Tab 1	**CS/SB 280** by **BI, Bean**; (Similar to H 00793) Telehealth

Tab 2	**SB 474** by **Brandes**; (Similar to H 01339) Physician Orders for Life-sustaining Treatment

156796	D		S	RCS	AHS, Brandes	Delete everything after	02/14 05:34 PM

Tab 3	**CS/SB 710** by **HP, Book**; (Compare to CS/H 00291) Prescription Drug Donation Program

717750	D		S	RCS	AHS, Book	Delete everything after	02/14 06:04 PM

Tab 4	**SB 1184** by **Gibson**; (Identical to H 01009) Closing the Gap Grant Program

Tab 5	**CS/SB 1876** by **HP, Young**; (Compare to CS/H 01165) Trauma Services

461182	D		S	L	RCS	AHS, Young	Delete everything after	02/14 06:04 PM

Tab 6	**CS/SB 1788** by **CF, Passidomo**; (Compare to CS/CS/H 01373) Medication Administration Training

895214	D		S	RCS	AHS, Passidomo	Delete everything after	02/14 06:04 PM

Tab 7	**CS/SB 1874** by **HP, Passidomo (CO-INTRODUCERS) Stargel**; (Compare to H 00327) Emergency Power for Nursing Home and Assisted Living Facilities

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

APPROPRIATIONS SUBCOMMITTEE ON HEALTH AND HUMAN SERVICES
Senator Flores, Chair
Senator Stargel, Vice Chair

MEETING DATE: Wednesday, February 14, 2018
TIME: 4:00—6:00 p.m.
PLACE: *James E. "Jim" King, Jr. Committee Room,* 401 Senate Office Building

MEMBERS: Senator Flores, Chair; Senator Stargel, Vice Chair; Senators Baxley, Book, Passidomo, Rader, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**CS/SB 280** Banking and Insurance / Bean (Similar H 793)	Telehealth; Establishing the standard of care for telehealth providers; providing that telehealth providers, under certain circumstances, are not required to research a patient's history or conduct physical examinations before providing services through telehealth; providing recordkeeping requirements for telehealth providers, etc. BI 01/16/2018 Fav/CS HP 01/30/2018 Favorable AHS 02/14/2018 Favorable AP	Favorable Yeas 6 Nays 0
2	**SB 474** Brandes (Similar H 1339, Compare H 1341, Linked CS/S 476)	Physician Orders for Life-sustaining Treatment; Establishing the Physician Orders for Life-Sustaining Treatment (POLST) Program within the Department of Health; requiring the Agency for Health Care Administration to establish and maintain a database of compassionate and palliative care plans by a specified date; authorizing specified personnel to withhold or withdraw cardiopulmonary resuscitation if presented with a POLST form that contains an order not to resuscitate the patient; requiring the Department of Elderly Affairs, in consultation with the agency, to adopt by rule procedures for the implementation of POLST forms in hospice care, etc. HP 01/16/2018 Favorable AHS 02/14/2018 Temporarily Postponed AP	Temporarily Postponed
3	**CS/SB 710** Health Policy / Book (Compare CS/H 291)	Prescription Drug Donation Program; Renaming the Cancer Drug Donation Program as the Prescription Drug Donation Program; authorizing the donation of prescription drugs, including cancer drugs, and supplies to eligible patients; authorizing nursing home facilities to participate in the program, etc. HP 12/05/2017 Fav/CS AHS 01/24/2018 Temporarily Postponed AHS 02/14/2018 Fav/CS AP	Fav/CS Yeas 6 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 1184** Gibson (Identical H 1009)	Closing the Gap Grant Program; Requiring a Closing the Gap grant proposal to address racial and ethnic disparities in morbidity and mortality rates relating to Lupus, etc. HP 01/30/2018 Favorable AHS 02/14/2018 Favorable AP	Favorable Yeas 6 Nays 0
5	**CS/SB 1876** Health Policy / Young (Compare CS/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 02/14/2018 Fav/CS AP RC	Fav/CS Yeas 6 Nays 0
6	**CS/SB 1788** Children, Families, and Elder Affairs / Passidomo (Similar CS/H 1373)	Medication Administration Training; Revising competency assessment and validation requirements for direct service providers who administer or supervise the self-administration of medication, etc. CF 01/29/2018 Fav/CS AHS 02/14/2018 Fav/CS AP	Fav/CS Yeas 6 Nays 0
7	**CS/SB 1874** Health Policy / Passidomo (Compare H 327, H 479, H 655, H 933, S 284, S 372, S 896, S 1260)	Emergency Power for Nursing Home and Assisted Living Facilities; Requiring the Agency for Health Care Administration, in consultation with the Department of Health and the Department of Elderly Affairs, to adopt and enforce rules requiring each facility to have an emergency power source and a supply of fuel which meet certain criteria by a specified date, etc. HP 01/30/2018 Fav/CS AHS 02/14/2018 Favorable AP RC	Favorable Yeas 6 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 Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 280
INTRODUCER:	Banking and Insurance Committee and Senator Bean
SUBJECT:	Telehealth
DATE:	February 13, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.	Lloyd	Stovall	HP	**Favorable**
3.	Kidd	Williams	AHS	**Recommend: Favorable**
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 280 establishes practice standards for telehealth health care services, addresses the prescribing of controlled substances and issuance of a physician certification for medical marijuana through telehealth, and prescribes recordkeeping and patient consent. Telehealth is the delivery of health care services using telecommunication technologies, which allows licensed practitioners in one location to diagnose and treat patients at a different location. The bill will remove regulatory ambiguity regarding the provision of health care services using this technology because it is not currently addressed in Florida Statutes.

The Department of Health indicates it can absorb within existing resources the costs associated with development and dissemination of education materials for telehealth licensees as required in the bill. There is no fiscal impact to the Agency for Health Care Administration.

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

II. Present Situation:

Health Care Professional Shortage

There is currently a health care provider shortage in the United States (U.S.). Approximately 20 percent of U.S. residents live in rural areas, but only 9 percent of physicians practice in these

areas.[1] As of December 31, 2017,[2] the U.S. Department of Health and Human Services has designated 7,176 Primary Care Health Professional Shortage Areas (HPSA), 5,866 Dental HPSA and 5,042 Mental Health HPSA.[3] An estimated 31,449 practitioners are needed to eliminate the shortage nationwide. Florida is experiencing a health care provider shortage. This is evidenced by the fact that there are 647 federally designated Health Professional Shortage Areas (HPSA) within the state for primary care, dental care, and mental health,[4] and it would take an estimated 2,936 practitioners to eliminate these shortage areas in Florida.

Telehealth

The term, "telehealth," is sometimes used interchangeably with telemedicine. Telehealth, however, generally refers to a wider range of health care services that may or may not include clinical services.[5] Telehealth often collectively defines the telecommunications equipment and technology that are used to collect and transmit the data for a telemedicine consultation or evaluation. Telemedicine may refer to clinical services that are provided remotely via telecommunication technologies. Telemedicine is not a separate medical specialty and does not change what constitutes proper medical treatment and services. There is no consensus among federal programs and health care providers on the definition of either term.

The federal Centers for Medicare & Medicaid Services (CMS) defines telehealth as:

> The use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance. Telehealth includes technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devises, which are used to collect and transmit data for monitoring and interpretation.[6]

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[1] Health Affairs, Health Policy Brief: *Telehealth Parity Laws*, (Aug. 15, 2016) (on file with the Banking and Insurance Committee).

[2] *See* U.S. Department of Health and Human Services, Bureau of Health Workforce, Designated Health Professional Shortage Areas Statistics, *First Quarter of Fiscal Year 2018 Designated HPSA Quarterly Summary* (as of Dec. 31, 2017), available at; https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false. (last viewed Jan. 25, 2018).

[3] HPSA designations are used to identify areas and population groups within the U.S. that are experiencing a shortage of health professionals. The primary factor used to determine a HPSA designation is the number of health professionals relative to the population with consideration of high need. Federal regulations stipulate that in order for an area to be considered as having a shortage of providers, an area must have a population-to-provider ratio of a certain threshold. For example, for primary medical care, the population to provider ratio must be at least 3,500 to 1 (3,000 to 1 if there are unusually high needs in the community). *See* https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last viewed January 25, 2018).

[4] *Id.*

[5] Anita Majerowicz and Susan Tracy, *"Telemedicine: Bridging Gaps in Healthcare Delivery,"* Journal of AHIMA 81, no. 5, (May 2010): 52-53, 56. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_047324.hcsp?dDocName=bok1_047324 (last viewed Jan. 25, 2018).

[6] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telemedicine*, available at https://www.medicaid.gov/medicaid/benefits/telemed/index.html (last viewed Jan. 5, 2018).

The federal Medicaid statutes and regulations do not recognize telemedicine as a distinct service, but as an alternative method for the delivery of services. Medicaid defines telemedicine and telehealth separately using telemedicine to define the interactive communication between the provider and patient and telehealth to describe the technologies, such as telephones and information systems.[7]

According to the American Telemedicine Association,[8] telemedicine is a significant and rapidly growing component of health care in the U.S. There are currently about 200 telemedicine networks, with 3,500 service sites in the U.S. Nearly one million Americans are currently using remote cardiac monitors. In 2011, the Veterans Administration delivered over 300,000 remote consultations using telemedicine. Over half of all U.S. hospitals now use some form of telemedicine. Around the world, millions of patients use telemedicine to monitor their vital signs, remain healthy, and out of hospitals and emergency rooms. Consumers and physicians download health and wellness applications for use on their cell phones.

Florida Telehealth Advisory Council

In 2016, legislation[9] was enacted that required the Agency for Health Care Administration (AHCA), with assistance from the Department of Health (DOH) and the Office of Insurance Regulation (OIR), to survey health care practitioners, facilities, and insurers on telehealth utilization and coverage, and submit a report on the survey findings to the Governor, President of the Senate , and Speaker of the House of Representatives by December 31, 2016. The law also created a 15-member Telehealth Advisory Council, and required it to submit a report with recommendations based on the survey findings to the Governor, President of the Senate , and Speaker of the House of Representatives by October 31, 2017.

Summary of the Survey Findings of the Telehealth Advisory Council[10]

The types of health care services provided via telehealth in the state. The most frequent uses of telehealth reported by licensed health care facilities in Florida include neurology (including stroke care), home health/patient monitoring, primary care, behavioral health, and radiology. About 44 percent of home health agencies responding to the AHCA's survey indicated using telehealth to assist with remote patient monitoring.

The extent to which telehealth is used by health care practitioners and health care facilities nationally and in the state. At the national level, an estimated 63 percent of practitioners use some type of telehealth platform to provide services. In contrast, only 6 percent of surveyed practitioners in Florida indicated they use telehealth for the provision of health care services. About 52 percent of hospitals in the U.S. use telehealth, and 45 percent of surveyed Florida hospitals stated they offer care through some form of telehealth. Major factors driving the

[7] *Id.*
[8] *See* https://www.americantelemed.org/about/telehealth-faqs- (last viewed Jan. 5, 2018).
[9] Ch. 2016-240, Laws of Fla. The law designated the Secretary of the Agency for Health Care Administration as the council Chair, and designated the State Surgeon General and Secretary of the Department of Health as a member. The AHCA's Secretary and the Surgeon General appointed 13 council members representing specific stakeholder groups.
[10] *See* Telehealth Advisory Council website available at http://www.ahca.myflorida.com/SCHS/telehealth/ (last viewed Jan. 8, 2018).

adoption of telehealth include advancing technologies, an aging population, health practitioner shortage, and greater acceptance of innovative treatment by patients.

The estimated costs and cost savings to provide health care services. Benefits reported from health care facilities and professionals offering telehealth services include improved convenience for both patients and providers, improved efficiencies, and improved patient care outcomes. Financial barriers are the most frequently reported obstacles among health care facilities and providers during both implementation and ongoing operations of telehealth programs. The American Hospital Association notes that direct return on investment for health care providers is limited; particularly when there is limited coverage and reimbursement by health plans for the services offered by telehealth. Twenty-five Florida health facilities and practitioners identify costs, reimbursement, and inability to determine a Return on Investment (ROI) as challenges in providing telehealth services.

The extent of insurance coverage for providing health care services via telehealth and how such coverage compares to coverage for in-person services. Some public and private payers limit reimbursement for health services offered through telehealth technology by the type of telehealth service offered and/or by the locations where care is provided and received. Approximately 43 percent of Florida health insurers indicate that they cover some form of telehealth services. Companies that offer Medicare Advantage plans were shown as having the largest percentage of plans offering reimbursement to health care providers for service provided through telehealth technologies. Coverage typically is limited to certain delivery types and requires special coding. A majority of health insurers indicate very limited coverage.

As of December 2016, 28 states and the District of Columbia have parity laws, which require private payer coverage and payment for telehealth services to be equitable with coverage and reimbursements for face-to-face health services. The definition of telehealth in each of these states varies, and some state definitions may include limitations on the telehealth modalities encompassed in required coverage and payment models.

Notable differences in the state regulations include whether telehealth services must be reimbursed at the same rate as in-person services; or whether the state only requires that the same services be covered but allow for variable rates of reimbursement. Florida does not currently have any statutory requirements related to private payer parity for telehealth services. Some private payers in the state have voluntarily opted to provide coverage and reimbursement for telehealth services.

According to the survey, 48 states offer some type of live video reimbursement in Medicaid to varying levels of reimbursement and coverage levels.[11] At least 21 states have some reimbursement for remote patient monitoring; 15 states reimburse for store and forward services under their Medicaid program; and 9 state programs reimburse for all three types.[12] Within each

[11] Center for Connect Health Policy, *State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and District of Columbia (Fall 2017)*, pg. 3, http://www.cchpca.org/sites/default/files/resources/Telehealth%20Laws%20and%20Policies%20Report%20FINAL%20Fall%202017%20PASSWORD.pdf, (last visited Jan. 25, 2018).

[12] *Id.* In their Fall 2017 survey of states, the Center for Connected Health Policy also found that 31 states provide a transmission or facility fee. *See* Center for Connected Health Policy, *50 State Scan of Telehealth Reimbursement Laws and Medicaid Policies-Factsheet* (Fall 2017) (on file with Health Policy Committee).

of these reimbursement models, there are variances in the types of services, specialties, providers, and locations that are covered. The Florida Medicaid fee-for-service rules were updated in June 2016 to expand telehealth payments to a broader array of practitioners. Similar to Medicare, Medicaid coverage in Florida is limited to live video conferencing, and pays the practitioner that provides the diagnosis only. With the vast majority of Florida Medicaid beneficiaries enrolled in managed care, Florida's Medicaid managed care plans are authorized to cover telehealth services with greater flexibility; however, there is no mandate for coverage. Based on survey responses by Florida health plans, coverage for telehealth is greatest for Medicaid managed care and Affordable Care Act Exchange Plans. Florida health care providers indicate very little reimbursement for telehealth services no matter the plan type.

Barriers to using or accessing services through telehealth. The primary issues related to telehealth often cited are financial, interoperability, and licensure. Florida providers and practitioners cited financial issues, such as inadequate reimbursement from payers, insufficient funding capital, and the inability to determine return on investment. An estimated 44 percent of the health plans surveyed noted government regulations and liability as barriers for covering telehealth services. The issue of interstate practice and reimbursement is among the legal issues health plans must consider. For example, health plans must ensure they are reimbursing health providers that are licensed appropriately in the jurisdiction where they are treating patients.[47] Florida facility and practitioner licensees who responded to the survey indicated the top three barriers to implementing telehealth involve finances: inadequate reimbursement from payers, insufficient funding capital, and the inability to determine return on investment.

Summary of the Recommendations of the Telehealth Advisory Council[13]

The report contained the following recommendations:

1. **Create definition of telehealth and replace existing telehealth and telemedicine definitions in Florida statutes and rules.** Telehealth is defined as the mode of providing health care and public health services through synchronous and asynchronous information and communication technology by a Florida licensed health care practitioner, within the scope of his or her practice, who is located at a site other than the site where a recipient (patient or licensed health care practitioner) is located.
2. **Coverage Parity.** A health insurance policy issued, amended, or renewed on or after July 1, 2018, shall provide coverage for services (excluding Medicare plans) provided via telehealth to the same extent the services are covered, if provided in-person. An insurer shall not impose any additional conditions for coverage of services provided via telehealth.[14]
3. **Payment Parity.** For the purpose of health insurance payment (excluding Medicare plans), payment rates for services provided via telehealth shall be equivalent to the rates for comparable services provided via in-person consultation or contact contained in the participation agreement between the insurer and the health care practitioner.[15]

[13] *See* Telehealth Advisory Council, *Expanding Florida's Use and Accessibility of Telehealth* (Oct. 31, 2017), available at http://www.ahca.myflorida.com/SCHS/telehealth/docs/TAC_Report.pdf (last visited January 5, 2018).

[14] According to the report, the intent of this recommendation is to ensure appropriate insurance coverage for the use of telehealth in treating patients. Any legislative language developed should not require insurers to add additional service lines or specialties, mandate a fee-for-service arrangement, inhibit value-based payment programs, or limit health care insurers and practitioners from negotiating contractual coverage terms.

[15] According to the report, the intent of this recommendation is to ensure appropriate insurance reimbursement for the use of telehealth in treating patients. Any legislative language developed should not require insurers to add additional service lines

4. **Medicaid Reimbursement.** The council recommends the AHCA modify the Medicaid telehealth fee-for-service rule to include coverage of store-and-forward and remote patient monitoring modalities in addition to the currently reimbursed live video conferencing modality.
5. **Medicaid Network Adequacy.** The council recommends the AHCA develop a model that would allow Medicaid managed care plans to utilize telehealth for meeting network adequacy.
6. **Interstate Licensure.** In order to ensure the best care for Florida patients and maximize available resources and access to care, the council recommends the following:
   - Maintain the requirement of Florida licensure for health practitioners providing patient care in Florida via telehealth. This recommendation requires no change to current regulations and does not inhibit the use of telehealth to treat patients.
   - The Legislature adopt laws allowing participation in health care practitioner licensure compacts that have licensure requirements that are equivalent to or more stringent than Florida Law.
7. **Standards of Care.** To ensure clarity for Florida licensed health care practitioners and stakeholders regarding the ability to use telehealth as a modality of care, the council recommends the DOH, healthcare regulatory boards and councils continue to educate and raise awareness among licensees that they may use telehealth modalities to serve patients.
8. **Patient-Practitioner Relationships and Continuity of Care**. The council offers the following language for inclusion in Florida statutes: A health care practitioner-patient relationship may be established through telehealth.
9. **Patient Consent.** The council recommends maintaining current consent laws in Florida.
10. **Telehealth and Prescribing.** The council offers the following language:
    Health care practitioners, authorized by law, may prescribe medications via telehealth to treat a patient as is deemed appropriate to meet the standard of care established by his or her respective health care regulatory board or council. The prescribing of controlled substances through telehealth should be limited to the treatment of psychiatric disorders and emergency medical services. This should not prohibit an authorized health care practitioner from ordering a controlled substance for an inpatient at a facility licensed under ch. 395, F.S., or a patient of a hospice licensed under ch. 400, F.S.
11. **Technology and Health Care Facilities/Practitioners.** The council notes that technology-related barriers for practitioners will decrease as technological advances and market forces drive cost reductions. Barriers remain related to interoperability of health care information systems. The council recommends:
    - The AHCA identify existing resources for health information exchange to expand interoperability between telehealth technologies and integration into electronic health record (EHR) platforms.
    - The AHCA continue promotion of existing programs and services available to increase access to technology, access to broadband networks, and improved interoperability.
    - Medical schools, schools of allied health practitioners, and health care associations provide information and educational opportunities related to the utilization to telehealth for serving patients.

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or specialties, mandate fee-for-service arrangements, inhibit value-based payment programs, limit health care insurers and practitioners from negotiating contractual coverage terms, or require insurers to pay for facsimiles or audio only communication.

Florida Board of Medicine

Florida's Board of Medicine (board) convened a Telemedicine Workgroup in 2013 to review its rules on telemedicine, which had not been amended since 2003. The 2003 rules focused on standards for the prescribing of medicine via the Internet. On March 12, 2014, the board's new Telemedicine Rule, 64B8-9.0141, became effective for Florida-licensed physicians. The new rule defined telemedicine,[16] established standards of care, prohibited the prescription of controlled substances, permitted the establishment of a doctor-patient relationship via telemedicine, and exempted emergency medical services.[17]

Two months after the initial rule's implementation, the board proposed the development of a rule amendment to address concerns that the prohibition on physicians ordering controlled substances may also preclude physicians from prescribing controlled substances via telemedicine for hospitalized patients. The board indicated such a prohibition was not intended.[18] The amended rule took effect July 22, 2014. Additional changes followed to clarify medical record requirements and the relationship between consulting or cross-coverage physicians. On December 18, 2015, the board published another proposed rule change to allow controlled substances to be prescribed through telemedicine for the limited treatment of psychiatric disorders.[19] The proposed rule amendment, Rule 64B8-9.0141-Standards for Telemedicine Practice, became effective March 7, 2016.[20]

On February 3, 2017, the Board of Medicine held a public hearing on a proposed amendment to Rule 64B8-9.0141 to prohibit the ordering of low-THC cannabis or medical cannabis through telemedicine. Additional public hearings were noticed for April and August on the amended rule; however, the rule was eventually withdrawn in August 2017 without being amended.

Florida's Medicaid Program[21]

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.[22] The Statewide Medicaid Managed Care (SMMC) program is comprised of the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) managed care program. The AHCA

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[16] The term, "telemedicine," is defined to mean the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.

[17] Rule 64B15-14.0081, F.A.C., also went into effect March 12, 2014, for osteopathic physicians.

[18] Florida Board of Medicine, *Latest News - Emergency Rule Related to Telemedicine*, http://flboardofmedicine.gov/latest-news/emergency-rule-related-to-telemedicine/ (last visited Jan. 14, 2018).

[19] Vol. 41/244, Fla. Admin. Weekly, Dec. 18, 2015, available at https://www.flrules.org/BigDoc/View_Section.asp?Issue=2011&Section=1 (last visited Jan. 14,2018).

[20] Florida Board of Medicine, Latest News, Feb. 23, 2016, available at http://flboardofmedicine.gov/latest-news/board-revises-floridas-telemedicine-practice-rule/ (last viewed Jan. 7, 2018).

[21] *See* Agency for Health Care Administration, *Analysis of SB 280* (Oct. 9, 2017) (on file with the Senate Banking and Insurance Committee).

[22] Part III of ch. 409, F.S., governs the Medicaid program.

contracts with managed care plans to provide services to eligible enrollees.[23] Under the Managed Medical Assistance (MMA) component of Statewide Medicaid Managed Care, managed care plans may use telemedicine for behavioral health, dental services, and physician services.[24] The AHCA may also approve other telemedicine services provided by the managed care plans if approval is sought by those plans under the MMA component.

Florida Medicaid has adopted a rule on telemedicine, which authorizes services to be delivered via telemedicine. The rule defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where a recipient is located for the purposes of evaluation, diagnosis, or treatment.[25] Further, telemedicine services must be provided by licensed practitioners operating within their scope of practice and involve the use of interactive telecommunications equipment which includes, at a minimum, audio and video equipment permitting two-way, real time, communication between the enrollee and the practitioner.[26] Additionally, the rule provides that Medicaid reimburses a practitioner rendering services in the fee-for-service delivery system who is providing the evaluation, diagnosis, or treatment recommendation located at a site other than where the recipient is located.

Equipment is also required to meet specific federal technical safeguards, which require implementation of procedures for protection of health information.[27] The safeguards include unique user identifications, automatic log- offs, encryption, authentication of users, and transmission security. Telemedicine services must also comply with all other state and federal laws regarding patient privacy.

Florida Medicaid statutes and the federal Medicaid statutes and regulations consider telemedicine to be a delivery system rather than a distinct service; as such, Florida Medicaid does not have reimbursement rates specific to the telemedicine mode of service. In the fee-for-service system, Florida Medicaid reimburses services delivered via telemedicine at the same rate and in the same manner as if the service were delivered face-to-face.

Medicaid health plans can negotiate rates with providers, so they have the flexibility to pay different rates for services delivered via telemedicine. The managed care plans are required to submit their telemedicine policies and procedures to the AHCA for approval, but are not required to do so prior to use.[28] Telephone conversations, chart review, electronic mail messages, or facsimile transmissions are not reimbursable as telemedicine.

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[23] A managed care plan that is eligible to provide services under the SMMC program must have a contract with the AHCA to provide services under the Medicaid program and must also be a health insurer; an exclusive provider organization or a HMO authorized under chs. 624, 627, or 641, F.S., respectively; a provider service network authorized under s. 409.912(2), F.S., or an accountable care organization authorized under federal law. Section 409.962, F.S.

[24] Agency for Health Care Administration, *2012-2015 Medicaid Health Plan Model Agreement Attachment II - Exhibit II-A,* p. 63-64 http://ahca.myflorida.com/medicaid/statewide_mc/pdf/mma/Attachment_II_Exhibit_II-A_MMA_Model_2014-01-31.pdf , (last visited Jan. 11, 2018).

[25] *See* Rule 59G-1.057, F.A.C.

[26] *Id.*

[27] 45 CFR s. 164.312.

[28] Agency for Health Care Administration, *Statewide Medicaid Managed Care (SMMC) Policy Transmittal (March 11, 2016), http://ahca.myflorida.com/medicaid/statewide_mc/pdf/plan_comm/PT_16-06_Telemedicine_03-11-2016.pdf*, (last visited Jan.. 25, 2018).

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities.[29] The 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.[30] As part of the certification process used by the AHCA, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[31]

Federal Telemedicine Provisions

Federal laws and regulations address telemedicine from several perspectives, including prescriptions for controlled substances, hospital emergency room guidelines, and reimbursement requirements and rates for the Medicare program.

Prescribing Via the Internet

Federal law specifically prohibits the prescribing of controlled substances via the Internet without an in-person evaluation. Federal regulation 21 CFR s. 829 provides:

> No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed or dispensed by means of the Internet without a valid prescription.

A valid prescription is further defined under the same regulation as one issued by a practitioner who has conducted an in-person evaluation. The in-person evaluation requires that the patient be in the physical presence of the provider without regard to the presence or conduct of other professionals.[32] However, the Ryan Haight Online Pharmacy Consumer Protection Act,[33] signed into law in October 2008, created an exception for the in-person medical evaluation for telemedicine practitioners. The practitioner is still subject to the requirement that all controlled substances be issued for a legitimate purpose by a practitioner acting in the usual course of professional practice.

The Drug Enforcement Administration (DEA) of the federal Department of Justice issued its own definition of telemedicine in April 2009, as required under the Haight Act.[34] The federal regulatory definition of telemedicine under the DEA includes, but is not limited to, the following elements:

- The patient and practitioner are located in separate locations;
- Patient and practitioner communicate via a telecommunications system;
- The practitioner must meet other registration requirements for the dispensing of controlled substances via the Internet; and

[29] Section 20.121(3)(a), F.S.
[30] Section 641.21(1), F.S.
[31] Section 641.495, F.S.
[32] 21 CFR s. 829(e)(2).
[33] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-425 (H.R. 6353).
[34] Id., at sec. 3(j).

- Certain practitioners (Department of Veterans Affairs' employees, for example) or practitioners in certain situations (public health emergencies) may be exempted from registration requirements.[35]

Medicare Coverage

Specific services that are covered under Part B of Medicare[36] which are delivered at designated rural sites as a telehealth service are covered under Medicare. Federal CMS regulations require both a distant site (location of physician delivering the service via telecommunications) and an originating site (location of the patient).

To qualify for Medicare reimbursement, the Medicare beneficiary must be located at an originating site that meets one of three qualifications. These three qualifications are:

- A rural health professional shortage area (HPSA) that is either outside a metropolitan statistical area (MSA) or in a rural census tract[37];
- A county outside of an MSA; or
- Participation in a federal telemedicine demonstration project approved by the Secretary of Health and Human Services as of December 31, 2000.[38]

Additionally, federal requirements provide that an originating site must be one of the following location types as further defined in federal law and regulation:

- The office of a physician or practitioner;
- A hospital;
- A critical access hospital (CAH);
- A rural health clinic;
- A federally qualified health center;
- A hospital-based or CAH-based renal dialysis center (including satellite offices);
- A skilled nursing facility; or
- A community mental health center.[39]

Under Medicare, distant site practitioners are limited, subject also to state law, to:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse-midwives;
- Clinical nurse specialists;

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[35] 21 CFR s. 802(54).

[36] Part B of Medicare is the medical insurance portion and covers services such as physician office visits and consultations, mental health services (inpatient and outpatient), and partial hospitalization.

[37] The United States Census Bureau does not define rural, but defines urban leaving all other areas not urban to be considered rural. "Urbanized areas" are those of 50,000 or more people. "Urban clusters" are those of at least 2,500 and less than 50,000 people. *See* Health Resources and Services Administration, *Defining Rural Population,* *https://www.hrsa.gov/rural-health/about-us/definition/index.html*, (last visited Jan. 25, 2018).

[38] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Telehealth Services- Rural Health Fact Sheet* (Dec. 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf (last visited Jan. 7, 2018).

[39] *See* 42 U.S.C. sec. 1395(m)(m)(4)(C)(ii).

- Certified registered nurse anesthetists;
- Clinical psychologists and clinical social workers; and
- Registered dietitians and nutrition professionals.

Medicare added new services under telehealth in 2015:
- Annual wellness visits;
- Psychoanalysis;
- Psychotherapy; and
- Prolonged evaluation and management services.[40]

For 2018, the CMS conducted additional rulemaking to add more telehealth services related to health risk assessments, psychotherapy, and care planning for chronic care management. The proposed rule also sought comment on ways CMS could further expand access to telehealth services within its existing statutory authority.[41] Federal legislation to expand the scope of telehealth to include telestroke services for Medicare beneficiaries has also been under discussion and passed through the House Committee on Energy and Commerce favorably.[42]

Protection of Personal Health Information

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information (PHI). Initial privacy rules were initially issued in 2000 by the federal Department of Health and Human Services and later modified in 2002. These rules address the use and disclosure of an individual's health information and create standards for privacy rights. Additional privacy and security measures were adopted in 2009 with the Health Information Technology for Economic Clinical Health (HITECH) Act.

Only certain entities are subject to HIPAA's provisions. These "covered entities" include:
- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of the entities listed above.

While not a covered entity as an individual, the patient still maintains his or her privacy and confidentiality rights regardless of the method in which a medical service is delivered. The HITECH Act specifically identified telemedicine as an area for review and consideration, and funding was provided to, in part, strengthen infrastructure and tools to promote telemedicine.[43]

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[40] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *MLN Matters* (Dec. 24, 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9034.pdf (last visited Jan. 7, 2018).
[41] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Fact Sheet: Final Policy, Payment, and Quality Provisions in the Medicare Physician Fee Schedule for Calendar Year 2018 (November 2, 2017), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-02.html* (last visited Jan. 25, 2018).
[42] *See "Furthering Access to Stroke Telemedicine Act of 2017" or the "FAST Act of 2017," H.R. 1148,* 115th Cong. (2017-2018).
[43] Public Law 111-5, s. 3002(b)(2)(C)(iii) and s. 3011(a)(4).

Under the provisions of HIPAA and the HITECH Act, a health care provider or other covered entity participating in telemedicine is required to meet the same technical and physical HIPAA and HITECH requirements as would be required for a physical office visit. These requirements include ensuring that the equipment and technology are HIPAA compliant.

Department of Veterans Affairs Telehealth Initiative

A draft federal rule proposed in October 2017 would permit a health care provider who met certain requirements set by the Department of Veterans Affairs to provide telehealth services within the scope of his or her practice, and the privileges as granted by the Department of Veterans Affairs, irrespective of state or location within the state where the health care provider or the beneficiary was physically located. The health care provider would be required to:

- Be a licensed, registered, and certified health care provider under 38 U.S.C. 7402(b);
- Be appointed to a specified occupation in the federal Veterans Health Administration;[44]
- Maintain the credentials (license, registration, and certification) required for his or her medical specialty; and
- Not be a Veterans Administration-contracted employee.[45]

Under the draft rule, the health care provider can only practice within the scope of his or her license and would be subject to the limitations of the federal Controlled Substances Act.[46] This federal regulation would also preempt any conflicting state laws relating to the practice of health care when the providers are practicing within the scope of their license.[47]

III. Effect of Proposed Changes:

Section 1 creates s. 456.4501, F.S., which addresses the provision of health care services through telehealth. The section provides definitions of the terms "information and telecommunications technologies," "store and forward," "synchronous," and "telecommunications system," which are terms used in defining the technological means by which telehealth services may be provided.

This section also defines the term, "telehealth," as the mode of providing health care services and public health care services by a Florida licensed practitioner, within the scope of his or her practice, through synchronous and asynchronous information and telecommunication technologies where the practitioner is located at a site other than the site where the recipient, whether a patient or another licensed practitioner, is located.

The section defines "telehealth provider" as a person providing health care services and related services through telehealth, and who is licensed under ch. 457, F.S. (acupuncture); ch. 458, F.S. (medical practice); ch. 459, F.S. (osteopathic medicine); ch. 460, F.S. (chiropractic medicine); ch. 461, F.S. (podiatric medicine); ch. 462, F.S. (naturopathy); ch. 463, F.S. (optometry);

[44] Health care providers listed under this section must meet the individual qualifications for each provider listed and the named providers include physicians, dentists, nurses, directors of a hospital, domiciliary, center, or outpatient clinic, podiatrist, optometrist, pharmacist, psychologist, social worker, marriage and family therapist, licensed mental health counselor, chiropractor, peer specialist, and other designated health care positions as the Secretary shall prescribe.
[45] Authority of Health Care Providers to Practice Telehealth, 82 Fed. Reg. 45756, 45762 (proposed Oct. 2, 2017) (to be codified at 38 CFR 17.417)
[46] *See* 21 U.S.C. 801, et seq.
[47] *Supra,* note 45 at 45762.

ch. 464, F.S. (nursing); ch. 465, F.S. (pharmacy); ch. 466, F.S. (dentistry); ch. 467, F.S. (midwifery); part I (speech-language pathology and audiology), part III (occupational therapy), part IV (radiological personnel), part V (respiratory therapy), part X (dietetics and nutrition practice), part XIII (athletics trainers), or part XIV (orthotics, prosthetics, and pedorthics) of ch. 468, F.S.; ch, 478, F.S. (electrolysis); ch. 480, F.S. (massage practice); parts III (clinical lab personnel) and IV (medical physicists) of ch. 483, F.S.; ch. 484, F.S. (dispensing of optical devices and hearing aids); ch. 486, F.S. (physical therapy); ch. 490, F.S. (psychological services); or ch. 491, F.S. (clinical, counseling, and psychotherapy services); or who is certified under s. 393.17, F.S., (behavior analyst) or part III of ch 401, F.S. (medical transportation services).

The section establishes practice standards for the provision of telehealth services. The standard of care for a telehealth provider is the same as that for an in-person health care provider. However, a telehealth provider is not required to research patient's medical history or conduct a physical examination if a patient evaluation conducted by telehealth is sufficient to diagnose and treat the patient. The bill specifies that the telehealth provider and the patient may be in separate locations and telehealth providers who are not physicians, and who are acting within their relevant scope of practice, are not practicing medicine without a license.

The section specifically provides that telehealth providers who are licensed to prescribe controlled substances listed in Schedule I through V may prescribe those controlled substances through telehealth except to treat chronic nonmalignant pain as defined in s. 458.3265(1)(a), F.S., and s. 459.0137(1)(a), F.S. Telehealth may not be used to issue a physician certification for marijuana pursuant to s. 381.986, F.S. This subsection does not apply when prescribing a controlled substance for an inpatient at a facility licensed under ch. 395, F.S., or a patient of a hospice licensed under ch. 400, F.S.

The Department of Health, in coordination with the relevant boards, must develop and disseminate educational materials for telehealth licensees delineated in s. 456.4501(1)(f), F.S., on using telehealth modalities to treat patients by January 1, 2019.

The section provides that a patient's medical records must be updated by a telehealth provider according to the same standards that apply to an in-person health care provider. Finally, the section provides that while a patient need not specifically consent to be treated via telehealth, the patient must still provide consent for treatment as provided under current law. The patient would retain the right to withhold consent for any particular procedure or treatment to be provided through telehealth.

Section 2 provides that the bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

According to the Telehealth Advisory Council's report,[48] health practitioners indicated the need for a definition of the term, "telehealth" that would clarify the use of technological modalities as an acceptable way to treat patients within their scope of practice. Further, health plans noted the need for clarity in the allowable modes of telehealth for coverage and reimbursement purposes.

These changes may encourage the use of telehealth options, which may result in reduced health care costs; increased patient access to providers, especially in medically underserved areas; improved quality and continuity of care; and faster and more convenient treatment resulting in reduction of lost work time and travel costs for patients. Preventing the unnecessary use of intensive services, such as emergency department visits, improves health outcomes and can reduce overall health care costs.

C. Government Sector Impact:

Department of Health. The Department of Health anticipates additional workload relating to the implementation of the bill. The costs associated with this increased workload and the costs associated with the development and dissemination of educational materials for licensees on using telehealth modalities to treat patients are indeterminate, but Department of Health's current resources and budget authority are adequate to absorb these costs.[49]

Agency for Health Care Administration. To maintain uniform naming conventions and practice standards throughout the state's policies, the AHCA will need to amend the Medicaid state plan, which will require federal approval.

VI. Technical Deficiencies:

None.

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[48] *See* Telehealth Advisory Council, *Expanding Florida's Use and Accessibility of Telehealth* (Oct. 31, 2017), available at http://www.ahca.myflorida.com/SCHS/telehealth/docs/TAC_Report.pdf (last visited January 5, 2018).
[49] Department of Health, *Analysis of SB 280* (Oct. 12, 2017) (on file with Senate Banking and Insurance Committee).

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 456.4501 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 Banking and Insurance on January 16, 2018:
The CS eliminates telehealth provisions relating to the State Group Insurance program, Medicaid, and the Insurance Code and provides a technical change.

B. Amendments:

None.

By the Committee on Banking and Insurance; and Senator Bean

597-02153-18 2018280c1

A bill to be entitled

An act relating to telehealth; creating s. 456.4501, F.S.; defining terms; establishing the standard of care for telehealth providers; authorizing telehealth providers to use telehealth to perform patient evaluations; providing that telehealth providers, under certain circumstances, are not required to research a patient's history or conduct physical examinations before providing services through telehealth; providing that a nonphysician telehealth provider using telehealth and acting within her or her relevant scope of practice is not deemed to be practicing medicine without a license; authorizing certain telehealth providers to use telehealth to prescribe specified controlled substances; providing for construction; requiring the Department of Health to develop and disseminate certain educational materials to specified licensees by a specified date; providing recordkeeping requirements for telehealth providers; providing requirements for patient consent for telehealth treatment; providing an effective date.

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

Section 1. Section 456.4501, Florida Statutes, is created to read:

456.4501 Use of telehealth to provide services.—

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

(a) "Information and telecommunications technologies" means

597-02153-18 2018280c1

those secure electronic applications used by health care practitioners and health care providers to provide health care services, evaluate health care information or data, provide remote patient monitoring, or promote healthy behavior through interactions that include, but are not limited to, live video interactions, text messages, or store and forward transmissions.

(b) "Store and forward" means the type of telehealth encounter which uses still images of patient data for rendering a medical opinion or patient diagnosis. The term includes the asynchronous transmission of clinical data from one site to another site.

(c) "Synchronous" means live or two-way interactions using a telecommunications system between a provider and a person who is a patient, caregiver, or provider.

(d) "Telecommunications system" means the transfer of health care data through advanced information technology using compressed digital interactive video, audio, or other data transmission; clinical data transmission using computer image capture; and other technology that facilitates access to health care services or medical specialty expertise.

(e) "Telehealth" means the mode of providing health care services and public health services by a Florida licensed practitioner, within the scope of his or her practice, through synchronous and asynchronous information and telecommunications technologies where the practitioner is located at a site other than the site where the recipient, whether a patient or another licensed practitioner, is located.

(f) "Telehealth provider" means a person who provides health care services and related services through telehealth and

who is licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; parts III and IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; or who is certified under s. 393.17 or part III of chapter 401.

(2) PRACTICE STANDARDS.—

(a) The standard of care for a telehealth provider providing medical care to a patient is the same as the standard of care generally accepted for a health care professional providing in-person health care services to a patient. A telehealth provider may use telehealth to perform a patient evaluation. If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research the patient's medical history or conduct a physical examination of the patient before using telehealth to provide services to the patient.

(b) A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to the patient.

(c) A nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice is not deemed to be practicing medicine without a license under any provision of law listed in paragraph (1)(f).

(d) A telehealth provider who is authorized to prescribe a controlled substance named or described in Schedules I through V of s. 893.03 may use telehealth to prescribe a controlled substance, except that telehealth may not be used to prescribe a

controlled substance to treat chronic nonmalignant pain as defined in ss. 458.3265(1)(a) and 459.0137(1)(a) or to issue a physician certification for marijuana pursuant to s. 381.986. This paragraph does not prohibit a physician from using telehealth to order a controlled substance for an inpatient admitted to a facility licensed under chapter 395 or a patient of a hospice licensed under chapter 400.

(e) By January 1, 2019, the department, in coordination with the applicable boards, shall develop and disseminate educational materials for the licensees listed in paragraph (1)(f) on the use of telehealth modalities to treat patients.

(3) RECORDS.—A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standard used for in-person health care services pursuant to ss. 395.3025(4) and 456.057.

(4) CONSENT.—Patients are not required to provide specific authorization for treatment through telehealth, but must authorize treatment that meets the requirements of the applicable practice acts and s. 766.103, and must be allowed to withhold consent for any specific procedure or treatment through telehealth.

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

The Florida Senate

Committee Agenda Request

To: Senator Anitere Flores, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: January 31, 2018

I respectfully request that **Senate Bill # 280**, relating to Telehealth, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Aaron Bean

Senator Aaron Bean
Florida Senate, District 4

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)

2/14/18
Meeting Date

SB 280
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Telehealth

Name Brittney Hunt

Job Title Policy Director

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Street

Tallahassee FL 32301
City *State* *Zip*

Phone (850) 521-1200

Email bhunt@flchamber.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Chamber of Commerce

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)

2-14-18
Meeting Date

CS/SB 280
Bill Number (if applicable)

Topic Telehealth

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 AARP FL

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)

2/14/15
Meeting Date

SB 280
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

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Tlh
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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

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)

2/14/18
Meeting Date

280
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Joe Anne Hart

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Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Dental Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/14/18
Meeting Date

280
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Telehealth

Name Ron Watson

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Rural Coalition FRC

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)

2/14/18
Meeting Date

SB 280
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Telehealth

Name Leah Courtney

Job Title Communications Coordinator

Address _____
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_____
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Email Courtney@floridataxwatch.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida TaxWatch

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 Appropriations Subcommittee on Health and Human Services

BILL:	SB 474
INTRODUCER:	Senator Brandes
SUBJECT:	Physician Orders for Life-sustaining Treatment
DATE:	February 13, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.	Kidd	Williams	AHS	**Pre-meeting**
3.			AP	

I. Summary:

SB 474 recognizes a Physician Order for Life Sustaining Treatment (POLST) and creates the POLST Program within the Department of Health (DOH). The bill establishes requirements for the contents of the POLST form and its proper execution, and addresses the relationship of a POLST with other advance directives. The DOH is required to develop the form by rule.

The bill directs the Agency for Health Care Administration (AHCA) to establish a Clearinghouse for Compassionate and Palliative Care Plans (clearinghouse) for state residents as a central registry for advance directives for health care. The AHCA is directed to establish and maintain the registry, either independently or through a national or private clearinghouse. Plans are required to be electronically accessible. The AHCA is also directed to disseminate information about the clearinghouse once available. POLSTs may be submitted to the clearinghouse also.

A separate public records exemption bill, CS/SB 476, is linked to SB 474.

The Agency for Health Care Administration indicates the need for three additional full time equivalent positions and additional funds for contracted services to implement the provisions of the bill. The funding requested by AHCA to implement this bill is $1,097,565 from the Health Care Trust Fund.

The Department of Health responsibilities under the bill can be accomplished within existing resources.

The bill takes effect July 1, 2018.

II. Present Situation:

End of Life Decision-Making

An individual may express his or her end of life health care decisions through one or more different mechanisms such as formal or informal discussions with a health care provider or a loved one or through one of several recognized legal documents. Such discussions may occur because of an individual's particular medical condition, age, or as part of an annual medical examination. Sometimes, the conversation may be the result of a recent hospitalization and the health care provider seeks guidance from the patient or the patient's caregiver about how to treat the individual's condition next, such as when and if to change to comfort (palliative or hospice) care rather than care that is aimed at a cure for the patient's illness.[1]

Florida law defines an advance directive as any witnessed, oral statements or written instructions that express a person's desires about any aspect of his or her future health care, including the designation of a health care surrogate, a living will, or an anatomical gift.[2] Designation of a health care surrogate, a living will, or an anatomical gift each serve different purposes and have their own unique requirements and specifications under the law.

One type of advance directive, a "do not resuscitate order" (DNRO), results in the withholding of cardiopulmonary resuscitation (CPR) from an individual if a DNRO is presented to the health care professional treating the patient. For the DNRO to be valid, it must be on the form adopted by the DOH, signed by the patient's physician and by the patient, or if the patient is incapacitated, the patient's health care surrogate or proxy, court-appointed guardian, or attorney in fact under a durable power of attorney.[3] Florida's DNRO form is printed on yellow paper.[4] It is the responsibility of the Emergency Medical Services provider to ensure that the DNRO form or the patient identification device, which is a miniature version of the form, accompanies the patient.[5] A DNRO may be revoked by the patient at any time, if signed by the patient, or the patient's health care surrogate, proxy, court-appointed guardian or a person acting under a durable power of attorney.[6]

Not available in Florida, a Physician Order for Life-Sustaining Treatment (POLST), documents a patient's health care wishes in the form of a physician order for a variety of end of life measures, including CPR.[7] A DNRO is limited only to the withholding of CPR. The POLST form can be completed only by a physician and is then provided to the patient to be kept secured in a visible location for emergency personnel.[8] It is suggested that the form be completed when an individual has a serious illness or frailty, regardless of age, as the POLST serves as a medical order for a

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[1] Information from Your Family Doctor: *End of Life Choices for Families,* Am Fam Physician, 2004 Aug 15; 70(4): 725-726, https://www.aafp.org/afp/2004/0815/p725.html (last visited: Dec. 22, 2017).
[2] *See* s. 765.101, F.S.
[3] *See* ss. 395.1041, 400.142, 400.487, 400.605, 400.6095, 401.35, 401.45, 429.255, 429.73, and 7665.205, F.S.
[4] Rule 64J-2.018, F.A.C.
[5] Id.
[6] Id.
[7] POLST.ORG, *About the National POLST Paradigm,* http://www.polst.org/about-the-national-polst-paradigm/ (last visited Jan. 8, 2018).
[8] POLST.ORG, *FAQ,* http://www.polst.org/advance-care-planning/faq/ (last visited Dec. 22, 2017).

current, life-threatening illness where the patient has a life expectancy of a year or less.[9] The POLST is intended to express the patient's treatment wishes when the patient is unable to speak for himself or herself during a medical crisis.

Other states' POLST forms include questions relating to what level of care is wanted for CPR (attempt or do not attempt); medical intervention (comfort only, limited additional intervention, or full treatment); and artificially administered nutrition (none, trial, or long-term). Many POLST forms also include information on how to void the authorization before the expiration date, contact information for the surrogate, and information about the medical professionals who may have completed the form. At least 22 other states have implemented or endorsed a POLST program, with California, Oregon and West Virginia being identified as having mature programs.[10]

In comparison to a POLST, an advance directive's purpose is to give instructions on the appointment of a health care representative, express intentions for future treatment or health care, or for an anatomical gift.[11] Florida law allows such advance directives to be expressed in writing or by an oral designation of another person to make health care decisions upon that person's incapacity.[12]

A living will is another mechanism used by individuals to express life-prolonging wishes through a written document or a witnessed oral statement.[13] Any competent adult may make a living will or written declaration, at any given time, to address the providing, withholding, or withdrawing of life-prolonging procedures should that individual have a terminal or end-stage condition.[14] A living will requires the signature of the individual in the presence of two witnesses, one of whom is not the spouse nor a blood relative. It becomes the individual's responsibility to notify health care providers about the living will, so it can be made a part of the individual's medical record.

The statute also provides a suggested form, but in all capital letters, makes clear that a living will does not need to follow the form to be accepted as part of the patient's medical records.[15] Many non-profit organizations also make similar advance directive forms easily available online or in hard copy formats for the designation of health care surrogates or the creation of living wills.[16]

Effective January 1, 2016, advance care planning (ACP) services from physicians and other health care professionals was available as a separate billed service covered by Medicare.[17] If a Medicare beneficiary wants to discuss advance care planning at his or her first annual visit with a

[9] POLST.ORG, *POLST v. Advance Directives*, http://www.polst.org/advance-care-planning/polst-and-advance-directives/ (last visited Dec. 22, 2017).
[10] POLST.ORG, *Programs in Your State*, http://www.polst.org/programs-in-your-state/ (last visited Dec. 22, 2017).
[11] *See* s. 765.101, F.S.
[12] *See* s. 765.101(2), F.S.
[13] *See* s. 765.101(13), F.S.
[14] Section 765.302, F.S.
[15] Section 765.303, F.S.
[16] *See* Aging with Dignity, *Five Wishes – Florida*, https://www.agingwithdignity.org/Florida, (last visited: Dec. 22, 2017); Florida Health Care Association, http://www.fhca.org/consumers/health_care_advanced_directives/, (last visited: Dec. 22, 2017); and AARP-Florida, http://www.caringinfo.org/files/public/ad/Florida.pdf (last visited: Dec. 22, 2017).
[17] 42 CFR 410.15.

physician and then any updates during any subsequent annual wellness visit, physicians and other health care professionals may provide the service during those visits and bill Medicare separately for it. Such services can be provided in both facility and non-facility settings. Before this date, ACP services could only be billed as part of another visit; it could not be the sole reason for the physician visit.[18] Providers must also notify their patients if they are unwilling to follow the individual's wishes as expressed in an advance directive document.

Clearinghouse for Compassionate and Palliative Care Plans

In addition to the availability of the POLST form, several states also have registries for the collection of advance directives. The Oregon Legislature followed its POLST form creation with its registry in July 2009.[19] Overseen by the Oregon Health Authority, the Oregon POLST Registry received more than 55,000 POLST forms via fax, eFax, mail, electronic files transfer, or other secure messaging means in 2015.[20] In total, Oregon's registry had an estimated 300,000 forms representing almost 200,000 registrants as of the end of 2015.[21]

An individual is not required to send a completed POLST form to the registry. If an individual does not want his or her form in the registry, the Oregon POLST form contains an "opt-out" box that can be checked.[22] When a POLST form is submitted to the registry by the primary care physician, the individual receives a confirmation letter in return, a magnet, and a set of stickers with their registry identification number for future access.[23] The number is to be given to the individual's primary care physician and the magnet and stickers put in prominent places, including something the person might usually carry with them. Beginning in January 2018, Naturopathic Physicians became authorized to sign POLST forms in Oregon.

West Virginia has its WV e-Directive Registry, which makes advance directives, DNROs, West Virginia Physician Orders for Scope of Treatments (POSTs), living wills, and medical powers of attorney available online 24/7 to health care practitioners and facilities when the individual specifically opts in to the registry. While the registry is currently under re-construction, providers must make a request for information via fax sheet and records are distributed between 8:00 a.m. and 4:00 p.m. via a toll-free fax number.[24] Usually, the e-Directive Registry accepts new forms through its direct upload process online or toll-free fax.[25]

Idaho's Health Care Directives Registry is offered through its Secretary of State's office. Individuals may submit several types of health care directive documents, including a Physician

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[18] Henry J. Kaiser Family Foundation, *10 FAQs: Medicare's Role in End of Life Care*, http://kff.org/medicare/fact-sheet/10-faqs-medicares-role-in-end-of-life-care/ (last visited Jan. 8, 2018).
[19] Oregon POLST Registry 2015 Annual Report, http://polst.org/wp-content/uploads/2016/09/2015OregonPOLSTRegistryAnnualReport.pdf, p. 5, (last visited Jan. 2, 2018).
[20] Id at 7.
[21] Id at 20.
[22] POLST Oregon, http://www.or.polst.org/registry-resources (last visited Dec. 22, 2017).
[23] Id.
[24] West Virginia Center for End-of-Life Care, *e-Directive Registry, Request for Release of Records from the WV e-Directive Registry*, http://wvendoflife.org/media/1113/registry-treating-provider-release-of-information-rev-july2017.pdf (last visited Dec. 27, 2017).
[25] West Virginia Center for End-of-Life Care, *Introducing the WV E-Directive Registry*, *http://wvendoflife.org/for-providers/e-directive-registry/* (last visited: Dec. 27, 2017).

Order for Scope of Treatment (POST) form, living will, or durable power of attorney for health care.[26] Documents can be submitted online to the Secretary of State or via the mail. Once registration is confirmed, individuals receive a wallet sized registration card with an individualized filing number, password, and information about using the registry.[27]

New York utilizes a secure web-based application for its electronic Medical Orders for Life-Sustaining Treating (eMOLST) forms. The forms may be printed for the medical record and then stored and linked to the electronic eMOLST registry. Emergency medical services, hospitals, nursing homes, and most all health care providers in the community via the online portal may access the forms.[28] The eMOLST form may also be used for minor patients.[29]

III. Effect of Proposed Changes:

Physician Orders for Life-Sustaining Treatment (POLST) Program (Section 1)

The bill creates s. 401.451, F.S., the Physician Order for Life-Sustaining Treatment (POLST) program, within the DOH. The DOH is directed to implement and administer the program and to collaborate with the AHCA on the implementation and operation of the Clearinghouse for Compassionate and Palliative Care plans (clearinghouse).

Under s. 401.451, F.S., definitions are provided for the following terms:

- "Advance directive" means the same as in s. 765.101, F.S.;[30]
- "Agency" means the Agency for Health Care Administration;
- "Clearinghouse for Compassionate and Palliative Care Plans" [31] or "clearinghouse" means the same as in s. 408.064, F.S.,[32](which is created in **Section 2** of this bill);
- "End-stage condition" means the same as in s. 765.101, F.S.;[33]
- "Examining physician" means a physician who examines a patient who wishes, or whose legal representative wishes, to execute a POLST form; who attests to the patient's or the patient's representative's ability to make and communicate health care decisions; who signs

[26] Idaho Secretary of State, *Health Care Directive Registry*, https://sos.idaho.gov/hcdr/index.html (last visited Dec. 22, 2017).
[27] Id.
[28] eMOLST - Electronic Medical Orders for Life Sustaining Treatment in New York State, *available at* http://www.compassionandsupport.org/index.php/for_professionals/molst_training_center/emolst (last visited Dec. 22, 2017).
[29] Medical Orders for Life Sustaining Treatment - Professionals (FAQS), *available at* http://www.compassionandsupport.org/index.php/for_professionals/molst_training_center/frequently_asked_questions/molst_faqs_page_1 (last visited Dec. 22, 2017).
[30] "Advance directive" means a witnessed written document or oral statement in which instructions are given by a principal or in which the principal's desires are expressed concerning any aspect of the principal's health care or health information, and includes, but is not limited to, the designation of a health care surrogate, a living will, or an anatomical gift made pursuant to part V of ch. 765, F.S.
[31] "Compassionate and palliative care plan" means any end-of-life document or medical care directive document recognized by this state and executed by a resident of this state, including, but not limited to, an advance directive, an order not to resuscitate, a physician order for life-sustaining treatment, or a health care surrogate designation.
[32] "Clearinghouse" means the state's electronic database of compassionate and palliative care plans submitted by residents of this state and managed by the agency pursuant to s. 408.064, F.S.
[33] "End-stage condition" means an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective.

the POLST form; and who attests to the patient's or the patient's legal representative's execution of the POLST form;
- "Health care provider" means the same as in s. 408.07, F.S.;
- "Legal representative" means a patient's legally authorized health care surrogate or proxy as provided in ch. 765, F.S., a patient's court-appointed guardian as provided in ch. 744, F.S., who has been delegated authority to make health care decisions on behalf of the patient; an attorney in fact under a durable power of attorney as provided in ch. 709, F.S., who has been delegated authority to make health care decisions on behalf of the patient, or a patient's parent if the patient is a minor;
- "Order not to resuscitate " means an order issued pursuant to s. 401.45(3), F.S.; and
- "Physician order for life-sustaining treatment" or "POLST" means an order issued pursuant to s. 401.451, F.S., which specifies a patient with an end stage condition and provides directives for that patient's medical treatment under certain conditions.

Section 1 establishes specific duties for the DOH for the POLST program. These duties include the requirement to:
- Adopt rules to implement and administer the POLST program;
- Prescribe a standardized POLST form;
- Provide the POLST form in an electronic format on the DOH's website and prominently state the requirements for a POLST form;
- Consult with health care professional licensing groups, provider advocacy groups, medical ethicists, and other appropriate stakeholders on the development of rules and forms;
- Collaborate with the AHCA to develop and maintain the clearinghouse;
- Ensure that the DOH staff receive ongoing training on the POLST program and the availability of POLST forms;
- Recommend a statewide, uniform process through which a patient that has, or whose legal representative has, executed a POLST form is identified and the health care providers currently treating the patient are provided with contact information for the examining physician who signed the POLST form;
- Adopt POLST-related continuing education requirements for health care providers licensed by the DOH; and
- Develop a process for collecting provider feedback to facilitate the periodic re-design of the POLST form consistent with current health care best practices.

POLST Form (Section 1)

A POLST from may not include a directive regarding hydration or the preselection of any decisions or directives. The form must be voluntarily executed by the patient, or if the patient is incapacitated or a minor, by the patient's legal representative. All directives included in the form must be made by the patient, or if the patient is a minor, the patient's legal representative.

To be valid and to be included in a patient's medical records, the POLST form must meet all of the following requirements:
- Be printed on one or both sides of a single piece of paper as determined by the DOH rule;
- Include the signatures of the patient and the patient's examining physician or, if the patient is incapacitated or a minor, the patient's legal representative and the patient's examining

physician, executed after consultation with the patient or the patient's legal representative as appropriate;
- Indicate prominently that completion of the form is voluntary, the use of the form is not a condition of any treatment, and the form cannot be given any affect if the patient is conscious and competent to make health care decisions;
- Prominently provide in a conspicuous location on the form a space for the examining physician to attest and affirm that, in his or her good faith clinical judgment, at the time the POLST form is completed and signed, the patient has the ability to make and communicate health care decisions or, if the patient is incapacitated or a minor, that the patient's legal representative has such an ability;
- Provide an expiration date, provided by the patient's examining physician, that is within one year after the patient or the patient's legal representative signs the form or that is contingent on the completion of the course of treatment addressed in the POLST form, whichever occurs first; and

Identify the medical condition or conditions, provided by the patient's examining physician, that necessitate the POLST form.

The POLST form may only be used by a patient whose examining physician has determined that the patient has an end-stage condition or who, in the good faith clinical judgment of the examining physician, is suffering from at least one life-limiting medical condition that will likely result in the death of the patient within one year.

At a minimum, the patient's physician must review the POLST form with the patient or the patient's representative, when the patient:
- Is transferred from one health care setting or level of care to another;
- Is discharged from a health care setting to return home before the expiration of the POLST form;
- Experiences a substantial change in his or her condition as determined by the patient's examining physician, in which case the review must occur within 24 hours of the substantial change; or
- Expresses an intent to change his or her treatment preferences.

A POLST form may be revoked at any time by a patient, or the patient's legal representative if the patient is a minor or the patient is incapacitated or and the authority to revoke a POLST form has been granted by the patient to his or her legal representative. The execution of a subsequent POLST form by a patient and his or her examining physician under this section automatically revokes any prior POLST form previously executed by the patient.

In addition, if any directive on a patient's POLST form conflicts with another advance directive of the patient, which addresses a substantially similar health care condition or treatment, the document most recently signed by the patient takes precedence. Such directives may include, but are not limited to:
- Living wills;
- Health care powers of attorney;
- POLST forms for the specific medical condition of treatment; or
- An order not-to-resuscitate.

If a family member of the patient, the health care facility providing services to the patient, or the patient's physician who may reasonably be expected to be affected by the patient's POLST form directives believes the directives executed by the patient's legal representative are in conflict with the patient's prior expressed desires regarding end-of-life care, he or she or the facility may seek expedited judicial intervention pursuant to the Florida Probate Rules.

The bill provides immunity from criminal prosecution, civil liability, or professional discipline for a licensee, physician, medical director, emergency medical technician, or paramedic who in good faith complies with or carries out the directives of a POLST form. In addition, any person, acting in good faith as a legal representative, is not subject to civil liability or criminal prosecution for executing a POLST form pursuant to this law.

If medical orders on a POLST form are carried out to withhold life-sustaining treatment for a minor, the order must include certification by a health care provider in addition to the physician executing the POLST form that, in their clinical judgement, the order is in the best interest of the minor patient. The minor patient's legal representative must also sign a POLST form for a minor patient. The minor patient's physician must certify the basis for the authority of the minor patient's legal representative to execute the POLST form, including his or her compliance with the relevant statutory provisions of ch. 765, F.S., relating to health care advance directives and ch. 744, F.S., relating to guardianship.

The bill further requires that when a patient who has executed a valid POLST form is transferred from one health care facility to another, the health care facility initiating the transfer must communicate the existence of the POLST form to the receiving facility before the transfer. Upon the patient's transfer, the receiving facility's treating physician must review the POLST form with the patient or if the patient is incapacitated or a minor, the patient's legal representative.

Facilities and providers may not require a person to complete, revise, or revoke a POLST as a prerequisite or condition of receiving services or treatment or as a condition of admission. The execution, revision, or revocation of a POLST form must be a voluntary decision of the patient, or if incapacitated or a minor, the patient's legal representative.

The presence or absence of a POLST form does not affect, impair, or modify a contract of life or health insurance or annuity to which an individual is a party and may not serve as the basis for any delay in issuing or refusing to issue an annuity or policy of life or health insurance or for an increase or decrease in premiums charged to an individual.

A POLST form is invalid if payment or other remuneration was offered or made in exchange for its execution.

The bill specifies that the act may not be construed to condone, authorize, or approve mercy killing or euthanasia. A statement of legislative intent provides that this act is not to be construed as permitting any affirmative or deliberate act to end a person's life, except to permit the natural process of dying.

Clearinghouse for Compassionate and Palliative Care Plans (Section 2)

Section 2 creates s. 408.064, F.S., to direct AHCA to establish the Clearinghouse for Compassionate and Palliative Care Plans (clearinghouse). The AHCA may establish and maintain the clearinghouse directly or through a designee. The clearinghouse must be a reliable and secure database that will allow Florida residents to submit electronically their individual plans for compassionate and palliative care. The database may only be accessed by a health care provider who is treating the patient-resident.

As used in this section, the bill provides definitions for these terms:

- "Advance directive" means the same as in s. 765.101, F.S.;[34]
- "Clearinghouse for Compassionate and Palliative Care Plans" or "clearinghouse" means the state's electronic database of compassionate and palliative care plans submitted by residents of this state and managed by the agency pursuant to this section;
- "Compassionate and palliative care plan" or "plan" means any end-of-life document or medical directive document recognized by this state and executed by a resident of this state, including, but not limited to, an advance directive, an order to do-not-resuscitate, a physician order for life-sustaining treatment, or a health care surrogate designation;
- "Department" means the Department of Health;
- "End-stage condition" means the same as in s. 765.101, F.S.;[35]
- "Order not to resuscitate" means an order issued pursuant to s. 401.45(3), F.S.; and
- "Physician order for life-sustaining treatment" or "POLST" means an order issued pursuant to s. 401.451, F.S., which specifies the care and medical treatment under certain medical conditions for a patient with an end stage condition.

The AHCA is required to establish and maintain the clearinghouse by January 1, 2019. The database must allow for electronic submission, storage, indexing, and retrieval of compassionate and palliative care plans. The AHCA must also develop and maintain an identity validation system that confirms the identity of the facility, health care provider, or other authorized individual seeking retrieval of plans while protecting the privacy of patient's personal and medical information. The system must meet all applicable state and federal privacy and security standards.

The AHCA is directed to seek input on the clearinghouse from state residents, compassionate and palliative care providers, and health care facilities for its development and implementation. The AHCA may subscribe to or participate in a national or private clearinghouse that will accomplish the same goals in lieu of establishing an independent clearinghouse. Once clearinghouse information is available, the AHCA is required to publish and disseminate information regarding the availability of the clearinghouse to Floridians. The AHCA must also provide training to health care providers and health care facilities on how to access plans.

[34] "Advance directive" means a witnessed written document or oral statement in which instructions are given by a principal or in which the principal's desires are expressed concerning any aspect of the principal's health care or health information, and includes, but is not limited to, the designation of a health care surrogate, a living will, or an anatomical gift made pursuant to part V of ch. 765, F.S.

[35] "End-stage condition" means an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective.

Statutory Revisions to Include POLST (Sections 3-10 and 12)

Provisions in statute requiring health professional staff to honor "do not resuscitate" orders (DNROs) are revised to include recognition of a POLST document in the same manner.

The table below reflects the statutes impacted by these revisions.

Statutory Revisions - Addition of POLST Language		
Bill Section	**F.S. Citation**	**Description**
3	§400.142	Nursing Homes; Emergency medication kits; DNROs
4	§400.487	Home Health Service Agreements; DNROs
5	§400.605	Hospices; Administration; forms; fees
6	§400.6095	Hospice; patient admission; assessment; plan of care; discharge; death
7	§401.35	Medical Transportation Services: Rules
8	§401.45	Denial of emergency treatment; civil liability
9	§429.255	Assisted Living Facilities; Use of personnel; emergency care
10	§429.73	Rules and standards relating to adult family-care homes
11	§456.072	Grounds for discipline; penalties; enforcement
12	§765.205	Responsibility of the surrogate

Section 11 amends s. 456.072, F.S., relating to discipline for health care practitioners generally, to allow a licensee to withhold or withdraw cardiopulmonary resuscitation (CPR) or the use of an automated external defibrillator if presented with an order not to resuscitate or a POLST that includes a DNRO. The DOH is directed to adopt rules for the implementation of such orders. Additionally, the bill provides that licensees who withhold CPR or the use of an automated external defibrillator may not be subject to criminal prosecution and may not be considered to have acted in a negligent or unprofessional manner for carrying out DNRO or POLST orders.

The bill further provides that the absence of an order [not] to resuscitate pursuant to s. 408.064, F.S., or a POLST form executed pursuant to s. 408.064, F.S., does not preclude a licensee from withholding or withdrawing CPR or the use of an external automated defibrillator or otherwise carrying out medical orders allowed by law.

Section 13 provides that the bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

A separate public records exemption bill for the Clearinghouse for Compassionate and Palliative Care Plans (SB 476) is linked to this bill to ensure that the personally identifying information contained on the POLST forms is kept confidential and exempt from s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution. The POLST forms contain sensitive medical information and personal identifying information.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The AHCA anticipates that a private sector vendor will be selected to operate the clearinghouse. The estimated costs are $661,101 for the first year and $618,434 annually thereafter.[36] Based on initial research conducted by the AHCA, there are no currently existing national databases that exist or regional databases that cover all of Florida that meet the requirements outlined in the bill, although it is possible that there might be one that could be customized to meet the requirements.[37]

Patients may request their providers to complete and submit POLST forms on their behalf to the clearinghouse, which may increase a provider's administrative costs.

C. Government Sector Impact:

The AHCA estimates its costs to implement this bill are $1,097,565 for the first year and $1,041,476 annually thereafter.[38] Cost estimates for the clearinghouse were based on experiences of Washington State and adjusted for Florida's population size and inflation, according to the AHCA.[39]

The AHCA requests 3.00 full time equivalent positions for the implementation and administration of the clearinghouse under the alternative option as a contracted service. The positions will be responsible for educating and conducting outreach activities for residents and providers about the availability of the POLST and the clearinghouse statewide.

[36] Agency for Health Care Administration, *Senate Bill 474 Analysis*, p. 7-9, (Oct. 13, 2017) (on file with the Senate Committee on Health Policy).
[37] Id at 5.
[38] Id.
[39] Id at 2.

The AHCA has noted that it does not believe that the clearinghouse can be implemented in the 6-month timeframe outlined in the bill and recommends a one-year timeframe.

The DOH responsibilities under the bill relate to developing rules and procedures for the POLST form and orders not to resuscitate pursuant to a POLST form and to create and maintain the clearinghouse in coordination with the AHCA and DOEA. Conducting these activities can be accomplished within existing DOH resources.

In 2016 under an identical bill, the Department of Elderly Affairs (DOEA) estimated a minimal fiscal impact related to rulemaking for implementation of the POLST forms at hospices, assisted living facilities, and adult family day cares. The DOEA indicated these costs could be absorbed within existing resources.[40] No fiscal impact has been received from DOEA for SB 474.

VI. Technical Deficiencies:

SB 474 does not amend s. 395.1041(3)(l), F.S., to protect hospital personnel for honoring a POLST form.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.142, 400.487, 400.605, 400.6095, 401.35, 401.45, 429.255, 429.73, 456.072, and 765.205.

This bill creates the following sections of the Florida Statutes: 401.451 and 408.064.

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.

[40] Id at 4.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/14/2018	.	
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Appropriations Subcommittee on Health and Human Services (Brandes) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (l) of subsection (3) of section 395.1041, Florida Statutes, is amended to read:

395.1041 Access to emergency services and care.—

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—

(l) Hospital personnel may withhold or withdraw

156796

cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or POLST form. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 which contains an order not to resuscitate does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise authorized ~~permitted~~ by law.

Section 2. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate.—

(3) Facility staff may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 that contains an order not to resuscitate. Facility staff and facilities are not subject to criminal prosecution or civil liability, or considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or POLST form. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s.

401.451 which contains an order not to resuscitate does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise authorized ~~permitted~~ by law.

Section 3. Subsection (7) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate; physician orders for life-sustaining treatment.—

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or POLST form and rules adopted by the agency.

Section 4. Paragraph (e) of subsection (1) of section 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.—

(1) The agency, in consultation with the department, may

adopt rules to administer the requirements of part II of chapter 408. The department, in consultation with the agency, shall by rule establish minimum standards and procedures for a hospice pursuant to this part. The rules must include:

(e) Procedures relating to the implementation of advance ~~advanced~~ directives; physician order for life-sustaining treatment (POLST) forms executed pursuant to s. 401.451 which contain orders not to resuscitate; and orders not to resuscitate ~~do-not-resuscitate orders~~.

Section 5. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

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

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such orders. Hospice staff are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or POLST form and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 which contains an order not to resuscitate does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise authorized ~~permitted~~ by law.

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Section 6. Subsection (4) of section 401.35, Florida Statutes, is amended to read:

401.35 Rules.—The department shall adopt rules, including definitions of terms, necessary to carry out the purposes of this part.

(4) The rules must establish circumstances and procedures under which emergency medical technicians and paramedics may honor orders by the patient's physician not to resuscitate executed pursuant to s. 401.45 or physician order for life-sustaining treatment (POLST) forms executed pursuant to s. 401.451 that contain orders not to resuscitate and the documentation and reporting requirements for handling such requests.

Section 7. Paragraph (a) of subsection (3) of section 401.45, Florida Statutes, is amended to read:

401.45 Denial of emergency treatment; civil liability.—

(3)(a) Resuscitation or other forms of medical intervention may be withheld or withdrawn from a patient by an emergency medical technician, ~~or~~ paramedic, or other health care professional if evidence of an order not to resuscitate by the patient's physician or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate is presented to the emergency medical technician, ~~or~~ paramedic, or other health care professional. To be valid, an order not to resuscitate or not to perform other medical intervention~~, to be valid,~~ must be on the form adopted by rule of the department. The form must be signed by the patient's physician and by the patient or, if the patient is incapacitated, the patient's health care surrogate or proxy

as provided in chapter 765, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709 or, if the patient is a minor, the patient's parent or legal guardian. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

Section 8. Section 401.451, Florida Statutes, is created to read:

401.451 Physician Order for Life-Sustaining Treatment Program.—

(1) POLST FORM.—A physician order for life-sustaining treatment (POLST) must be on the form adopted by rule of the department which must include the requirements specified in this section and must be executed as required by this section.

(a) A POLST form may only be completed by or for a patient determined by the patient's physician to have an end-stage condition as defined in s. 765.101(4) or a patient who, in the good faith clinical judgment of her or his physician, is suffering from at least one terminal medical condition that will likely result in the death of the patient within 1 year.

(b) A POLST form must be signed by the patient's physician. The form must contain a certification by the physician signing the POLST form that the physician consulted with the patient signing the form, or if the patient is incapable of making health care decisions for herself or himself or is incapacitated, with the patient's health care surrogate, proxy, court-appointed guardian or attorney-in-fact authorized to execute a POLST form on behalf of the patient as provided in

156796

paragraph (c), and must include information about the patient's care goals and preferences as reflected on the POLST form, specifically including the use of and the effect of removal or refusal of life-sustaining medical treatment. The physician signing the POLST form must further indicate the medical circumstance justifying the execution of the POLST.

(c) A POLST form must also be signed by the patient, or if the patient is incapable of making health care decisions for herself or himself or is incapacitated, by the patient's health care surrogate or proxy as provided in chapter 765, or if none exists, by the patient's court-appointed guardian if the guardian has such authority as provided in chapter 744, or if none exists, by the patient's attorney-in-fact if the patient has delegated the power to make all health care decisions to the attorney-in-fact as provided in chapter 709. If a POLST form is signed by a health care surrogate, proxy, court-appointed guardian, or attorney-in-fact, the patient's physician must certify the basis for the authority of the appropriate individual to execute the POLST form on behalf of the patient including compliance with chapter 765, chapter 744, or chapter 709.

(d) The execution of a POLST form by the patient automatically revokes all POLST forms previously executed by the patient.

(e) A patient's health care surrogate, proxy, court appointed guardian, or attorney-in-fact authorized to execute a POLST form on behalf of the patient as provided in paragraph (c) may subsequently revoke a POLST form for a patient, unless a valid advance directive or prior POLST form executed by the

patient expressly forbids changes by a surrogate, proxy, guardian, or attorney-in-fact.

(f) An individual acting in good faith as a surrogate, proxy, court-appointed guardian, or attorney-in-fact who executes a POLST form on behalf of an incapacitated patient or a minor patient in accordance with this section and rules adopted by the department is not subject to criminal prosecution or civil liability for executing the POLST form.

(g) If a family member of the patient, the health care facility providing services to the patient, or the patient's physician, who may reasonably be expected to be affected by the patient's POLST form directives, believes that directives executed by the patient's legal representative are in conflict with the patient's prior expressed desires regarding end-of-life care, the family member, facility, or physician may seek expedited judicial intervention pursuant to the Florida Probate Rules if that person believes:

1. The POLST form regarding the patient's wishes regarding life-sustaining treatment is ambiguous or the patient has changed her or his mind after execution of the advance directive or POLST form;

2. The POLST form was executed by a surrogate, proxy, court-appointed guardian, or attorney-in-fact authorized to execute a POLST form on behalf of a patient as provided in paragraph (c) and the POLST form is not in accord with the patient's known desires or chapter 765, chapter 744, or chapter 709;

3. The POLST was executed by a surrogate, proxy, court-appointed guardian, or attorney-in-fact on behalf of a patient

as provided in paragraph (c) and the surrogate, proxy, court-appointed guardian, or attorney-in-fact was improperly designated or appointed, or the designation of the surrogate, proxy, court-appointed guardian, or attorney-in-fact is no longer effective or has been removed;

4. The surrogate, proxy, court-appointed guardian, or attorney-in-fact who executed the POLST form on behalf of the patient as provided in paragraph (c) has failed to discharge her or his duties, or incapacity or illness renders her or him incapable of discharging those duties;

5. The POLST was executed by surrogate, proxy, court-appointed guardian, or attorney-in-fact authorized to execute a POLST form on behalf of a patient as provided in paragraph (c) who has abused her or his powers; or

6. The patient has sufficient capacity to make her or his own health care decisions.

(h) A POLST form may not include a directive regarding hydration or the preselection of any decision or directive. A POLST form must be voluntarily executed by the patient or, if the patient is incapacitated or a minor, the patient's legal representative, and all directives included in the form must be made by the patient or, if the patient is incapacitated or a minor, the patient's legal representative, at the time of signing the form. A POLST form is not valid and may not be included in a patient's medical records or submitted to the clearinghouse unless the form:

1. Is clearly printed on one or both sides of a single piece of paper as determined by department rule;

2. Includes the signatures of the patient and the patient's

156796

examining physician or, if the patient is incapacitated or a minor, the signatures of the patient's legal representative and the patient's examining physician. The POLST form may be executed only after the examining physician consults with the patient or the patient's legal representative, as appropriate;

3. Prominently states that completion of a POLST form is voluntary, that the execution or use of a POLST form may not be required as a condition for medical treatment, and that a POLST form may not be given effect if the patient is conscious and competent to make health care decisions;

4. Prominently provides in a conspicuous location on the form a space for the patient's examining physician to attest that, in her or his clinical judgment and with good faith at the time the POLST form is completed and signed, the patient has the ability to make and communicate health care decisions or, if the patient is incapacitated or a minor, that the patient's legal representative has such ability;

5. Includes an expiration date, provided by the patient's examining physician, that is within 1 year after the patient or the patient's legal representative signs the form or that is contingent on completion of the course of treatment addressed in the POLST form, whichever occurs first; and

6. Identifies the medical condition or conditions, provided by the patient's examining physician, that necessitate the POLST form.

(2) DUTIES OF THE DEPARTMENT.—The department shall:

(a) Adopt rules to implement and administer the POLST program.

(b) Prescribe a standardized POLST form.

156796

(c) Provide the POLST form in an electronic format on the department's website and prominently state on the website the requirements for a POLST form as specified in this section.

(d) Consult with health care professional licensing groups, provider advocacy groups, medical ethicists, and other appropriate stakeholders on the development of rules and forms to implement and administer the POLST program.

(e) Recommend a uniform method of identifying persons who have executed a POLST form and provide health care providers with contact information regarding a patient's primary health care provider.

(f) Oversee the education of health care providers licensed by the department regarding implementation of the POLST program.

(g) Develop a process for collecting provider feedback to enable periodic redesign of the POLST form in accordance with current health care best practices.

(3) DUTY TO COMPLY WITH POLST; OUT-OF-STATE POLST; LIMITED IMMUNITY.—

(a) Emergency medical service personnel, health care providers, physicians, and health care facilities, absent actual notice of revocation or termination of a POLST form, may comply with the orders on a person's POLST form without regard to whether the POLST-ordering provider is on the medical staff of the treating health care facility. If the POLST-ordering provider is not on the medical staff of the treating health care facility, the POLST form must be reviewed by the treating health care professional at the receiving facility with the patient, or the patient's health care surrogate, proxy, court-appointed guardian, or attorney-in-fact authorized to execute a POLST form

on behalf of a patient as provided in paragraph (1)(c), and shall be made into a medical order at the receiving facility, unless the POLST form is replaced or voided as provided in this section.

(b) A POLST form from another state, absent actual notice of revocation or termination, shall be presumed to be valid and shall be effective in this state and shall have the same burden of compliance as a POLST form executed in this state.

(c) Any licensee, physician, medical director, or emergency medical technician or paramedic who acts in good faith on a POLST is not subject to criminal prosecution or civil liability and has not engaged in negligent or unprofessional conduct as a result of carrying out the directives of the POLST made in accordance with this section and rules adopted by the department.

(4) PATIENT TRANSFER; POLST FORM REVIEW REQUIRED.—If a patient whose goals and preferences for care have been entered in a valid POLST form is transferred from one health care facility or level of care to another, the health care facility initiating the transfer must communicate the existence of the POLST form to the receiving facility before the transfer. Upon the patient's transfer, the treating health care provider at the receiving facility must review the POLST form with the patient or, if the patient is incapacitated or a minor, the patient's health care surrogate, proxy, court-appointed guardian, or attorney-in-fact.

(5) CONFLICTS WITH ADVANCE DIRECTIVES.—To the extent that a directive made on a patient's POLST form conflicts with another advance directive of the patient which addresses a substantially

156796

similar health care condition or treatment, the document most recently signed by the patient takes precedence. Such directives may include, but are not limited to:

(a) A living will.

(b) A health care power of attorney.

(c) A POLST form for the specific medical condition or treatment.

(d) An order not to resuscitate.

(6) POLST FORM FOR A MINOR PATIENT.—If a medical order on a POLST form executed for a minor patient directs that life-sustaining treatment may be withheld from the minor patient, the order must include certifications by the patient's examining physician and a health care provider other than the examining physician stating that, in their clinical judgment, an order to withhold medical treatment is in the best interest of the minor patient. A POLST form for a minor patient must be signed by the minor patient's legal representative. The minor patient's examining physician must certify the basis for the authority of the minor patient's legal representative to execute the POLST form on behalf of the minor patient, including the legal representative's compliance with the relevant provisions of chapter 744 or chapter 765.

(7) POLST FORM NOT A PREREQUISITE.—A POLST form may not be a prerequisite for receiving medical services or for admission to a health care facility. A health care facility or health care provider may not require an individual to complete, revise, or revoke a POLST form as a condition of receiving medical services or treatment or as a condition of admission. The execution, revision, or revocation of a POLST form must be a voluntary

decision of the patient or, if the patient is incapacitated or a minor, the patient's legal representative.

(8) REVOCATION OF A POLST FORM.—

(a) A POLST form may be revoked at any time by a patient deemed to have capacity by means of:

1. A signed, dated writing;

2. The physical cancellation or destruction of the POLST form by the patient or by another in the patient's presence and at the patient's direction;

3. An oral expression of intent to revoke; or

4. A subsequently executed POLST form or advance directive that is materially different from a previously executed POLST form or advance directive.

(b) A surrogate, proxy, court-appointed guardian, or attorney-in-fact permitted to execute a POLST form on behalf of a patient as provided in paragraph (1)(c) who created a POLST form for a patient may revoke a POLST form at any time in a writing signed by such surrogate, proxy, court-appointed guardian, or attorney-in-fact.

(c) Any revocation of a POLST form shall be promptly communicated to the patient's primary health care provider, primary physician, and any health care facility at which the patient is receiving care. Further, a health care professional, surrogate, proxy, court-appointed guardian, or attorney-in-fact who is informed of the revocation of a POLST form shall promptly communicate the fact of the revocation to the patient's primary care physician, the current supervising health care professional, and any health care facility at which the patient is receiving care, to the extent known to the surrogate, proxy,

court-appointed guardian, or attorney-in-fact.

(d) Upon revocation, a POLST form shall be void. A POLST form may only be revoked in its entirety. A partial revocation of a POLST form renders the entirety of the POLST form void.

(9) INSURANCE NOT AFFECTED.—The presence or absence of a POLST form does not affect, impair, or modify a contract of life or health insurance or an annuity to which an individual is a party, and may not serve as the basis for a delay in issuing or refusing to issue a policy of life or health insurance or an annuity or for an increase or decrease in premiums charged to the individual.

(10) INVALIDITY.—A POLST form is invalid if payment or other remuneration was offered or made in exchange for execution of the form.

(11) CONSTRUCTION.—This section may not be construed to condone, authorize, or approve mercy killing or euthanasia. The Legislature does not intend that this act be construed as authorizing an affirmative or deliberate act to end an individual's life, except to allow the natural process of dying.

Section 9. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 that contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such an order or POLST form

~~orders~~. Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator pursuant to such an order or POLST form and rules adopted by the department. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 which contains an order not to resuscitate does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator as otherwise authorized ~~permitted~~ by law.

Section 10. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) The department shall adopt rules providing for the implementation of orders not to resuscitate and physician order for life-sustaining treatment (POLST) forms executed pursuant to s. 401.451 which contain orders not to resuscitate. The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 which contains an order not to resuscitate. The provider is ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and is not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or POLST form and applicable rules.

Section 11. Subsections (7) and (8) of section 456.072, Florida Statutes, are renumbered as subsections (8) and (9), respectively, and a new subsection (7) is added to that section to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) A licensee may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such an order or POLST form. A licensee is not subject to criminal prosecution or civil liability and is not considered to have engaged in negligent or unprofessional conduct for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with such an order or POLST form. The absence of such an order or POLST form does not preclude a licensee from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator as otherwise authorized by law.

Section 12. Paragraph (c) of subsection (1) of section 765.205, Florida Statutes, is amended to read:

765.205 Responsibility of the surrogate.—

(1) The surrogate, in accordance with the principal’s instructions, unless such authority has been expressly limited by the principal, shall:

(c) Provide written consent using an appropriate form whenever consent is required, including a physician’s order not

to resuscitate or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate.

Section 13. 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 physician orders for life-sustaining treatment; amending ss. 395.1041, 400.142, and 400.487, F.S.; authorizing specified personnel to withhold or withdraw cardiopulmonary resuscitation if presented with orders not to resuscitate or POLST forms that contain orders not to resuscitate; providing such personnel with immunity from criminal prosecution or civil liability for such actions; providing that the absence of such orders or forms does not preclude physicians or home health agency personnel from withholding or withdrawing cardiopulmonary resuscitation under certain conditions; amending s. 400.605, F.S.; requiring the Department of Elderly Affairs, in consultation with the Agency for Health Care Administration, to adopt by rule procedures for the implementation of POLST forms in hospice care; amending s. 400.6095, F.S.; authorizing hospice care teams to withhold or withdraw cardiopulmonary resuscitation if presented with POLST

forms that contain orders not to resuscitate; providing hospice staff with immunity from criminal prosecution or civil liability for such actions; providing that the absence of a POLST form does not preclude physicians from withholding or withdrawing cardiopulmonary resuscitation; amending s. 401.35, F.S.; requiring the Department of Health to establish circumstances and procedures for honoring POLST forms; amending s. 401.45, F.S.; authorizing emergency medical personnel to withhold or withdraw cardiopulmonary resuscitation or other medical interventions if presented with POLST forms that contain orders not to resuscitate; creating s. 401.451, F.S.; establishing the Physician Order for Life-Sustaining Treatment (POLST) Program within the Department of Health; providing requirements for POLST forms; providing duties of the department; providing a restriction on the use of POLST forms; providing for the revocation of POLST forms under certain circumstances; specifying which document takes precedence when directives in POLST forms conflict with other advance directives; providing limited immunity for legal representatives and specified health care providers relying in good faith on POLST forms; specifying additional requirements for POLST forms executed on behalf of minor patients under certain circumstances; requiring the review of POLST forms upon the transfer of a patient; prohibiting POLST forms from being required as a condition for

treatment or admission to health care facilities; providing for the revocation of POLST forms under certain circumstances; providing that the presence or absence of POLST forms does not affect, impair, or modify certain insurance contracts; declaring POLST forms invalid if they are executed in exchange for payment or other remuneration; providing construction; amending s. 429.255, F.S.; authorizing assisted living facility personnel to withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with POLST forms that contain orders not to resuscitate; providing facility staff and facilities with immunity from criminal prosecution or civil liability for such actions; providing that the absence of a POLST form does not preclude physicians from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator; amending s. 429.73, F.S.; requiring the Department of Elderly Affairs to adopt rules for the implementation of POLST forms in adult family-care homes; authorizing providers of such homes to withhold or withdraw cardiopulmonary resuscitation if presented with a POLST form that contains orders not to resuscitate; providing such providers with immunity from criminal prosecution or civil liability for such actions; amending s. 456.072, F.S.; authorizing licensees to withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if

presented with orders not to resuscitate or POLST forms that contain orders not to resuscitate; requiring the Department of Health to adopt rules providing for the implementation of such orders or forms; providing licensees with immunity from criminal prosecution or civil liability for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with such orders or forms; providing that the absence of such orders or forms does not preclude licensees from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator; amending s. 765.205, F.S.; requiring health care surrogates to provide written consent for POLST forms under certain circumstances; providing an effective date.

By Senator Brandes

24-00549-18 2018474__

A bill to be entitled

An act relating to physician orders for life-sustaining treatment; creating s. 401.451, F.S.; establishing the Physician Orders for Life-Sustaining Treatment (POLST) Program within the Department of Health; defining terms; providing duties of the department; providing requirements for POLST forms; providing a restriction on the use of POLST forms; requiring periodic review of POLST forms; providing for the revocation of POLST forms under certain circumstances; authorizing expedited judicial intervention under certain circumstances; specifying which document takes precedence when directives in POLST forms conflict with other advance directives; providing limited immunity for legal representatives and specified health care providers acting in good faith in reliance on POLST forms; specifying additional requirements for POLST forms executed on behalf of minor patients under certain circumstances; requiring the review of a POLST form upon the transfer of a patient; prohibiting POLST forms from being required as a condition for treatment or admission to health care facilities; providing that the presence or absence of POLST forms does not affect, impair, or modify certain insurance contracts; declaring a POLST form invalid if it is executed in exchange for payment or other remuneration; providing construction; creating s. 408.064, F.S.; defining terms; requiring the Agency for Health Care Administration to establish

24-00549-18 2018474__

and maintain a database of compassionate and palliative care plans by a specified date; providing duties of the agency; authorizing the agency to subscribe to or participate in a public or private clearinghouse in lieu of establishing and maintaining an independent database; amending ss. 400.142 and 400.487, F.S.; authorizing specified personnel to withhold or withdraw cardiopulmonary resuscitation if presented with a POLST form that contains an order not to resuscitate the patient; providing immunity from criminal prosecution or civil liability to such personnel for such actions; providing that the absence of a POLST form does not preclude physicians or home health agency personnel from withholding or withdrawing cardiopulmonary resuscitation under certain conditions; amending s. 400.605, F.S.; requiring the Department of Elderly Affairs, in consultation with the agency, to adopt by rule procedures for the implementation of POLST forms in hospice care; amending s. 400.6095, F.S.; authorizing hospice care teams to withhold or withdraw cardiopulmonary resuscitation if presented with POLST forms that contain an order not to resuscitate; providing immunity from criminal prosecution or civil liability to hospice staff for such actions; providing that the absence of a POLST form does not preclude physicians from withholding or withdrawing cardiopulmonary resuscitation; amending s. 401.35, F.S.; requiring the Department of Health to establish

circumstances and procedures for honoring certain POLST forms; amending s. 401.45, F.S.; authorizing emergency medical personnel to withhold or withdraw cardiopulmonary resuscitation or other medical interventions if presented with POLST forms that contain an order not to resuscitate; amending s. 429.255, F.S.; authorizing assisted living facility personnel to withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with POLST forms that contain an order not to resuscitate; providing immunity from criminal prosecution or civil liability to facility staff and facilities for such actions; providing that the absence of a POLST form does not preclude physicians from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator; amending s. 429.73, F.S.; requiring the Department of Elderly Affairs to adopt rules for the implementation of POLST forms in adult family-care homes; authorizing providers of such homes to withhold or withdraw cardiopulmonary resuscitation if presented with POLST forms that contain an order not to resuscitate; providing immunity from criminal prosecution or civil liability to providers for such actions; amending s. 456.072, F.S.; authorizing certain licensees to withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with orders not to resuscitate or POLST forms that contain

an order not to resuscitate; requiring the Department of Health to adopt rules providing for the implementation of such orders; providing immunity from criminal prosecution or civil liability to licensees for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator or for carrying out specified orders under certain circumstances; providing that the absence of a POLST form does not preclude a licensee from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator under certain conditions; amending s. 765.205, F.S.; requiring health care surrogates to provide written consent for POLST forms under certain circumstances; providing an effective date.

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

Section 1. Section 401.451, Florida Statutes, is created to read:

401.451 Physician Orders for Life-Sustaining Treatment Program.—The Physician Orders for Life-Sustaining Treatment Program is established within the Department of Health to implement and administer the development and use of physician orders for life-sustaining treatment consistent with this section and to collaborate with the Agency for Health Care Administration in the implementation and operation of the Clearinghouse for Compassionate and Palliative Care Plans created under s. 408.064.

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

(a) "Advance directive" has the same meaning as provided in s. 765.101.

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

(c) "Clearinghouse for Compassionate and Palliative Care Plans" or "clearinghouse" has the same meaning as provided in s. 408.064.

(d) "End-stage condition" has the same meaning as provided in s. 765.101.

(e) "Examining physician" means a physician who examines a patient who wishes, or whose legal representative wishes, to execute a POLST form; who attests to the ability of the patient or the patient's legal representative to make and communicate health care decisions; who signs the POLST form; and who attests to the execution of the POLST form by the patient or by the patient's legal representative.

(f) "Health care provider" has the same meaning as provided in s. 408.07.

(g) "Legal representative" means a patient's legally authorized health care surrogate or proxy as provided in chapter 765, a patient's court-appointed guardian as provided in chapter 744 who has been delegated authority to make health care decisions on behalf of the patient, an attorney in fact under a durable power of attorney as provided in chapter 709 who has been delegated authority to make health care decisions on behalf of the patient, or a patient's parent if the patient is under 18 years of age.

(h) "Order not to resuscitate" means an order issued under

s. 401.45(3).

(i) "Physician order for life-sustaining treatment" or "POLST" means an order issued pursuant to this section which specifies a patient with an end-stage condition and provides directives for that patient's medical treatment and care under certain conditions.

(2) DUTIES OF THE DEPARTMENT.—The department shall:

(a) Adopt rules to implement and administer the POLST program.

(b) Prescribe a standardized POLST form.

(c) Provide the POLST form in an electronic format on the department's website and prominently state on the website the requirements for a POLST form as specified under paragraph (3)(a).

(d) Consult with health care professional licensing groups, provider advocacy groups, medical ethicists, and other appropriate stakeholders on the development of rules and forms to implement and administer the POLST program.

(e) Collaborate with the agency to develop and maintain the clearinghouse.

(f) Ensure that department staff receive ongoing training on the POLST program and are aware of the availability of POLST forms.

(g) Recommend a statewide, uniform process for identifying a patient who has, or whose legal representative has, executed a POLST form and for providing the contact information for the examining physician to the health care providers currently treating the patient.

(h) Adopt POLST-related continuing education requirements

for health care providers licensed by the department.

(i) Develop a process for collecting feedback from health care providers to facilitate the periodic redesign of the POLST form in accordance with current health care best practices.

(3) POLST FORM.—

(a) *Requirements*.—A POLST form may not include a directive regarding hydration or the preselection of any decision or directive. A POLST form must be voluntarily executed by the patient or, if the patient is incapacitated or a minor, the patient's legal representative, and all directives included in the form must be made by the patient or, if the patient is incapacitated or a minor, the patient's legal representative at the time of signing the form. A POLST form is not valid and may not be included in a patient's medical records or submitted to the clearinghouse unless the form:

1. Is clearly printed on one or both sides of a single piece of paper as determined by department rule;

2. Includes the signatures of the patient and the patient's examining physician or, if the patient is incapacitated or a minor, the patient's legal representative and the patient's examining physician. The POLST form may be executed only after the examining physician consults with the patient or the patient's legal representative, as appropriate;

3. Prominently states that completion of a POLST form is voluntary, that the execution or use of a POLST form may not be required as a condition for medical treatment, and that a POLST form may not be given effect if the patient is conscious and competent to make health care decisions;

4. Prominently provides in a conspicuous location on the

form a space for the patient's examining physician to attest that, in his or her clinical judgment and with good faith, at the time the POLST form is completed and signed, the patient has the ability to make and communicate health care decisions or, if the patient is incapacitated or a minor, that the patient's legal representative has such ability;

5. Includes an expiration date, provided by the patient's examining physician, that is within 1 year after the patient or the patient's legal representative signs the form or that is contingent on completion of the course of treatment addressed in the POLST form, whichever occurs first; and

6. Identifies the medical condition or conditions, provided by the patient's examining physician, that necessitate the POLST form.

(b) *Restriction on the use of a POLST form*.—A POLST form may be completed only by or for a patient determined by the patient's examining physician to have an end-stage condition or a patient who, in the good faith clinical judgment of the examining physician, is suffering from a life-limiting medical condition that will likely result in the death of the patient within 1 year after the execution of the form.

(c) *Periodic review of a POLST form*.—At a minimum, the patient's examining physician must review the patient's POLST form with the patient or the patient's legal representative, as appropriate, when the patient:

1. Is transferred from one health care facility or level of care to another in accordance with subsection (6);

2. Is discharged from a health care facility to return home before the expiration of the POLST form;

3. Experiences a substantial change in his or her condition as determined by the patient's examining physician, in which case the review must occur within 24 hours after the substantial change; or

4. Expresses an intent to change his or her medical treatment preferences.

(d) *Revocation of a POLST form.*—

1. A POLST form may be revoked at any time by the patient or the patient's legal representative if the patient is a minor or if the patient is incapacitated and has granted the authority to revoke a POLST form to his or her legal representative.

2. The execution of a POLST form by a patient and the patient's examining physician or, if the patient is incapacitated or a minor, by the patient's legal representative and the patient's examining physician under this section automatically revokes all POLST forms previously executed by the patient.

(e) *Review of a legal representative's decision on a POLST form.*—If a family member of the patient, the health care facility providing services to the patient, or the patient's physician who may reasonably be expected to be affected by the patient's POLST form directives believes that directives executed by the patient's legal representative are in conflict with the patient's prior expressed desires regarding end-of-life care, the family member, facility, or physician may seek expedited judicial intervention pursuant to the Florida Probate Rules.

(f) *Conflicting advance directives.*—To the extent that a directive made on a patient's POLST form conflicts with another

advance directive of the patient which addresses a substantially similar health care condition or treatment, the document most recently signed by the patient takes precedence. Such directives may include, but are not limited to:

1. A living will.

2. A health care power of attorney.

3. A POLST form for the specific medical condition or treatment.

4. An order not to resuscitate.

(4) ACTING IN GOOD FAITH; LIMITED IMMUNITY.—

(a) An individual acting in good faith as a legal representative who executes a POLST form on behalf of an incapacitated patient or a minor patient in accordance with this section and rules adopted by the department is not subject to criminal prosecution or civil liability for executing the POLST form.

(b) A licensee, physician, medical director, emergency medical technician, paramedic, or registered nurse who in good faith complies with a POLST form is not subject to criminal prosecution or civil liability for complying with the POLST form, and has not engaged in negligent or unprofessional conduct as a result of carrying out the directives of a POLST form executed in accordance with this section and rules adopted by the department.

(5) POLST FORM FOR A MINOR PATIENT.—If a medical order on a POLST form executed for a minor patient directs that life-sustaining treatment may be withheld from the minor patient, the order must include certifications by the patient's examining physician and a health care provider other than the examining

physician stating that, in their clinical judgment, an order to withhold medical treatment is in the best interest of the minor patient. A POLST form for a minor patient must be signed by the minor patient's legal representative. The minor patient's examining physician must certify the basis for the authority of the minor patient's legal representative to execute the POLST form on behalf of the minor patient, including the legal representative's compliance with the relevant provisions of chapter 744 or chapter 765.

(6) PATIENT TRANSFER; POLST FORM REVIEW REQUIRED.—If a patient whose goals and preferences for care have been entered in a valid POLST form is transferred from one health care facility or level of care to another, the health care facility or level of care initiating the transfer must communicate the existence of the POLST form to the receiving facility or level of care before the transfer. Upon the patient's transfer, the treating health care provider at the receiving facility or level of care must review the POLST form with the patient or, if the patient is incapacitated or a minor, the patient's legal representative.

(7) POLST FORM NOT A PREREQUISITE.—A POLST form may not be a prerequisite for receiving medical services or for admission to a health care facility. A health care facility or health care provider may not require a person to complete, revise, or revoke a POLST form as a condition of receiving medical services or treatment or as a condition of admission. The execution, revision, or revocation of a POLST form must be a voluntary decision of the patient or, if the patient is incapacitated or a minor, the patient's legal representative.

(8) INSURANCE NOT AFFECTED.—The presence or absence of a POLST form does not affect, impair, or modify a contract of life or health insurance or annuity to which an individual is a party and may not serve as the basis for a delay in issuing or refusing to issue a policy of life or health insurance or an annuity or for an increase or decrease in premiums charged to the individual.

(9) INVALIDITY.—A POLST form is invalid if payment or other remuneration was offered or made in exchange for execution of the form.

(10) CONSTRUCTION.—This section may not be construed to condone, authorize, or approve mercy killing or euthanasia. The Legislature does not intend that this act be construed as authorizing an affirmative or deliberate act to end a person's life, except to allow the natural process of dying.

Section 2. Section 408.064, Florida Statutes, is created to read:

408.064 Clearinghouse for Compassionate and Palliative Care Plans.—

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

(a) "Advance directive" has the same meaning as provided in s. 765.101.

(b) "Clearinghouse for Compassionate and Palliative Care Plans" or "clearinghouse" means the state's electronic database of compassionate and palliative care plans submitted by residents of this state and managed by the agency pursuant to this section.

(c) "Compassionate and palliative care plan" or "plan" means an end-of-life document or medical directive document

recognized by this state and executed by a resident of this state, including, but not limited to, an advance directive, an order not to resuscitate, a physician order for life-sustaining treatment, or a health care surrogate designation.

(d) "Department" means the Department of Health.

(e) "End-stage condition" has the same meaning as provided in s. 765.101.

(f) "Order not to resuscitate" means an order issued pursuant to s. 401.45(3).

(g) "Physician order for life-sustaining treatment" or "POLST" means an order issued pursuant to s. 401.451 which specifies a patient with an end-stage condition and provides directions for that patient's medical treatment and care under certain conditions.

(2) ELECTRONIC DATABASE.—The Agency for Health Care Administration shall:

(a) By January 1, 2019, establish and maintain the Clearinghouse for Compassionate and Palliative Care Plans, a reliable and secure database consisting of compassionate and palliative care plans submitted by residents of this state which is accessible to health care providers, health care facilities, and other authorized individuals through a secure electronic portal. The clearinghouse must allow the electronic submission, storage, indexing, and retrieval of such plans and allow access to them by the treating health care providers of the patients.

(b) Develop and maintain a validation system that confirms the identity of the health care facility, health care provider, or other authorized individual seeking the retrieval of a plan and provides privacy protections that meet all state and federal

privacy and security standards for the release of a patient's personal and medical information to a third party.

(c) Consult with compassionate and palliative care providers, health care facilities, and residents of this state as necessary and appropriate to facilitate the development and implementation of the clearinghouse.

(d) Publish and disseminate to residents of this state information regarding the clearinghouse.

(e) In collaboration with the department, develop and maintain a process for the submission of compassionate and palliative care plans by residents of this state or by health care providers on behalf of, and at the direction of, their patients, or the patients' legal representatives as defined in s. 401.451, for inclusion in the clearinghouse.

(f) Provide training to health care providers and health care facilities in this state on how to access plans in the clearinghouse.

(3) ALTERNATIVE IMPLEMENTATION.—In lieu of establishing and maintaining the clearinghouse, the agency may subscribe to or otherwise participate in a database operated by a public or private entity if that database meets the requirements of this section. The alternative database must operate on a statewide basis in this state, and may operate on a nationwide or regionwide basis.

Section 3. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate.—

(3) Facility staff may withhold or withdraw cardiopulmonary

resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. Facility staff and facilities are not subject to criminal prosecution or civil liability, or considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order or a POLST form. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise authorized ~~permitted~~ by law.

Section 4. Section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate; physician orders for life-sustaining treatment.—

(1) Services provided by a home health agency must be covered by an agreement between the home health agency and the patient or the patient's legal representative specifying the home health services to be provided, the rates or charges for services paid with private funds, and the sources of payment, which may include Medicare, Medicaid, private insurance, personal funds, or a combination thereof. A home health agency providing skilled care must make an assessment of the patient's

needs within 48 hours after the start of services.

(2) If ~~When~~ required by ~~the provisions of~~ chapter 464; part I, part III, or part V of chapter 468; or chapter 486, the attending physician, physician assistant, or advanced registered nurse practitioner, acting within his or her respective scope of practice, shall establish treatment orders for a patient who is to receive skilled care. The treatment orders must be signed by the physician, physician assistant, or advanced registered nurse practitioner before a claim for payment for the skilled services is submitted by the home health agency. If the claim is submitted to a managed care organization, the treatment orders must be signed within the time allowed under the provider agreement. The treatment orders shall be reviewed, as frequently as the patient's illness requires, by the physician, physician assistant, or advanced registered nurse practitioner in consultation with the home health agency.

(3) A home health agency shall arrange for supervisory visits by a registered nurse to the home of a patient receiving home health aide services in accordance with the patient's direction, approval, and agreement to pay the charge for the visits.

(4) Each patient has the right to be informed of and to participate in the planning of his or her care. Each patient must be provided, upon request, a copy of the plan of care established and maintained for that patient by the home health agency.

(5) If ~~When~~ nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation

visits, and the discharge visit by a direct employee. Services provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with this part and applicable rules.

(6) The skilled care services provided by a home health agency, directly or under contract, must be supervised and coordinated in accordance with the plan of care.

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such orders ~~an order~~ and rules adopted by the agency.

Section 5. Paragraph (e) of subsection (1) of section 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.—

(1) The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter 408. The department, in consultation with the agency, shall by

rule establish minimum standards and procedures for a hospice pursuant to this part. The rules must include:

(e) Procedures relating to the implementation of advance ~~advanced~~ directives; physician orders for life-sustaining treatment (POLST) forms executed pursuant to s. 401.451; and orders not to resuscitate ~~do-not-resuscitate orders~~.

Section 6. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

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

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such orders. Hospice staff are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such orders ~~an order~~ and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise authorized ~~permitted~~ by law.

Section 7. Subsection (4) of section 401.35, Florida Statutes, is amended to read:

401.35 Rules.—The department shall adopt rules, including

definitions of terms, necessary to carry out the purposes of this part.

(4) The rules must establish circumstances and procedures under which emergency medical technicians and paramedics may honor orders by the patient's physician not to resuscitate executed pursuant to s. 401.45, or under a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate, or honor orders to withhold or withdraw other forms of medical intervention, and the documentation and reporting requirements for handling such requests.

Section 8. Paragraph (a) of subsection (3) of section 401.45, Florida Statutes, is amended to read:

401.45 Denial of emergency treatment; civil liability.—

(3)(a) Resuscitation or other forms of medical intervention may be withheld or withdrawn from a patient by an emergency medical technician, ~~or~~ paramedic, or other health care professional if the technician, paramedic, or professional is presented with evidence of an order not to resuscitate by the patient's physician or evidence of a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate or an order not to perform other medical intervention, as applicable ~~is presented to the emergency medical technician or paramedic~~. To be valid, an order not to resuscitate or not to perform other medical intervention~~, to be valid,~~ must be on the form adopted by rule of the department. The form must be signed by the patient's physician and by the patient or, if the patient is incapacitated, the patient's health care surrogate or proxy as

provided in chapter 765, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709 or, if the patient is a minor, the patient's parent or legal guardian. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

Section 9. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such orders. Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and are not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator pursuant to such an order or a POLST form which contains an order not to resuscitate and rules adopted by the department. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator as otherwise authorized ~~permitted~~ by law.

Section 10. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) The department shall adopt rules providing for the implementation of orders not to resuscitate and physician orders for life-sustaining treatment (POLST) forms executed pursuant to s. 401.451. The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 which contains an order not to resuscitate. The provider is ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, and is not ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such orders ~~an order~~ and applicable rules.

Section 11. Present subsections (7) and (8) of section 456.072, Florida Statutes, are redesignated as subsections (8) and (9), respectively, and a new subsection (7) is added to that section, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) A licensee may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45 or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451 which contains an order not to resuscitate. The department shall adopt rules providing for the implementation of such orders. A licensee is not subject to criminal prosecution or civil liability, and is

not considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator, or otherwise carrying out an order in an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451, pursuant to the order not to resuscitate or the POLST form and pursuant to rules adopted by the department. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a POLST form executed pursuant to s. 401.451 does not preclude a licensee from withholding or withdrawing cardiopulmonary resuscitation or the use of an automated external defibrillator or otherwise carrying out a medical order authorized by law.

Section 12. Paragraph (c) of subsection (1) of section 765.205, Florida Statutes, is amended to read:

765.205 Responsibility of the surrogate.—

(1) The surrogate, in accordance with the principal's instructions, unless such authority has been expressly limited by the principal, shall:

(c) Provide written consent using an appropriate form whenever consent is required, including a physician's order not to resuscitate or a physician order for life-sustaining treatment (POLST) form executed pursuant to s. 401.451.

Section 13. This act shall take effect July 1, 2018.

The Florida Senate

Committee Agenda Request

To: Senator Anitere Flores
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: January 18, 2018

I respectfully request that **Senate Bill #474**, relating to **Physician Orders for Life-sustaining Treatment**, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Jeff Brandes
Florida Senate, District 24

THE FLORIDA SENATE

APPEARANCE RECORD

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

February 14, 2018
Meeting Date

SB 424
Bill Number (if applicable)

Topic (POLST)

Amendment Barcode (if applicable)

Name Belinda Henning

Job Title Retired

Address 4730 NW 13th Ave.
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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 St. Ciana Guild of Catholic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2-14-18
Meeting Date

SB 474
Bill Number (if applicable)

Topic SB 474 (POLST)

Amendment Barcode (if applicable)

Name Diane Gowski, MD

Job Title FL State director for the Catholic Medical Association

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Clearwater FL 33756
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 FL guilds of the Catholic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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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)

2/14
Meeting Date

SB 474
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic P.O.L.S.T.

Name Linda Bell

Job Title President

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Tavares FL 32310
City *State* *Zip*

Email

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Florida Right to Life

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

2/14/2018
Meeting Date

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

SB 474
Bill Number (if applicable)

Topic P.O.L.S.T.

Amendment Barcode (if applicable)

Name Mark Bell

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Self

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/15/18
Meeting Date

474
Bill Number (if applicable)

Topic POLST

Amendment Barcode (if applicable)

Name Marco Paredes

Job Title Associate Director for Health

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Speaking: ☐ For ☐ Against ☑ Information

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

Representing FL Conference of Catholic Bishops

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

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 Appropriations Subcommittee on Health and Human Services

BILL:	PCS/CS/SB 710 (471064)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services; Health Policy Committee; and Senator Book
SUBJECT:	Prescription Drug Donation Program
DATE:	February 15, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Loe	Williams	AHS	**Recommend: Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 710 creates the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state. The Program:

- Permits Florida residents with valid prescriptions who are either indigent, uninsured, or underinsured to receive donated prescription drugs and supplies under the Program.
- Limits entities that may donate prescription drugs to those that can ensure the drugs have been maintained entirely by licensed or permitted professionals and not by patients.
- Limits dispensing of prescription drugs under the Program to persons who are licensed, registered, or otherwise permitted by state law.
- Establishes eligibility criteria for prescription drugs donated to the Program.
- Provides procedures for inventorying, storing, dispensing, recalling, and destroying prescription drugs under the Program.
- Provides recordkeeping and reporting requirements for participating facilities.
- Requires DOH to maintain and publish on its website registries of all participating facilities and available donated drugs and supplies.
- Creates a direct-support organization (DSO) to provide funding for the Program.
- Requires DOH to adopt rules necessary to implement the Program.

The bill amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

The DOH will experience an increase in workload to administer the Program; however, these costs should be absorbed through funding collected by the DSO in support of the Program.

The bill is effective July 1, 2018.

II. Present Situation:

State Prescription Drug Donation and Reuse Programs

State prescription drug donation and reuse programs have been in effect for two decades beginning with a pilot program in Georgia in 1997.[1] Such drug donation and reuse programs permit unused prescription or non-prescription drugs to be donated and re-dispensed to patients within certain federal guidelines. More than 38 states have passed laws authorizing such programs; however, many are not currently operational.[2] Georgia's program started with a prescription drug reuse program only in long-term care facilities and has been expanded to a collection and donation program that accepts prescription and non-prescription drugs.[3]

Pharmaceutical donation programs and reuse programs involve the voluntary collection of donated, unused prescription and non-prescription drugs from patients. States vary in the types of drugs and supplies that are accepted, the number and types of sites that are considered eligible locations where patients or donors may deposit donations, participant eligibility requirements, and the dispensing fees for the donated drugs. Generally, the drugs are not controlled substances. Some programs, such as Florida's, are limited to only cancer treatment drugs. Twelve other states besides Florida - Colorado, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin - have prescription drug donation and reuse programs limited to only cancer treatment drugs.

Pharmacies, charitable clinics, and hospitals are locations where such donations are accepted. In Florida's Cancer Drug Donation Program,[4] only Class II hospital pharmacies that elect or volunteer to participate in the program are eligible to accept donations of cancer drugs from designated individuals or entities.[5]

Individuals may be required to meet certain eligibility requirements beyond a cancer diagnosis to participate in the donation program such as proof of state residency (Minnesota), lack of access to other insurance coverage, or Medicaid ineligibility (Florida). Dispensing fees are set based on a maximum relative threshold above the Medicaid dispensing fee or capped at an absolute dollar amount that typically ranges from $10 to $15.

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[1] National Conference of State Legislatures, *State Prescription Drug Return, Reuse and Recycling Laws* (March 31, 2017), http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx (last visited Nov. 28, 2017).
[2] *Supra* note 1.
[3] GA. CODE ANN. § 31-8-301-304 (2017).
[4] Section 499.029, F.S.
[5] *See* s. 465.019, F.S. Class II institutional pharmacies are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to the patients of that institution, for use on the premises of that institution.

The statutory provisions of many pharmaceutical donation programs have several common requirements:

- No controlled substances are accepted as donations;
- No adulterated or misbranded medications are allowed;
- All pharmaceuticals must be checked by a pharmacist prior to being dispensed;
- Pharmaceuticals must not be expired and most pharmaceuticals must have at least six months or longer before expiration;
- All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging; and
- Liability protection is assured for both donors and recipients.[6]

Most states permit the donation of any non-controlled substance to a designated medical facility, clinic, or pharmacy that has elected to participate in the program. Twenty states have operational repository programs – either cancer drug programs or broader collection programs – including states such as Iowa which has served over 70,000 patients and re-distributed $15 million in donated supplies since 2007.[7] The Iowa program is limited to residents with incomes at or below 200 percent of the federal poverty level (FPL), or $49,200 for a family of four under the current guidelines, who are uninsured or underinsured, and are eligible to receive the donated medications and supplies.[8] The Iowa program accepts donations from any organization or individual in the country with the medication provided in its sealed or original, tamper-resistant packaging. Any pharmacy or medical facility with authorization to dispense under Iowa administrative rules may then re-dispense the donated medication or supplies.[9]

Wyoming has also had a long-running Medication Donation Program. The state's program filled over 150,000 prescriptions since its inception in 2007 and provided more than $2.4 million worth of donated prescriptions in 2016.[10] Assistance under the program is time-limited and recipients must have incomes under 200 percent of the FPL, and be without prescription insurance or Medicaid coverage. A dispensing site may also charge a recipient up to $10 per prescription to cover dispensing fees. Controlled substances are not covered in the program.[11]

Florida Cancer Drug Donation Program

The Florida Cancer Drug Donation Program (CDDP) was created in 2006[12] and is administratively housed within the DBPR. The CDDP allows eligible donors to donate cancer drugs and related supplies to participating facilities that may dispense the donations to eligible cancer patients. Eligible donors include patients, patient representatives, health care facilities,

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[6] *Supra* note 1.
[7] *Supra* note 1.
[8] Iowa Department of Public Health, *SafeNetRx Program*, https://idph.iowa.gov/ohds/rural-health-primary-care/repository, (last visited Nov. 28, 2017).
[9] *Id.*
[10] Wyoming Department of Health, *Wyoming Medication Donation Program*, https://health.wyo.gov/healthcarefin/medicationdonation/ (last visited Nov. 28, 2017).
[11] *Id.*
[12] Chapter 2006-310, Laws of Fla. (creating s. 499.029, effective July 1, 2006). It was originally created within the Department of Health, but was part of a programmatic transfer by the 2010 Legislature to DBPR effective October 1, 2011.

nursing home facilities, hospices, or hospitals with a closed drug delivery system; or pharmacies, drug manufacturers, medical device manufacturers, or suppliers or wholesalers of drugs or supplies.[13]

Eligible participating facilities that may collect donations are limited to only those Florida hospital pharmacies with a Class II institutional pharmacy permit.[14] These pharmacies participate on a voluntary basis and must agree to accept, inspect, and dispense the donated drugs to the eligible patients in accordance with the statute. The DBPR is required to establish and maintain a participant facility registry for the CDDP. The law provides the content for the registry and a requirement for a website posting. Currently, 14 hospital pharmacies participate in the CDDP.[15]

Florida's recipient eligibility requirements limit participation to Florida residents who:

- Have been diagnosed with cancer; and
- Are ineligible for the Medicaid program, or any other prescription drug program funded in whole or in part by the federal government, or do not have third party insurance unless the benefits have been exhausted or a certain cancer drug is not covered.[16]

Donated drugs may only be prescribed by a licensed practitioner and dispensed by a licensed pharmacist to an eligible patient.[17] Dispensed drugs and supplies under the CDDP are not eligible for reimbursement by third parties, either public or private. However, the facility may charge the recipient of the donated drug a handling fee of no more than 300 percent of the Medicaid dispensing fee or no more than $15, whichever is less, for each cancer drug that is dispensed.[18]

The DBPR, Division of Drugs, Devices, and Cosmetics, maintains a list of available donated medications on its website; however, no cancer medications are currently reported on the list.[19] As of November 2017, the DBPR does not require the participating facilities to report the medications that are available for inclusion on the CDDP website or the number of donated drugs that have been administered.[20] A facility is required to maintain its data for three years.[21]

The CDDP will only accept drugs if:

- The drug expires at least six months after the date of donation and the drug's tamper-resistant packaging is intact;
- The drug is in its original, unopened, sealed, tamper-evident unit dose packaging with lot number and expiration date, if so packaged; and
- The drug is not a substance listed on Schedule II, III, IV, or V of s. 893.03, F.S.[22]

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[13] Section 499.029(3)(c), F.S.
[14] Section 499.029(2)(e), F.S.
[15] Florida Department of Business and Professional Regulation, *Cancer Drug Donation Program Participation Report*, http://www.myfloridalicense.com/dbpr/ddc/documents/ParicipatingHospital.pdf (last visited Nov. 28, 2017).
[16] Rule 61N-1.026(1), F.A.C.
[17] Section 499.029(5), F.S.
[18] Section 409.029(7)(b), F.S. and Rule 61N-1.026(5), F.A.C.
[19] Florida Department of Business and Professional Regulation, *Medication Supply Availability List*.
[20] Email correspondence from Colton Madill, Department of Business and Professional Regulation (Nov. 29, 2017) (on file with the Senate Committee on Health Policy).
[21] *Id.*
[22] Rule 61N-1.026(6), F.A.C.

Under the act, a donor or a participant in the program who acts with reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies is immune from civil or criminal liability or professional disciplinary action for any kind of injury, death, or loss relating to such activities.[23]

Regulation of Pharmacy

The DBPR is the state agency charged with the regulation and licensure of businesses and professionals.[24] Under the provisions of chapter 499, F.S., the Division of Drugs, Devices, and Cosmetics safeguards the health, safety, and welfare of the state's citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients and cosmetics. The Division oversees: the CDDP; issuance and regulation of licensure and permits for drug manufacturers, wholesalers, and distributers; controlled substance reporting requirements for certain wholesale distributors; issuance and regulation of other permits and licenses; and the Drug Wholesale Distributor Advisory Council.[25]

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 – 499.081, F.S. The Act provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics. The Act provides definitions for what is considered a device, drug, and, specifically, a prescription drug.[26]

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in the Department of Health. Section 465.019(2)(b), F.S., provides requirements for institutional pharmacies. "Class II institutional pharmacies" are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution for use on the premises of that institution.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacist from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.[27] There is an exception for a closed drug delivery system in which unit dose or

[23] Section 409.029(11), F.S.
[24] Section 20.165, F.S.
[25] Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, http://www.myfloridalicense.com/dbpr/ddc/index.html (last visited Nov. 29, 2017).
[26] A "prescription drug" under s. 499.003(40) is defined as a "prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by, s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.
[27] Rule 64B16-28.118(2), F.A.C.

customized patient medication packages are dispensed to in-patients. The unused medication may be returned to the pharmacy for re-dispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system – or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part – is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any. In the case of controlled substances, such drugs may only be returned as permitted under federal law.[28] A "closed drug delivery system" means a system in which control of the unit-dose medication is maintained by the facility rather than by the individual patient. A "unit dose system" means a system in which all the individually sealed unit doses are physically connected as a unit.[29]

For nursing facility residents, s. 400.141(1)(d), F.S., requires a pharmacist licensed in Florida that is under contract with a nursing home to repackage a resident's bulk prescription medication which has been packaged by another pharmacist into a unit-dose system compatible with the system used by the nursing facility, if requested by the facility. In order to be eligible for the repacking service, the resident or the resident's spouse's prescription medication benefits must be covered through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. part 831, or a long-term care policy as defined under specified state law. A pharmacist who correctly repackages and relabels the medication, and the nursing home who correctly administers the repackaged medication, cannot be held liable in any civil or administrative action arising from the repackaging. The pharmacist may charge a reasonable fee for costs of the repackaging.

A nursing home typically has a Class I institutional permit. This permit authorizes the nursing home to have patient-specific medications that have already been dispensed to the resident. Prescription drugs may not be dispensed in a Class I pharmacy.[30]

Federal Law and Regulations

The federal Controlled Substances Act (CSA) was enacted by Congress in 1970 and codified as 21 U.S.C. §801, et seq. The CSA regulates the manufacture and distribution of controlled substances in the United States. The federal Drug Enforcement Agency (DEA) is responsible for the enforcement of the CSA.

The CSA categorizes drugs into five "schedules" based on their potential for abuse and safety or dependence liability.[31] The CSA provides for specific dispensing requirements for controlled

[28] Rule 64B16-28-118(2), F.A.C.
[29] Rule 64B16-28-118(1), F.A.C.
[30] Section 465.019(2)(a), F.S.
[31] U.S. Department of Justice, Diversion Control Division, *Controlled Substance Security Manual*, https://www.deadiversion.usdoj.gov/pubs/manuals/sec/app_law.htm (last visited Nov. 28, 2017). Drugs classified as Schedule I are those that are considered to have no medical use in the United States and have a high abuse potential and include drugs such as heroin, LSD, and marijuana. Schedule II substances have a high abuse potential with severe psychological or physical dependency, but have accepted medical use. Examples of Schedule II drugs include opium, morphine, codeine, and oxycodone. Schedule III drugs have an abuse potential and dependency liability less than Schedule II with an accepted medical use. Schedule III drugs may also contain limited quantities of certain narcotic and non-narcotic drugs. Schedule IV drugs have an abuse potential and dependency liability less than those drugs in Schedule III and have an

substances, including written prescriptions, retention requirements, and refill restrictions, depending on the drug's schedule.[32] Prescriptions must also meet specific labeling and packaging requirements. For Schedule II, III, and IV drugs, the label must clearly contain a warning that it is a crime to transfer the drug to any person other than the patient.[33]

The CSA permits the delivery of controlled substances by an "ultimate user,"[34] who has lawfully obtained the drug, to a designated covered entity for disposal and destruction such as through a prescription drug take-back program.[35] An authorized covered entity is defined in federal law as:

- A specified law enforcement agency;
- A manufacturer, distributor, or reverse distributor of prescription medications;
- A retail pharmacy;
- A registered narcotic treatment program;
- A hospital or clinic with an onsite pharmacy;
- An eligible long-term care facility; or
- Any other entity authorized by the DEA to dispose of prescription medications.[36]

The last National Prescription Take Back Day sponsored by the DEA resulted in more than 912,305 pounds of expired, unused, and unwanted prescription drugs returned at 5,300 sites on November 7, 2017.[37] The goal of the take-back program is to prevent the diversion of unwanted drugs to misuse and abuse and to avoid the potential safety hazard of drugs flushed down the toilet.[38]

Citizen-Support Organizations and Direct-Support Organizations

Citizen-support organizations (CSOs) and direct-support organization (DSOs) are statutorily created non-profit organizations[39] authorized to carry out specific tasks in support of public entities or public causes.[40] The function and purpose of a CSO or DSO are prescribed by an enacting statute and a written contract with the agency the CSO or DSO supports.[41]

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accepted medical use and include drugs such as Valium, Xanax, and Darvon. The drugs in the fifth and final schedule, Schedule V, have an abuse potential less than those listed in Schedule IV, have an accepted medical use, and are often available without a prescription, including some for antitussive and antidiarrheal purposes.

[32] 21 U.S.C. §829 and 21 CFR §§1306.21 and 1306.22.

[33] 21 U.S.C. §825.

[34] An "ultimate user" is defined under 21 U.S.C. 802(27), as the person who has lawfully obtained, and who possesses, a controlled substance for his own use or the use of a member of his household or for an animal owned by him or by a member of his household.

[35] 21 U.S.C. 822a.

[36] *Id.*

[37] Drug Enforcement Administration, *Drug Enforcement Administration collects record number of unused pills as part of its 14th Prescription Drug Take Back Day* (November 7, 2017), https://www.dea.gov/divisions/hq/2017/hq110717.shtml (last visited Nov. 28, 2017).

[38] *Id.*

[39] Chapter 617, F.S.

[40] *E.g.*, ss. 1009.983 and 413.0111, F.S.

[41] *See* ss. 14.29(9)(a), 16.616(1), and 258.015(1), F.S. *See also* Rules of the Florida Auditor General, Audits of Certain Nonprofit Organizations (effective June 30, 2016), Rule 10.720(1)(b) and (d), *available at* http://www.myflorida.com/audgen/pages/pdf_files/10_700.pdf.

CSO and DSO Transparency and Reporting Requirements

In 2014, the Legislature created s. 20.058, F.S., establishing a comprehensive set of transparency and reporting requirements for CSOs and DSOs.[42] Specifically, the law requires each CSO and DSO to annually submit the following information to the appropriate agency by August 1:[43]

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the organization;
- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's ethics code; and
- A copy of the organization's most recent Internal Revenue Service (IRS) Form 990.[44]

Each agency receiving information from a CSO or DSO pursuant to law must make such information available to the public through the agency's website.[45] If the organization maintains a website, the agency's website must provide a link to the organization's website.[46] Any contract between an agency and a CSO or DSO must be contingent upon the CSO or DSO submitting and posting the required information to the agency as specified in law.[47] If a CSO or DSO fails to submit the required information to the agency for two consecutive years, the agency head must terminate any contract between the agency and the CSO or DSO.[48]

By August 15 of each year, the agency must report to the Governor, President of the Senate, Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability (OPPAGA) the information submitted by each CSO or DSO along with the agency's recommendation and supporting rationale to continue, terminate, or modify the agency's association with the CSO or DSO.[49]

Any law creating, or authorizing the creation of a CSO or DSO must state that the authorization for the organization repeals on October 1 of the 5th year after enactment, unless reviewed and reenacted by the Legislature. CSOs and DSOs in existence prior to July 1, 2014, must be reviewed by the Legislature by July 1, 2019.[50]

CSO and DSO Audit Requirements

Section 215.981, F.S., requires each CSO and DSO with annual expenditures in excess of $100,000 to provide for an annual financial audit of its accounts and records.[51] An independent certified public accountant in accordance with rules adopted by the Auditor General must

[42] Section 3, ch. 2014-96, L.O.F
[43] Section 20.058(1), F.S.
[44] The IRS Form 990 is an annual information return required to be filed with the IRS by most organizations exempt from federal income tax under 26 U.S.C. 501. 26 C.F.R. 1.6033-2.
[45] Section 20.058(2), F.S.
[46] *Id.*
[47] Section 20.058(4), F.S.
[48] *Id.*
[49] *Id.* at (3).
[50] *Id.* at (5).
[51] The independent audit requirement does not apply to a CSO or DSO for a university, district board of trustees of a community college, or district school board. Additionally, the expenditure threshold for an independent audit is $300,000 for a CSO or DSO for the Department of Environmental Protection and the Department of Agriculture and Consumer Services.

conduct the audit. The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency the CSO or DSO supports.[52] Additionally, the Auditor General may, pursuant to his or her own authority, or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of a CSO's or DSO's accounts and records.[53]

CSO and DSO Ethics Code Requirement

Section 112.3251, F.S., requires a CSO or DSO to adopt a code of ethics. The code of ethics must contain the specified standards of conduct and disclosures provided in ss. 112.313 and 112.3143(2), F.S.[54] A CSO or DSO may adopt additional or more stringent standards of conduct and disclosure requirements and must post its code of ethics on its website.[55]

Governor's Executive Powers

During a declared state of emergency, the Governor has extensive authority to act as he or she deems necessary. Section 252.36(1), F.S., provides, in part, that "in the event of an emergency beyond local control, the Governor…may assume" or delegate "direct operational control over all or any part of the emergency management functions within this state…" In addition, the Governor may "issue executive orders, proclamations, and rules" which "shall have the force and effect of law." Subsection (5) specifically authorizes the Governor to use all resources of the state government and of each political subdivision of the state, as reasonably necessary to cope with the emergency.

The Governor is also directed to "take such action and give such direction to state and local law enforcement officers," and state health officials as may be "reasonable and necessary" to secure compliance with the State Emergency Management Act and the Florida Hazardous Materials Emergency Response and Community Right-To-Know Act in ch. 252, F.S.

A declared State of Emergency is limited to 60 days, unless renewed by the Governor or terminated by the Legislature.

III. Effect of Proposed Changes:

Section 1 creates s. 465.1902, F.S., to establish the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH). The purpose of the program is to authorize and facilitate the donation and distribution of prescription drugs and supplies to eligible patients through a system of local and centralized repositories. The DOH may contract with a third party to implement and administer the Program.

The bill authorizes the following individuals or entities to donate prescription drugs and supplies:

- Nursing home facilities with closed drug delivery systems.

[52] Section 215.981(1), F.S.
[53] Section 11.45(3), F.S.
[54] Some of the standards of conduct and disclosures in ss. 112.313 and 112.3143(2), F.S., include misuse of public position, solicitation or acceptance of gifts, unauthorized compensation, and voting conflicts.
[55] Section 112.3251, F.S.

- Hospices that have maintained control of a patient's prescription drug.
- Hospitals with closed drug delivery systems.
- Pharmacies.
- Drug manufacturers or wholesale distributors.
- Medical device manufacturers or suppliers.
- Prescribing individuals who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

The bill authorizes prescription drugs to be donated at the discretion of the centralized repository or a local repository if the drug:

- Is approved for medical use in the United States;
- Does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S.;
- Is in its original sealed and tamper-evident packaging, and does not have any physical signs of tampering or adulteration;
- Requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia, and has been stored according to these requirements;
- Packaging contains a lot number and expiration date of the drug, and will not expire within three months after the donation is made;
- Is not eligible for return to the Medicaid program for restocking; and
- Is not subject to a Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy with Elements to Assure Safe Use.

The bill requires prescription drugs or supplies be donated at a repository and prohibits the use of a drop box and donation to a specific patient. Repositories must destroy any donated drug not eligible for dispensing and make a record of the destruction on a form developed by DOH.

The bill requires a licensed pharmacist employed by, or under contract with, a repository to inspect all donated prescription drugs and supplies to determine whether they are eligible for donation under the Program, have been adulterated or misbranded, and are safe and suitable for dispensing. The pharmacist must sign an inspection record affirming the eligibility of the prescription drug or supply, and attach the form to the inventory record. The pharmacist is not required to re-inspect the prescription drug if the inspected drugs are redistributed to another repository under the Program.

The bill requires repositories to store all donated prescription drugs and supplies in a secure storage area, separate from non-donated inventory, and under the environmental conditions required by the manufacturer or the U.S. Pharmacopeia. Repositories must quarantine donated drugs and supplies from dispensing inventory until they have been inspected and approved for dispensing by the pharmacist.

The bill requires local repositories to maintain an inventory of all donated prescription drugs and supplies they receive, and to notify the centralized repository within five days of receipt. The centralized repository maintains an inventory of all prescription drugs and supplies donated to the Program, including donations made at local repositories. The centralized repository may redistribute drugs and supplies to facilitate dispensing as needed throughout the state.

The bill makes participation in the Program voluntary and requires an eligible entity to notify the DOH of its intent to participate before accepting or dispensing any prescription drugs or supplies under the Program. The DOH shall establish in rule a form for such notification, to include, at a minimum:

- The name, street address, website, and telephone number of the local repository, and any state-issued license or registration number issued to the local repository, including the name of the issuing agency;
- The name and telephone number of the pharmacist employed by or under contract with the local repository responsible for the inspection of donated prescription drugs and supplies; and
- A statement signed and dated by the responsible pharmacist affirming that the local repository meets the eligibility requirements.

An eligible patient wishing to receive drugs or supplies under the Program may contact a local repository, and submit an intake collection form. This form, to be created by DOH in rule, shall include, at a minimum:

- The name, street address, and telephone number of the eligible patient;
- The specific basis for eligibility, which must be indigent, uninsured, or underinsured, as defined in the Program;[56] and
- A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of the Program.

The bill requires local repositories to collect an executed intake form from each eligible patient receiving drugs or supplies under the Program. Upon receiving a duly executed intake form, the local repository shall issue the eligible patient an identification card that is valid for up to one year. Local repositories must send a summary of the intake collection form data to the centralized repository within five days of receipt.

The bill permits licensed pharmacists and those health care practitioners already authorized by law to dispense prescription drugs and supplies in Florida to do so under the Program. Prior to dispensing a prescription drug or supply to an eligible patient, the dispenser must:

- Verify that the patient is eligible to receive donations under the Program, either through a Program identification card or a duly executed intake collection form; and
- Inspect the donated prescription drug or supply to confirm it is still eligible for dispensing under the Program.

The bill prohibits repositories from reselling drugs, submitting claims, or otherwise seeking reimbursement from any public or private third-party payor for donated drugs or supplies dispensed under the Program. However, the dispensing facility may charge a nominal handling fee, to be determined by the DOH in rule.

[56] The bill defines "indigent" as persons with an income below 200 percent of the federal poverty level, "uninsured" as persons who have no third-party insurance and are not eligible under Medicaid or any other federal program, and "underinsured" as persons who have third-party insurance or are eligible under Medicaid or other federal program, but have exhausted these benefits or do not have prescription drug coverage for the drug prescribed.

In the event of a prescription drug recall, the bill requires a local or centralized repository to:

- Have an established protocol to notify recipients of the drug;
- Destroy all of the recalled prescription drugs in the repository; and
- Complete a destruction information form for all donated prescription drugs that were destroyed.

The bill requires local repositories to maintain records of all prescription drugs and supplies accepted, donated, dispensed, distributed, or destroyed under the Program. Local repositories must submit these records quarterly to the centralized repository for data collection and the centralized repository submits these records and the collected data in annual reports to the DOH.

The bill requires the DOH to maintain a registry on its website of all available drugs and supplies, including the name, strength, available quantity, and expiration date of each drug and supply, as well as the contact information for the repositories where it is available. The DOH is required to maintain a registry on its website of all participating local repositories, to include each repository's name, address, website, and telephone number.

The bill grants immunity from civil or criminal liability, and professional disciplinary actions, to a donor or participant relating to activities under the Program. Additionally, a pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the transfer of prescription drugs under the Program.

The bill requires the dispenser to provide written notification to the patient, or his or her legal representative, before dispensing a prescription drug that the drug was donated to the Program, the dispenser is not liable for any injury, death, or loss related to the dispensing of the drug, and the requirement of a nominal handling fee.

The bill authorizes the DOH to establish a direct-support organization (DSO) to provide assistance, funding, and promotional support for the activities authorized for the Program. The DSO is repealed on October 1, 2023, unless reviewed and saved from repeal by the Legislature.

The bill provides rulemaking authority to the DOH to administer the Program and establish the DSO.

Section 2 amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

Section 3 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.

B. Private Sector Impact:

Participation in the program is voluntary. Those hospitals and nursing homes volunteering to participate in the program may incur costs associated with collecting, storing, and re-dispensing of donated prescription drugs. Those same hospitals and nursing homes may enjoy cost savings to the extent their patients may be receiving needed health care services on a more timely basis. Without such donations, some patients could return as sicker, more costlier patients at a later date.

Hospitals and facilities participating in the program are permitted to recoup some costs through a small handling fee. Current state regulations permit a handling fee of up to 300 percent of the Medicaid dispensing fee or $15, whichever is less, for each cancer drug or supply dispensed.[57]

C. Government Sector Impact:

The DOH will experience a significant increase in workload to administer the program. The DSO established under the bill is responsible for collecting the necessary funds for the DOH to administer the program effectively. The DOH will need to submit a legislative budget request for the Legislature to appropriate an indeterminate, yet significant, amount of general revenue funds to support the Program if the DSO is unsuccessful in collecting the required resources.

Public facilities that elect to participate in the program will face similar costs associated with collecting, storing, and dispensing the prescription drugs. Likewise, these public facilities may enjoy additional savings through the participation of the uninsured or underinsured from their communities.

VI. Technical Deficiencies:

None.

[57] Rule 61N-1.026(5), F.A.C.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 252.36 of the Florida Statutes.

This bill creates section 465.1902 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.)

Recommended CS by Appropriations Subcommittee on Health and Human Services on February 14, 2018:
The committee substitute:

- Eliminates the expansion of the Cancer Drug Donation Program and creates the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state.
- Establishes eligibility criteria to donate, dispense and receive prescription drugs under the program.
- Provides inspection and storage requirements for donated prescription drugs.
- Authorizes the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

CS by Health Policy on December 5, 2017:
The CS amends the term "prescription drug" to exclude the donation of drugs to the program which fall under Schedules II through V of s. 803.03, F.S.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/14/2018	.	
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Appropriations Subcommittee on Health and Human Services (Book) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 465.1902, Florida Statutes, is created to read:

465.1902 Prescription Drug Donation Repository Program.—

(1) SHORT TITLE.—This section may be cited as the "Prescription Drug Donation Repository Program Act."

(2) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.—The Prescription Drug Donation Repository Program is created within the Department of Health for the purpose of authorizing and facilitating the donation of prescription drugs and supplies to eligible patients. The department may contract with a third party to implement and administer the program.

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

(a) "Centralized repository" means a distributor permitted pursuant to chapter 499 which is approved by the department or the contractor to accept, inspect, inventory, and distribute donated drugs and supplies under this section.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c) "Contractor" means the third-party vendor approved by the department to implement and administer the program.

(d) "Controlled substance" means any substance listed under Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(e) "Department" means Department of Health.

(f) "Direct-support organization" means an entity that is established pursuant to s. 20.058 and is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds and request and receive grants, gifts, and bequests of moneys; acquire, receive, hold, and invest, in

its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the program.

(g) "Dispenser" means a dispensing health care practitioner or pharmacist licensed to dispense medicinal drugs in the state.

(h) "Donor" means an entity that meets the requirements of subsection (4).

(i) "Eligible patient" means a Florida resident who is indigent, uninsured, or underinsured and has a valid prescription for a prescription drug or supply that is eligible for dispensing under the program.

(j) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.

(k) "Health care practitioner" or "practitioner" means a practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, or chapter 466.

(l) "Indigent" means a person with an income that is below 200 percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

(m) "Local repository" means a health care practitioner's office, a pharmacy, a hospital with a closed drug delivery system, a nursing home facility with a closed drug delivery system, a free clinic, or a nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

(n) "Nonprofit health clinic" means a nonprofit legal entity that provides medical care to patients who are indigent,

uninsured, or underinsured, including, but not limited to, a federally qualified health center as defined in 42 U.S.C. s. 1396d(l)(2)(B) and a rural health clinic as defined in 42 U.S.C. s. 1396d(l)(1).

(o) "Nursing home facility" has the same meaning as in s. 400.021(12).

(p) "Prescriber" means a prescribing physician, prescribing practitioner, or other health care practitioner authorized by the laws of this state to prescribe medicinal drugs.

(q) "Prescription drug" has the same meaning as defined in s. 465.003(8), but does not include controlled substances or cancer drugs donated under s. 499.029.

(r) "Program" means the Prescription Drug Donation Repository Program created by this section.

(s) "Supplies" means any supply used in the administration of a prescription drug.

(t) "Tamper-evident packaging" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

(u) "Underinsured" means a person who has third-party insurance or is eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription drug program funded in whole or in part by the Federal Government, but has exhausted these benefits or does not have prescription drug coverage for the drug prescribed.

(v) "Uninsured" means a person who has no third-party insurance and is not eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription

drug program funded in whole or in part by the Federal Government.

(4) DONOR ELIGIBILITY.—The program may only accept a donation of a prescription drug or supply from:

(a) Nursing home facilities with closed drug delivery systems.

(b) Hospices that have maintained control of a patient's prescription drug.

(c) Hospitals with closed drug delivery systems.

(d) Pharmacies.

(e) Drug manufacturers or wholesale distributors.

(f) Medical device manufacturers or suppliers.

(g) Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(5) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION.—

(a) All prescription drugs and supplies that have been approved for medical use in the United States and meet the criteria for donation established by this section may be accepted for donation under the program.

(b) The centralized repository or a local repository may accept a prescription drug only if:

1. The drug is in its original sealed and tamper-evident packaging. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened.

2. The drug requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia.

3. The drug has been stored according to manufacturer or United States Pharmacopeia storage requirements.

4. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.

5. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.

6. The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall.

7. The drug has an expiration date that is more than 3 months after the date that the drug was donated.

(c) The central repository or a local repository may only accept supplies that are in their original, unopened, sealed packaging and have not been adulterated or misbranded.

(d) Prescription drugs and supplies may be donated on the premises of the centralized repository or a local repository to a person designated by the repository. A drop box may not be used to accept donations.

(e) Prescription drugs or supplies may not be donated to a specific patient.

(f) Prescription drugs billed to and paid for by Medicaid in long-term care facilities which are eligible for return to stock under federal Medicaid regulations must be credited to Medicaid and are not eligible for donation under the program.

(g) Prescription drugs that are subject to a Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy with Elements to Assure Safe Use are not eligible for donation under the program.

(h) Nothing in this section requires the central repository or a local repository to accept a donation of a prescription drug or supplies.

(6) INSPECTION AND STORAGE.—

(a) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine whether the donated prescription drugs or supplies:

1. Are eligible for donation under the program;

2. Have been adulterated or misbranded; and

3. Are safe and suitable for dispensing.

(b) The pharmacist who inspects the donated prescription drugs or supplies shall sign an inspection record on a form prescribed by the department and adopted in rule verifying that the criteria of paragraph (a) have been met and attach such record to the copy of the inventory record. If a local repository receives drugs and supplies from the centralized repository, the local repository is not required to reinspect the drugs and supplies.

(c) The centralized repository and local repositories shall store donated prescription drugs and supplies in a secure storage area under the environmental conditions specified by the manufacturer or United States Pharmacopeia for the prescription drugs or supplies being stored. Donated prescription drugs and supplies may not be stored with nondonated inventory. A local repository shall quarantine any donated prescription drugs or supplies from all dispensing stock until the donated prescription drugs or supplies are inspected and approved for dispensing under the program.

(d) A local repository shall maintain an inventory of all donated prescription drugs or supplies it receives. Such inventory shall be recorded on a form prescribed by the department and adopted in rule.

(e) A local repository shall notify the centralized repository within 5 days after receipt of any donation of prescription drugs or supplies to the program. The notification shall be on a form prescribed by the department and adopted by rule.

(f) The centralized repository shall maintain an inventory of all prescription drugs and supplies donated to the program.

(g) The centralized repository may redistribute prescription drugs and supplies to facilitate dispensing to either the centralized repository or to a local repository, as needed.

(7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

(a) A local repository must notify the department of its intent to participate in the program before accepting or dispensing any prescription drugs or supplies pursuant to this section. The notification shall be on a form prescribed by the department and adopted by rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the local repository and any state-issued license or registration number issued to the local repository, including the name of the issuing agency.

2. The name and telephone number of the pharmacist employed by or under contract with the local repository who is responsible for the inspection of donated prescription drugs and supplies.

717750

3. A statement signed and dated by the responsible pharmacist affirming that the local repository meets the eligibility requirements of this section.

(b) A local repository may withdraw from participation in the program at any time by providing written notice to the department or contractor on a form prescribed by the department and adopted by rule. The department shall adopt rules addressing the disposition of any prescription drugs in the possession of the local repository.

(8) DISPENSING.—

(a) Each eligible patient without a program identification card must submit an intake collection form to a local repository before receiving prescription drugs or supplies under the program. The form shall be prescribed by the department and adopted by rule and, at a minimum, must include:

1. The name, street address, and telephone number of the eligible patient.

2. The basis for eligibility, which must specify that the patient is indigent, uninsured, or underinsured.

3. A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of this section.

(b) A local repository shall collect a signed and dated intake collection form from each eligible patient receiving prescription drugs or supplies under the program. The local repository must issue a program identification card upon receipt of a duly executed intake collection form. The program identification card is valid for 1 year after issuance and must be in a form prescribed by the department and adopted in rule.

(c) A local repository must send a summary of the intake collection form data to the centralized pharmacy within 5 days after receipt of a duly executed intake collection form.

(d) A dispenser may only dispense a donated prescription drug or supplies, if available, to an eligible patient with a program identification card or a duly executed intake collection form.

(e) A dispenser shall inspect the donated prescription drugs or supplies prior to dispensing such drugs or supplies.

(f) A dispenser may provide dispensing and consulting services to an eligible patient.

(g) Donated prescription drugs and supplies may not be sold or resold under this program.

(h) A dispenser of donated prescription drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs or supplies dispensed to any patient under this program. However, a repository may charge a nominal handling fee, established by department rule, for the preparation and dispensing of prescription drugs or supplies under the program.

(i) A local repository that receives donated prescription drugs or supplies may, with authorization from the centralized repository, distribute the prescription drugs or supplies to another local repository.

(9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND SUPPLIES.—

(a) The centralized repository and a local repository shall be responsible for drug recalls and shall have an established protocol to notify recipients in the event of a prescription

drug recall.

(b) Local repositories shall destroy all of the recalled or expired prescription drugs or prescription drugs that are not suitable for dispensing in the repository and complete a destruction information form for all donated prescription drugs destroyed, in accordance with rules adopted by the department.

(10) RECORDKEEPING.—

(a) Local repositories shall maintain records of prescription drugs and supplies that were accepted, donated, dispensed, distributed, or destroyed under the program.

(b) All records required to be maintained as a part of the program shall be maintained in accordance with any applicable practice acts. Local repositories shall submit these records quarterly to the centralized repository for data collection, and the centralized repository shall submit these records and the collected data in annual reports to the department.

(11) REGISTRIES AND FORMS.—

(a) The department shall establish and maintain registries of all local repositories and available drugs and supplies under the program. The registry of local repositories must include the repository's name, address, website, and telephone number. The registry of available drugs and supplies must include the name, strength, available quantity, and expiration date of the drug or supply and the name and contact information of the repositories where such drug or supply is available. The department shall publish the registries on its website.

(b) The department shall publish all forms required by this section on its website.

(12) IMMUNITY.—

(a) Any donor of prescription drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program, and the rules adopted pursuant thereto, is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(b) A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the transfer of any prescription drug under this section, including but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, including the expiration date of the transferred drug.

(13) NOTICE TO PATIENTS.-Before dispensing a prescription drug that has been donated under this program, the dispenser must provide written notification to the patient, or to his or her legal representative, receipt of which must be acknowledged in writing, that:

(a) The prescription drug was donated to the program;

(b) The donors and participants in the program are granted certain immunities as described in subsection (12); and

(c) The patient may not be required to pay for the prescription drug, except for a nominal handling fee which may not exceed the amount established by department rule.

(14) DIRECT-SUPPORT ORGANIZATION.-The department may establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized

for the program.

(a) *Purposes and objectives*.-The purposes and objectives of the direct-support organization of the program must be consistent with the goals of the department, in the best interest of the state, and in accordance with the adopted goals and mission of the department.

(b) *Prohibition against lobbying*.-The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045. All expenditures of the direct-support organization must be used for the program. No expenditures of the direct-support organization may be used for the purpose of lobbying as defined in s. 11.045.

(c) *Contract*.—The direct-support organization shall operate under a written contract with the department. The contract must provide for a submission by the direct-support organization to the department, by each August 1, and posting on the direct-support organization's and department's websites, the following information:

1. The articles of incorporation and bylaws of the direct-support organization as approved by the department.

2. An annual budget for the approval of the department.

3. The code of ethics of the direct-support organization.

4. The statutory authority or executive order that created the direct-support organization.

5. A brief description of the direct-support organization's mission and any results obtained by the direct-support organization.

6. A brief description of the direct-support organization's plans for the next 3 fiscal years.

7. A copy of the direct-support organization's most recent federal Internal Revenue Service Return Organization Exempt from Income Tax form (Form 990).

8. Certification by the department that the direct-support organization is complying with the terms of the contract and operating in a manner consistent with the goals and purposes of the department and the best interest of the program and the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

9. The reversion, without penalty, of moneys and property held in trust by the direct-support organization for the benefit of the program to the state if the department ceases to exist; or reversion to the department if the direct-support organization is no longer approved to operate or ceases to exist.

10. The fiscal year of the direct-support organization, which must begin on July 1 of each year and end on June 30 of the following year.

11. The disclosure of material provisions of the contract, and the distinction between the department and the direct-support organization, to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications.

12. All prescription drugs solicited by the direct-support organization to be distributed to the centralized repository or a local repository. The direct-support organization may not possess any prescription drugs on behalf of the program.

(d) *Board of directors.*—The State Surgeon General shall

717750

appoint a board of directors of the direct-support organization. The board of directors shall consist of at least 5 members, but not more than 15 members, who serve at the pleasure of the State Surgeon General. The board members must elect a chair from among its members. Board members must serve without compensation but may be entitled to reimbursement of travel and per diem expenses in accordance with s. 112.061, if funds are available for this purpose.

(e) *Use of property.*—The department may allow, without charge, appropriate use of fixed property, facilities, and personnel services of the department by the direct-support organization, subject to this subsection. For the purposes of this paragraph, the term "personnel services" includes full-time or part-time personnel, as well as payroll processing services.

1. The department may prescribe any condition with which the direct-support organization must comply in order to use fixed property or facilities of the department.

2. The department may not permit the use of any fixed property or facilities of the department by the direct-support organization if it does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin.

3. The department shall adopt rules prescribing the procedures by which the direct-support organization is governed and any conditions with which a direct-support organization must comply to use property or facilities of the department.

(f) *Deposit of funds.*—Any moneys may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the contract with

the department.

(g) *Use of funds*.-Funds designated for the direct-support organization must be used for the enhancement of the projects of the program and used in a manner consistent with that purpose. Any administrative costs of running and promoting the purposes of the corporation or program must be paid by private funds.

(h) *Audit*.—The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(i) *Repeal*.—This subsection shall stand repealed on October 1, 2023, unless reviewed and saved from repeal by the Legislature.

(15) RULEMAKING.—The department shall adopt rules necessary to implement the requirements of this section. When applicable, the rules may provide for the use of electronic forms, recordkeeping, and meeting by teleconference.

Section 2. Paragraph (o) is added to subsection (5) of section 252.36, Florida Statutes, to read:

252.36 Emergency management powers of the Governor.—

(5) In addition to any other powers conferred upon the Governor by law, she or he may:

(o) Waive the patient eligibility requirements of s. 465.1902.

Section 3. 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


717750

An act relating to the Prescription Drug Donation Repository Program; creating s. 465.1902, F.S.; providing a short title; creating the Prescription Drug Donation Repository Program within the Department of Health; providing purpose; authorizing the department to contract with a third party to implement and administer the program; providing definitions; specifying entities that are eligible donors; providing criteria for eligible donations; prohibiting donations to specific patients; providing that certain prescription drugs eligible for return to stock must be credited to Medicaid under specified conditions and are not program eligible; prohibiting the donation of certain drugs pursuant to federal restrictions; authorizing repositories to refuse to accept donations of prescription drugs or supplies; providing inspection, inventory, and storage requirements for centralized and local repositories; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; requiring a local repository to notify the centralized repository within a specified timeframe after receiving a donation of prescription drugs or supplies; authorizing a centralized repository to redistribute prescription drugs or supplies; requiring local repositories to notify the department regarding participation in the program; providing conditions for dispensing donated prescription drugs and supplies to eligible patients; requiring repositories to establish a protocol for


717750

notifying recipients of a prescription drug recall; providing for destruction of donated prescription drugs in the event of a drug recall; providing recordkeeping requirements; requiring the department to maintain and publish a registry of participating local repositories and available donated prescription drugs and supplies; specifying certain notice to patients; providing immunity from civil and criminal liability for participants under certain circumstances; authorizing the department to establish a direct-support organization to provide assistance funding and promotional support for program activities; specifying direct-support organization purposes and objectives; prohibiting such direct-support organization from lobbying and specifying that such direct-support organization is not a lobbying firm; specifying that the direct-support organization mush operate under contract with the department; specifying required contract terms; providing for the direct-support organization board of directors; specifying the membership of such board; specifying requirements relating to a direct-support organization’s use of department property; specifying requirements for the deposit of funds by the direct-support organization; providing for audits of a direct-support organization; specifying a repeal, unless reviewed and saved from repeal by the Legislature on a specified date; requiring the department to adopt rules; amending s. 252.36, F.S.;

authorizing the Governor to waive the patient eligibility requirements of s. 465.1902, F.S., during a declared state of emergency; providing an effective date.

By the Committee on Health Policy; and Senator Book

588-01792-18 2018710c1

A bill to be entitled

An act relating to the Prescription Drug Donation Program; amending s. 499.029, F.S.; renaming the Cancer Drug Donation Program as the Prescription Drug Donation Program; authorizing the donation of prescription drugs, including cancer drugs, and supplies to eligible patients; revising definitions; authorizing nursing home facilities to participate in the program; providing an effective date.

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

Section 1. Section 499.029, Florida Statutes, is amended to read:

499.029 Prescription ~~Cancer~~ Drug Donation Program.—

(1) This section may be cited as the "Prescription ~~Cancer~~ Drug Donation Program Act."

(2) There is created a Prescription ~~Cancer~~ Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of prescription ~~cancer~~ drugs and supplies to eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the Federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. The term ~~"Cancer drug"~~ does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

588-01792-18 2018710c1

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c) "Donor" means a patient or patient representative who donates prescription ~~cancer~~ drugs or supplies needed to administer prescription ~~cancer~~ drugs that have been maintained within a closed drug delivery system; health care facilities, nursing home facilities ~~homes~~, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. The term ~~"Donor"~~ includes a physician licensed under chapter 458 or chapter 459 who receives prescription ~~cancer~~ drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(d) "Eligible patient" means a person who the department determines is eligible to receive prescription ~~cancer~~ drugs from the program.

(e) "Participant facility" means a hospital that operates a class II institutional ~~hospital~~ pharmacy or a nursing home facility licensed under part II of chapter 400 with a closed drug delivery system that has elected to participate in the program and that accepts donated prescription ~~cancer~~ drugs and supplies under the rules adopted by the department for the program.

(f) "Prescribing practitioner" means a physician licensed under chapter 458 or chapter 459 or any other medical professional with authority under state law to prescribe

prescription drugs ~~cancer medication~~.

(g) "Prescription drug" has the same meaning as provided in s. 499.003, and includes cancer drugs. The term does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(h)~~(g)~~ "Program" means the Prescription ~~Cancer~~ Drug Donation Program created by this section.

(i)~~(h)~~ "Supplies" means any supplies used in the administration of a prescription ~~cancer~~ drug.

(4) Any donor may donate prescription ~~cancer~~ drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Prescription ~~Cancer~~ drugs or supplies may not be donated to a specific ~~cancer~~ patient, and donated drugs or supplies may not be resold by the program. Prescription ~~Cancer~~ drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital or nursing home facility.

(5) The prescription ~~cancer~~ drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A prescription ~~cancer~~ drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose

packaging, except that a prescription ~~cancer~~ drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b) A prescription ~~cancer~~ drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c) Prior to being dispensed to an eligible patient, the prescription ~~cancer~~ drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d) A dispenser of donated prescription ~~cancer~~ drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription ~~cancer~~ drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated prescription ~~cancer~~ drugs or supplies dispensed to any patient under the program.

(7)(a) A donation of prescription ~~cancer~~ drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated prescription ~~cancer~~ drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated prescription ~~cancer~~ drugs or supplies.

(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of prescription ~~cancer~~ drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. ~~Initial rules under this section shall be adopted no later than 90 days after the effective date of this act.~~ The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated prescription ~~cancer~~ drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense prescription ~~cancer~~ drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated prescription ~~cancer~~ drugs or supplies.

(e) Categories of prescription ~~cancer~~ drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive prescription ~~cancer~~

drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain prescription ~~cancer~~ drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate prescription ~~cancer~~ drugs or supplies to the program. The department's website shall also contain links to prescription ~~cancer~~ drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of prescription ~~cancer~~ drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing prescription ~~cancer~~ drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any prescription ~~cancer~~ drug under this section, including, but not limited to,

liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Prescription ~~Cancer~~ Drug Donation Program.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on the Environment and Natural Resources, *Chair*
Appropriations
Appropriations Subcommittee on Health and Human Services
Education
Environmental Preservation and Conservation
Health Policy
Rules

SENATOR LAUREN BOOK
Democratic Leader Pro Tempore
32nd District

December 6, 2017

Chair Anitere Flores
Appropriations Subcommittee on Health and Human Services
201 The Capitol
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Flores,

I respectfully request that you place CS/SB 710, relating to Prescription Drug Donation Program, on the agenda of the Appropriations Subcommittee on Health and Human Services at your earliest convenience.

Should you have any questions or concerns, please feel free to contact my office or me. Thank you in advance for your consideration.

Thank you,

Senator Lauren Book
Senate District 32

cc: Phil Williams, Staff Director
Robin Jackson, Administrative Assistant

REPLY TO:
❒ 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
❒ 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

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

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

2-14-18
Meeting Date

710
Bill Number (if applicable)

Topic Rx Drug Donation

Amendment Barcode (if applicable)

Name Dawn Steward

Job Title

Address 2130 Blossom Lane
Street
Winter Park FL 32789
City *State* *Zip*

Phone 407-645-0273

Email stu2130@aol.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Dawn Steward

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

2-14-18 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 710

Meeting Date *Bill Number (if applicable)*

Topic Prescription Drug Donation *Amendment Barcode (if applicable)*

Name Carlos Cruz

Job Title Government Consultant

Address 307 W Park Avenue Phone 904-214-5724

Street

Tallahassee, FL 32301 Email Carlos@Cruzco.com

City *State* *Zip*

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

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

Representing Polaris Pharmacy 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 Appropriations Subcommittee on Health and Human Services

BILL:	SB 1184
INTRODUCER:	Senator Gibson
SUBJECT:	Closing the Gap Grant Program
DATE:	February 13, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Favorable**
2.	Gerbrandt	Williams	AHS	**Recommend: Favorable**
3.			AP	

I. Summary:

SB 1184 expands the list of priority health areas eligible for funding under the "Closing the Gap" grant program to include lupus. The "Closing the Gap" program provides state grants for activities designed to reduce racial and ethnic health disparities.

The bill does not affect state revenues or expenditures.

The bill takes effect July 1, 2018.

II. Present Situation:

The Closing the Gap Grant Program

In 2000, the Florida Legislature created the Reducing the Racial and Ethnic Health Disparities: "Closing the Gap" (CTG) grant program to improve health outcomes of racial and ethnic populations.[1] The CTG program provides grants to stimulate the development of community-based and neighborhood-based projects that improve health outcomes of racial and ethnic populations within Florida counties.[2]

The CTG program is administered by the Department of Health (department). The department is responsible for publicizing the availability of the CTG program and grant funds, establishing the grant application process, providing technical assistance and training, developing uniform data reporting requirements, evaluating progress towards meeting grant objectives, and coordinating with other state and local programs to avoid duplication of effort.[3]

[1] Chapter 2000-256, ss. 31-32, Laws of Fla. (2000).
[2] Section 381.7352, F.S.
[3] Section 381.7353, F.S.

Eligibility

Any person, entity, or organization within a Florida county may submit a proposal for a CTG grant.[4] Persons, entities, or organizations within adjoining counties, with populations of less than 100,000, based on the annual estimates produced by the Population Program of the University of Florida Bureau of Economic and Business Research, may submit a multi-county proposal.[5] At least 20 percent of the appropriation for the CTG grant must be dedicated to proposals that address improving the racial and ethnic health status within specific Front Porch Florida Communities.[6]

Grant Proposals

Currently, CTG grants are awarded for proposals with strategies designed to:

- Address the physical and social determinants of health, particularly as it relates to evidence-based prevention, intervention, and local policy initiatives demonstrated to improve health outcomes.
- Address evidence-based interventions proven to:
  - Increase the percentage of minority children and adults who are at a healthy weight.
  - Reduce the non-white infant mortality rate.
  - Decrease the percentage of HIV-infected people in minority groups.
  - Increase the number of minorities who have access to and are receiving culturally and linguistically appropriate prevention, care and treatment services.
  - Increase access to resources that promote healthy behaviors.
  - Promote chronic disease self-management education.
  - Promote early detection and screening for chronic diseases such as cancer, heart disease and diabetes.
  - Increase immunization rates among adults, particularly among people over the age of 65.
  - Decrease racial and ethnic disparities in morbidity and mortality rates relating to cancer, HIV/AIDS, cardiovascular disease, diabetes and sickle cell disease.[7]

In fiscal year 2016-2017, the department awarded $3,004,666 to18 CTG proposals. The proposals covered priority health areas in diabetes, cardiovascular disease, HIV/AIDS, sickle cell disease, maternal and infant mortality, cancer, colorectal cancer, and oral health.[8]

Grant Awards

The amount of a grant award varies and is based on the county or neighborhood's population or the combined population from which a multi-county proposal is submitted.[9] The maximum grant

[4] Section 381.7354 (1), F.S.
[5] *Id.* at (2).
[6] *Id.* at (3). The Front Porch Florida Initiative was created by the Florida Legislature as a comprehensive, community-based urban core redevelopment program to encourage economic revitalization is the state's most distressed communities. *See* s. 20.60(5)(b), F.S.
[7] Department of Health, Office of Minority Health and Health Equity, *Reducing Racial and Ethnic Health Disparities Closing the Gap Grant Program (CTG) Request for Applications, RFA # 17-007, FY 2018-2019*, http://www.floridahealth.gov/programs-and-services/minority-health/closing-the-gap.html, (last visited Feb. 8, 2018).
[8] Department of Health, *Closing the Gap Contract Spreadsheet FY 2016-17*, (on file with the Senate Committee on Health Policy).
[9] Section 381.7356(3), F.S.

award per applicant is $200,000 for a twelve-month period.[10] Grant awards may be renewed annually subject to the availability of funds and the grantee's achievement of quality standards, objectives, and outcomes.[11]

Currently, the department is accepting applications until February 16, 2018, for grants beginning July 1, 2018.[12]

Matching Fund Requirements

Certain grantees are required to provide $1 in local matching funds for every $3 in state grant funds requested. Depending on the size of the county, in-kind contributions can be substituted for the required cash match.[13] The following table illustrates the matching fund requirements for each type of grantee.[14]

Closing the Gap Matching Funds Contribution Combinations	
Grantee Type	**Matching Funds Requirements**
County Population greater than 50,000	One dollar in local matching funds for every 3 dollars of grant funds - At least 50 percent of the local match must be in cash - Up to 50 percent of the local match may be in-kind contributions such as free services, office space or human resources.
County Population of 50,000 or less	Up to 100 percent of the local match may be in-kind contributions such as free services, office space or human resources.
Grantee is a Front Porch Community	No matching funds required

Health Disparities in Florida

In Florida, the ethnic and racial disparity in some health categories is significant (see table below).

Minority Health Profiles – Select Indicators for 2016				
Indicator **(per 100,000, unless noted)**	**White Rate**	**Black Rate[15]**	**Hispanic Rate[16]**	**Non-Hispanic Rate[17]**
Fetal Deaths (per 1,000 deliveries)	5.3	12.2	5.4	7.2
Infant Deaths (per 1,000 births)	4.4	11.3	5.1	6.4
Maternal Deaths	15.7	32.5	8.9	24.4

[10] *Supra* note 7.
[11] Section 381.7356(4), F.S.
[12] *Supra* note 7.
[13] Section 381.7356(2), F.S.
[14] *Id.*
[15] Department of Health, FLHealthCHARTS.com, *Minority Health Profile – Black – 2016*, http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=ChartsProfiles.MinorityHealthProfile-Black, (last visited Feb. 8, 2018).
[16] Department of Health, FLCharts, *Minority Health Profile – Hispanic – 2016*, http://www.flhealthcharts.com/ChartsReports/rdPage.aspx?rdReport=ChartsProfiles.MinorityHealthProfile-Hispanic, (last visited Feb. 8, 2018).
[17] *Id.*

Minority Health Profiles – Select Indicators for 2016				
Indicator (per 100,000, unless noted)	**White Rate**	**Black Rate**[15]	**Hispanic Rate**[16]	**Non-Hispanic Rate**[17]
Diabetes death rate	38.5	17.4	18.5	20.0
HIV Infection Cases,	10.5	65.7	30.1	22.0
Coronary Heart Disease death rate	96.9	100	87.4	98.7
Stroke death rate	34.6	53.6	35.8	37.0

A 2017 statistical brief from the department noted that the gap between the black age-adjusted mortality rate and the white age-adjusted mortality rate had decreased over time. Specifically, in 1995, the black rate was 50.9% higher than the white rate while in in 2015, the black rate was only 29.6% higher than the white rate.[18]

Lupus

Lupus is a chronic autoimmune disease that triggers inflammation in bodily tissues. The body's immune system attacks its own tissues and organs and the resulting inflammation can impact joints, skin, kidneys, blood cells, brain, heart and lungs. Symptoms of lupus can include fatigue, fever, stiff, swollen and painful joints, skin lesions, rash, chest pain, headaches and memory loss.[19]

Types of Lupus

There are four different forms of lupus. *Systemic lupus* affects a major organ or tissue of the body, such as the heart, lungs, kidney, or brain. Systemic lupus is the most common and most serious type of lupus accounting for approximately 70 percent of all lupus cases. *Cutaneous lupus* affects only the skin in the form of a rash or lesions and accounts for approximately 10 percent of all lupus cases. *Drug-induced lupus* is caused by a reaction to high doses of certain medications and accounts for 10 percent of all lupus cases. *Neonatal lupus* is a rare condition where the mother's antibodies affect the fetus. At birth, the baby may have a skin rash, liver problems, or low blood cell counts, but these issues usually disappear within 6 months.[20]

Causes of Lupus

In most cases, the cause of Lupus is unknown; however, it is believed to be linked to environmental, genetic, or hormonal factors. Most researchers today think that environmental factors, such as a virus or a chemical, trigger lupus in certain susceptible individuals. Examples of environmental triggers for lupus include:

- Sunlight – exposure to the sun may bring on lupus skin lesions in certain individuals;
- Infections – an infection can initiate lupus or cause a relapse; and

[18] Department of Health, FLHealthCHARTS.com Statistical Brief, *Gap Between Black and White Death Rate Narrows,* http://www.flhealthcharts.com/Charts/documents/StatisticalBriefs/GapNarrows.pdf, (last visited Feb. 7, 2018).
[19] Mayo Clinic, *Lupus - Overview*, https://www.mayoclinic.org/diseases-conditions/lupus/symptoms-causes/syc-20365789, (last visited Feb. 7, 2018).
[20] The National Resource Center on Lupus, *What is Lupus,* https://resources.lupus.org/entry/what-is-lupus?utm_source=lupusorg&utm_medium=answersFAQ, (last visited Feb. 7, 2018).

- Medications – certain types of blood pressure medication, anti-seizure medications, and antibiotics may trigger lupus.[21]

Diagnosis and Treatment

More than 16,000 new cases of lupus are reported each year and most people who develop lupus are women between the ages of 15 and 44. It is estimated that more than 1.5 million Americans have a form of lupus.[22] Lupus can be difficult to diagnose because the symptoms often mimic other illness. Common symptoms include extreme fatigue, headaches, painful and swollen joints, fever, hair loss, anemia, and skin rashes and lesions.[23] The American College of Rheumatology developed a list of 11 measures to help with the diagnosis of lupus. If an individual has had or has, at least four of the measures there is a strong chance that the individual has lupus.[24]

Lupus is generally not a fatal disease; however, causes of premature death associated with lupus are active disease, organ failure, infection, or cardiovascular disease.[25] There is no cure for lupus but, medications, medical interventions and lifestyle changes can help control its symptoms.[26]

Racial and Ethnic Health Disparities

Certain ethnic groups have a greater chance of developing lupus than other groups. Lupus is 2 to 3 times more prevalent among women of color (African American, Hispanic/Latino, Asian, Native American, Alaska Natives, Native Hawaiians and other Pacific Islanders) than among Caucasian women. Lupus affects one in 537 young African American women and African American women are more likely to have organ system involvement, develop lupus at a younger age, have more serious complications, and have a higher mortality rate due to lupus.

Economic Impact

Lupus also imposes a significant financial burden on individuals because of direct health care costs and loss of productivity due to work disability.[27] On average, only 46 percent of those with lupus report being employed.[28] The annual direct health care costs of a patient with lupus is $12,643 (in 2004 U.S. dollars) and the lost annual productivity costs of an employment-aged patient is $8,659.[29]

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[21] The National Resource Center on Lupus, *What Causes Lupus,* https://resources.lupus.org/entry/what-causes-lupus, (last visited Feb. 7, 2018).
[22] *Supra* note 20.
[23] The National Resource Center on Lupus, *Common symptoms of lupus*, https://resources.lupus.org/entry/common-symptoms, (last visited Feb. 8, 2018).
[24] For a list of the 11 common criteria or measures to help diagnose lupus see: The National Resource Center on Lupus, *What doctors look for to confirm a diagnosis,* https://resources.lupus.org/entry/what-doctors-look-for, (last visited Feb. 7, 2018).
[25] Centers for Disease Control and Prevention, *Lupus Detailed Fact Sheet,* https://www.cdc.gov/lupus/facts/detailed.html, (last visited Feb. 8, 2018).
[26] Mayo Clinic, *Lupus – Diagnosis and Treatment,* https://www.mayoclinic.org/diseases-conditions/lupus/diagnosis-treatment/drc-20365790, (last visited Feb. 7, 2018).
[27] Pantelis Panopalis, et al, *Heath Care costs and Costs Associated with Changes in Work Productivity Among Persons with Systematic Lupus Erythematosus,* Arthritis & Rheumatism (Arthritis Care and Research), Vol. 59, No. 12, (Dec. 15, 2008).
[28] Centers for Disease Control and Prevention, *Lupus Basic Fact Sheet,* https://www.cdc.gov/lupus/basics/index.html, (last visited Feb. 8, 2018).
[29] *Supra* note 27.

III. Effect of Proposed Changes:

The bill amends s. 381.7355, F.S., to expand the priority areas that may be addressed in a CTG proposal to include projects focused on decreasing the racial and ethnic disparities in morbidity and mortality rates relating to lupus.

The bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill expands the types of project proposals that are eligible to receive grant funds under the Closing the Gap Grant program.

C. Government Sector Impact:

The Department of Health reports no impact on expenditures.[30]

The availability of state funds for the CTG grant program is subject to an annual appropriation. The addition of lupus as new priority health area eligible for grant funding does not impact the overall cost of the program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.7355 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Gibson

6-01248-18 20181184__

A bill to be entitled

An act relating to the Closing the Gap grant program; amending s. 381.7355, F.S.; requiring a Closing the Gap grant proposal to address racial and ethnic disparities in morbidity and mortality rates relating to Lupus; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 381.7355, Florida Statutes, is amended to read:

381.7355 Project requirements; review criteria.—

(2) A proposal must include each of the following elements:

(a) The purpose and objectives of the proposal, including identification of the particular racial or ethnic disparity the project will address. The proposal must address one or more of the following priority areas:

1. Decreasing racial and ethnic disparities in maternal and infant mortality rates.

2. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer.

3. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to HIV/AIDS.

4. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cardiovascular disease.

5. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to diabetes.

6. Increasing adult and child immunization rates in certain racial and ethnic populations.

6-01248-18 20181184__

7. Decreasing racial and ethnic disparities in oral health care.

8. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease.

9. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to Lupus.

10.~~9.~~ Improve neighborhood social determinants of health, such as transportation, safety, and food access, as outlined by the Centers for Disease Control and Prevention's "Tools for Putting Social Determinants of Health into Action."

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR AUDREY GIBSON
6th District

COMMITTEES:
Military and Veterans Affairs, Space, and Domestic Security, *Chair*
Appropriations
Appropriations Subcommittee on Transportation, Tourism, and Economic Development
Commerce and Tourism
Judiciary
Regulated Industries

JOINT COMMITTEE:
Joint Legislative Auditing Committee

January 30, 2018

Senator Anitere Flores, Chair
Appropriations Subcommittee Health and Human Services
201 The Capitol
404 South Monroe Street
Tallahassee, Florida 32399-1100

Chair Flores:

I respectfully request that SB 1184, addressing racial and ethnic disparities in morbidity and mortality rates relating to Lupus, be placed on the next committee agenda.

SB 1184, adds Lupus a chronic disease, to Closing the Gap grant proposals. Closing the Gap grant program provides funding to decrease racial or ethnic disparities for a variety of diseases and illnesses, such as Cancer and HIV/AIDS.

Thank you for your time and consideration.

Sincerely,

Audrey Gibson
State Senator
District 6

101 E. Union Street, Suite 104, Jacksonville, Florida 32202 (904) 359-2553
405 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5006

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

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

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 Appropriations Subcommittee on Health and Human Services

BILL:	PCS/CS/SB 1876 (764628)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services; Health Policy Committee and Senator Young
SUBJECT:	Trauma Services
DATE:	February 19, 2018 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1876 amends various sections of law related to the selection and approval 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 composition of certain TSAs.
- Restricts the DOH from designating additional Level I trauma centers in the same TSA where another Level I trauma center 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 assigned to each TSA for a total of 35 trauma centers statewide and specifies that each TSA may have no more than five total Level I, Level II, Level II/pediatric, and stand-alone pediatric trauma centers, and no more than one standalone pediatric trauma center.
- Requires the DOH to establish the Florida Trauma System Advisory Council (FTSAC) by October 1, 2018. The bill specifies the composition of the FTSAC and allows the FTSAC to submit recommendations to the DOH on how to maximize existing resources to achieve an inclusive trauma system.

- Requires the DOH to prepare an analysis of the Florida trauma system every three years, beginning August 2020, to include information on the population growth in each TSA, the caseload levels of severely injured patients for each trauma center and acute care hospital in the TSA, and the percentage of minimum caseload levels established under the bill for each trauma center.
- Revises the procedure for the DOH to select and approve new trauma centers if there is statutory capacity within a TSA.
- Allows the DOH to approve new trauma centers that exceed the statutory limit in a TSA if there is a sufficient volume of severely injured patients.
- Provides grandfathering language for currently verified trauma centers and for certain provisionally approved trauma centers and provides that if any of the grandfathering provisions are found to be invalid, the entire act is invalid.
- 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 (DOAH) 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.
- Replaces provisions requiring the use of data in the trauma registry with provisions requiring the use of data reported to the Agency for Health Care Administration (AHCA) pursuant to s. 408.061.

The DOH may experience an increase in workload. The cost of this additional workload will be absorbed within existing resources of the DOH.

The bill takes effect July 1, 2018.

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 three 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

[1] Department of Health, *Senate Bill 1876 Analysis* (January 17, 2018) (on file with the Senate Committee on Health Policy).

- 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]

Trauma Center Apportionment

Pursuant to s. 395.402, F.S., Florida is divided into 19 trauma service areas (TSA). A TSA 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.

Administrative Rule Litigation

Since 2011, the DOH has been involved in 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 June 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.[6]

In 2016, the DOH attempted to promulgate an apportionment rule that interpreted need to mean the "minimum" number of trauma centers in a TSA. Several hospitals subsequently challenged the proposed rule.[7] The DOAH issued an order that invalidated the proposed rule in March

[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).
[6] Shands Teaching Hospital and Clinics, Inc., d/b/a UF Shands Hospital v. Dep't of Health and Osceola Regional Hospital, Inc., d/b/a Osceola Regional Medical Center, DOAH Case No. 14-1022RP (June 20, 2014). This order also resolved the rule challenges filed by The Public Health Trust of Miami-Dade County (DOAH Case No. 14-1027RP); St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (DOAH Case No. 14-1028RP); Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 14-1034RP); and Bayfront HMA Medical Center, LLC, d/b/a Bayfront Medical Center (DOAH Case No. 14-1035RP).
[7] According to the DOAH's website, the challenges were filed by St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (Tampa) (DOAH Case No. 16-5841RP); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Heath – St. Petersburg (DOAH Case No. 16- 5840RP); Lee Memorial Health System, d/b/a Lee Memorial Hospital (DOAH Case No. 16-5839RP);

2017.[8] The administrative law judge recognized the challenges faced by the DOH and Florida's trauma system in his final order by stating, "[a]fter 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."[9] The case was appealed to the First District Court of Appeals (DCA) and is awaiting final disposition.[10] Since the invalidation of the rule, the DOH has been unable to promulgate a new rule.

In 2016, 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.[11] In addition, he indicated the DOH's determination of need happens at the point in which a trauma center is granted verification.[12] On appeal, the First DCA stated that a hospital may apply over multiple years without jeopardizing the previous application.[13] In a separate case, the First DCA addressed the issue of need and concurred that need is not addressed at the provisional licensure and is relevant only upon verification.[14]In combination, a hospital may essentially operate indefinitely as a provisional trauma center so long as they submit and receive approval of their provisional application annually.

The DOH has been unable to promulgate a valid allocation rule since July 2014.[15]

Trauma Center Approval

Section 395.4025, F.S., provides a scheduled application process and specific criteria for trauma center selection. Standards for verification and approval are based on national guidelines established by the American College of Surgeons.[16] Standards for verification and approval as a

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Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 16-5838RP); and Shands Jacksonville Medical Center, Inc., d/b/a U.F. Hospital Jacksonville (DOAH Case No. 16-5837RP). Intervenors included JFK Medical Center Limited Partnership, d/b/a JFK Medical Center (Atlantis); The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson South Community Hospital; and Orange Park Medical Center, Inc., d/b/a Orange Park Medical Center.

[8] Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Dep't of Health, DOAH Case No. 16-5837RP (March 28, 2017). This order also resolved the rule challenges filed by Florida Health Science Center, Inc., d/b/a Tampa General Hospital (DOAH Case No. 16-5838RP); Lee Memorial Health System, d/b/a Lee Memorial Hospital (DOAH Case No. 16-5839RP); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health – St. Petersburg (DOAH Case No. 16-5840RP); and St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (DOAH Case No. 16-5841RP).

[9] Id.

[10] Dep't of Health, et al. v. Shands Jacksonville Medical Center, Inc., et al., Case No. 1D17-1713.

[11] The Public Health Trust of Miami-Dade County, Florida d/b/a Jackson South Community Hospital v. Dep't of Health and Kendall Healthcare Group, Ltd., d/b/a Kendall Regional Medical Center, DOAH Case No. 15-3171)

[12] Id. *See also* Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson Medical Center and Jackson South Community Hospital v. Dep't of Health et al., DOAH Case No. 16-3370, 16-3372 ("Order Granting Motion to Partially Dismiss Petition for Administrative Hearing," pg. 4).

[13] The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson South Community Hospital v. Dep't of Health and Kendall Healthcare Group, Ltd., d/b/a Kendall Regional Medical Center, Case No. 1D16-3244.

[14] State of Florida, Department of Health v. Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg, Case No. 1D17-2174 (consolidated with Galencare, Inc., d/b/a Northside Hospital v. Bayfront HMA. Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg, Case No. 1D17-2229).

[15] Supra note 1

[16] The American College of Surgeons 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).

pediatric trauma center are developed in conjunction with the DOH's Division of 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.[17] 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*.[18] 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.[19]

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 comply with the requirements of s. 395.4025, F.S., are approved to operate as a verified trauma center.[20]

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.[21]

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 to receive 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 local, regional, and statewide 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 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

[17] The required criteria included in the application package is outlined in the DOH'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.
[18] Section 395.4025(5), F.S.
[19] Section 395.4025(6), F.S.
[20] Id.
[21] Supra note 1. A list of current litigation is on file with Senate Health Policy Committee staff.

six months after the end of the reporting period. The DOH 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.[22]

Injury Severity Score

An injury severity score (ISS) is a score assigned to a patient that has suffered an injury to one or more parts of his or her body. A lower ISS indicates a less severe injury with the threshold of 15 commonly used to indicate major trauma or severe injury.[23] A hospital generates an ISS by converting and aggregating individual injury scores assigned to regions of a patient's body using the Abbreviated Injury Scale (AIS). The AIS classifies an individual injury by body region according to its relative severity on a six point scale from one being minor injury to six indicating maximal injury in that region.[24] An ISS is the sum of the squares of each individual injury score generated by the AIS. In Florida, an ISS is typically calculated by a hospital using software provided to the hospital by the DOH.[25]

Health Care Data Submitted to the AHCA

Section 408.061, F.S., requires health care facilities to submit data to the AHCA including:

- Case-mix data;
- Patient admission and discharge data;
- Hospital emergency department data which includes the number of patients treated in the emergency department reported by patient acuity level;
- Data on hospital-acquired infections as specified by rule;
- Data on complications as specified by rule:
- Data on readmissions as specified by rule, with patient and provider-specific identifiers included;
- Actual charge data by diagnostic groups or other bundled groupings as specified by rule;
- Financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, and depreciation expenses based on the expected useful life of the property and equipment involved; and
- Demographic data.

Additionally, s. 408.05, F.S., creates the Florida Center for Health Information and Transparency (Center) within the AHCA to collect, compile, coordinate, analyze, index, and disseminate health-related data and statistics. Among its other duties, the Center is required to promote data sharing through dissemination of state-collected health data by making such data available,

[22] Supra note 1.
[23] Association for the Advancement of Automotive Medicine, *Major Trauma and the Injury Severity Score – Where Should We Set the Bar?*, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217501/, (last visited on Feb., 16, 2018).
[24] AIS Overview, available at https://www.aaam.org/abbreviated-injury-scale-ais/, (last visited on Feb. 16, 2018).
[25] Email from Paul Runk, DOH Director of the Office of Legislative Planning, and Steve McCoy, Emergency Medical Services Administrator, Feb. 12, 2018, on file with Senate Health Policy Committee staff.

transferable, and readily usable[26] and to develop written agreements with local, state, and federal agencies to facilitate the sharing of data related to health care.[27]

III. Effect of Proposed Changes:

Sections 1-4 and 8 amend ss. 318.14, 318.18, 318.21, 395.4001, and 395.4036, F.S., respectively, to replace provisions requiring the use of data in the trauma registry with provisions requiring the use of data reported to the AHCA pursuant to s. 408.061, F.S.

Section 5 amends s. 395.402, F.S., to:

- Delete language requiring Level I and Level II trauma centers to be capable of treating a minimum of 1,000 and 500 patients annually (or 1,000 in a county with 500,000 or more population) with an injury severity score (ISS) of 9 or greater, respectively.
- Delete outdated language requiring the DOH to conduct a one-time assessment of the trauma system.
- Delete a requirement that the DOH conduct annual assessments of the assignment of the counties in TSAs.
- Revise the composition 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; and
  - Move Collier County from TSA 17 to TSA 15.
- Restrict the DOH from designating a Level II trauma center as a Level I or pediatric trauma center in a TSA that already has a Level I trauma center or pediatric trauma center.
- Delete the delegation of authority to the DOH to allocate the number of trauma centers by TSA and, instead, set by law the number of trauma centers allowed in each TSA for a total of 35, 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.
- Specify that no TSA may have more than five total Level I, Level II, Level II/pediatric, and stand-alone pediatric trauma centers, and more than one stand-alone pediatric trauma center.
- Require the DOH to establish the FTSAC by October 1, 2018. The FSTAC will consist of the following 11 members appointed by the Governor:
  - The State Trauma Medical Director;
  - 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 actively working in a trauma center who represents an investor-owned hospital with a trauma center;
  - A trauma program manager or trauma medical director actively working in a trauma center who represents a nonprofit or public hospital with a trauma center;
  - A trauma surgeon who is board-certified in critical care and actively practicing medicine in a Level II trauma center who represents an investor-owned hospital with a trauma center;

[26] Section 408.05(3)(b), F.S.
[27] Section 408.05(3)(d), F.S.

  - A trauma surgeon who is board-certified in critical care and actively practicing medicine who represents a nonprofit or public hospital with a trauma center;
  - A representative of the American College of Surgeons Committee on Trauma;
  - A representative of the Safety Net Hospital Alliance of Florida;
  - A representative of the Florida Hospital Association; and
  - A trauma surgeon who is board-certified in critical care and actively practicing medicine in a Level I trauma center.
- Require members of the FTSAC to be appointed for staggered terms and no two members may be employed by the same health care facility.
- Require the FTSAC to conduct its first meeting no later than January 5, 2019 and quarterly thereafter.
- Allow the FTSAC to submit recommendations to the DOH on how to maximize existing trauma center, emergency department, and emergency medical services infrastructure and personnel to achieve the statutory goal of developing an inclusive trauma system..

Section 6 amends s. 395.4025, F.S., to:

- Require the DOH to prepare an analysis of the Florida trauma system every three years, beginning in August 2020. The DOH must use discharge data collected by the AHCA pursuant to s. 408.061, F.S., and the most current five years of population data for Florida available from the United States Census Bureau. The report must include the following:
  - The population growth for each trauma service area and for the state of Florida;
  - The number of severely injured patients with an Injury Severity Score of 15 or greater treated at each trauma center within each trauma service area, including pediatric trauma centers;
  - The total number of severely injured patients with an Injury Severity Score of 15 or greater treated at all acute care hospitals inclusive of non-trauma centers in the trauma service area; and
  - The percentage of each trauma center's sufficient volume of trauma patients, as described in subparagraph (3)(d)2., in accordance with the Injury Severity Score for the trauma center's designation, inclusive of the additional caseload volume required for those trauma centers with graduate medical education programs.
- Rework how the DOH selects and licenses trauma centers.[28] 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 5** of the bill, the report generated by the DOH detailed above, and the exception to the statutory capacity limits established in s. 395.4025(3)(d), F.S. The DOH may not accept a letter of intent from a hospital if there is not statutory capacity, in accordance with the limits established in **Section 5** of the bill, the DOH's report, and exceptions to the statutory capacity limits provided in the bill.

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

Letters of Intent must be postmarked by October 1 of year one. [29]

Application

By October 15 of year one, 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].[30] Between April 1 and May 1 [of year two], the DOH will conduct an initial review of each application package 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.

The bill specifies that the DOH may not approve an application for a trauma center if the approval would exceed the limits on the number of trauma centers established in **Section 5** of the bill. However, the DOH may approve an application that will exceed the limits if the applicant demonstrates and the DOH determines that:

- Each existing trauma centers' caseload volume of severely injured patients with an ISS of 15 or more in that TSA is double the minimum volume requirement for Level I and Level II trauma centers and more than triple the minimum volume requirements for stand-alone pediatric trauma centers and the population growth for the trauma service area exceeds the statewide population growth by more than 15 percent based on the United States census data for the five-year period before the date the applicant files its letter of intent; and
- A sufficient volume of potential trauma patients exists within the trauma service area to ensure that existing trauma centers' volumes are at the following levels:[31]

Level I trauma center; In a TSA with a population > 1.5 million.	1,200 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
Level I trauma center; In a TSA with a population < 1.5 million.	1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
Level II or Level II/Pediatric trauma center; In a TSA with a population > 1.25 million.	1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

[29] 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.
[30] The actual year that this takes place is not specified in the bill, however for the purposes of the timeline in this analysis the year will be assumed to be year two.
[31] Calculations of patient caseloads must be based on the most recent available hospital discharge data collected by the AHCA pursuant to s. 408.061, F.S.

Level II or Level II/Pediatric trauma center; In a TSA with a population < 1.25 million.	500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
All pediatric stand-alone trauma centers.	500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

By May 1 [of year two],[32] the DOH must select one or more hospitals that meet the operating criteria detailed above, up to the statutory capacity designated in s. 395.402, F.S., or allowed by the exception detail above 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 initial and in-depth review and approves the applicant to operate as a provisional trauma center. A hospital that is not ready to operate by April 30 of year three may not be designated as trauma center.

In-Depth Evaluation

Following the initial review, the DOH must conduct an in-depth evaluation of each application against the criteria enumerated in the application packages. An applicant may not operate as a provisional trauma center until the DOH completes and approves the applicant through the initial and in-depth review stages. Within the year after the hospital begins operating as a provisional trauma center, the DOH must assemble a review team of out-of-state experts to make 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 out-of-state review team, the DOH must designate a trauma center that complies with trauma center standards, as established by the DOH in rule, and the requirements in s. 395.4025, F.S. A trauma center is designated for a seven-year approval period after which it must apply for renewal of its designation.

The bill also restricts protests against any decision made by the DOH regarding approval of an application or whether need has been established for a new trauma center unless the protest is made by an applicant or a hospital with an existing trauma center in the same or contiguous TSA.

Grandfathering

Notwithstanding any other provision of the act including statutory capacity limits and the limits placed on protests of DOH decisions, the bill deems certain currently operational trauma centers to be compliant with trauma center application and operational standards as follows:

[32] Supra n. 30

- 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 and must be verified and designated as a trauma center.
- 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 and must be verified and designated as a Level II 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 before January 1, 2017, and is operating as a Level I trauma center is deemed to have met the application and operational requirements for a Level I trauma center and must be verified and designated as a Level I trauma center.
- 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 and, upon successful completion of the in-depth and site review process, must be verified and designated as a pediatric trauma center. The bill prohibits protests of the in-depth review, site survey, and verification decisions made by the DOH regarding an applicant that meets the requirements of this paragraph.

Notwithstanding the statutory capacity limits established in s. 395.402(1), F.S., or any other provisions of the act, a hospital operating as a Level II after January 1, 2017, must be designated and verified if all of the following apply:

- The hospital was provisionally approved after January 1, 2017, to operate as a Level II trauma center, and was in operation on or before January 1, 2018;
- The department's decision to approve the hospital to operate a provisional Level II trauma center was in litigation on or before January 1, 2018;
- The hospital receives a recommended order from the Division of Administrative Hearings, a final order from the department, or an order from a court of competent jurisdiction that it was entitled to be designated and verified as a Level II trauma center; and
- The department determines that the hospital is in substantial compliance with the Level II trauma center standards, including the in-depth and site reviews.

A provisional trauma center operating under this provision may not be required to cease operations unless a court of competent jurisdiction or the DOH determines that is has failed to meet the trauma center standards established by the DOH in rule.

The bill specifies that nothing in the grandfathering provisions limits the DOH's authority to review and approve trauma center applications.

Section 9 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. The bill requires the DOH to solely use the National Trauma Data Bank for quality and assessment purposes. 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.

Sections 7 and 10 amend ss. 395.403 and 395.401, F.S., respectively, to make conforming and cross-reference changes.

Section 11 creates an undesignated section of Florida law to specify that if any provision in the act relating to the grandfathering provisions established in s. 395.4025(16), F.S., is found to be invalid or inoperative for any reason, the remaining provisions of the act shall be deemed void and of no effect, it being the legislative intent that this act as a whole would not have been adopted had any provision of the act not been included.

Section 12 provides that the bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues

When establishing the grandfathering provisions in s. 395.4025(16), F.S., the bill provides that "notwithstanding the provisions of subsection (8), no existing trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant is located may protest the in-depth review, site survey, or verification decision of the department regarding an applicant that meets the requirements of this paragraph." Additionally, the provisions of s. 395.4025(8), F.S., restrict any party from brining protests of DOH decisions related to application approval and need determination unless the party is the applicant or a hospital with a trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant is located. These provisions together may provide an unconstitutional restriction on access to the courts.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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

Hospitals that are currently verified trauma centers in TSAs where new trauma centers are designated under the provisions of the bill may experience a loss in volume of trauma patients and other economic impacts of competition.

C. Government Sector Impact:

The DOH may experience an increase in workload. The cost of this additional workload will be absorbed within existing resources of the DOH.

VI. Technical Deficiencies:

See below.

VII. Related Issues:

The bill contains multiple technical and related issues that may cause certain provisions in the bill to be misinterpreted or that may cause internal conflicts within the provisions of the bill. Topics in the bill that contain such technical and related issues include, but are not limited to:

- The report that the DOH is required to prepare;
- Certain portions of the application and approval process for new trauma centers;
- Calculations of statutory capacity and determinations of need; and
- Data the DOH may use for quality and assessment purposes.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 318.14, 318.18, 318.21, 395.4001, 395.401, 395.402, 395.4025, 395.403, 395.4036, and 395.404.

The bill creates one undesignated section of Florida law.

IX. Additional Information:

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

Recommended CS by Appropriations Subcommittee on Health and Human Services on February 14, 2018:

The CS:

- Adds references to AHCA discharge data collected pursuant to s. 408.061, F.S., to replace data reported to the DOH's Trauma Registry in multiple sections of the Florida Statutes.
- Corrects additional cross-references related to the elimination of the Trauma Registry.
- Specifies that no TSA may have more than five total Level I, Level II, Level II/pediatric, and stand-alone pediatric trauma centers and no more than one stand-alone pediatric trauma center.
- Revises the make-up and duties of the Florida Trauma System Advisory Council.
    - Eliminates the requirement that the Council determine the need for additional trauma centers and the adequacy of the existing trauma system.
    - Eliminates the requirement to submit a biennial report to the Governor and the Legislature on whether to recommend an increase in the number of trauma centers within each service area.
    - Allows the Council to submit recommendations to the DOH on how to maximize existing trauma center, emergency department, and emergency medical services infrastructure and personnel to achieve the statutory goal of developing an inclusive trauma system.
    - Eliminates the following members of the Council: The State Surgeon General, a representative from the AHCA; a trauma program manager recommended by the Florida Teaching Hospital Council of Florida; a trauma surgeon recommended by the Florida Teaching Hospital Council of Florida, a representative of the Associated Industries of Florida, and a trauma program manager or medical director representing a public hospital.
    - Adds the state Trauma Medical Director and a trauma surgeon board-certified in critical care actively practicing medicine in a Level I trauma center to the council.
    - Requires the Council to meet quarterly.
- Requires the DOH to prepare an analysis of the Florida trauma system every three years, beginning in August 2020. The DOH must make all data, formulas, methodologies, and risk adjustment tools used in the report available.
- Requires the analysis to use AHCA discharge data and the most current 5 years of population data for Florida and must include:
    - The population growth for each TSA and for the state of Florida;
    - The number of severely injured patients with an ISS of 15 or more at each trauma center within each TSA;
    - The total number of severely injured patients with an ISS of 15 or more at all acute care hospitals, including non-trauma centers in each TSA; and
    - The percentage of each trauma center's sufficient volume of trauma patients as established in the bill.
- Allows the DOH accept a letter of intent and to approve an application for a new trauma center in a TSA that is already at its statutory maximum if each existing trauma centers' case load volume of severely injured patients with an ISS of 15 or more is double the minimum volume requirement for Level I and Level II trauma centers and more than triple the minimum volume requirements for stand-alone pediatric trauma centers.
- The minimum caseload volumes established in the bill are as follows:

  - Level I trauma center in a TSA with a population > 1.5 million: 1,200 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level I trauma center in a TSA with a population < 1.5 million: 1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level II or Level II/Pediatric trauma center in a TSA with a population > 1.25 million: 1,000 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - Level II or Level II/Pediatric trauma center in a TSA with a population < 1.25 million: 500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
  - All pediatric stand-alone trauma centers: 500 severely injured patients + 40 additional patients per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.
- Allows an applicant to operate as a provisional trauma center after the DOH has completed the initial and in-depth review processes.
- Requires the out-of-state review team to perform an onsite visit within the year after the trauma center has begun provisionally operating.
- Requires (rather than allows) the DOH to designate a trauma center that is in compliance with trauma center standards based on the recommendation from the review team.
- Allows the applicant, as well as hospitals with trauma centers in the same or contiguous TSAs, to protest decisions made by the DOH regarding application approval and determination of need.
- Restricts such protests for the designation of a pediatric trauma center that is grandfathered in.
- Specifies that certain provisional trauma centers must be allowed to continue operations until a court or the DOH determines that they have failed to meet the Florida trauma standards.
- Specifies that none of the grandfathering provisions limit the DOH's authority to review and approve trauma center applications.
- Specifies that if the grandfathering provisions of the act are found to be invalid or inoperative, the entire act becomes invalid.
- Changes the effective date from upon becoming a law to July 1, 2018.

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; specifies the required court actions that qualify a trauma center under the paragraph; and conforms the title of the bill to changes made by the amendment.

B. Amendments:

None.

461182

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/14/2018	.	
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	.	
	.	

Appropriations Subcommittee on Health and Human Services (Young) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (b) of subsection (5) of section 318.14, Florida Statutes, is amended to read:

318.14 Noncriminal traffic infractions; exception; procedures.—

(5) Any person electing to appear before the designated official or who is required so to appear shall be deemed to have

waived his or her right to the civil penalty provisions of s. 318.18. The official, after a hearing, shall make a determination as to whether an infraction has been committed. If the commission of an infraction has been proven, the official may impose a civil penalty not to exceed $500, except that in cases involving unlawful speed in a school zone or involving unlawful speed in a construction zone, the civil penalty may not exceed $1,000; or require attendance at a driver improvement school, or both. If the person is required to appear before the designated official pursuant to s. 318.19(1) and is found to have committed the infraction, the designated official shall impose a civil penalty of $1,000 in addition to any other penalties and the person’s driver license shall be suspended for 6 months. If the person is required to appear before the designated official pursuant to s. 318.19(2) and is found to have committed the infraction, the designated official shall impose a civil penalty of $500 in addition to any other penalties and the person’s driver license shall be suspended for 3 months. If the official determines that no infraction has been committed, no costs or penalties shall be imposed and any costs or penalties that have been paid shall be returned. Moneys received from the mandatory civil penalties imposed pursuant to this subsection upon persons required to appear before a designated official pursuant to s. 318.19(1) or (2) shall be remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Trust Fund to provide financial support to certified trauma centers to assure the availability and accessibility of trauma services throughout the state. Funds deposited into the Emergency Medical Services

Trust Fund under this section shall be allocated as follows:

(b) Fifty percent shall be allocated among Level I, Level II, and pediatric trauma centers based on each center's relative volume of trauma cases as calculated using the agency's hospital discharge data collected pursuant to s. 408.061 ~~reported in the Department of Health Trauma Registry~~.

Section 2. Paragraph (h) of subsection (3) of section 318.18, Florida Statutes, is amended to read:

318.18 Amount of penalties.—The penalties required for a noncriminal disposition pursuant to s. 318.14 or a criminal offense listed in s. 318.17 are as follows:

(3)

(h) A person cited for a second or subsequent conviction of speed exceeding the limit by 30 miles per hour and above within a 12-month period shall pay a fine that is double the amount listed in paragraph (b). For purposes of this paragraph, the term "conviction" means a finding of guilt as a result of a jury verdict, nonjury trial, or entry of a plea of guilty. Moneys received from the increased fine imposed by this paragraph shall be remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Trust Fund to provide financial support to certified trauma centers to assure the availability and accessibility of trauma services throughout the state. Funds deposited into the Emergency Medical Services Trust Fund under this section shall be allocated as follows:

1. Fifty percent shall be allocated equally among all Level I, Level II, and pediatric trauma centers in recognition of readiness costs for maintaining trauma services.

2. Fifty percent shall be allocated among Level I, Level

II, and pediatric trauma centers based on each center's relative volume of trauma cases as calculated using the agency's hospital discharge data collected pursuant to s. 408.061 ~~reported in the Department of Health Trauma Registry~~.

Section 3. Paragraph (b) of subsection (15) of section 318.21, Florida Statutes, is amended to read:

318.21 Disposition of civil penalties by county courts.—All civil penalties received by a county court pursuant to the provisions of this chapter shall be distributed and paid monthly as follows:

(15) Of the additional fine assessed under s. 318.18(3)(e) for a violation of s. 316.1893, 50 percent of the moneys received from the fines shall be appropriated to the Agency for Health Care Administration as general revenue to provide an enhanced Medicaid payment to nursing homes that serve Medicaid recipients with brain and spinal cord injuries. The remaining 50 percent of the moneys received from the enhanced fine imposed under s. 318.18(3)(e) shall be remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Trust Fund to provide financial support to certified trauma centers in the counties where enhanced penalty zones are established to ensure the availability and accessibility of trauma services. Funds deposited into the Emergency Medical Services Trust Fund under this subsection shall be allocated as follows:

(b) Fifty percent shall be allocated among Level I, Level II, and pediatric trauma centers based on each center's relative volume of trauma cases as calculated using the agency's hospital discharge data collected pursuant to s. 408.061 ~~reported in the~~


461182

~~Department of Health Trauma Registry~~.

Section 4. Subsection (13) of section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.—As used in this part, the term:

(13) "Trauma caseload volume" means the number of trauma patients calculated by the department using the data reported by each designated trauma center to the hospital discharge data reported to the agency pursuant to s. 408.061 ~~reported by individual trauma centers to the Trauma Registry and validated by the department~~.

Section 5. 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, as well as the need to ensure the viability of existing trauma centers when designating new trauma centers. Consistent with national standards, future trauma center designations shall be based on need as a factor of demand and capacity. ~~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~~


461182

~~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~~

461182

~~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 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. Except as otherwise provided in s. 395.4025(15), the department may not designate an existing Level II trauma center as a new pediatric trauma center or designate an existing Level II trauma center as a Level I trauma center in a trauma service area that already has an existing Level I or pediatric trauma center ~~The department shall allocate, by rule, the number of trauma centers needed for each trauma service area~~.

(c) Trauma centers, including Level I, Level II, Level II/pediatric, and stand-alone pediatric 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.

Notwithstanding other provisions in this chapter, a trauma service area may not have more than a total of five Level I, Level II, Level II/pediatric, and stand-alone pediatric trauma centers. A trauma service area may not have more than one stand-alone pediatric trauma center. ~~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 promote an inclusive trauma system and enhance cooperation among trauma system stakeholders. The advisory council may submit recommendations to the department on how to maximize existing trauma center, emergency department, and emergency medical services infrastructure and personnel to achieve the statutory goal of developing an inclusive trauma system.

(b)1. The advisory council shall consist of 11 representatives appointed by the Governor, including:

a. The State Trauma Medical Director;

b. A representative from an emergency medical services organization;

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

d. A trauma program manager or trauma medical director actively working in a trauma center who represents an investor-owned hospital with a trauma center;

e. A trauma program manager or trauma medical director actively working in a trauma center who represents a nonprofit or public hospital with a trauma center;

f. A trauma surgeon board-certified in critical care actively practicing medicine in a Level II trauma center who represents an investor-owned hospital with a trauma center;

g. A trauma surgeon board-certified in critical care actively practicing medicine who represents a nonprofit or public hospital with a trauma center

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

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

j. A representative of the Florida Hospital Association.

k. A trauma surgeon board-certified in critical care actively practicing medicine in a Level I trauma center.

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, four representatives shall be appointed to 1-year terms, four representatives shall be appointed to 2-year terms, and three representatives shall be appointed to 3-year terms.

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

Section 6. 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) The department shall prepare an analysis of the


461182

Florida trauma system every 3 years, beginning in August 2020, using the Agency for Health Care Administration hospital discharge database described in s. 408.061 for the most current year and the most current 5 years of population data for Florida available from the U.S. Census Bureau. The department's report must include all of the following:

1. The population growth for each trauma service area and for the state of Florida;

2. The number of severely injured patients with an Injury Severity Score of equal to or greater than 15 treated at each trauma center within each trauma service area, including pediatric trauma centers;

3. The total number of severely injured patients with an Injury Severity Score of equal to or greater than 15 treated at all acute care hospitals inclusive of non-trauma centers in the trauma service area;

4. The percentage of each trauma center's sufficient volume of trauma patients, as described in subparagraph (3)(d)2., in accordance with the Injury Severity Score for the trauma center's designation, inclusive of the additional caseload volume required for those trauma centers with graduate medical education programs.

The department shall make available all data, formulas, methodologies, and risk adjustment tools used in the report.

(3)(a) The department shall ~~annually~~ notify each acute care general hospital and each local and each regional trauma agency in the trauma service area with an identified need for an additional trauma center ~~state~~ that the department is accepting

letters of intent from hospitals that are interested in becoming trauma centers. The department may accept a letter of intent only if there is statutory capacity for an additional trauma center in accordance with paragraphs (2)(a) and (d), and s. 395.402. ~~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.~~ Letters of intent must be postmarked no later than midnight October 1 of the year in which the department notifies hospitals that it plans to accept letters of intent.

(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 of the year following submission of the letter of intent. 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

461182

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. 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.~~ Except as otherwise provided in this act, the Department of Health may not approve an application for a Level I, Level II, Level II/pediatric, or stand-alone pediatric trauma center if approval of the application would exceed the limits on the numbers of Level I, Level II, Level II/pediatric, or stand-alone pediatric trauma centers set forth in s. 395.402(1). However, the department shall review and may approve an application for a trauma center when approval of the application would result in a number of trauma centers which exceeds the limit on the numbers of trauma centers in a trauma service area as set forth in s. 395.402(1), if the applicant demonstrates and the department determines that:

1. The existing trauma centers' actual caseload volume of severely injured patients with an Injury Severity Score equal to or greater than 15 exceeds the minimum caseload volume capabilities, inclusive of the additional caseload volume for graduate medical education critical care and trauma surgical subspecialties by more than two times the statutory minimums listed in paragraphs (2)(i)-(iv) and three times the statutory minimum listed in paragraph (2)(v), and the population growth for the trauma service area exceeds the statewide population growth by more than 15 percent based on the United States census data, for the 5-year period before the date the applicant files its letter of intent; and

2. A sufficient volume of potential trauma patients exists within the trauma service area to ensure that existing trauma center volumes are at the following levels:

a. For Level I trauma centers in trauma service areas with a population of greater than 1.5 million, the minimum caseload of the greater of 1,200 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year or 1,200 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 plus 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

b. For Level I trauma centers in trauma service areas with a population of less than 1.5 million, the minimum caseload of the greater of 1,000 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year or 1,000 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 plus 40 cases per year for

each accredited critical care and trauma surgical subspecialty medical resident or fellow.

c. For Level II and Level II/pediatric trauma centers in trauma service areas with a population of greater than 1.25 million, the minimum caseload of the greater of 1,000 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year or 1,000 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 plus 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

d. For Level II and Level II/pediatric trauma centers in trauma service areas with a population of less than 1.25 million, the minimum caseload of the greater of 500 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year or 500 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year plus 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

e. For pediatric trauma centers, the minimum caseload of the greater of 500 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year or 500 severely injured admitted patients with an Injury Severity Score equal to or greater than 15 per year plus 40 cases per year for each accredited critical care and trauma surgical subspecialty medical resident or fellow.

The Injury Severity Score calculations and caseload volume shall be calculated using the most recently available hospital


461182

discharge data collected by the agency from all acute care hospitals pursuant to s. 408.061, F.S.

(e) If the department determines that the hospital is capable of attaining and operating with the components required in paragraph (2)(c), the applicant must be ready to operate in compliance with Florida trauma center standards no later than April 30 of the year following the department's initial review and approval of the hospital's application to proceed with preparation to operate as a trauma center. 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) By May 1, the department shall select one or more hospitals ~~After April 30, 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). 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 greatest improvement in access to trauma services and the highest quality patient care using the most recent technological, medical, and staffing resources available. The number of applicants selected is limited to available statutory need in the specified trauma service area, as designated in paragraph (3)(d) or s. 395.402(1) ~~as a provisional trauma center~~.

(4) Following the initial review, ~~Between May 1 and October 1 of 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. An applicant may not operate as a provisional trauma center until the department completes the initial and in-depth review and approves the application through those review stages.

(5) Within ~~Beginning October 1 of each year and ending no later than June 1 of~~ the ~~following~~ year after the hospital

begins operations as a provisional trauma center, a review team of out-of-state experts assembled by the department shall make onsite visits to all 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 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 shall 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 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 an applicant, or existing trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant has applied to operate a trauma center, may protest a decision made by the department with regard to whether the application should be approved, or whether need has been established through the criteria in s. 395.4025(3)(d) ~~Any hospital that wishes to 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) Notwithstanding the statutory capacity limits established in s. 395.402(1), the provisions of subsection (7)

or any other provision of this act, an adult Level I trauma center, an adult Level II trauma center, or a pediatric 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 and shall be verified and designated as a trauma center.

(b) Notwithstanding the statutory capacity limits established in s. 395.402(1)the provisions of subsection (7), or any other provision of this act, 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 and shall be verified and designated as a Level II trauma center.

(c) Notwithstanding the statutory capacity limits established in s. 395.402(1), the provisions of subsection (7), or any other provision of this act, 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 to be in substantial compliance with Level I trauma standards before January 1, 2017, and is operating as a Level I trauma center is deemed to have met the application and operational requirements of this section for a trauma center and shall be verified and designated as a Level I trauma center.

(d) Notwithstanding the statutory capacity limits established in s. 395.402(1), the provisions of subsection (7), or any other provision of this act, a trauma center that was not

verified by the department before December 15, 2017, as a pediatric trauma center but 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 and, upon successful completion of the in-depth and site review process, shall be verified and designated as a pediatric trauma center. Notwithstanding the provisions of subsection (7), no existing trauma center in the same trauma service area or in a trauma service area contiguous to the trauma service area where the applicant is located may protest the in-depth review, site survey, or verification decision of the department regarding an applicant that meets the requirements of this paragraph.

(e) Notwithstanding the statutory capacity limits established in s. 395.402(1) or any other provision of this act, any hospital operating as a Level II trauma center after January 1, 2017, must be designated and verified 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, and was in operation on or before January 1, 2018.

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

3. The hospital receives a recommended order from the Division of Administrative Hearings, a final order from the department, or an order from a court of competent jurisdiction

461182

that it was entitled to be designated and verified 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, including the in-depth and site reviews.

Any provisional trauma center operating under this paragraph may not be required to cease trauma operations unless a court of competent jurisdiction or the department determines that it has failed to meet the Florida trauma standards.

(f) Nothing in this subsection shall limit the department's authority to review and approve trauma center applications.

Section 7. Section 395.403, Florida Statutes, is amended to read:

395.403 Reimbursement of trauma centers.—

(1) All verified trauma centers shall be considered eligible to receive state funding when state funds are specifically appropriated for state-sponsored trauma centers in the General Appropriations Act. Effective July 1, 2010, the department shall make payments from the Emergency Medical Services Trust Fund under s. 20.435 to the trauma centers. Payments shall be in equal amounts for the trauma centers approved by the department as of July 1 of the fiscal year in which funding is appropriated. In the event a trauma center does not maintain its status as a trauma center for any state fiscal year in which such funding is appropriated, the trauma center shall repay the state for the portion of the year during which it was not a trauma center.

(2) Trauma centers eligible to receive distributions from

461182

the Emergency Medical Services Trust Fund under s. 20.435 in accordance with subsection (1) may request that such funds be used as intergovernmental transfer funds in the Medicaid program.

(3) In order to receive state funding, a hospital shall be a verified trauma center and shall:

(a) Agree to conform to all departmental requirements as provided by rule to assure high-quality trauma services.

(b) Agree to report trauma data to the National Trauma Data Bank ~~Agree to provide information concerning the provision of trauma services to the department, in a form and manner prescribed by rule of the department~~.

(c) Agree to accept all trauma patients, regardless of ability to pay, on a functional space-available basis.

(4) A trauma center that fails to comply with any of the conditions listed in subsection (3) or the applicable rules of the department shall not receive payments under this section for the period in which it was not in compliance.

Section 8. Section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.—

(1) Recognizing the Legislature’s stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers, the department shall utilize funds collected under s. 318.18 and deposited into the Emergency Medical Services Trust Fund of the department to ensure the availability and accessibility of trauma services throughout the state as provided in this

subsection.

(a) Funds collected under s. 318.18(15) shall be distributed as follows:

1. Twenty percent of the total funds collected during the state fiscal year shall be distributed to verified trauma centers that have a local funding contribution as of December 31. Distribution of funds under this subparagraph shall be based on trauma caseload volume for the most recent calendar year available.

2. Forty percent of the total funds collected shall be distributed to verified trauma centers based on trauma caseload volume for the most recent calendar year available. The determination of caseload volume for distribution of funds under this subparagraph shall be based on the agency hospital discharge data reported by each trauma center pursuant to s. 408.062 and meeting the criteria for classification as a trauma patient ~~department's Trauma Registry data~~.

3. Forty percent of the total funds collected shall be distributed to verified trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this subparagraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule.


461182

(b) Funds collected under s. 318.18(5)(c) and (20) shall be distributed as follows:

1. Thirty percent of the total funds collected shall be distributed to Level II trauma centers operated by a public hospital governed by an elected board of directors as of December 31, 2008.

2. Thirty-five percent of the total funds collected shall be distributed to verified trauma centers based on trauma caseload volume for the most recent calendar year available. The determination of caseload volume for distribution of funds under this subparagraph shall be based on the hospital discharge data reported by each trauma center pursuant to s. 408.062 and meeting the criteria for classification as a trauma patient ~~department's Trauma Registry data~~.

3. Thirty-five percent of the total funds collected shall be distributed to verified trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this subparagraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule.

(2) Funds deposited in the department's Emergency Medical Services Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for

461182

such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Emergency Medical Services Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. Funds collected under ss. 318.14 and 318.18 and deposited in the Emergency Medical Services Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent calendar year data available. Such data shall not be used for more than four quarterly distributions unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available shall continue to be used and appropriate adjustments shall be made as soon as the more recent data becomes available.

(3)(a) Any trauma center not subject to audit pursuant to s. 215.97 shall annually attest, under penalties of perjury, that such proceeds were used in compliance with law. The annual attestation shall be made in a form and format determined by the department. The annual attestation shall be submitted to the department for review within 9 months after the end of the organization’s fiscal year.

(b) Any trauma center subject to audit pursuant to s. 215.97 shall submit an audit report in accordance with rules adopted by the Auditor General.

(4) The department, working with the Agency for Health Care


461182

Administration, shall maximize resources for trauma services wherever possible.

Section 9. Section 395.404, Florida Statutes, is amended to read:

395.404 Reporting ~~Review~~ of trauma ~~registry~~ data; report to National Trauma Data Bank ~~central registry; confidentiality and limited release~~.—

(1)~~(a)~~ Each trauma center shall participate in the National Trauma Data Bank and the department shall solely use the National Trauma Data Bank Florida trauma data for quality and assessment purposes.

(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 10. If the provisions of this act relating to s. 395.4025(15), Florida Statutes. are held to be invalid or inoperative for any reason, the remaining provisions of this act shall be deemed to be void and of no effect, it being the legislative intent that this act as a whole would not have been adopted had any provision of the act not been included.

Section 11. 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 trauma services; amending ss. 318.14, 318.18, and 318.21, F.S.; providing that moneys received from specified penalties shall be allocated to certain trauma centers by a calculation that uses the Agency of Health Care Administration’s hospital discharge data; amending s. 395.4001, F.S.; redefining the term “trauma caseload volume”; amending s. 395.402, F.S.; revising legislative intent; revising the trauma service areas and provisions relating to the number and location of trauma centers;

prohibiting the Department of Health from designating an existing Level II trauma center as a new pediatric trauma center or designate an existing Level II trauma center as a Level I trauma center in a trauma service area which already has an existing Level I or pediatric trauma center; apportioning trauma centers within each trauma service area; requiring the department to establish the Florida Trauma System Advisory Council by a specified date; 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 at least quarterly; amending s. 395.4025, F.S.; conforming provisions to changes made by the act; requiring the department to prepare an analysis of the Florida Trauma system periodically by using the agency's hospital discharge data and specified population data; specifying contents of the report; requiring the department to make available all data, formulas, methodologies, and risk adjustment tools used in the report; requiring the department to notify each acute care general hospital and local and regional trauma agency in the trauma service area with an identified need for an additional trauma center that the department is accepting letters of intent; prohibiting the department from accepting a letter of intent and from approving an application for a trauma center if there is not statutory capacity for an additional trauma


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center; revising the department's review process for hospitals seeking designation as a trauma center; authorizing the department to approve certain applications for designation as trauma center if specified requirements are met; providing that a hospital applicant that meets such requirements must be ready to operate in compliance with specified trauma standards by a specified date; deleting a provision authorizing the department to grant a hospital applicant an extension time to meet certain standards and requirements; 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 the department has completed its review process and approved the application; requiring a specified review team to make onsite visits to newly operational trauma centers within a certain timeframe; requiring the department to designate a trauma center that is in compliance with specified requirements based on recommendations from the review team; deleting the date by which the department must select trauma centers; 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 before specified dates are deemed to have met application and operational requirements;


461182

requiring the department to designate a certain provisionally approved Level II trauma center as a trauma center if certain criteria are met; prohibiting such designated trauma center from being required to cease trauma operations unless the department or a court determines that it has failed meet certain standards; providing construction; amending ss. 395.403 and 395.4036, F.S.; conforming provisions to changes made by the act; 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 for invalidity; providing an effective date.

By the Committee on Health Policy; and Senator Young

588-02384-18 20181876c1

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

Florida Senate - 2018 **CS for SB 1876**

588-02384-18 20181876c1

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

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

deemed to have met application and operational requirements; providing that certain currently operating trauma centers are eligible to be designated as trauma centers by the department 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), 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;

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.

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

Tallahassee, Florida 32399-1100

COMMITTEES:
Health Policy, *Chair*
Appropriations Subcommittee on Pre-K - 12 Education, *Vice Chair*
Commerce and Tourism
Communications, Energy, and Public Utilities
Regulated Industries

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR DANA YOUNG
18th District

January 24, 2018

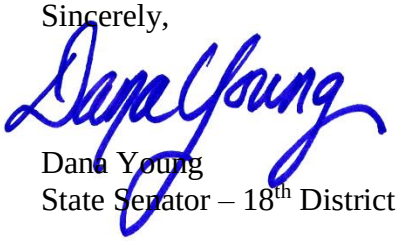
Senator Anitere Flores, Chair
Appropriations Subcommittee on Health and Human Services
201 The Capitol
404 S. Monroe Street
Tallahassee, Florida 32399-1100

Dear Chair Flores,

My Senate Bill 1876 regarding Trauma Services has been referred to your committee. I respectfully request that this bill be placed on your next available agenda.

If you have any questions, please do not hesitate to reach out to me.

Sincerely,



Dana Young
State Senator – 18th District

cc: Phil Williams, Staff Director – Appropriations Subcommittee on Health and Human Services

REPLY TO:
❒ 1211 N. Westshore Blvd, Suite 409, Tampa, Florida 33607 (813) 281-5507
❒ 316 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5018

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)

2/14/2018
Meeting Date

SB 1876
Bill Number (if applicable)

461182
Amendment Barcode (if applicable)

Topic Trauma Center

Name Mark Delegal

Job Title General Counsel

Address 315 S. Calhoun Street #600 Phone 850 224-7000
Street

TLH FL 32301 Email
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Safety Net Hospital Alliance

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)

2-14-18
Meeting Date

SB 1876
Bill Number (if applicable)

461182
Amendment Barcode (if applicable)

Topic Trauma Centers

Name Tom Panza

Job Title Panza, Maurer & Maynard

Address 201 East Park Avenue, Suite 200
Street

Phone 850-681-0980

Tallahassee, FL
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Jackson Memorial Hospital

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

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)

2-14-18
Meeting Date

CS SB 1876
Bill Number (if applicable)

strike all
Amendment Barcode (if applicable)

Topic _____

Name Dr. Mark McKenney

Job Title Trauma Medical Director

Address Kendall Hosp. 11750 Bird Rd Phone 786 417 4080
Street

Miami FL 33175 Email mark.mckenney@HCAHealthcare.com
City *State* *Zip*

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)

THE FLORIDA SENATE

APPEARANCE RECORD

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

2/14/18
Meeting Date

CS SB 1876
Bill Number (if applicable)

Strike all
Amendment Barcode (if applicable)

Topic _____

Name Steve Ecenia

Job Title Attorney

Address P. O. Box 551
Street

Tallahassee FL 32302
City *State* *Zip*

Phone 850-509-4996

Email steve@enpblaw.com

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.

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 Appropriations Subcommittee on Health and Human Services

BILL:	PCS/CS/SB 1788 (847484)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services; Children, Families, and Elder Affairs Committee; and Senator Passidomo
SUBJECT:	Medication Administration Training
DATE:	February 15, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Delia	Hendon	CF	**Fav/CS**
2.	Gerbrandt	Williams	AHS	**Recommend: Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 1788 revises training, competency and validation requirements for certain direct service providers who administer or assist with the administration of prescription medications to persons with developmental disabilities.

The bill increases from 4 hours to 6 hours the minimum number of training hours that a direct service provider must complete before the provider is permitted to supervise the self-administration of medication or administer certain prescription medications. The bill implements new competency and validation requirements based on the route of medication administered.

The bill requires each direct service provider to complete an annual 2-hour agency-developed in-service training course in medication administration and error prevention.

The bill revises the type of licensed professional that can provide training, competency determination, and initial and annual validations to include licensed practical nurses.

The bill expands the Agency for Persons with Disabilities (APD) rule making authority to include adopting rules to establish qualification requirements for trainers, and methods of enforcement to ensure compliance with the revised training, competency and validation requirements.

The APD is expected to incur minimal costs to implement this bill. Such costs can be absorbed within its existing resources.

The bill takes effect July 1, 2018.

II. Present Situation:

Direct Service Providers

Clients receiving services from the Agency for Persons with Disabilities (APD) in home and community-based settings often receive care from direct service providers.[1] A direct service provider is defined as a person 18 years of age or older who has direct face-to-face contact with a client while providing services to the client or has access to a client's living areas or to a client's funds or personal property.[2]

Administration of Medication

A direct service provider may supervise a client's self-administration of medication or may directly administer medication to a client.[3] Currently, a trained unlicensed direct service provider may use the following routes to supervise or administer medications to clients:

- Oral,
- Transdermal,
- Ophthalmic,
- Otic,
- Rectal,
- Inhaled,
- Enteral, or
- Topical.[4]

The client or the client's guardian or legal representative must give his or her informed consent to self-administering medication under the supervision of an unlicensed direct service provider or to receiving medication administered by an unlicensed direct service provider.[5]

Training Requirements

In order to supervise the self-administration of medication or to administer medications, a direct service provider must satisfactorily complete a 4-hour training course in medication administration and be found competent by a registered nurse or physician to administer or supervise the self-administration of medication to a client in a safe and sanitary manner.[6]

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[1] The Agency for Persons with Disabilities, *Agency Legislative Bill Analysis for Senate Bill 1788* (Dec. 21, 2017), *available at*: http://abar.laspbs.state.fl.us/ABAR/Document.aspx?id=22337&yr=2018 (last visited February 5, 2018).
[2] Section 393.063(13), F.S.
[3] Section 393.506(1), F.S.
[4] *Id.*
[5] Section 393.506(3), F.S.
[6] See ss. 393.506(2), and (4), F.S.

Currently, competency is assessed and validated at least annually for all routes of medication administration in an onsite setting, and must include the registered nurse or physician personally observing the direct service provider satisfactorily supervising the self-administration of medication by a client, and administering medication to a client.[7]

III. Effect of Proposed Changes:

The bill amends s. 393.506, F.S., to require all direct service providers to complete an initial training course of no less than 6 hours (rather than 4 hours) and be validated as competent before supervising the self-administration of medications or administering certain prescription medications to a client.

The bill requires all direct service providers to complete an annual 2-hour agency developed in-service training course in medication administration and error prevention conducted by an agency-approved trainer.

For oral, enteral, ophthalmic, rectal and inhaled routes of medication administration, the bill requires annual revalidation while maintaining that initial competency and validation require onsite administration of medication on an actual client.

For otic, transdermal, or topical routes of medication administration, the bill removes the annual onsite competency and validation requirement and provides that competency may be validated by simulation during an initial training course and does not need to be revalidated annually. The bill exempts direct providers from the 6-hour training course requirement if they have taken an initial 4-hour training course but are not currently validated for otic, transdermal or topical medication administration before July 1, 2018. The provider must seek validation and the bill allows the validation to be performed through simulation.

For oral and enteral routes of medication administration, the bill exempts direct service providers from the 6-hour training course requirement if they have taken an initial 4-hour training course and they have a current validation on or before July 1, 2018. The bill requires direct service providers who do not maintain their annual validation to retake a 6-hour initial training course and obtain additional validations before administering medications.

The bill revises the type of licensed professional that can provide training, competency determination, and initial and annual validations to include licensed practical nurses.

The bill expands the APD rule making authority to include adopting rules to establish qualification requirements for trainers, and methods of enforcement to ensure compliance with the revised training, competency and validation requirements.

The effective date of the bill is July 1, 2018.

[7] See 393.506(2), F.S.

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:

Employers of the direct service providers may have increased costs due to the expanded initial training hours required by the bill.[8] However, the employers of the direct service providers will no longer incur the annual costs of a registered nurse or doctor validating direct service providers for otic, topical, and transdermal routes Providers will only be responsible for the initial validation of direct service providers for ophthalmic, rectal, and inhaled routes. The only drug administration routes that will continue to require annual validation are oral and enteral.[9]

C. Government Sector Impact:

The Agency for Persons with Disabilities may incur minimal costs associated with updating forms and rule promulgation, which the agency can absorb within existing resources.[10]

VI. Technical Deficiencies:

None.

VII. Related Issues:

According to the APD, the intent of the bill is to revise the training and competency requirements for unlicensed direct service providers. However, subsection (6) of s. 393.506, F.S., as amended by section 1 of this bill states that only direct service providers who have met the training requirements of this section and who are validated as competent may administer

[8] *Supra* Note at 1.
[9] *Supra* Note at 1.
[10] *Supra* Note at 1.

medication to a client. Subsection (6) may preclude licensed professionals, such as nurses and physicians, from being able to administer medications to ADP clients if they have not gone through the APD training and competency determination.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 393.506.

IX. Additional Information:

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

Recommended CS by Appropriations Subcommittee on Health and Human Services on February 14, 2018:

- Requires direct service providers to complete an initial training course of no less than 6 hours before supervising the self-administration of medication or administering medication;
- Requires direct service providers to annually complete a 2-hour agency-developed inservice training course and allows the course to count toward annual inservice training hours;
- Revises the type of licensed professional that can provide training, the determination of competency, and initial and annual validations to include licensed practical nurses;
- Provides that certain direct service providers who have taken an initial training course and have a current validation on or before July 1, 2018, do not have to retake the initial 6 hour training course and certain validations may be obtained through simulation;
- Provides that certain validations may be obtained through simulation during the initial training course and do not require annual revalidation; and
- Expands the APD rulemaking authority to include adopting rules to establish qualification requirements for trainers, and methods of enforcement to ensure compliance with the revised training, competency and validation requirements.

CS by Children, Families, and Elder Affairs on January 29, 2018:

- Removes language requiring that new comprehensive transitional education programs (CTEPs) may not be licensed in Florida after July 1, 2018, and existing licenses may not be renewed after December 31, 2020.
- Expands the requirement for direct service providers to complete an annual 2-hour training course on medication administration and error prevention to apply to all unlicensed staff administering or supervising self-administration of medication, not strictly those who administer oral or enteral medications.

B. Amendments:

None.

895214

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/14/2018	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Passidomo) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 393.506, Florida Statutes, is amended to read:

393.506 Administration of medication.—

(1) A direct service provider who is not currently licensed to administer medication may supervise the self-administration of medication or may administer oral, transdermal, ophthalmic,

otic, rectal, inhaled, enteral, or topical prescription medications to a client if the provider meets the requirements of ~~as provided in~~ this section.

(2) In order to supervise the self-administration of medication or to administer medications as provided in subsection (1), a direct service provider must satisfactorily complete an initial ~~a~~ training course conducted by an agency-approved trainer of not less than 6 ~~4~~ hours in medication administration and be found competent to supervise the self-administration of medication by a client and ~~or~~ to administer medication to a client in a safe and sanitary manner. The competency of the direct service provider to supervise and administer otic, transdermal, and topical medication must be assessed and validated using simulation during the course, and need not be revalidated annually. If the direct service provider has already completed an initial training course of at least 4 hours and has a current validation for oral or enteral routes of medication administration on or before July 1, 2018, then he or she is not required to complete the course. If for any reason the direct service provider loses his or her validation by failing to meet the annual validation requirement for oral or enteral medication administration, or the annual inservice training requirement in subsection (3), then the direct service provider must complete the initial training course and obtain all required validations before he or she may supervise the self-administration of medication by a client or administer medication to a client. If a direct service provider has completed an initial training course of at least 4 hours, but has not received validation for otic, transdermal, or topical

medication administration before July 1, 2018, then that direct service provider must seek separate validation before administering otic, transdermal, and topical medication. Those validations may be performed through simulation.

(3) In addition to the initial training course, a direct service provider must annually and satisfactorily complete a 2-hour agency-developed inservice training course in medication administration and medication error prevention conducted by an agency-approved trainer. The inservice training course will count toward annual inservice training hours. This subsection may not be construed to require an increase in the total number of hours required for annual inservice training for direct service providers.

(4) Competency must be validated initially and revalidated annually for oral, enteral, ophthalmic, rectal, and inhaled medication administration. The initial and annual validations of medication administration must be performed onsite with an actual client using the client's actual medication and must include the validating practitioner personally observing the direct service provider satisfactorily:

(a) Supervising the oral, enteral, ophthalmic, rectal, or inhaled self-administration of medication by a client; and

(b) Administering medication to a client by oral, enteral, ophthalmic, rectal, or inhaled medication routes.

(5) Any unlicensed direct service provider who completes the required initial training course and is validated in the oral or enteral route of medication administration is not required to retake the initial training course unless he or she fails to maintain annual validation in the oral or enteral

route, in which case, the provider must complete again the initial 6-hour training course and any additional validations before he or she may supervise the self-administration of medication by a client or to administer any medication to a client.

(6) Only a direct service provider who has met the training requirements of this section and who has been validated as competent may administer medication to a client. In addition, a direct service provider who is not currently licensed to administer medication may supervise the self-administration of medication by a client or may administer medication to a client only if the client, or the client's guardian or legal representative, has given his or her informed written consent ~~must be assessed and validated at least annually in an onsite setting and must include personally observing the direct service provider satisfactorily:~~

~~(a) Supervising the self-administration of medication by a client; and~~

~~(b) Administering medication to a client~~.

~~(3) A direct service provider may supervise the self-administration of medication by a client or may administer medication to a client only if the client, or the client's guardian or legal representative, has given his or her informed consent to self-administering medication under the supervision of an unlicensed direct service provider or to receiving medication administered by an unlicensed direct service provider. Such informed consent must be based on a description of the medication routes and procedures that the direct service provider is authorized to supervise or administer. Only a~~


895214

~~provider who has received appropriate training and has been validated as competent may supervise the self-administration of medication by a client or may administer medication to a client~~.

(7)~~(4)~~ The training, determination of competency, and initial and annual validations ~~validation~~ required in this section shall be conducted by a registered nurse licensed pursuant to chapter 464 or by a practical nurse licensed under chapter 464. A physician licensed pursuant to chapter 458 or chapter 459 may validate or revalidate competency.

(8)~~(5)~~ The agency shall establish by rule standards and procedures that a direct service provider must follow when supervising the self-administration of medication by a client and when administering medication to a client. Such rules must, at a minimum, address qualification requirements for trainers, requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication or supervision of self-administered medication, informed-consent requirements and records, and the training curriculum and validation procedures. The agency shall adopt rules to establish methods of enforcement to ensure compliance with this section.

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 medication administration; amending

s. 393.506, F.S.; revising training requirements for direct service providers to assist with the administration of or to supervise the self-administration of medication under certain circumstances; providing requirements for the competency and skills of direct service providers to be validated; requiring direct service providers to complete an annual inservice training course in medication administration and medication error prevention developed by the Agency for Persons with Disabilities; providing construction; requiring the validation and revalidation of competency for certain medication administrations to be performed with an actual client; requiring the agency to adopt specified rules; providing an effective date.

By the Committee on Children, Families, and Elder Affairs; and Senator Passidomo

A bill to be entitled

An act relating to medication administration training; amending s. 393.506, F.S.; revising competency assessment and validation requirements for direct service providers who administer or supervise the self-administration of medication; providing an effective date.

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

Section 1. Subsections (2) and (4) of section 393.506, Florida Statutes, are amended, and subsections (1), (3), and (5) of that section are republished, to read:

393.506 Administration of medication. —

(1) A direct service provider who is not currently licensed to administer medication may supervise the self-administration of medication or may administer oral, transdermal, ophthalmic, otic, rectal, inhaled, enteral, or topical prescription medications to a client as provided in this section.

(2) In order to supervise the self-administration of medication or to administer medications as provided in subsection (1), a direct service provider must satisfactorily complete a training course of not less than 8 ~~4~~ hours in medication administration and be found competent to supervise the self-administration of medication by a client or to administer medication to a client in a safe and sanitary manner. In addition, a direct service provider must annually and satisfactorily complete a 2-hour course in medication administration and error prevention provided by the agency or its designee.

(a) Competency must be assessed and validated at least annually if oral or enteral medication administration is performed in the ~~an~~ onsite setting and must include personally observing the direct service provider satisfactorily:

1.~~(a)~~ Supervising the oral or enteral self-administration of medication by a client; and

2.~~(b)~~ Orally or enterally administering medication to a client.

(b) Competency must be assessed and validated during the initial medication administration training course if otic, transdermal, or topical medication administration is performed in the onsite setting. The competency assessment must include personally observing the direct service provider satisfactorily simulating otic, transdermal, or topical medication administration.

(c) Competency must be assessed and validated and need not be revalidated if ophthalmic, rectal, or inhaled medication administration is performed in the onsite setting. The competency assessment must include the performance of ophthalmic, rectal, or inhaled medication administration on an actual client in the onsite setting.

(3) A direct service provider may supervise the self-administration of medication by a client or may administer medication to a client only if the client, or the client's guardian or legal representative, has given his or her informed consent to self-administering medication under the supervision of an unlicensed direct service provider or to receiving medication administered by an unlicensed direct service

provider. Such informed consent must be based on a description of the medication routes and procedures that the direct service provider is authorized to supervise or administer. Only a provider who has received appropriate training and has been validated as competent may supervise the self-administration of medication by a client or may administer medication to a client.

(4) The determination of competency and annual validation described ~~required~~ in this section shall be conducted by a registered nurse licensed pursuant to chapter 464 or a physician licensed pursuant to chapter 458 or chapter 459.

(5) The agency shall establish by rule standards and procedures that a direct service provider must follow when supervising the self-administration of medication by a client and when administering medication to a client. Such rules must, at a minimum, address requirements for labeling medication, documentation and recordkeeping, the storage and disposal of medication, instructions concerning the safe administration of medication or supervision of self-administered medication, informed-consent requirements and records, and the training curriculum and validation procedures.

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

The Florida Senate

Committee Agenda Request

To: Senator Anitere Flores, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: January 31, 2018

I respectfully request that **Senate Bill #1788**, relating to The Agency for Persons With Disabilities, 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

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

2/14/16
Meeting Date

1788
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name CALEB HAWKES

Job Title LEGISLATIVE AFFAIRS DIRECTOR

Address _____ Phone _____
Street

_____ Email _____
City *State* *Zip*

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

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

Representing AGENCY FOR PERSONS WITH DISABILITIES

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

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

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

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

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 Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 1874
INTRODUCER:	Health Policy Committee and Senator Passidomo and others
SUBJECT:	Emergency Power for Nursing Home and Assisted Living Facilities
DATE:	February 13, 2018 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1874 requires each nursing home and assisted living facility (ALF), by June 1, 2018, have an operational emergency power source and fuel to sustain an air temperature set in rule[1] for at least 96 hours. The bill requires each facility to prepare a plan to monitor residents to ensure that they do not suffer from complications from heat exposure and a plan to safely transport residents to an appropriate facility if the facility's management knows it will be unable to sustain safe temperatures. The bill also requires each ALF to have an operational carbon monoxide alarm that is approved by the Florida Building Commission and meets certain requirements.

The bill has no impact on state revenues or expenditures.

The bill's provisions take effect upon becoming law.

II. Present Situation:

Hurricane Irma

Between September 10 and September 16, 2017, Hurricane Irma swept across Florida causing heavy damage and widespread loss of power. In the aftermath of the hurricane, the nursing home

[1] By the Agency for Health Care Administration for nursing homes and by the Department of Elder Affairs for ALFs.

Rehabilitation Center at Hollywood Hills (Center) was left without power and air conditioning for multiple days. As a consequence of the uncontrolled heat in the Center and because the Center's staff neglected to evacuate its residents, 12 Center residents died from heat exposure.[2]

On September 16, 2017, (after eight of the 12 resident deaths had occurred) Governor Scott issued a press release announcing emergency action for nursing homes and ALFs. In the press release, the Governor stated that "[a]ssisted living facilities and nursing homes serve our elderly and Florida's most vulnerable residents, and so many families rely on the health care professionals at these facilities to care for their loved ones… During emergencies, health care facilities must be fully prepared to ensure the health, safety and wellbeing of those in their care and there is absolutely no excuse not to protect life. The inability for this nursing home in Broward County to protect life has shined the light on the need for emergency action."[3]

Emergency Rules for Nursing Home and ALF Generators

In complying with the Governor's order, the Agency for Health Care Administration (AHCA) and the Department of Elder Affairs (DOEA) published emergency rules requiring all nursing homes[4] and ALFs[5] to install emergency generators. These emergency rules took effect on September 18, 2017; were renewed on December 15, 2017; [6] and established:

- The requirement that each facility provide a detailed plan within 45 days of the effective date of the rule for the acquisition and installation of an emergency generator and sufficient fuel to power the generator for 96 hours. The generator must be sufficiently large to cool the facility to 80 degrees Fahrenheit or below for the required time period;
- The requirement that each facility implement its plan within 60 days of the effective date of the rule; and
- Penalties for violating the emergency rule including possible license revocation and monetary penalties of up to $1,000 per day for continuing violations.

Both emergency rules were challenged at the Division of Administrative Hearings (DOAH) and were ruled invalid on October 27, 2017. The DOAH judge ruled that there was no emergency that required the rules and that the rules were invalid exercises of delegated legislative authority. The judge ruled that the rules:

- Were arbitrary and capricious in that complying with the rules in the timeframes allowed was impossible;

---

[2] Eight residents died before the Center evacuated the facility and six more died in the following weeks. Two of the 14 deaths were found not to be related to heat exposure. See The Associated Press, *12 of 14 Nursing Home Deaths After Irma Ruled Homicides*, WUSF NEWS, Nov. 27, 2017 available at http://wusfnews.wusf.usf.edu/post/12-14-nursing-home-deaths-after-irma-ruled-homicides, (last visited on Jan. 26, 2018).

[3] See https://www.flgov.com/2017/09/16/gov-scott-i-am-aggressively-fighting-to-keep-vulnerable-floridians-safe-during-emergencies/, (last visited on Jan. 26, 2018).

[4] Rule 59AER17-1, F.A.R.

[5] Rule 58AER17-1, F.A.R.

[6] Generally, emergency rules expire after 90 days and are not renewable. See s. 120.54(c), F.S. However, s. 120.54(4)(c)2., F.S., allows an agency to extend the period of time that emergency rules are effective if the agency has initiated the rulemaking process on the same subject and the proposed rules are awaiting legislative ratification. Currently, the AHCA and the DOEA have initiated rulemaking to adopt rules on the same subject (see section below) and the agencies' have submitted the proposed rules to the Legislature for ratification.

- Vested unbridled discretion in the AHCA and the DOEA in that the rules were so vague as to require agency discretion to implement them; and
- Contravened the implementing statute in that the penalties made no effect to classify noncompliance in a manner consistent with statute.[7]

These cases have been appealed to the Florida First District Court of Appeal[8] (DCA). The DCA denied a motion to stay the effect of the rules on November 11, 2017, and consequently, both emergency rules continue to be in effect pending appeal.

Permanent Rules for Nursing Home and ALF Generators

Concurrently with the emergency rules, the AHCA and the DOEA have also begun the process for adopting permanent rules related to generators in nursing homes and ALFs.[9] The AHCA and the DOEA initiated the rulemaking process on October 11, 2017, with rules published on November 14, 2017. The AHCA issued a notice of change published on January 10, 2017, and the DOEA issued a notice of change on January 19, 2018. Leading Age Florida challenged the validity of the AHCA's proposed rules for nursing homes, and the Florida Senior Living Association challenged the DOEA's proposed rules for ALFs. The challenges were withdrawn on January 26, 2018.

The proposed permanent rules require each nursing home and ALF to have a plan to acquire an alternative power source to ensure that ambient air temperatures are maintained at or below 81 degrees Fahrenheit for at least 96 hours during an emergency. In addition, ALFs are required to plan for the acquisition and maintenance of a carbon monoxide alarm. The rules allow each facility to plan to cool a portion of the facility with sufficient space to accommodate the facility's residents.[10] Facilities are required to plan for the storage or availability of sufficient fuel to power the generator for 96 hours.[11] Each facility's plan must be submitted within 30 days of the rule taking effect and will be reviewed by the AHCA and the local emergency management agency in the facility's area. Approved plans must be implemented no later than June 1, 2018, but the AHCA[12] may grant an extension up to January 1, 2019, if the facility's plan implementation is delayed due to necessary construction, delivery of equipment, or zoning or other regulatory approval processes.

The rules also require each facility to implement policies and procedures to ensure that it can effectively and immediately activate, operate, and maintain the emergency power source. The

[7] *Florida Association of Homes and Services for the Aging, Inc., d/b/a, Leadingage Florida v. the Agency for Health Care Administration,* case no. 17-5388RE, and *Florida Assisted Living Association, Inc., a Florida not for Profit Corporation v. the Florida Department of Elder Affairs,* case no. 17-5409RE

[8] Case no. 1D17-4534.

[9] Rule 59A-4.1265, F.A.R., for nursing homes and Rule 58A-5.036, F.A.R., for ALFs.

[10] Nursing homes are required to cool 30 square feet per resident and ALFs are required to cool 20 square feet per resident and may use 80 percent of its bed count to determine the total square footage.

[11] Sixteen bed or less ALFs must store 48 hours of fuel onsite and 17 or more bed ALFs and nursing homes must store 72 hours of fuel onsite. Facilities must also have a plan to obtain the remaining 24 or 48 hours of fuel at least 24 hours prior to the depletion of its fuel stores and may use portable fuel containers for the remainder during an emergency. Using piped natural gas as a fuel source is allowed.

[12] Under the provisions of ch. 429, F.S., the DOEA has responsibility for rulemaking for ALFs, but the AHCA is responsible for inspections and licensure activities.

policies and procedures must be resident-focused and ensure that the residents do not suffer complications from heat exposure. The policies and procedures must be available for inspection by residents, their representatives, and any other parties authorized in law.

The rules specify that the AHCA may seek any statutory remedy for noncompliance including, but not limited to, license revocation, license suspension, and administrative fines.

Federal Regulations for Nursing Home Emergency Power

Federal regulations currently in effect require nursing homes[13] to obtain emergency power in a similar manner to the permanent rules in development by the AHCA. The regulations in 42 CFR 483.73 require each long term care facility, including nursing homes, to develop and implement emergency preparedness policies and procedures that must include alternative sources of energy to maintain safe air temperatures for residents. Based on the facility's policies and procedures, each facility must implement emergency and standby power systems and maintain on onsite fuel source and a plan to keep the power systems operational, unless the facility evacuates. These regulations took effect on November 16, 2017, and are a requirement for the nursing home to participate in the Medicare or Medicaid programs.

Carbon Monoxide Alarms

Section 553.885, F.S., requires certain new buildings and additions to existing buildings[14] to have a carbon monoxide alarm if the building has certain features such as a fossil fuel burning heater or fireplace. The section defines "carbon monoxide alarm" as a device that is meant for the purpose of detecting carbon monoxide, that produces a distinct audible alarm, and that meets the requirements of and is approved by the Florida Building Commission. The section also provides that a stand-alone carbon monoxide alarm or a combination smoke and carbon monoxide alarm meets the requirements of the section and the alarms may be hard-wired or battery operated.

III. Effect of Proposed Changes:

Sections 1 and 2 amend ss. 400.23 and 429.41, F.S., regulating nursing homes and ALFs, respectively, to require, by June 1, 2018, that each facility have an operational emergency power source and fuel to sustain an air temperature set in rule[15] for at least 96 hours. The bill requires that each facility have a plan to monitor residents to ensure that they do not suffer from complications from heat exposure and a plan to safely transport residents to an appropriate facility if the facility's management knows it will be unable to sustain safe temperatures. Section 3 also requires that each ALF to have an operational carbon monoxide alarm installed that is approved by the Florida Building Commission and meets the requirements of s. 553.885, F.S.

The bill takes effect upon becoming a law.

[13] While nursing homes are federally regulated, the regulation of ALFs is delegated to the states.
[14] Hospitals, nursing homes, and hospice facilities that are constructed after July 1, 2008, are required to have carbon monoxide alarms in every area with a specified feature and the alarm must be connected to the fire alarm system of the facility.
[15] Supra note 1.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Nursing homes and ALFs that are required to acquire or upgrade emergency power systems to comply with the requirements in the bill will incur indeterminate costs.

The Agency for Health Care Administration provided in the Statement of Estimated Regulatory Costs for proposed rule 59A-4.1265, the following estimates[16]:

- The nursing home industry provided the estimated cost for a 120-bed facility to add a generator to meet the rule requirements is $315,200. This would result in a cost of $2,626.66 per bed.
- The AHCA estimates there are 70,229 beds not in compliance resulting in a high-end estimate of (70,229 x $2,626.66) $184,467,705.
- Estimates provided by a national generator supplier indicated a total cost of $145,700 per facility to comply with the rule. There are 577 facilities not currently in compliance, resulting in a lower estimate of $84,068,900.

The Department of Elder Affairs provided in the Statement of Estimated Regulatory Costs and Legislative Ratification for proposed rule 58A-5.036, the following estimates[17]:

- The department reports:
    - There are 1500 facilities with 6 or fewer beds that are not in compliance and the average cost per facility is estimated to be $19,033, resulting in a total cost of $28,549,500.

[16] Florida Administrative Register, Vol.44/07, ID 19939822, January 10, 2018.
[17] Florida Administrative Register, Vol 44/13, ID 19972511, January 19, 2018

- There are 732 facilities with beds numbering between 7 and 49 beds that are not in compliance and the average cost per facility is estimated to be $68,637, resulting in a total cost of $50,242,284
- There are 416 facilities with beds numbering between 50 and 100 that are not in compliance and the average cost per facility is estimated to be $106,721, resulting in a total cost of $44,395,936.
- There are 275 facilities with 100 beds or more that are not in compliance and the average cost per facility is estimated to be $424,165, resulting in a total cost of $116,645,400.
- Estimates provided by a national generator supplier indicated a total cost of $145,700 for facilities with exactly 120 beds. There are 28 facilities with 120 beds, resulting in a total cost of $4,079,600.

- Thus the total costs for all assisted living facilities to comply with the proposed rule is $243,912,720.

C. Government Sector Impact:

The Agency for Health Care Administration and the Department of Elder Affairs indicate the bill will have no fiscal impact to their operations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 400.23 and 429.41.

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 30, 2018:
The CS adds the requirement that each ALF have an operational carbon monoxide alarm installed that is approved by the Florida Building Commission and meets the requirements of s. 553.885, F.S.

B. Amendments:

None.

By the Committee on Health Policy; and Senators Passidomo and Stargel

588-02617-18 20181874c1

A bill to be entitled

An act relating to emergency power for nursing home and assisted living facilities; amending s. 400.23, F.S.; requiring the Agency for Health Care Administration, in consultation with the Department of Health and the Department of Elderly Affairs, to adopt and enforce rules requiring each facility to have an emergency power source and a supply of fuel which meet certain criteria by a specified date; requiring the agency to adopt rules establishing minimum criteria for a comprehensive emergency management plan that includes a plan to monitor residents and a plan to transport them in certain situations to avoid complications from heat exposure; amending s. 429.41, F.S.; requiring the Department of Elderly Affairs, in consultation with the agency, the Department of Children and Families, and the Department of Health, to adopt and enforce rules requiring each facility to maintain an emergency power source and a supply of fuel which meet certain criteria by a specified date and requiring facilities to have a certain carbon monoxide alarm installed which meets certain requirements; requiring the Department of Elderly Affairs to establish minimum criteria for a comprehensive emergency management plan that includes a plan to monitor residents and transport them in certain situations to avoid complications from heat exposure; providing an effective date.

588-02617-18 20181874c1

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

Section 1. Paragraphs (d) and (g) of subsection (2) of section 400.23, Florida Statutes, are amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, shall adopt and enforce rules to implement this part and part II of chapter 408, which shall include reasonable and fair criteria in relation to:

(d) The equipment essential to the health and welfare of ~~the~~ residents, including an operational emergency power source and a supply of fuel sufficient to sustain the emergency power source for at least 96 hours during a power outage. The emergency power source must provide enough electricity to consistently maintain an air temperature described in rule. Each facility must be in compliance with this paragraph by no later than June 1, 2018.

(g) The preparation and annual update of a comprehensive emergency management plan, which must include provisions for emergency power equipment. The agency shall adopt rules establishing minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and

transfer of records; a plan to monitor residents to ensure they do not experience complications from heat exposure during a power outage; a plan to safely transport residents to an appropriate facility if a facility's management knows it will be unable to maintain the residents in a safe temperature range; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

Section 2. Paragraphs (a) and (b) of subsection (1) of section 429.41, Florida Statutes, are amended to read:

429.41 Rules establishing standards.—

(1) It is the intent of the Legislature that rules published and enforced pursuant to this section shall include criteria by which a reasonable and consistent quality of resident care and quality of life may be ensured and the results of such resident care may be demonstrated. Such rules shall also ensure a safe and sanitary environment that is residential and noninstitutional in design or nature. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a

facility. Uniform firesafety standards for assisted living facilities shall be established by the State Fire Marshal pursuant to s. 633.206. The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter 408. In order to provide safe and sanitary facilities and the highest quality of resident care accommodating the needs and preferences of residents, the department, in consultation with the agency, the Department of Children and Families, and the Department of Health, shall adopt rules, policies, and procedures to administer this part, which must include reasonable and fair minimum standards in relation to:

(a) The requirements for and maintenance of facilities, not in conflict with chapter 553, relating to plumbing, heating, cooling, lighting, ventilation, living space, and other housing conditions, which will ensure the health, safety, and comfort of residents suitable to the size of the structure.

1. Firesafety evacuation capability determination.—An evacuation capability evaluation for initial licensure shall be conducted within 6 months after the date of licensure.

2. Firesafety requirements.—

a. The National Fire Protection Association, Life Safety Code, NFPA 101 and 101A, current editions, shall be used in determining the uniform firesafety code adopted by the State Fire Marshal for assisted living facilities, pursuant to s. 633.206.

b. A local government or a utility may charge fees only in an amount not to exceed the actual expenses incurred by the local government or the utility relating to the installation and

maintenance of an automatic fire sprinkler system in a licensed assisted living facility structure.

c. All licensed facilities must have an annual fire inspection conducted by the local fire marshal or authority having jurisdiction.

d. An assisted living facility that is issued a building permit or certificate of occupancy before July 1, 2016, may at its option and after notifying the authority having jurisdiction, remain under the provisions of the 1994 and 1995 editions of the National Fire Protection Association, Life Safety Code, NFPA 101, and NFPA 101A. The facility opting to remain under such provisions may make repairs, modernizations, renovations, or additions to, or rehabilitate, the facility in compliance with NFPA 101, 1994 edition, and may use ~~utilize~~ the alternative approaches to life safety in compliance with NFPA 101A, 1995 edition. However, a facility for which a building permit or certificate of occupancy is issued before July 1, 2016, that undergoes Level III building alteration or rehabilitation, as defined in the Florida Building Code, or seeks to use ~~utilize~~ features not authorized under the 1994 or 1995 editions of the Life Safety Code must thereafter comply with all aspects of the uniform firesafety standards established under s. 633.206, and the Florida Fire Prevention Code, in effect for assisted living facilities as adopted by the State Fire Marshal.

3. Resident elopement requirements.—Facilities are required to conduct a minimum of two resident elopement prevention and response drills per year. All administrators and direct care staff must participate in the drills which shall include a

review of procedures to address resident elopement. Facilities must document the implementation of the drills and ensure that the drills are conducted in a manner consistent with the facility's resident elopement policies and procedures.

4. Emergency power sources for use during power outages.—Facilities are required to maintain an operational emergency power source and a supply of fuel sufficient to sustain the emergency power source for at least 96 hours during a power outage. The emergency power source must provide enough electricity to consistently maintain an air temperature described in rule. Each facility must be in compliance with this subparagraph by no later than June 1, 2018.

5. Carbon monoxide alarm required.—All facilities, regardless of date of construction, must have an operational carbon monoxide alarm installed which is approved by the Florida Building Commission and which meets the requirements of s. 553.885.

(b) The preparation and annual update of a comprehensive emergency management plan. Such standards must be included in the rules adopted by the department after consultation with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including provision of emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; a plan to monitor residents to ensure they do not experience complications from heat exposure during a power outage; a plan to safely transport residents to an

appropriate facility if a facility's management knows it will be unable to maintain the residents in a safe temperature range; communication with families; and responses to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

Section 3. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

To: Senator Anitere Flores, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: January 31, 2018

I respectfully request that **Senate Bill #1874**, relating to Emergency Power for Nursing Home and Assisted Living Facilities, 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

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

2-14-18
Meeting Date

CS/SB 1874
Bill Number (if applicable)

Topic Emergency Power for NH + ALF's

Amendment Barcode (if applicable)

Name Dorene Barker

Job Title Associate State Director for Advocacy

Address 200 W. College Ave, Suite 304 Phone 850-228-6387
Street

Tallahassee FL 32301 Email dobarker@aarp.org
City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

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

Representing AARP Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

2-14-18 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 1874

Meeting Date *Bill Number (if applicable)*

Topic Generators for Nursing Homes *Amendment Barcode (if applicable)*

Name Amy Datz

Job Title Self

Address 1130 Crestview Ave. *Street*

Tallahassee FL 32303 *City* *State* *Zip*

Phone 850 322-2599

Email amaliedatz@mac.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Self

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

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

SENATOR KEVIN J. RADER
29th District

COMMITTEES:
Agriculture, *Vice Chair*
Appropriations Subcommittee on Health and Human Services
Appropriations Subcommittee on Transportation, Tourism, and Economic Development
Governmental Oversight and Accountability
Transportation

JOINT COMMITTEE:
Joint Administrative Procedures Committee, *Alternating Chair*

February 14, 2018

The Honorable Anitere Flores
404 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1300

Dear Chairwoman Flores:

In accordance with Senate Rule 1.21 I am writing to you to be excused from the Appropriations Subcommittee on Health and Human Services meeting that will be held on February 14, 2018 at 4:00pm due to an urgent matter within my district. I sincerely apologize for any inconvenience this may cause.

Thank you for your consideration. Please feel free to contact me at 561-866-4020 if you have any questions.

Sincerely

Kevin Rader

Kevin Rader
State Senator
District 29

cc: Phil Williams, Staff Director

REPLY TO:
❒ 5301 N. Federal Hwy, Suite 135, Boca Raton, Florida 33487
❒ 222 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5029

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

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

CourtSmart Tag Report

Room: SB 401 **Case No.:** **Type:**
Caption: Appropriations Subcommittee on Health and Human Services **Judge:**

Started: 2/14/2018 4:02:05 PM
Ends: 2/14/2018 5:03:49 PM **Length: 01:01:45**

4:02:20 PM Sen. Flores (Chair)
4:02:41 PM Sen. Book
4:03:49 PM Sen. Flores
4:04:08 PM S 710
4:04:12 PM Sen. Book
4:04:22 PM Am. 717750
4:06:15 PM Sen. Flores
4:06:30 PM S 710 (cont.)
4:06:36 PM Carlos Cruz, Government Consultant, Polaris Pharmacy Services (waives in support)
4:06:39 PM Dawn Steward
4:08:59 PM Sen. Flores
4:09:03 PM Sen. Book
4:09:32 PM S 1788
4:09:40 PM Sen. Passidomo
4:10:39 PM Sen. Flores
4:10:57 PM Am. 895214
4:11:03 PM Sen. Passidomo
4:11:26 PM Sen. Flores
4:11:39 PM S 1788 (cont.)
4:11:42 PM Caleb Hawkes, Legislative Affairs Director, Agency for Persons with Disabilities (waives in support)
4:12:15 PM Sen. Bean
4:13:10 PM S 280
4:14:11 PM Sen. Flores
4:14:18 PM Brittney Hunt, Policy Director, Florida Chamber of Commerce (waives in support)
4:14:23 PM Dorene Barker, Associate State Director of Advocacy, AARP Florida (waives in support)
4:14:27 PM Brewster Bevis, Senior Vice President, Associated Industries of Florida (waives in support)
4:14:30 PM Joe Anne Hart, Chief Legislative Officer, Florida Dental Association (waives in support)
4:14:37 PM Ron Watson, Lobbyist, Florida Renal Coalition FRC (waives in support)
4:14:43 PM Leah Courtney, Communications Coordinator, Florida Tax Watch (waives in support)
4:14:50 PM Sen. Book
4:15:32 PM Sen. Flores
4:16:09 PM S 1874
4:16:59 PM Sen. Passidomo
4:17:08 PM Sen. Rouson
4:17:42 PM Sen. Passidomo
4:18:05 PM Dorene Barker, Associate State Director for Advocacy, AARP of Tallahassee (waives in support)
4:18:32 PM Amy Datz (waives in support)
4:18:36 PM Sen. Flores
4:18:55 PM S 1184
4:19:00 PM Sen. Gibson
4:20:34 PM Sen. Flores
4:21:21 PM Sen. Stargel
4:21:57 PM Sen. Flores
4:22:03 PM Sen. Brandes
4:22:14 PM S 474
4:23:20 PM Am. 156796
4:24:09 PM Sen. Brandes
4:25:19 PM Sen. Passidomo
4:25:26 PM Sen. Brandes
4:26:02 PM Sen. Flores
4:26:28 PM Belinda Herring, retired, Saint Giana Guild of Catholic Medical Association
4:28:39 PM Sen. Flores

4:28:42 PM Diane Gowski, M.D., Florida State Director, Florida Guilds of the Catholic Medical Association
4:33:42 PM Lynda Bell, President, Florida Right to Life
4:39:35 PM Mark Bell (waives against)
4:39:46 PM Marco Pavedes, Associate Director for Health, Florida Conference of Catholic Bishops
4:40:37 PM Sen. Flores
4:40:42 PM Sen. Book
4:41:11 PM Sen. Brandes
4:41:48 PM Sen. Book
4:42:26 PM Sen. Passidomo
4:43:41 PM Sen. Baxley
4:47:16 PM Sen. Stargel
4:48:51 PM Sen. Brandes
4:50:36 PM Sen. Flores
4:50:49 PM S 1876
4:51:10 PM Sen. Young
4:51:24 PM Am. 461182
4:57:53 PM Sen. Flores
4:57:59 PM Sen. Rouson
4:59:39 PM Sen. Flores
4:59:42 PM Mark Delegal, General Council, Safety Net Hospital Alliance
5:00:33 PM Tom Panza, Panza, Maurer and Maynard, Jackson Memorial Hospital (waives in support)
5:00:39 PM Mark McKenney, Trauma Medical Director, HCA (waives in support)
5:00:54 PM Steve Ecenia, Attorney, HCA
5:01:38 PM Sen. Flores
5:02:00 PM S 1876 (cont.)
5:02:32 PM Sen. Young
5:03:02 PM Sen. Flores
5:03:42 PM Adjourn