918) (with title amendment)

Delete lines 521 - 538
and insert:
(e) Notwithstanding the statutory capacity limits established in s. 395.402(1), a trauma center is eligible for designation if all of the following apply:
1. The trauma center was not verified by the department before December 15, 2017;

647210

2. The department initially provisionally approved the trauma center to begin operations in May 2017;

3. The trauma center is currently operating as a provisional Level II trauma center;

4. The department determines that the trauma center has met the application and operational requirements of this section for a Level II trauma center; and

5. The department's decision to provisionally approve the trauma center is:

a. Supported by a recommended order from the Division of Administrative Hearings and, if the order is appealed, the department's decision is upheld on appeal; or

b. Not supported by a recommended order from the Division of Administrative Hearings, but the department's decision is upheld on appeal.

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

And the title is amended as follows:

Delete lines 60 - 62

and insert:

requirements; providing that certain currently operating trauma centers are eligible to be designated as trauma centers by the department if certain criteria are met;

By Senator Young

18-01126C-18 20181876__

A bill to be entitled

An act relating to trauma services; amending s. 395.402, F.S.; revising the trauma service areas and provisions relating to the number and location of trauma centers; prohibiting the Department of Health from designating an additional Level I trauma center in a trauma service area where a Level I trauma center currently exists, from designating an existing Level II trauma center as a pediatric trauma center, and from designating an existing Level II trauma center as a Level I trauma center; reducing the total number of trauma centers authorized in this state; apportioning trauma centers within each trauma service area; requiring the department to establish the Florida Trauma System Advisory Council by a specified date; requiring the council to review specified materials; authorizing the council to submit certain recommendations to the department; providing membership of the council; requiring the council to meet no later than a specified date and to meet annually; requiring the council to submit by a specified date, and biennially thereafter, a report to the Legislature and the Governor which must assess whether an increase in the number of trauma centers within each trauma service area is recommended based on certain factors; requiring the report to include specified information; amending s. 395.4025, F.S.; conforming provisions to changes made by the act; requiring the department to select and designate

certain hospitals as trauma centers based on statutory capacity; prohibiting the department from accepting a letter of intent or designating a trauma center unless a specified number of patients have been served by an existing Level I trauma center in the same or in a contiguous trauma service area; revising the department's review process for hospitals seeking designation as a trauma center; providing that a proposed trauma center must be ready to operate by a specified date; requiring the department to select one or more hospitals for approval to prepare to operate as a trauma center; providing selection requirements; prohibiting the applicant from operating as a trauma center until a final evaluation has been completed by the department; requiring a specified review team to make onsite visits to all existing trauma centers within a certain timeframe; authorizing the department to designate a trauma center that is in compliance with specified requirements; deleting a provision authorizing an applicant to request an extension of its provisional status; deleting the date by which the department must select trauma centers; prohibiting an applicant from operating as a trauma center unless it has been designated and certain requirements are met; providing that only certain hospitals may protest a decision made by the department; providing that certain trauma centers that were verified by the department or determined by the department to be in substantial compliance with specified standards are

deemed to have met application and operational requirements; requiring the department to designate a certain provisionally approved Level II trauma center as a trauma center if certain criteria are met; amending s. 395.404, F.S.; requiring trauma centers to participate in the National Trauma Data Bank; requiring trauma centers and acute care hospitals to report trauma patient transfer and outcome data to the department; deleting provisions relating to the department review of trauma registry data; providing an effective date.

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

Section 1. Section 395.402, Florida Statutes, is amended to read:

395.402 Trauma service areas; number and location of trauma centers.—

(1) The Legislature recognizes the need for a statewide, cohesive, uniform, and integrated trauma system. ~~Within the trauma service areas, Level I and Level II trauma centers shall each be capable of annually treating a minimum of 1,000 and 500 patients, respectively, with an injury severity score (ISS) of 9 or greater. Level II trauma centers in counties with a population of more than 500,000 shall have the capacity to care for 1,000 patients per year.~~

~~(2) Trauma service areas as defined in this section are to be utilized until the Department of Health completes an assessment of the trauma system and reports its finding to the~~

~~Governor, the President of the Senate, the Speaker of the House of Representatives, and the substantive legislative committees. The report shall be submitted by February 1, 2005. The department shall review the existing trauma system and determine whether it is effective in providing trauma care uniformly throughout the state. The assessment shall:~~

~~(a) Consider aligning trauma service areas within the trauma region boundaries as established in July 2004.~~

~~(b) Review the number and level of trauma centers needed for each trauma service area to provide a statewide integrated trauma system.~~

~~(c) Establish criteria for determining the number and level of trauma centers needed to serve the population in a defined trauma service area or region.~~

~~(d) Consider including criteria within trauma center approval standards based upon the number of trauma victims served within a service area.~~

~~(e) Review the Regional Domestic Security Task Force structure and determine whether integrating the trauma system planning with interagency regional emergency and disaster planning efforts is feasible and identify any duplication of efforts between the two entities.~~

~~(f) Make recommendations regarding a continued revenue source which shall include a local participation requirement.~~

~~(g) Make recommendations regarding a formula for the distribution of funds identified for trauma centers which shall address incentives for new centers where needed and the need to maintain effective trauma care in areas served by existing centers, with consideration for the volume of trauma patients~~

~~served, and the amount of charity care provided.~~

~~(3) In conducting such assessment and subsequent annual reviews, the department shall consider:~~

~~(a) The recommendations made as part of the regional trauma system plans submitted by regional trauma agencies.~~

~~(b) Stakeholder recommendations.~~

~~(c) The geographical composition of an area to ensure rapid access to trauma care by patients.~~

~~(d) Historical patterns of patient referral and transfer in an area.~~

~~(e) Inventories of available trauma care resources, including professional medical staff.~~

~~(f) Population growth characteristics.~~

~~(g) Transportation capabilities, including ground and air transport.~~

~~(h) Medically appropriate ground and air travel times.~~

~~(i) Recommendations of the Regional Domestic Security Task Force.~~

~~(j) The actual number of trauma victims currently being served by each trauma center.~~

~~(k) Other appropriate criteria.~~

~~(4) Annually thereafter, the department shall review the assignment of the 67 counties to trauma service areas, in addition to the requirements of paragraphs (2)(b)-(g) and subsection (3). County assignments are made for the purpose of developing a system of trauma centers. Revisions made by the department shall take into consideration the recommendations made as part of the regional trauma system plans approved by the department and the recommendations made as part of the state~~

~~trauma system plan. In cases where a trauma service area is located within the boundaries of more than one trauma region, the trauma service area's needs, response capability, and system requirements shall be considered by each trauma region served by that trauma service area in its regional system plan. Until the department completes the February 2005 assessment, the assignment of counties shall remain as established in this section.~~

(a) The following trauma service areas are ~~hereby~~ established:

1. Trauma service area 1 shall consist of Escambia, Okaloosa, Santa Rosa, and Walton Counties.

2. Trauma service area 2 shall consist of Bay, Gulf, Holmes, and Washington Counties.

3. Trauma service area 3 shall consist of Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties.

4. Trauma service area 4 shall consist of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties.

5. Trauma service area 5 shall consist of Baker, Clay, Duval, Nassau, and St. Johns Counties.

6. Trauma service area 6 shall consist of Citrus, Hernando, and Marion Counties.

7. Trauma service area 7 shall consist of Flagler and Volusia Counties.

8. Trauma service area 8 shall consist of Lake, Orange, Osceola, Seminole, and Sumter Counties.

9. Trauma service area 9 shall consist of Pasco and

Pinellas Counties.

10. Trauma service area 10 shall consist of Hillsborough County.

11. Trauma service area 11 shall consist of Hardee, Highlands, and Polk Counties.

12. Trauma service area 12 shall consist of Brevard and Indian River Counties.

13. Trauma service area 13 shall consist of Charlotte, DeSoto, Manatee, and Sarasota Counties.

14. Trauma service area 14 shall consist of Martin, Okeechobee, and St. Lucie Counties.

15. Trauma service area 15 shall consist of Collier ~~Charlotte~~, Glades, Hendry, and Lee Counties.

16. Trauma service area 16 shall consist of Palm Beach County.

17. Trauma service area 17 shall consist of Broward ~~Collier~~ County.

18. Trauma service area 18 shall consist of ~~Broward County.~~

~~19. Trauma service area 19 shall consist of~~ Miami-Dade and Monroe Counties.

(b) Each trauma service area must ~~should~~ have at least one Level I or Level II trauma center. The department may not designate an additional Level I trauma center in a trauma service area in which a Level I trauma center currently exists. The department may not designate an existing Level II trauma center as a pediatric trauma center. The department may not designate an existing Level II trauma center as a Level I trauma center ~~The department shall allocate, by rule, the number of trauma centers needed for each trauma service area~~.

(c) The total number of trauma centers in this state may not exceed 35. Trauma centers shall be apportioned as follows:

1. Trauma service area 1 shall have three trauma centers.
2. Trauma service area 2 shall have one trauma center.
3. Trauma service area 3 shall have one trauma center.
4. Trauma service area 4 shall have one trauma center.
5. Trauma service area 5 shall have three trauma centers.
6. Trauma service area 6 shall have one trauma center.
7. Trauma service area 7 shall have one trauma center.
8. Trauma service area 8 shall have three trauma centers.
9. Trauma service area 9 shall have three trauma centers.
10. Trauma service area 10 shall have two trauma centers.
11. Trauma service area 11 shall have one trauma center.
12. Trauma service area 12 shall have one trauma center.
13. Trauma service area 13 shall have two trauma centers.
14. Trauma service area 14 shall have one trauma center.
15. Trauma service area 15 shall have one trauma center.
16. Trauma service area 16 shall have two trauma centers.
17. Trauma service area 17 shall have three trauma centers.
18. Trauma service area 18 shall have five trauma centers.

~~There shall be no more than a total of 44 trauma centers in the state.~~

(2)(a) By October 1, 2018, the department shall establish the Florida Trauma System Advisory Council to determine the need for additional trauma centers. The advisory council shall review and consider materials submitted by the department and stakeholders, materials published by the American College of Surgeons Committee on Trauma, and other relevant materials as the council deems appropriate before issuing a recommendation.

The advisory council may submit recommendations to the department on the adequacy and continuing development of the state's trauma system, including the demand for new trauma centers.

(b)1. The advisory council shall consist of 15 representatives appointed by the Governor, including:

a. The State Surgeon General;

b. A representative from the Agency for Health Care Administration;

c. A representative from an emergency medical services organization;

d. A representative of a local or regional trauma agency;

e. A trauma program manager or trauma medical director representing an investor-owned hospital with a trauma center;

f. A trauma program manager recommended by the Teaching Hospital Council of Florida;

g. A representative of the Florida Hospital Association;

h. A trauma program manager or trauma medical director representing a public hospital;

i. A trauma program manager or trauma medical director representing a nonprofit hospital with a trauma center;

j. A trauma surgeon representing an investor-owned hospital with a trauma center;

k. A trauma surgeon recommended by the Teaching Hospital Council of Florida;

l. A trauma surgeon representing a not-for-profit hospital with a trauma center;

m. A representative of the American College of Surgeons Committee on Trauma;

n. A representative of Associated Industries of Florida; and

o. A representative of the Safety Net Hospital Alliance of Florida.

2. No two representatives may be employed by the same health care facility.

3. Each representative of the council shall be appointed to a 3-year term; however, for the purpose of providing staggered terms, of the initial appointments, 5 representatives shall be appointed to 1-year terms, 5 representatives shall be appointed to 2-year terms, and 5 representatives shall be appointed to 3-year terms.

(3) The advisory council shall convene its first meeting no later than January 5, 2019, and shall meet at least annually.

(4)(a) By January 5, 2020, and at least every 2 years thereafter, the advisory council shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which assesses whether an increase in the number of trauma centers within each trauma service area is recommended based on all of the following factors:

1. Population changes within a trauma service area;

2. The impact of tourism on a trauma service area;

3. The number of patients with an injury severity score of less than 0.9 who are treated in hospitals that are not trauma centers;

4. Ground and air transport times to a trauma center within each service area;

5. The number of patients treated in existing trauma centers;

6. The capacity of existing trauma centers to treat additional trauma patients;

7. The potential financial impact on existing trauma centers of the designation of additional trauma centers;

8. The financial impact on commercial and government payors of health care insurance and on Florida taxpayers caused by the designation of additional trauma centers;

9. A cost comparison of the charges of existing trauma centers as contrasted with the charges of any prospective trauma centers;

10. Any impacts on graduate medical education programs and resident training for trauma and surgical specialties in the state;

11. The negative impacts, if any, of the designation of new trauma centers on the ability of existing centers to meet standards established by the American College of Surgeons Committee on Trauma;

12. A survey of literature relating to trauma center allocation, including peer-reviewed and academic publications; and

13. Any other factor the advisory council deems appropriate.

(b) The report must state whether each Level I trauma center within the trauma service areas is capable of annually treating at least 1,000 patients with an injury severity score of 9 or greater and whether each Level II trauma center is capable of annually treating 500 patients with an injury severity score of 9 or greater. The report must state whether each Level II trauma center located in a county with a

population greater than 500,000 has the capacity to care for at least 1,000 patients per year.

Section 2. Subsections (1) through (7) of section 395.4025, Florida Statutes, are amended, and subsection (15) is added to that section, to read:

395.4025 Trauma centers; selection; quality assurance; records.—

(1) For purposes of developing a system of trauma centers, the department shall use the 18 ~~19~~ trauma service areas established in s. 395.402. ~~Within each service area and based on the state trauma system plan, the local or regional trauma services system plan, and recommendations of the local or regional trauma agency, the department shall establish the approximate number of trauma centers needed to ensure reasonable access to high-quality trauma services.~~ The department shall select those hospitals that are to be recognized as trauma centers.

(2)(a) If there is statutory capacity for an additional trauma center in accordance with s. 395.402(1), the department shall ~~annually~~ notify each acute care general hospital and each local and each regional trauma agency in the state that the department is accepting letters of intent from hospitals that are interested in becoming trauma centers. The department may not accept a letter of intent from an applicant and may not designate an applicant a trauma center if the applicant has applied to locate the trauma center in a trauma service area where the number of patients served by an existing Level I trauma center in that area or in a contiguous trauma service area fails to exceed 1,000 patients annually. In order to be

considered by the department, a hospital that operates within the geographic area of a local or regional trauma agency must certify that its intent to operate as a trauma center is consistent with the trauma services plan of the local or regional trauma agency, as approved by the department, if such agency exists. The department may accept a letter of intent only if there is statutory capacity for an additional trauma center in accordance with s. 395.402(1). Letters of intent must be postmarked no later than midnight October 1.

(b) By October 15, the department shall send to all hospitals that submitted a letter of intent an application package that will provide the hospitals with instructions for submitting information to the department for selection as a trauma center. The standards for trauma centers provided for in s. 395.401(2), as adopted by rule of the department, shall serve as the basis for these instructions.

(c) In order to be considered by the department, applications from those hospitals seeking selection as trauma centers, including those current verified trauma centers that seek a change or redesignation in approval status as a trauma center, must be received by the department no later than the close of business on April 1. The department shall conduct an initial ~~a provisional~~ review of each application for the purpose of determining that the hospital's application is complete and that the hospital is capable of constructing and operating a trauma center that includes ~~has~~ the critical elements required for a trauma center. This critical review must ~~will~~ be based on trauma center standards and must ~~shall~~ include, but need not be limited to, a review as to ~~of~~ whether the hospital is prepared

to attain and operate with all of the following components before April 30 of the following year ~~has~~:

1. Equipment and physical facilities necessary to provide trauma services.

2. Personnel in sufficient numbers and with proper qualifications to provide trauma services.

3. An effective quality assurance process.

4. A submitted written confirmation by the local or regional trauma agency that the hospital applying to become a trauma center is consistent with the plan of the local or regional trauma agency, as approved by the department, if such agency exists.

(d)~~1.~~ If the department determines that the hospital is capable of attaining and operating with the components required in paragraph (c), the applicant must be ready to operate no later than April 30 of the following year. A hospital that fails to comply with this subsection may not be designated as a trauma center ~~Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, as provided by rule of the department. An applicant that is granted additional time pursuant to this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. Any applicant that demonstrates an ongoing effort to complete the activities within the~~

~~timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center.~~

~~2. Timeframes provided in subsections (1)-(8) shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center~~.

(3) After April 30, the department shall select one or more hospitals ~~any hospital~~ that submitted an application found acceptable by the department based on initial ~~provisional~~ review for approval to prepare ~~shall be eligible~~ to operate with the components required in paragraph (2)(c). The number of applicants selected is limited to available statutory capacity in the specified trauma service area, as designated in s. 395.402(1). If the department receives more applications than may be approved under the statutory capacity in the specified trauma service area, the department must select the best applicant or applicants from the available pool based on the department's determination of the capability of an applicant to provide the highest quality patient care using the most recent technological, medical, and staffing resources available, as well as any other criteria as determined by the department by rule. The applicant may not operate as a ~~provisional~~ trauma center until the final evaluation has been completed by the department.

(4) Between May 1 and April 30 ~~October 1~~ of the following ~~each~~ year, the department shall conduct an in-depth evaluation

of all applications found acceptable in the initial ~~provisional~~ review. The applications shall be evaluated against criteria enumerated in the application packages as provided to the hospitals by the department.

(5) Between May 1 and April 30 ~~Beginning October 1 of each year and ending no later than June 1~~ of the following year, a review team of out-of-state experts assembled by the department shall make onsite visits to all existing ~~provisional~~ trauma centers. The department shall develop a survey instrument to be used by the expert team of reviewers. The instrument must ~~shall~~ include objective criteria and guidelines for reviewers based on existing trauma center standards such that all trauma centers are assessed equally. The survey instrument must ~~shall~~ also include a uniform rating system that ~~will be used by~~ reviewers must use to indicate the degree of compliance of each trauma center with specific standards, and to indicate the quality of care provided by each trauma center as determined through an audit of patient charts. In addition, hospitals being considered as proposed ~~provisional~~ trauma centers must ~~shall~~ meet all the requirements of a trauma center and must ~~shall~~ be located in a trauma service area that has a need for such a trauma center.

(6) Based on recommendations from the review team, the department may designate a trauma center that is in compliance with trauma center standards and with this section ~~shall select trauma centers by July 1~~. An applicant may not operate as a trauma center unless it has been designated as a trauma center and maintains compliance with the operating requirements listed in paragraph (2)(c) ~~An applicant for designation as a trauma center may request an extension of its provisional status if it~~

~~submits a corrective action plan to the department. The corrective action plan must demonstrate the ability of the applicant to correct deficiencies noted during the applicant's onsite review conducted by the department between the previous October 1 and June 1. The department may extend the provisional status of an applicant for designation as a trauma center through December 31 if the applicant provides a corrective action plan acceptable to the department. The department or a team of out-of-state experts assembled by the department shall conduct an onsite visit on or before November 1 to confirm that the deficiencies have been corrected. The provisional trauma center is responsible for all costs associated with the onsite visit in a manner prescribed by rule of the department. By January 1, the department must approve or deny the application of any provisional applicant granted an extension~~. Each trauma center shall be granted a 7-year approval period during which time it must continue to maintain trauma center standards and acceptable patient outcomes as determined by department rule. An approval, unless sooner suspended or revoked, automatically expires 7 years after the date of issuance and is renewable upon application for renewal as prescribed by rule of the department.

(7) Only a ~~Any~~ hospital in the same trauma service area or in a trauma service area contiguous ~~that wishes~~ to the trauma service area where the applicant has applied to locate a trauma center may protest a decision made by the department ~~based on the department's preliminary or in-depth review of applications or on the recommendations of the site visit review team pursuant to this section shall proceed as provided in chapter 120~~. Hearings held under this subsection shall be conducted in the

same manner as provided in ss. 120.569 and 120.57. Cases filed under chapter 120 may combine all disputes between parties.

(15)(a) A trauma center that was verified by the department before December 15, 2017, is deemed to have met the trauma center application and operational requirements of this section.

(b) A trauma center that was not verified by the department before December 15, 2017, but that was provisionally approved by the department to be in substantial compliance with Level II trauma standards before January 1, 2017, and is operating as a Level II trauma center is deemed to have met the application and operational requirements of this section for a trauma center.

(c) A trauma center that was not verified by the department before December 15, 2017, as a Level I trauma center but that was provisionally approved by the department as a Level I trauma center in calendar year 2016 is deemed to have met the application and operational requirements for a Level I trauma center, if the trauma center complies with the American College of Surgeons Committee on Trauma standards for adult Level I trauma centers and does not treat pediatric trauma patients.

(d) A trauma center that was not verified by the department before December 15, 2017, as a pediatric trauma center but that was provisionally approved by the department to be in substantial compliance with the pediatric trauma standards established by rule before January 1, 2018, and is operating as a pediatric trauma center is deemed to have met the application and operational requirements of this section for a pediatric trauma center.

(e) Notwithstanding the statutory capacity limits established in s. 395.402(1), any hospital operating as a Level

II trauma center after January 1, 2017, must be designated by the department as a Level II trauma center if all of the following apply:

1. The hospital was provisionally approved after January 1, 2017, to operate as a Level II trauma center.

2. The department's decision to approve the hospital to operate a provisional Level II trauma center was pending in litigation on or before January 1, 2018;

3. The hospital has received a final recommended order from the Division of Administrative Hearings, a final determination from the department, or an order from a court of competent jurisdiction that it was entitled to be designated as a Level II trauma center; and

4. The department determines that the hospital is in substantial compliance with the Level II trauma center standards.

Section 3. Section 395.404, Florida Statutes, is amended to read:

395.404 Review of trauma ~~registry~~ data; report to central registry~~; confidentiality and limited release~~.—

(1)~~(a)~~ Each trauma center shall participate in the National Trauma Data Bank.

(2) Each trauma center and acute care hospital shall report to the department all transfers of trauma patients and the outcomes of such patients ~~furnish, and, upon request of the department, all acute care hospitals shall furnish for department review trauma registry data as prescribed by rule of the department for the purpose of monitoring patient outcome and ensuring compliance with the standards of approval.~~

~~(b) Trauma registry data obtained pursuant to this subsection are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. However, the department may provide such trauma registry data to the person, trauma center, hospital, emergency medical service provider, local or regional trauma agency, medical examiner, or other entity from which the data were obtained. The department may also use or provide trauma registry data for purposes of research in accordance with the provisions of chapter 405~~.

(3)~~(2)~~ Each trauma center~~, pediatric trauma center,~~ and acute care hospital shall report to the department's brain and spinal cord injury central registry, consistent with the procedures and timeframes of s. 381.74, any person who has a moderate-to-severe brain or spinal cord injury, and shall include in the report the name, age, residence, and type of disability of the individual and any additional information that the department finds necessary.

Section 4. This act shall take effect upon becoming a law.

THE FLORIDA SENATE

APPEARANCE RECORD

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

1-23-2018
Meeting Date

SB # 1876
Bill Number (if applicable)

Topic TRAUMA

Amendment Barcode (if applicable)

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Job Title

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Speaking: ☐ For ☐ Against ☒ Information

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

Representing Safety Net Hospital Alliance of FL (SNHAF)

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)

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THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

1876
Bill Number (if applicable)

647210
Amendment Barcode (if applicable)

Topic Trauma

Name Clint Shouppe

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing BayCare Health System

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

1/23/18
Meeting Date

1876
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Steve Feenia

Job Title _____

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Speaking: ☑ For ☐ Against ☐ Information

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

Representing HCA

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)