The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Monday, April 3, 2017
TIME: 4:00—6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

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

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 406** Bradley (Compare H 1397, S 614, S 1388, S 1666, S 1758)	Compassionate Use of Low-THC Cannabis and Marijuana; Authorizing physicians to issue physician certifications to specified patients who meet certain conditions; requiring written consent of a parent or legal guardian for the treatment of minors; requiring that certain physicians annually reexamine and reassess patients and update patient information in the compassionate use registry; requiring the Department of Health to register caregivers meeting certain requirements on the compassionate use registry; requiring the department to register certain dispensing organizations as medical marijuana treatment centers by a certain date; requiring that certain receptacles be child proof; requiring a medical marijuana treatment center to keep a copy of a transportation manifest in certain vehicles at certain times, etc. HP 04/03/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
2	**SB 732** Steube (Compare CS/H 1307)	Physician Assistants; Requiring that a physician assistant license renewal include the submission of a physician assistant survey; requiring the Department of Health to create a physician assistant survey that includes specified information, etc. HP 04/03/2017 Fav/CS AHS AP	Fav/CS Yeas 7 Nays 0
3	**SB 782** Mayfield (Identical H 6015)	High School Graduation Requirements; Removing a requirement that a student participating in an interscholastic sport pass a competency test on personal fitness to satisfy the physical education credit requirement for high school graduation, etc. ED 03/21/2017 Workshop-Discussed ED 03/27/2017 Favorable HP 04/03/2017 Favorable RC	Favorable Yeas 6 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**CS/SB 800** Banking and Insurance / Broxson (Similar CS/H 1191)	Medication Synchronization; Requiring health insurers and health maintenance organizations, respectively, which issue or deliver certain policies or contracts to offer medication synchronization to allow insureds and subscribers to align refill dates for certain drugs at least once in a plan year; requiring such insurers and health maintenance organizations to implement a process for aligning such dates, etc. BI 03/27/2017 Fav/CS HP 04/03/2017 Favorable AP	Favorable Yeas 7 Nays 0
5	**SB 840** Clemens (Compare CS/CS/H 557)	Prescription Drug Monitoring Program; Revising requirements for reporting the dispensing of controlled substances; limiting an exception to reporting requirements for certain facilities dispensing controlled substances, etc. HP 04/03/2017 Fav/CS GO RI RC	Fav/CS Yeas 6 Nays 0
6	**SB 1056** Garcia (Identical H 6021)	Home Health Care Agency Licenses; Removing a prohibition against the issuance of an initial home health agency license to an applicant who shares common controlling interests with another licensed home health agency located within 10 miles of the applicant and in the same county, etc. HP 04/03/2017 Favorable AHS AP	Favorable Yeas 5 Nays 1
7	**SB 1354** Young (Similar CS/H 723)	Maintenance of Certification; Prohibiting the Boards of Medicine and Osteopathic Medicine, respectively, and the Department of Health, health care facilities, and insurers from requiring certain certifications as conditions of licensure, reimbursement, employment, or admitting privileges, etc. HP 04/03/2017 Fav/CS BI RC	Fav/CS Yeas 6 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**SB 1446** Rouson (Identical H 1187)	Pay-for-success Contracts; Authorizing a state agency to negotiate and enter into a pay-for-success contract with a private entity, subject to authorization in the General Appropriations Act; requiring a contracted private entity to annually report to the appropriate state agency for the length of the contract; authorizing the Department of Health to implement the Nurse-Family Partnership pay-for-success program, etc. GO 03/22/2017 Favorable HP 04/03/2017 Favorable AP RC	Favorable Yeas 6 Nays 1
9	**SB 1550** Artiles (Compare CS/CS/H 1209)	Florida Center for Health Information and Technology; Requiring the Agency for Health Care Administration to contract with a vendor relating to development of systems to leverage existing public and private health care data sources for specified purposes, etc. HP 04/03/2017 Fav/CS AP RC	Fav/CS Yeas 6 Nays 0
10	**SB 1578** Gibson (Identical H 967)	Diabetes Educators; Providing requirements for registration as a diabetes educator; prohibiting an unregistered person from certain activities relating to diabetes self-management training, etc. HP 04/03/2017 Fav/CS AHS AP	Fav/CS 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 Committee on Health Policy

BILL:	CS/SB 406
INTRODUCER:	Health Policy Committee and Senator Bradley and others
SUBJECT:	Compassionate Use of Low-THC Cannabis and Marijuana
DATE:	April 4, 2017
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 406 amends s. 381.986, F.S., to implement the provisions of article X, section 29 of the State Constitution, Medical Marijuana Production, Possession, and Use. The bill makes numerous changes to the section including:

- Adding legislative intent ;
- Amending definitions to incorporate terms used in article X, section 29 of the State Constitution, and to add definitions for "chronic nonmalignant pain" and "close relative."
- Allowing allopathic[1] and osteopathic[2] physicians to certify the medical use of marijuana for patients with debilitating medical conditions and other specified patients, including certain patients from other states who meet Florida requirements.
- Establishing requirements that a physician must meet before certifying a patient and after certification. Reduces the required course a physician must take prior to certifying patients to a 4-hour course that must only be taken once.[3] Removes the 3-month patient treatment prerequisite.
- Amending current criminal penalties to conform with other changes in the bill and establishing new criminal violations for patients and caregivers cultivating or purchasing marijuana from a source other than a medical marijuana treatment center (MMTC) or who violate other provisions of the act.

[1] Licensed under ch. 458, F.S.
[2] Licensed under ch. 459, F.S.
[3] Current law requires that physicians take an 8-hour course annually.

- Prohibiting unlicensed activity and providing for criminal and financial penalties.
- Establishing requirements for caregivers including limiting a patient to one caregiver and a caregiver to one patient with certain exceptions and requiring that caregivers pass a Level 2 background screening, with certain exceptions for a caregiver who is a close relative.
- Requiring the Department of Health (DOH) to begin issuing identification cards to patients and caregivers by October 3, 2017.
- Requiring the DOH to establish requirements for the licensure and certification of independent testing laboratories (ITL), a marijuana quality control program, and a seed-to-sale tracking program for marijuana.
- Grandfathering in existing dispensing organizations as MMTCs,[4] adding five MMTCs by October 3, 2017, and increasing the overall number of MMTCs that may be registered when certain numbers of patients are registered on the compassionate use registry.
- Requiring MMTCs to maintain compliance with the representations made in their applications for registration and allowing the DOH to grant variances in certain circumstances.
- Authorizing emergency rulemaking for implementation and timeframes for initiating nonemergency rulemaking.

The bill also creates s. 1004.4351, F.S., to establish the "Medical Marijuana Research and Education Act" and the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.

The bill also makes other conforming and technical changes to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.411, F.S.

The bill's provisions take effect upon becoming law.

II. Present Situation:

Treatment of Marijuana in Florida

Florida law defines cannabis as "all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin,"[5] and places it, along with other sources of THC, on the list of Schedule I controlled substances.[6] The definition excludes "low-THC cannabis" as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed in conformance with that section.

Schedule I controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States.[7] As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first-degree misdemeanor[8] up to a first-degree felony with a mandatory minimum sentence of 15 years in

[4] Including dispensing organizations that are currently in litigation but would qualify under ch. 2016-1236, L.O.F.
[5] Section 893.02(3), F.S.
[6] Section 893.03(1)(c)7. and 37., F.S.
[7] Section 893.03(1), F.S.
[8] This penalty is applicable to possession or delivery of less than 20 grams of cannabis. *See* s. 893.13(3) and (6)(b), F.S.

state prison and a $200,000 fine.[9] Paraphernalia[10] that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.[11]

Medical Marijuana in Florida: the Compassionate Medical Cannabis Act of 2014

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014[12] (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[13] for medical use[14] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. The act provides that a Florida licensed allopathic or osteopathic physician who has completed the required training[15] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order for a physician to order low-THC cannabis for a patient, all of the following conditions must apply:

- The patient is a permanent resident of Florida;
- The physician has treated the patient for at least 3 months immediately preceding the patient's registration and has determined that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;[16]
- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the DOH and updates the registry to reflect the contents of the order;
- The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;

[9] Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first-degree felony with a mandatory minimum sentence that varies from 3 to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.
[10] Section 893.145, F.S.
[11] Section 893.147, F.S.
[12] Chapter 2014-157, Laws of Fla., codified in s. 381.986, F.S.
[13] Section 381.986(b), F.S., defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.
[14] Section 381.986(1)(c), F.S., defines "medical use" as administration of the ordered amount of low-THC cannabis; and the term does not include the possession, use, or administration by smoking, or the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative. Section 381.986(1)(e), F.S., defines "smoking" as burning or igniting a substance and inhaling the smoke; smoking does not include the use of a vaporizer.
[15] Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing.
[16] If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record.

- The physician submits the patient treatment plan quarterly to the University of Florida, College of Pharmacy (UFCP) for research on the safety and efficacy of low-THC cannabis on patients; and
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community about the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.[17]

The act creates exceptions to existing law to allow qualified patients[18] and their legal representatives to purchase, acquire, and possess low-THC cannabis (up to the amount ordered) for that patient's medical use; and to allow dispensing organizations (DO) and their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and to possess, process, and dispense low-THC cannabis. The DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.[19]

Patient Treatment with Medical Cannabis

Chapter 2016-123, Laws of Fla., amended the act to expand the regulatory structure relating to dispensing low-THC cannabis and authorized approved dispensing organizations to cultivate and dispense medical cannabis to eligible patients as defined under the Right to Try Act (RTTA).[20] In conjunction with s. 381.986, F.S., the RTTA allows physicians to treat eligible patients with terminal conditions with medical cannabis by including medical cannabis[21] within the definition of a "investigational drug, biological product, or device." Physicians must order the use of medical cannabis for those patients pursuant to the provisions of s. 381.986, F.S.

Dispensing Organizations under the Act

Section 381.986, F.S., requires that the DOH approve five DOs, one in each of five regions throughout the state. In order to be approved as a DO, an applicant must possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years. Applicants are also required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as a DO;
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;

[17] Section 381.986(2), F.S.
[18] Section 381.986(1)(d), F.S., defines a "qualified patient" as a Florida resident who has been added by a physician licensed under ch. 458, F.S., or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO.
[19] Section 381.986(7), F.S.
[20] Section 499.0295, F.S.
[21] "Medical cannabis" means all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a DO for medical use by an eligible patient as defined in the Right to Try Act.

- An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department;
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department;
- That all owners and managers have been fingerprinted and have successfully passed a Level 2 background screening pursuant to s. 435.04, F.S; and
- The employment of a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.[22]

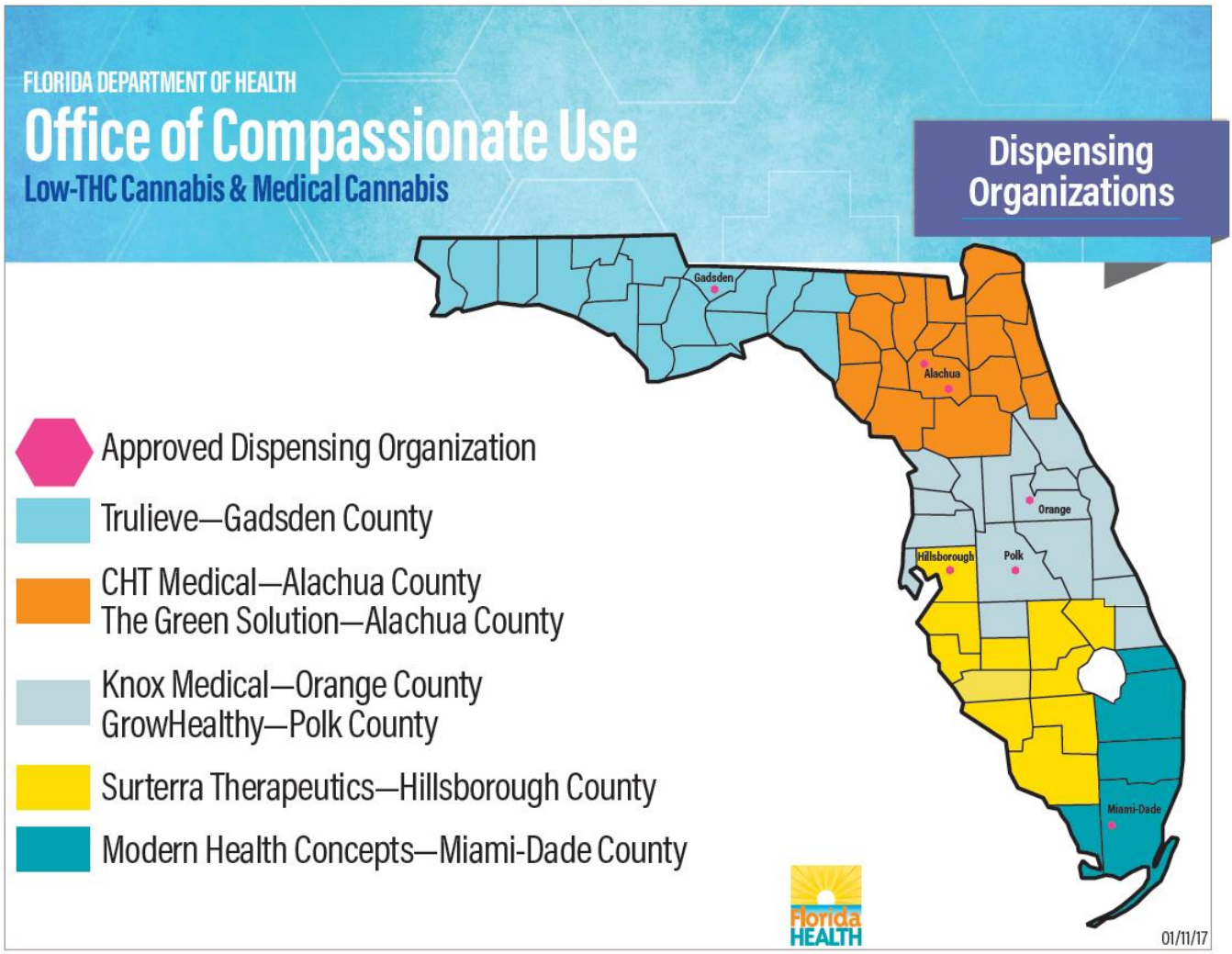
An approved DO must post a $5 million performance bond within 10 business days of approval. The DOH is authorized to charge an initial application fee and a licensure renewal fee, but is not authorized to charge an initial licensure fee.[23] An approved DO must maintain all approval criteria at all times.[24]

Beginning on July 7, 2014, the DOH held several rule workshops[25] to write and adopt rules implementing the provisions of s. 381.986, F.S., and the DOH put forward a proposed rule on September 9, 2014.[26] This proposed rule was challenged by multiple organizations involved in the rulemaking workshops and was found to be an invalid exercise of delegated legislative authority by an administrative law judge on November 14, 2014.[27] Afterward, the DOH held a negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule being published on February 6, 2015.[28] The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs and the DOH's conclusion that the rule will not require legislative ratification. Hearings were held on April 23 and 24, 2015, and a final order was issued on May 27, 2015, which found the rule to be valid.[29] The rules took effect June 17, 2015, and the DOH held an application period for DO approval which ended on July 8, 2015. Twenty-eight applications were submitted.[30]

On November 23, 2015, the DOH approved a DO in each of the following five regions as required by the act: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.[31] Numerous petitions were filed challenging the DOH's selection process. In

[22] *Id.*
[23] *Id.*
[24] Section 381.986(6), F.S.
[25] Audio recordings of the rule development workshops are available on the DOH website at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/rulemaking/index.html (last visited Mar. 20, 2017).
[26] Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).
[27] Tornello Landscape Corp. v. DOH, Case No. 14-4547RP; Fl. Medical Cannabis Assoc. v. DOH, Case No. 14-4517RP; Plants of Ruskin, Inc. v. DOH, Case No. 14-4299RP; Costa Farms, LLC v. DOH, Case No. 14-4296RP (Fla. DOAH 2014). A copy of each Final Order is available on the Division of Administrative Hearings website.
[28] Proposed Rule ch. 64-4, ID 15645147, (Feb. 2, 2015).
[29] Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).
[30] Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, Resources website, available at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/dispensing-organizations/dispensing-application-process/index.html (last visited Mar. 20, 2017).
[31] Section 381.986(5)(b), F.S. A map of the dispensing regions and approved dispensing organizations is available on the DOH website at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/_documents/ocu-dispensing-map.pdf (last visited Mar. 20, 2017).

order to allow the approved DOs to begin dispensing products, the 2016 Legislature required the DOH to approve as a dispensing organization applicants that received the highest aggregate score through the DOH's evaluation process, notwithstanding any prior determination by the DOH that the applicant failed to meet the requirements of s. 381.986, F.S. The Legislature also provided that if the Division of Administrative Hearings, the DOH, or a court of competent jurisdiction makes a final determination that an applicant was entitled to be a DO, that both this DO and currently approved DOs may operate in the same region.[32] Currently, in addition to the five DOs originally approved, the DOH has since approved The Green Solution in Alachua County and Grow Health in Polk County. The following map depicts the currently approved DOs.



In addition to the currently approved DOs, s. 381.986(5)(c), F.S., requires the DOH to approve three additional DOs upon the registration of 250,000 active qualified patients in the compassionate use registry. At least one of the newly approved DOs must be an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association. These additional applicants are not required to meet the requirement

[32] Chapter 2016-123, Laws of Fla.

to possess a certificate of registration issued by the DACS for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years.

The Compassionate Use Registry

The act requires the DOH to create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by DOs, which is accessible to law enforcement.[33] The registry must allow DOs to record the dispensing of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians. Physicians must register qualified patients with the registry and DOs are required to verify that the patient has an active registration in the registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled before dispensing any low-THC cannabis. The DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.[34] The Compassionate Use Registry became operational on July 11, 2016.[35] As of the end of February, 2017, there were 4,079 patients registered with the Compassionate Use Registry.[36]

The Office of Compassionate Use and Research on Low-THC Cannabis

The DOH was required to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act.[37, 38]

The act includes several provisions related to research on low-THC cannabis and cannabidiol including:

- Requiring physicians to submit quarterly patient treatment plans to the UFCP for research on the safety and efficacy of low-THC cannabis;[39]
- Authorizing state universities to perform research on cannabidiol and low-THC cannabis and exempting them from the provisions in ch. 893, F.S., for the purposes of such research;[40] and
- Appropriating $1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.[41]

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[33] Section 381.986(5)(a), F.S.
[34] Section 381.986(6), F.S.
[35] Office of Compassionate Use, *Implementation Timeline* (October 2016) *available at* http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/_documents/ocu-timeline.pdf, (last visited Mar. 21, 2017).
[36] Revenue Estimating Conference, *Use of Marijuana for Debilitating Medical Conditions* (March 2, 2017), p. 3, (on file with the Senate Committee on Health Policy).
[37] Section 385.212, F.S.
[38] The Office of Compassionate Use is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by: creating a network of state universities and medical centers recognized for demonstrating excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in this state; making any necessary application to the U.S. Food and Drug Administration (FDA) or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and entering into agreements necessary to facilitate enhanced access to compassionate use for Florida patients. *See* ss. 381.925 and 385.212, F.S.
[39] Section 381.986(2)(e), F.S.
[40] Section 385.211, F.S.
[41] Chapter 2014-157, Laws of Fla.

Medical Marijuana in Florida: Amendment 2 (2016)

On November 4, 2016, Amendment 2 was voted into law and established article X, section 29 of the State Constitution. This section of the constitution became effective on January 3, 2017, and creates several exemptions from criminal and civil liability for:

- Qualifying patients medically using (acquiring, possessing, using, delivering, transferring, or administering) marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical Marijuana Treatment Centers (MMTCs), their agents and employees for actions or conduct under the amendment and in compliance with DOH rules.

The constitution defines multiple terms including:

- "Qualifying patient" meaning someone who:
  - Has been diagnosed with a "debilitating medical condition";
  - Has a "physician certification"; and
  - Has a valid qualifying patient identification card issued by the DOH.
  - Minor patients must also have the consent of a parent or legal guardian prior to both obtaining a physician certification and obtaining an identification card from the DOH.[42]
- "Debilitating Medical Condition" meaning:
  - Cancer;
  - Epilepsy;
  - Glaucoma;
  - HIV/AIDS;
  - Post-Traumatic Stress Disorder (PTSD);
  - ALS;
  - Crohn's Disease;
  - Parkinson's Disease;
  - Multiple Sclerosis; or
  - Another debilitating medical condition of the same kind or class as, or comparable to, the enumerated conditions.
  - Additionally, a physician must believe that the medical use of marijuana would likely outweigh the potential health risks for the patient.
- "Marijuana" as having the meaning given cannabis in Section 893.02(3), Florida Statutes (2014), and, in addition, "Low-THC cannabis" as defined in Section 381.986(1)(b), Florida Statutes (2014), shall also be included in the meaning of the term "marijuana."
- "Medical Marijuana Treatment Center" or "MMTC" meaning an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the DOH.
- "Medical use" meaning the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with DOH rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.

[42] This provision is included in the definition of "physician certification."

- "Physician Certification" meaning a written document signed by a person who is "licensed to practice medicine" in Florida stating:
  - The physician has conducted a medical examination of the patient and a full assessment of the patient's medical history;
  - That, in the physician's professional opinion, the patient has a debilitating medical condition;
  - That, in the physician's professional opinion, the medical use of marijuana will outweigh the health risks for the patient; and
  - For how long the physician recommends the medical use of marijuana for the patient.
- "Qualifying patient" meaning a person who has been diagnosed to have a debilitating medical condition, who has a physician certification and a valid qualifying patient identification card. If the DOH does not begin issuing identification cards within 9 months after the effective date of this section, then a valid physician certification will serve as a patient identification card in order to allow a person to become a "qualifying patient" until the DOH begins issuing identification cards.

Once certified, a patient may designate one or more caregivers to assist him or her with the medical use of marijuana. The amendment defines a "caregiver" as a person who is at least 21 years of age who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the DOH. Caregivers:

- Are prohibited from consuming medical marijuana;
- Caregivers must obtain an ID card from the DOH;
- The DOH has authority to establish standards and qualifications for caregivers including:
  - Background checks;
  - Procedures for issuing ID cards; and
  - Limitations on the number of caregivers per patient and the number of patients per caregiver.

The DOH is required to register Medical Marijuana Treatment Centers that will be authorized to acquire, cultivate, possess, process, transfer, transport, sell, distribute, dispense, or administer medical marijuana, related supplies, or educational materials to patients and caregivers. The DOH is required to adopt rules regarding MMTCs including:

- Procedures to register as an MMTC;
- Procedures for the issuance, renewal, suspension, and revocation of MMTC registrations; and
- Standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

The amendment requires the DOH to adopt rules no later than 6 months after its effective date (July 3, 2017). The stated purpose of the rules is to ensure the availability and safe use of medical marijuana by qualifying patients. Currently, the DOH has begun the rulemaking process to implement article X, section 29 of the State Constitution and has held several workshops around the state.[43] The DOH is required to adopt rules for:

- Issuing patient and caregiver ID cards;[44]

[43] Rule 64-4.012, F.A.C., rule notice published on Jan. 17, 2017, *available at* https://www.flrules.org/gateway/ruleNo.asp?id=64-4.012, (last visited on Mar. 20, 2017).

[44] On Feb. 18, 2017, the DOH adopted Rule 64-4.011, F.A.C., addressing the issuance of Compassionate Use Registry Identification Cards. This rule may bring the DOH into compliance with the requirement to adopt rules for issuing ID cards

- Procedures for establishing caregiver qualifications;
- Procedures for registering MMTCs; and
- A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply, based on the best available medical evidence. (This presumption can be overcome on an individual patient basis).

If the DOH does not have rules adopted by the deadline, the amendment creates a cause of action for any Florida citizen to seek judicial relief to compel the DOH's compliance. Additionally, the DOH is required to begin registering MMTCs and issuing patient and caregiver ID cards within 9 months of the amendment's effective date (Oct. 3, 2017). If the DOH does not comply with this requirement, the amendment states that a physician certification is sufficient for a person to become a qualifying patient without being issued an ID card from the DOH.

The amendment also creates a number of specific restrictions on its exemption from liability and its grants of authority including specifically:

- Not repealing or allowing violations of other laws related to the non-medical use of marijuana;
- Not permitting the operation of any vehicle under the influence of marijuana;
- Not requiring the accommodation of the use of marijuana in specific areas or in any public place;
- Not requiring any health insurance provider to cover the medical use of marijuana; and
- Not affecting laws related to negligence or malpractice on the part of any patient, caregiver, physician, or MMTC agent or employee.

Medical Marijuana in Florida: The Necessity Defense

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State* where the First District Court of Appeal found that "s. 893.03, F.S., does not preclude the defense of medical necessity" for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.[45]

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the court found that the defendants met the criteria to qualify for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

by July 3, 2017; however, the rule may need requiring amending to comply with constitutional terms and to comply with changes to s. 381.986, F.S., provided in this bill.

[45] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991).

Medical Marijuana Laws in Other States

Currently, 28 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.[46] These laws vary widely in detail but most are similar in that they touch on several recurring themes. For example, most state laws require an identification card and registry for patients and caregivers to use medical marijuana; require the patient to receive certification from up to two physicians that the patient has a qualifying condition before the patient may use medical marijuana; allow a patient to designate a caregiver who can possess the medical marijuana and assist the patient in using the medical marijuana; and provide general restrictions on how medical marijuana can be obtained (self-cultivated or from a dispensary) and where it can be used.[47]

Of the 17 states with low-THC cannabis laws similar to s. 381.986, F.S., most specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Florida allows the treatment of cancer and Georgia allows the treatment of end stage cancer and other specified conditions. Additionally, the definition of low-THC cannabis differs from state to state. The THC level allowed ranges from a high of below 5 percent to less than 0.3 percent; most states restrict the level of THC to below 1 percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.[48]

Interaction with the Federal Government

The federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.[49] Possession, manufacture, and distribution of marijuana is a crime under federal law.[50] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws, or Constitutional provisions, do not protect individuals from prosecution under federal law.

In 2013, the U.S. Department of Justice (USDOJ) issued statements indicating that the federal government would not pursue cases for low-level drug crimes, leaving such prosecutions largely up to state authorities. The U.S. Attorney General issued a statement that the USDOJ was changing policy such that individuals "who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels, will no longer be charged with

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[46] These states include: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation in June 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. National Conference of State Legislatures, *State Medical Marijuana Laws*, (Mar. 16, 2017), *available at* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited Mar. 20, 2017).

[47] Analysis by Senate Health Policy committee staff of s*upra* note 49.

[48] *Supra* note 49.

[49] 21 U.S.C. s. 812. Note: On August 11, 2016, the Federal Drug Enforcement Administration refused two petitions to reschedule marijuana under the Controlled Substances Act, see https://www.dea.gov/divisions/hq/2016/hq081116.shtml, (last visited on Mar. 20, 2017).

[50] The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* 21 U.S.C ss. 841-865.

offenses that impose draconian mandatory minimum sentences… [and] would instead receive sentences better suited to their individual conduct…"[51] Further, the USDOJ issued a memorandum clarifying that the department considers small-scale marijuana use to be a state matter which states may choose to punish and certain operations adhering to state laws legalizing marijuana in conjunction with robust state regulatory systems would be far less likely to come under federal scrutiny.[52] In addition, a rider in recent appropriations acts and continuing resolutions has prohibited the USDOJ from using appropriated funds to prevent specified states (including Florida) from implementing the states own medical marijuana laws.[53] It is worth noting that, with the election of President Trump and changes to the leadership of the USDOJ, the guidance issued by the USDOJ may be amended in the future; however, it would require an act of Congress to amend the rider preventing the USDOJ from using funds to prevent specified states from implementing medical marijuana laws.

III. Effect of Proposed Changes:

In addition to technical and conforming changes made by the bill to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.441, CS/SB 406 amends s. 381.986, F.S., as follows:

Definitions

The bill:

- Adds the legislative intent:
  - To implement s. 29, Art. X of the State Constitution by creating a unified regulatory structure for the acquisition, cultivation, possession, processing, transfer, transportation, sale, distribution, and dispensing of marijuana, marijuana products, related supplies, and educational materials;
  - That all rules adopted by the DOH to implement the section be adopted pursuant to ch. 120, F.S., and that the DOH may use emergency rulemaking procedures to adopt rules if necessary to meet any rulemaking deadlines established in s. 29, Art. X of the State Constitution; and
  - That all registrations (for MMTC activities) be issued solely in accordance with the requirements of this section and rules adopted under the section.
- Conforms the definitions for "caregiver," "debilitating medical condition," "marijuana," "medical marijuana treatment center" or "MMTC," to the definitions in article X section 29 of the State Constitution.
- Uses the constitutional definition for "medical use" but amends the definition to restrict:
  - Smoking;

[51] USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, (Aug. 2013), p. 3, *available at* http://www.justice.gov/ag/smart-on-crime.pdf (last visited on Mar. 20, 2017).
[52] USDOJ Memorandum for all U.S. Attorneys from James M. Cole, Deputy Attorney General, *Guidance Regarding Marijuana Enforcement* (August 29, 2013), *available at* http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf (last visited Mar. 20, 2017).
[53] *See* Pub. Law No. 114-113, s. 542 (Consolidated Appropriations Act, 2016). A recent court order by the U.S. District Court for the Northern District of California recently held that a similar provision in the previous appropriations act (s. 538, Pub. L. No. 113-235) does not prohibit the USDOJ from enforcing violations of *federal* marijuana laws by individuals or businesses who are complying with state medical marijuana laws. U.S. v. Marin Alliance for Medical Marijuana and Shaw, Order re: Motion to Dissolve Permanent Injunction, No. C 98-00086 CB, (Oct. 19, 2015), available at http://www.scribd.com/doc/286089509/US-vs-Marin-Alliance-for-Medical-Marijuana#scribd (last visited Mar. 20, 2017).

  - The possession, use, or administration of marijuana not purchased from an MMTC;
  - The transfer of marijuana to anyone other than a qualifying patient or his or her caregiver;
  - The use or administration of any type or amount of marijuana not specified on a qualifying patient's physician certification; and
  - The use or administration of marijuana:
    - On any form of public transportation;
    - In any public place;
    - In a qualifying patient's place of employment if restricted by his or her employer;
    - In a state correctional institution;
    - On the grounds of a preschool, primary school, or secondary school; or
    - On a school bus or in a vehicle, aircraft, or motorboat.
- Uses the constitutional definition for "qualifying patient" but also includes "eligible patients" as defined in the Right to Try Act, patients suffering from a physical medical condition that produces symptoms of seizures or severe and persistent muscle spasms, and patients suffering from chronic nonmalignant pain.
- Adds definitions for:
  - "Chronic nonmalignant pain" meaning pain that is caused by a debilitating medical condition or that originates from a debilitating medical condition and persists beyond the usual course of that debilitating medical condition; and
  - "Close relative" meaning a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half-blood, by marriage, or by adoption.

Physician Certifications

The bill allows physicians to issue physician certifications to:
- A patient suffering from a debilitating medical condition;
- A patient suffering from a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms;
  - Such patients may only receive low-THC cannabis if the patient does not meet any of the other qualifications;
- A patient suffering from chronic nonmalignant pain, if the physician has diagnosed an underlying debilitating medical condition as the cause of the pain, which allows the patient to receive marijuana for the patient's medical use to alleviate the patient's pain; or
- An eligible patient as defined in the Right to Try Act.
- A patient who is not a Florida resident and who qualifies under one of the above listed conditions and who can lawfully receive marijuana in the state that he or she resides in.

Before certifying a patient the physician must:
- Be licensed under chs. 458 or 459, F.S.;
- Have successfully completed the required 4-hour course and exam administered by the Florida Medical Association or the Florida Osteopathic Medical Association;[54]
- Have conducted a full assessment of the patient's medical history;

[54] Current law requires an 8-hour course and exam which must be retaken annually.

- Have determined that, in the physician's professional opinion, the patient meets one of the criteria specified above;
- Have determined that the medical use of marijuana would likely outweigh the potential health risks to the patient; and
- Have obtained the voluntary written informed consent of the patient or, if the patient is a minor, the patient's parent or legal guardian, after having sufficiently explained the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with marijuana and the potential risks and side effects.[55]

For patients under the age of 18, a second physician must concur with the treating physician's determination that the medical use of marijuana would likely outweigh the health risks for the patient. Additionally, patients under the age of 18 are restricted from purchasing marijuana and are required to have a parent, legal guardian, caregiver, or health care provider assist them in purchasing and administering marijuana.

The physician must also register as the treating physician with the compassionate use registry and maintain a patient treatment plan that must be submitted to the University of Florida College of Pharmacy on a quarterly basis. The bill increases the amount of marijuana a physician may certify a patient to receive from a 45-day supply to a 90-day supply and allows a physician to certify a patient for longer than the 90-day period if the physician believes that the patient will use the additional marijuana in a medically appropriate way. Patients must be recertified at least annually. A physician may not issue physician certifications if he or she is a medical director employed by an MMTC.

The bill also grandfathers in all orders for low-THC cannabis issued prior to the effective date of the act as physician certifications and requires the DOH to consider patients with such orders as qualifying patients until the DOH begins issuing compassionate use registry identification cards.

Prohibited Acts

The bill:

- Conforms existing penalties to the changes made by the bill;
- Creates two new misdemeanors for a qualifying patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than an MMTC[56] and a caregiver who violates any of the applicable provisions of this section or applicable department rules;.[57]
- Specifies that an MMTC may not advertise services that it is not registered to provide; and
- Prohibits any person or entity from offering or advertising services as an MMTC without being registered as an MMTC. The bill establishes penalties for unlicensed activity including fines of up to $10,000 per day and that the DOH or any state attorney may bring action for an injunction of the activity until compliance has been established to the satisfaction of the DOH. The bill also allows the DOH to assess reasonable investigative and legal costs for a successful prosecution.

[55] If the patient is an eligible patient, the physician must obtain written informed consent pursuant to s. 499.0295, F.S.
[56] A first degree misdemeanor.
[57] A second degree misdemeanor on the first offense and a first degree misdemeanor on subsequent offenses.

Caregivers

The bill allows a qualifying patient to designate a caregiver to assist him or her with the medical use of marijuana. The bill requires the DOH to register a caregiver and issue him or her a compassionate use registry identification card if designated by a qualifying patient and the caregiver:

- Is 21 years of age or older, unless the patient is a close relative of the caregiver;
- Agrees in writing to be the qualifying patient's caregiver;
- Does not receive compensation, other than actual expenses incurred, for assisting the qualifying patient with the medical use of marijuana unless the caregiver is acting pursuant to employment in a licensed facility in accordance with subparagraph (c)2.; and
- Passes a Level 2 screening pursuant to ch. 435, F.S., unless the patient is a close relative of the caregiver.

A qualifying patient may only have one designated caregiver at a time unless all of the patient's caregivers are his or her close relatives or legal representatives. A caregiver may only assist one patient at a time unless:

- All qualifying patients the caregiver is assisting are close relatives of each other and the caregiver is the legal representative of at least one of the patients; or
- All qualifying patients the caregiver is assisting are receiving hospice services, or are residents, in the same assisted living facility, nursing home, or other licensed facility and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice or licensed facility; and the caregiver provides personal care or services directly to clients of the hospice or licensed facility as a part of his or her employment duties at the hospice or licensed facility.

Duties of the DOH

Compassionate Use Registry

The bill requires the DOH to expand access to the compassionate use registry to:

- Practitioners licensed under chs. 458 or 459, F.S., to ensure proper care for patients requesting physician certifications;
- Practitioners licensed to prescribe prescription drugs, to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana;

The bill specifies that law enforcement agencies may check the registry to verify the authorization of a qualifying patient or a patient's caregiver to possess marijuana or a cannabis delivery device.

Compassionate Use Registry Identification Cards

By July 3, 2017, the bill requires the DOH to adopt rules establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for patients and caregivers who are residents of this state. The bill allows the DOH to charge a reasonable fee for issuing and renewal of identification cards. The bill requires that the DOH begin issuing identification cards to patients and caregivers by October 3, 2017. Minor

patients must provide the DOH with written consent from a parent or a legal guardian before being issued an identification card. Identification cards may be issued to out-of-state patients after the DOH confirms they are able to receive marijuana legally in their state of residency through a medical marijuana program.

The bill specifies that the identification cards must be resistant to counterfeiting and tampering and at a minimum contain:

- The name, address, and date of birth of the patient or caregiver, as appropriate;
- A full-face, passport-type, color photograph of the patient or caregiver, as appropriate, taken within the 90 days immediately preceding registration;
- Designation of the cardholder as a patient or caregiver;
- A unique numeric identifier for the patient or caregiver which is matched to the identifier used for such person in the department's compassionate use registry. A caregiver's identification number and file in the compassionate use registry must be linked to the file of the patient or patients the caregiver is assisting so that the caregiver's status may be verified for each patient individually;
- The expiration date, which shall be 1 year after issuance or the date treatment ends as provided in the patient's physician certification, whichever occurs first; and
- For caregivers who are assisting three or fewer qualifying patients, the names and unique numeric identifiers of the qualifying patient or patients that the caregiver is assisting.

Dispensing Organization Grandfathering

The bill requires the DOH to grandfather in all existing DOs as MMTCs as soon as practicable.[58] The DOH may not charge the DOs a registration fee and the bill states that, for the purposes of the act, all DOs are deemed to be MMTCs on the effective date of the act. The bill requires that the DOs continue to comply with all representations made in their applications to be dispensing organizations after being registered as MMTCs and allows the DOH to grant variances to those representations.

Additional MMTCs

The bill requires that, by October 3, 2017, the DOH register five additional MMTCs with at least one applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999) or In re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) and a member of the Black Farmers and Agriculturalists Association. Additionally, within 6 months of each instance of the registration of 75,000 patients in the compassionate use registry, the DOH must register four additional MMTCs. The bill eliminates the requirement that MMTCs possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years. The bill requires that all applicants must be registered to do business in Florida for at least five continuous years prior to applying. The bill also restricts the DOH from issuing more than one MMTC registration to a person or entity.

[58] Including DOs that become MMTCs pursuant to the results of litigation (see present situation for details).

Independent Testing Laboratories

The bill authorizes the establishment of ITLs to collect and accept samples of, possess, store, transport, and test marijuana. All MMTCs are required to have their marijuana tested at an ITL to ensure that it meets DOH standards before it is dispensed. All ITLs must be licensed by the DOH except clinical laboratories licensed by the Agency for Health Care Administration (AHCA) which are exempt from this requirement. The DOH is required to adopt rules for ITL licensure requirements and a process for licensing ITLs including an application form, an initial application fee, and a biennial renewal fee.

In addition to licensure, the bill also requires that ITLs be certified by the DOH to perform all required tests. The DOH must issue a certification to an ITL that has been certified by a third-party laboratory certification body approved by the DOH. The DOH must adopt rules for certifying ITLs including rules for personnel qualifications, equipment and methodology, proficiency testing, tracking, sampling, chain of custody, record and sample retention, reporting, audit and inspection, and security.

The bill specifies that an ITL may only accept samples from a sample source approved by the DOH which, at a minimum, must include an MMTC, a researcher affiliated with an accredited university or research hospital, a qualifying patient, or a caregiver.

Quality Control Program

The bill requires the DOH to establish a marijuana quality control program that must require MMTCs to submit samples from each batch or lot of marijuana harvested or manufactured to an ITL to ensure that, at a minimum, labeling of the potency of THC and other marketed cannabinoids or terpenes is accurate and that it is safe for human consumption. The MMTC is required to maintain records of all tests conducted including the results and any other information required by the DOH. The DOH is required to adopt rules to create and oversee the program which must, at a minimum, include:

- Permissible levels of variation in potency labeling and standards requiring THC be consistently distributed throughout edible marijuana products;
- Permissible levels of contaminants and mandatory testing for contaminants including, but not limited to, testing for microbiological impurity, residual solvents, and pesticide residues;
- The destruction of marijuana determined to be inaccurately labeled or unsafe for human consumption after the MMTC has an opportunity to take remedial action;
- The collection storage, handling, recording, and destruction of samples of marijuana by ITLs; and
- Security, inventory tracking, and record retention.

The bill also requires the DOH to reduce or suspend any testing requirement in its quality control program if the number of licensed and certified ITLs is insufficient to process the tests necessary to meet patient demand.

Seed-to-Sale Tracking System

The bill requires the DOH to establish, maintain, and control a computer software tracking system that traces marijuana from seed to sale. The tracking system must allow real-time, 24-hour access by the DOH to data from all MMTCs and ITLs and must, at a minimum, include notification of when marijuana seeds are planted, when marijuana plants are harvested and destroyed, and when marijuana is transported, sold, stolen, diverted, or lost. Each MMTC must use the seed-to-sale tracking system selected by the DOH.

MMTC Requirements

The requirements for MMTCs are substantially similar to the requirements for DOs in current law. The bill amends requirements for MMTCs so that:

- MMTCs are required to maintain compliance with all the representations made to the DOH in the MMTC's application for registration.
  - Upon request, the department may grant an MMTC one or more variances from the representations made in the MMTC's application.
  - Consideration of such a variance shall be based upon the individual facts and circumstances surrounding the request.
  - A variance may not be granted unless the requesting MMTC can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application.
- MMTCs are required to label all marijuana with the concentration of THC and CBD in the product and with the recommended dose for the qualifying patient receiving it.
- MMTCs are allowed to produce edible products, but may not produce such items that are designed to be attractive to children. Additionally, MMTCs must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of THC in each serving.
- When transporting marijuana, a copy of the transportation manifest must be in the vehicle at all times.

The bill also requires the DOH to adopt in rule a process for approving MMTC changes in ownership and changes in an MMTC owner's investment interest.

Rulemaking

The bill requires the DOH to adopt emergency rules pursuant to s. 120.54(4), F.S., as necessary to implement the section. The bill states that if an emergency rule adopted under this section is voided due to being held unconstitutional or an invalid exercise of delegated legislative authority, the DOH and any applicable boards may adopt an emergency rule to replace the voided rule. However, if the second emergency rule is voided, the DOH and the applicable boards must adopt rules based on standard procedures.

The bill exempts emergency rules from the requirement to make findings pursuant to s. 120.54(4)(a), F.S.;[59] from ss. 120.54(3)(b),[60] 120.541,[61] and 120.54(4)(c), F.S.[62] The DOH and applicable boards must meet the procedural requirements in s. 120.54(2)(a), F.S.,[63] if the DOH or the applicable boards have, before the effective date of the act, held any public workshops or hearings on the subject matter of the emergency rules. Additionally, challenges to emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5), F.S.[64] Emergency rules adopted under this section remain in effect until they are replaced by rules adopted through normal procedures. The DOH must begin nonemergency rulemaking by January 1, 2018, and may no longer use emergency rulemaking procedures after that date (unless replacing emergency rules deemed invalid).

Miscellaneous Provisions

The bill:

- Specifies that nothing in the act limits the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy and that an employer is not required to accommodate the use of marijuana in the workplace or any employee working while under the influence of the marijuana.
- Specifies that nothing in the section creates a cause of action against an employer for wrongful discharge or discrimination.
- Creates an additional exemption from criminal penalties related to marijuana for research institutions established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute, and for state universities that have achieved preeminent state research university designation.[65]

The Medical Marijuana Research and Education Act

The bill also creates s. 1004.4351, F.S., to create the Medical Marijuana Research and Education Act. The act:

- Establishes the Coalition for Medicinal Cannabis Research and Education (Coalition) within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (MCCRI) and provides that the Coalition's purpose is to conduct rigorous scientific research, provide education, disseminate research, and to guide policy for the adoption of a statewide policy on ordering and dosing practices for the medicinal use of cannabis.
- Creates the Medicinal Cannabis Research and Education Board (Board) to direct the Coalition's operations. Additionally, the bill specifies Board membership requirements and requires the Board to:

[59] Section 120.54(a)3., F.S., requires the agency publishing emergency rules to also publish in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances.
[60] The requirement to prepare a statement of estimated regulatory cost (SERC) and to consider the impact of rules on small business, small counties, and small cities.
[61] Detailing the requirements of a SERC.
[62] Restricting an emergency rule from being effective for more than 90 days with some exceptions.
[63] Requiring notice of rule developement be published prior to filing for rule adoption.
[64] The DOAH has 7 days to assign an administrative law judge who must conduct the hearing within 14 total days (including the days used in assigning the judge). The judge then has 14 days after the hearing to render a decision.
[65] Pursuant to s. 1001.7065, F.S.

  - Advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medicinal cannabis research and education in Florida.
  - Explore methods of implementing and enforcing medicinal cannabis laws in relation to cancer control, research, treatment, and education.
  - Annually adopt a plan for medicinal cannabis research, known as the Medicinal Cannabis Research and Education Plan (Plan) in accordance with state law, and must include recommendations for the coordination and integration of medical, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions, research related to the treatment of such conditions, and education.
  - Issue an annual report, by February 15, to the Governor, the President of the Senate, and the Speaker of the House Representatives on research projects, community outreach initiatives, and future plans for the Coalition.
- Provides that the Coalition must be administered by a director who, subject to Board approval, must:
  - Propose a budget.
  - Foster the collaboration of scientists, researchers, and other appropriate personnel.
  - Identify and prioritize the Coalition's research.
  - Prepare the Plan for submission to the Board.
  - Apply for grants to obtain funding for the Coalition's research.
  - Perform other Board specified duties.
  - Requires the MCCRI to allocate staff, information, and assistance to assist the Board.

The bill's provisions take effect upon becoming law.

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:

Article X, section 29 of the State Constitution is a unique provision of the constitution in that it directs a state agency, the DOH, to implement its provisions without requiring implementing legislation. However, article X, section 29(4)(e) of the State Constitution, does provide that nothing in that section shall limit the Legislature from enacting laws consistent with the section. Given the novelty of the constitutional provision, it is unclear how the courts will interpret its provisions as well as the interaction between its provisions and implementing legislation and rules.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 406 may have a positive fiscal impact on new MMTCs that are registered under its provisions. The bill may have a negative fiscal impact on currently approved DOs due to the increase in number of allowed suppliers of marijuana once the compassionate use registry registers the specified number of patients.

The bill may have a negative fiscal impact on patients and caregivers who are required to pay fees for identification cards and on caregivers who are required to pay for background screenings.

C. Government Sector Impact:

The bill may have an indeterminate fiscal impact on the DOH due to increased regulatory activity required by the bill. However, any expenditures required may be offset by fees and fines the DOH is allowed to assess. The DOH estimates that fees and fines may generate between $6.1 million and $8.6 million while total expenditures may be between $6 million and $8.9 million.[66]

The Florida Department of Law Enforcement (FDLE) estimates that revenues from SB 406 to the FDLE may range from $9 million to $18 million generated by fees for criminal history records checks.[67] The FDLE estimates that costs to the DOH at $1.278 million.

The bill may have a positive fiscal impact on the state as a whole due to an increase in general revenue generated by the collection of sales tax assessed on the sale of marijuana.[68]

The bill may have an indeterminate fiscal impact on local governments. Local governments may see a positive fiscal impact from fees associated with licensing and inspecting additional MMTC facilities as permitted by current law and may derive additional tax revenue from the sale of marijuana. Local governments may see a negative fiscal impact due to the expenses associated with implementing ordinances and undertaking regulatory activities required by such ordinances.

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[66] The DOH states that expenditures are highly dependent on the number of qualifying patients. See DOH, *Senate Bill 406 Analysis* (Feb. 14, 2017) (on file with the Senate Committee on Health Policy).
[67] The fee depends on whether or not caregivers are intended to be entered into the clearinghouse. See FDLE, *Senate Bill 406 Analysis* (Feb. 15, 2017) (on file with the Senate Committee on Health Policy).
[68] See supra note 36.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Although the bill allows MMTCs to use contractors in general, it is unclear from the text of the bill what limits are placed on how an MMTC may use a contractor. The bill should be clarified to specify the duties a contractor may perform for an MMTC.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.987, 385.211, 499.0295, and 1004.441.

The bill creates section 1004.4351 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on April 3, 2017:
The CS amends SB 406 to:

- Add legislative intent.
- Reinstate the requirement that a second physician confirm a diagnosis when certifying a person under the age of 18 and require a parent, legal guardian, caregiver, or health care provider to purchase marijuana for qualifying patients under the age of 18.
- Allow a physician to certify out of state patients that meet Florida requirements for treatment with marijuana.
- Allow a physician to certify a patient for greater than a 90 day supply if the physician believes the patient will use the marijuana appropriately.
- Specify that MMTCs may not advertise services that they are not registered to provide.
- Prohibit any person or entity from offering or advertising services as an MMTC without being registered as an MMTC and provide penalties for unlicensed activity.
- Require the DOH to register five additional MMTCs by October 3, 2017, including one that is a member of the Black Farmers and Agriculturalists Association.
- Require the Department of Health to add four new MMTCs within 6 months after the registration of each instance of 75,000 patients in the Compassionate Use Registry.
- Require that all applicants be registered to do business in Florida for at least five consecutive years prior to submitting their application.
- Prohibit any person or entity from being issued more than one MMTC registration;
- Require the DOH to license ITLs (clinical laboratories licensed by the AHCA are exempt from this requirement). ITLs must also be certified by the DOH to perform all required tests. The DOH must certify an ITL that has third party accreditation from an

accrediting body approved by the DOH. The DOH must adopt rules for licensure and certification of ITLs.

- Require the DOH to establish a quality control program for the testing of marijuana. The program must require MMTCs to submit samples of marijuana to an ITL to ensure minimum standards are met. The DOH must adopt rules to create and oversee the program.
- Require the DOH to establish, maintain, and control a seed-to-sale tracking system;
- Authorize an employer to deny accommodation for the ingestion of marijuana in the workplace or for any employee working while under the influence of marijuana;
- Specify that the section does not create a cause of action for wrongful discharge or discrimination.
- Incorporate an exemption from criminal laws for research institutions performing research on marijuana.
- Require the DOH to abide by the provisions of ch. 120, F.S., when adopting rules to implement this section and allows the department to use emergency rulemaking procedures.
- Establish the "Medical Marijuana Research and Education Act" to:
  - Create the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
  - Task the coalition with conducting rigorous scientific research, providing education, disseminating research, and guiding policy for the adoption of a statewide policy on ordering and dosing practices for medical marijuana;
  - Specify the make-up of the coalition including the duties of the director of the coalition;
  - Require the coalition to annually adopt a research plan; and
  - Require the coalition to annually report to the Governor and the Legislature on research projects, community outreach, and future plans.

B. Amendments:

None.

941824

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Between lines 66 and 67
insert:

(1) LEGISLATIVE INTENT.—

(a) It is the intent of the Legislature to implement s. 29, Art. X of the State Constitution by creating a unified regulatory structure within the framework of this section for the acquisition, cultivation, possession, processing, transfer, transportation, sale, distribution, and dispensing of marijuana,

941824

products containing marijuana, related supplies, and educational materials to qualifying patients or their caregivers.

(b) The Legislature intends that all rules adopted by the Department of Health to implement this section be adopted pursuant to s. 120.536(1) or s. 120.54. The Legislature intends that the department use emergency rulemaking procedures pursuant to s. 120.54(4) to adopt rules under this section if necessary to meet any deadline for rulemaking established in s. 29, Art. X of the State Constitution.

(c) Further, the Legislature intends that all registrations for the purposes specified in paragraph (a) be issued solely in accordance with the requirements of this section and all rules adopted under this section.

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

And the title is amended as follows:

Between lines 3 and 4

insert:

providing legislative intent;

882270

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment

Between lines 180 and 181
insert:
5. A patient who is not a resident of this state; who qualifies under subparagraph 1., subparagraph 2., subparagraph 3., or subparagraph 4.; and who can lawfully obtain marijuana through a medical marijuana program in the state that he or she resides in.

758850

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 203 - 215

and insert:

~~reasonable in light of the potential benefit to~~ the patient. If a patient is younger than 18 years of age:~~,~~

a. A second physician must concur with this determination, and such determination must be documented in the patient's medical record;

b. Only a parent, legal guardian, caregiver, or health care

758850

provider may assist the qualifying patient in the purchasing and administering of marijuana for medical use; and

c. The qualifying patient may not purchase marijuana.

6.~~(c)~~ Registers as the patient's physician ~~orderer of low-THC cannabis or medical cannabis for the named patient~~ on the compassionate use registry maintained by the department and updates the registry to reflect ~~the contents of the order, including~~ the amount of marijuana ~~low-THC cannabis or medical cannabis~~ that will provide the patient with not more than a 90-day ~~45-day~~ supply and a cannabis delivery device needed by the patient for the medical use of marijuana ~~low-THC cannabis or medical cannabis~~. A physician may certify an amount greater than a 90-day supply of marijuana if the physician has a reasonable belief that the patient will use the additional marijuana in a medically appropriate way. If the physician's recommended amount of

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

And the title is amended as follows:

Delete line 10

and insert:

determinations in physician certifications; specifying certain persons who may assist a qualifying patient under the age of 18 in the purchasing and administering of marijuana; prohibiting qualifying patients under the age of 18 from purchasing marijuana; providing that a physician may in certain circumstances certify an amount greater than a 90-day supply; requiring

601680

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 263 - 318
and insert:
(3) PROHIBITED ACTS ~~PENALTIES~~.—
(a) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician issues a physician certification for marijuana to ~~orders low-THC cannabis for~~ a patient in a manner other than as required in subsection (2) ~~without a reasonable belief that the~~


601680

~~patient is suffering from:~~

~~1. Cancer or A physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or~~

~~2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis~~.

~~(b) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition as defined in s. 499.0295.~~

(b) ~~(c)~~ A person who fraudulently represents that he or she has a debilitating medical condition ~~cancer~~, a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, chronic nonmalignant pain, or a terminal condition as defined in s. 499.0295 to a physician for the purpose of being issued a physician certification for marijuana ~~ordered low-THC cannabis, medical cannabis,~~ or a cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) ~~(d)~~ A qualifying patient ~~an eligible patient as defined in s. 499.0295~~ who uses marijuana ~~medical cannabis~~, and such patient's caregiver ~~legal representative~~ who administers marijuana ~~medical cannabis~~, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat, commits a

misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(d) A qualifying patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than an MMTC commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(e) A caregiver who violates any of the applicable provisions of this section or applicable department rules commits, upon the first offense, a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083 and, upon the second and subsequent offenses, a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(f) ~~(e)~~ A physician who issues a physician certification for marijuana ~~orders low-THC cannabis, medical cannabis,~~ or a cannabis delivery device and receives compensation from an MMTC ~~a dispensing organization~~ related to issuing the physician certification for marijuana ~~the ordering of low-THC cannabis, medical cannabis,~~ or a cannabis delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(g) An MMTC that advertises or holds out to the public that it may provide services other than services for which it is registered to provide violates this section, and the department may impose a fine on the MMTC pursuant to paragraph (8)(g).

(h) A person or entity that offers or advertises services as an MMTC without registering as an MMTC with the department violates this section. The operation or maintenance of a facility as an MMTC, or the performance of a service that


601680

requires registration, without proper registration is a violation of this section.

1. If after receiving notification from the department, such person or entity fails to cease operation, the department may impose an administrative fine of up to $10,000 per violation. Each day of continued operation is a separate offense.

2. The department or any state attorney may, in addition to other remedies provided in this section, bring an action for an injunction to restrain any unauthorized activity or to enjoin the future operation or maintenance of the unauthorized dispensing organization or entity or the performance of any service in violation of this section until compliance with this section and department rules has been demonstrated to the satisfaction of the department.

3. If found to be in violation of this paragraph, the department may assess reasonable investigative and legal costs for prosecution of the violation against the person or entity.

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

And the title is amended as follows:

Delete line 15

and insert:

revising criminal penalties; prohibiting a medical marijuana treatment center from advertising services it is not authorized to provide; providing fines; prohibiting a person or entity from advertising or providing medical marijuana treatment center services without being registered with the department as a

601680

medical marijuana treatment center; providing penalties; authorizing a distance

185250

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/04/2017	.	
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The Committee on Health Policy (Powell) recommended the following:

Senate Amendment

Delete lines 301 - 302
and insert:
marijuana commits a misdemeanor of the first

415864

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment

Delete lines 433 - 443

and insert:

caregivers. The department may charge a reasonable fee associated with the issuance and renewal of patient and caregiver identification cards. By October 3, 2017, the department shall begin issuing identification cards to adult patients who have a physician certification that meets the requirements of subsection (2); minor patients who have a

415864

physician certification that meets the requirements of subsection (2) and the written consent of a parent or legal guardian; and caregivers registered pursuant to subsection (5). In addition to the other requirements of this section, the department may issue a compassionate use registry identification card to a patient who is not a resident of this state only after the department has verified that the patient can lawfully obtain marijuana through a medical marijuana program in the state that he or she resides in. Patient and caregiver identification cards must

905618

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment

Delete lines 502 - 522
and insert:
(d) By October 3, 2017, register five additional MMTCs with at least one of the MMTCs being an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association.

905618

(e) Within 6 months after each instance of the registration of 75,000 qualifying patients with the compassionate use registry, register four additional MMTCs if a sufficient number of MMTC applicants meet the registration requirements established in this section and by department rule.

(f) Not issue more than one registration as an MMTC to a person or an entity.

(g) ~~The department shall~~ Develop an application form for registration as an MMTC and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. To be registered as an MMTC, the ~~an~~ applicant ~~for approval as a dispensing organization~~ must be able to demonstrate:

1. That the applicant has been registered to do business in this state for the previous 5 consecutive years before submitting the application.

533696

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/04/2017	.	
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The Committee on Health Policy (Young) recommended the following:

Senate Amendment to Amendment (905618)

Delete lines 5 - 10
and insert:
(d) By October 3, 2017:
1. Register all applicants that were denied dispensing organization licenses by the department under former s. 381.986(1)(a), Florida Statutes 2014, if:
a. The applicant filed a petition for an administrative hearing or appeal to challenge the department's denial of its

533696

application on or before March 1, 2017;

b. The applicant's petition was pending as of March 1, 2017; and

c. The applicant meets the requirements of this section.

For purposes of the requirement that an MMTC comply with the representations made in its application pursuant to subsection (7), an MMTC registered pursuant to this subparagraph shall continue to comply with the representations made in its application for approval as a dispensing organization, including any revision authorized by the department before the effective date of this act. After the effective date of this act, the department may grant variances from the representations made in a dispensing organization’s application for approval pursuant to subsection (7).

2. Register five additional MMTCs with at least one of the MMTCs being an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association.

737584

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/04/2017	.	
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The Committee on Health Policy (Powell) recommended the following:

Senate Amendment (with title amendment)

Between lines 573 and 574
insert:
(h) Meet the minority business enterprise procurement goals set forth in s. 287.042 in the procurement of commodities, contractual services, other services, and vendors in the administration of activities under this section. The goal for minority business enterprise participation in MMTC operations and subcontracting, as defined in s. 288.703(3) is 10 percent;

737584

however, no more than 35 percent of such minority business enterprises may be owned by any one of the minority persons specified in s. 288.703(4)(a)-(e), respectively.

1. This paragraph does not preclude or prohibit a minority person from competing for any MMTC registration or any other procurement of goods or services awarded by the department.

2. MMTCs have 12 months from the date of their registration to demonstrate to the department compliance with the minority business participation goal established in this paragraph.

(i) Implement training programs and other educational programs to enable minority persons to compete for MMTC registration and contracts on an equal basis.

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

And the title is amended as follows:

Between lines 39 and 40

insert:

requiring the department to meet a specified minority business enterprise procurement goal; requiring medical marijuana treatment centers to demonstrate to the department its compliance with the goal; requiring the department to implement training programs and other educational programs for minority business enterprises to enable them to compete for medical marijuana treatment center registration and contracts;

393994

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 616 - 775

and insert:

2. Have the marijuana tested by an independent testing laboratory to ensure it meets the standards established by the department's quality control program ~~Test the processed low-THC cannabis and medical cannabis~~ before it is ~~they are~~ dispensed. ~~Results must be verified and signed by two dispensing organization employees. Before dispensing low-THC cannabis, the~~

393994

~~dispensing organization must determine that the test results indicate that the low-THC cannabis meets the definition of low-THC cannabis and, for medical cannabis and low-THC cannabis, that all medical cannabis and low-THC cannabis is safe for human consumption and free from contaminants that are unsafe for human consumption. The dispensing organization must retain records of all testing and samples of each homogenous batch of cannabis and low-THC cannabis for at least 9 months. The dispensing organization must contract with an independent testing laboratory to perform audits on the dispensing organization's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the low-THC cannabis or medical cannabis meets the requirements of this section and that the medical cannabis and low-THC cannabis is safe for human consumption.~~

3. Package the marijuana ~~low-THC cannabis or medical cannabis~~ in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

4. Package the marijuana ~~low-THC cannabis or medical cannabis~~ in a child-proof receptacle that has a firmly affixed and legible label stating the following information:

a. A statement that the marijuana ~~low-THC cannabis or medical cannabis~~ meets the requirements of subparagraph 2.;

b. The name of the MMTC ~~dispensing organization~~ from which the marijuana ~~medical cannabis or low-THC cannabis~~ originates; ~~and~~

c. The batch number and harvest number from which the marijuana ~~medical cannabis or low-THC cannabis~~ originates; and

d. The concentration of tetrahydrocannabinol and

393994

cannabidiol in the product.

e. Any other information required by department rule

~~5. Reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of testing pursuant to the audit required under subparagraph 2~~.

(c) When dispensing marijuana ~~low-THC cannabis, medical cannabis,~~ or a marijuana ~~cannabis~~ delivery device, an MMTC ~~a dispensing organization~~:

1. May not dispense more than the ~~a 45-day~~ supply of marijuana authorized by a qualifying patient's physician certification ~~low-THC cannabis or medical cannabis~~ to a qualifying patient or caregiver ~~the patient's legal representative~~.

2. Must ensure its ~~have the dispensing organization's~~ employee who dispenses the marijuana ~~low-THC cannabis, medical cannabis,~~ or marijuana ~~a cannabis~~ delivery device enters ~~enter~~ into the compassionate use registry his or her name or unique employee identifier.

3. Must verify that the qualifying patient and the caregiver, if applicable, both have an active and valid compassionate use registry identification card and that the amount and type of marijuana dispensed matches the physician's certification in the compassionate use registry for that qualifying patient ~~that a physician has ordered the low-THC cannabis, medical cannabis, or a specific type of a cannabis delivery device for the patient~~.

4. Must label the marijuana with the recommended dose for the qualifying patient receiving the marijuana.

5.~~4.~~ May not dispense or sell any other type of marijuana

393994

~~cannabis~~, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a ~~physician-ordered~~ cannabis delivery device required for the medical use of marijuana that is specified in a physician certification ~~low-THC cannabis or medical cannabis, while dispensing low-THC cannabis or medical cannabis~~. A registered MMTC may produce and dispense marijuana as an edible or food product but may not produce such items in a format designed to be attractive to children. In addition to the requirements of this section and department rule, food products produced by an MMTC must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of THC in each serving.

~~5. Must verify that the patient has an active registration in the compassionate use registry, the patient or patient's legal representative holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.~~

6. Must, upon dispensing the marijuana ~~low-THC cannabis, medical cannabis,~~ or marijuana ~~cannabis~~ delivery device, record in the registry the date, time, quantity, and form of marijuana ~~low-THC cannabis or medical cannabis~~ dispensed; ~~and~~ the type of marijuana ~~cannabis~~ delivery device dispensed; and the name and compassionate use registry identification number of the qualifying patient or caregiver to whom the marijuana delivery device was dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of marijuana

393994

~~low-THC cannabis, medical cannabis,~~ or marijuana ~~cannabis~~ delivery devices, an MMTC ~~a dispensing organization~~ shall:

1.a. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms; or

b. Maintain a video surveillance system that records continuously 24 hours each day and meets at least one of the following criteria:

(I) Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms;

(II) Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points;

(III) Recorded images must clearly and accurately display the time and date; or

(IV) Retain video surveillance recordings for a minimum of 45 days, or longer upon the request of a law enforcement agency.

2. Ensure that the MMTC's ~~organization's~~ outdoor premises have sufficient lighting from dusk until dawn.

3. Implement ~~Establish and maintain~~ a tracking system using a vendor approved by the department which ~~that~~ traces the marijuana ~~low-THC cannabis or medical cannabis~~ from seed to sale. The tracking system must ~~shall~~ include notification of key events as determined by the department, including when cannabis seeds are planted, when cannabis plants are harvested and

393994

destroyed, and when marijuana ~~low-THC cannabis or medical cannabis~~ is transported, sold, stolen, diverted, or lost.

4. Not dispense from its premises marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver marijuana ~~low-THC cannabis and medical cannabis~~ to qualifying ~~qualified~~ patients 24 hours each day.

5. Store marijuana ~~low-THC cannabis or medical cannabis~~ in a secured, locked room or a vault.

6. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the premises at all times.

7. Require each employee or contractor to wear a photo identification badge at all times while on the premises.

8. Require each visitor to wear a visitor's pass at all times while on the premises.

9. Implement an alcohol and drug-free workplace policy.

10. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of marijuana ~~low-THC cannabis or medical cannabis~~.

(e) To ensure the safe transport of marijuana ~~low-THC cannabis or medical cannabis~~ to MMTC ~~dispensing organization~~ facilities, independent testing laboratories, or qualifying patients, the MMTC ~~dispensing organization~~ must:

1. Maintain a transportation manifest, which must be retained for at least 1 year. A copy of the manifest must be in the vehicle at all times when transporting marijuana.

2. Ensure only vehicles in good working order are used to

393994

transport marijuana ~~low-THC cannabis or medical cannabis~~.

3. Lock marijuana ~~low-THC cannabis or medical cannabis~~ in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting marijuana ~~low-THC cannabis or medical cannabis~~, and require at least one person to remain in the vehicle while the marijuana ~~low-THC cannabis or medical cannabis~~ is being delivered.

5. Provide specific safety and security training to employees transporting or delivering marijuana ~~low-THC cannabis or medical cannabis~~.

(8) MARIJUANA QUALITY CONTROL PROGRAM AND INDEPENDENT TESTING LABORATORY LICENSURE.—

(a) The department shall establish a quality control program requiring marijuana to be tested by an independent testing laboratory for potency and contaminants before sale to qualifying patients and caregivers.

1. The quality control program must require MMTCs to submit samples from each batch or lot of marijuana harvested or manufactured to an independent testing laboratory for testing to ensure, at a minimum, that the labeling of the potency of tetrahydrocannabinol and all other marketed cannabinoids or terpenes is accurate and that the medical cannabis dispensed to qualifying patients is safe for human consumption.

2. An MMTC must maintain records of all tests conducted, including the results of each test and any additional information, as required by the department.

3. The department shall adopt all rules necessary to create and oversee the quality control program, which must include, at

393994

a minimum:

a. Permissible levels of variation in potency labeling and standards requiring tetrahydrocannabinol in edible marijuana products to be distributed consistently throughout the product;

b. Permissible levels of contaminants and mandatory testing for contaminants to confirm that the tested marijuana is safe for human consumption. This testing must include, but is not limited to, testing for microbiological impurity, residual solvents, and pesticide residues;

c. The destruction of medical cannabis determined to be inaccurately labeled or unsafe for human consumption after the MMTC has an opportunity to take remedial action;

d. The collection, storage, handling, recording, and destruction of samples of marijuana by independent testing laboratories; and

e. Security, inventory tracking, and record retention.

(b) The department must license all independent testing laboratories to ensure that all marijuana is tested for potency and contaminants in accordance with the department's quality control program. An independent testing laboratory may collect and accept samples of, and possess, store, transport, and test marijuana. An independent testing laboratory may not be owned by a person who also possesses an ownership interest in an MMTC. A clinical laboratory licensed by the agency pursuant to Part I of chapter 483 and that performs non-waived clinical tests is exempt from the requirement to be licensed by the department pursuant to this paragraph but must be certified to perform all required tests pursuant to subparagraph 2.

1. The department shall develop rules establishing

393994

independent testing laboratory license requirements and a process for licensing independent testing laboratories; develop an application form for an independent testing laboratory license; and impose an initial application fee and a biennial renewal fee sufficient to cover the costs of administering this subsection.

2. In addition to licensure, an independent testing laboratory must be certified to perform all required tests by the department. The department must issue a certification to an independent testing laboratory that has been certified by a third-party laboratory certification body approved by the department. The department shall establish reasonable rules for the certification and operation of independent testing laboratories. Rules for certification must, at a minimum, address standards relating to:

a. Personnel qualifications;

b. Equipment and methodology;

c. Proficiency testing;

d. Tracking;

e. Sampling;

f. Chain of custody;

g. Record and sample retention;

h. Reporting;

i. Audit and inspection; and

j. Security.

3. The department shall suspend or reduce any mandatory testing requirement specified in its quality control program if the number of licensed and certified independent testing laboratories is insufficient to process the tests necessary to

393994

meet the patient demand for MMTCs.

4. An independent testing laboratory may accept only samples composed of marijuana which are obtained from a sample source approved by the department. At a minimum, these sources must include an MMTC, a researcher affiliated with an accredited university or research hospital, a qualifying patient, and a caregiver.

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

And the title is amended as follows:

Delete line 53

and insert:

times; requiring the department to establish a quality control program that requires medical marijuana treatment centers to submit samples from each batch or lot of marijuana to an independent testing laboratory; requiring a medical marijuana treatment center to maintain records of all tests conducted; requiring the department to adopt rules to create and oversee the quality control program; providing that the department must license independent testing laboratories; authorizing an independent testing laboratory to collect and accept samples of, possess, store, transport, and test marijuana; prohibiting a person with an ownership interest in a medical marijuana treatment center from owning an independent testing laboratory; requiring the department to develop rules and a process for licensing requirements; authorizing the department to impose application and renewal fees;

393994

specifying that an independent testing laboratory must be certified to perform required tests; requiring the department to suspend or reduce any mandatory testing if the number of licensed and certified independent testing laboratories is insufficient to process the tests necessary to meet the patient demand for medical marijuana treatment centers; providing that an independent testing laboratory may only accept certain samples; requiring the department to adopt rules related

868112

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Between lines 797 and 798
insert:

(e) The department shall establish, maintain, and control a computer software tracking system that traces marijuana from seed to sale and allows real-time, 24-hour access by the department to data from all MMTCs and independent testing laboratories. The tracking system must, at a minimum, include notification of when marijuana seeds are planted, when marijuana

868112

plants are harvested and destroyed, and when marijuana is transported, sold, stolen, diverted, or lost. Each MMTC shall use the seed-to-sale tracking system selected by the department.

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

And the title is amended as follows:

Delete line 55

and insert:

investment interest; requiring the department to establish, maintain, and control a seed-to-sale tracking system for marijuana; providing applicability;

633022

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
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The Committee on Health Policy (Bradley) recommended the following:

Senate Amendment (with title amendment)

Between lines 952 and 953
insert:

(h) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a research institute established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute established under s. 1004.43, or a state university that has achieved the

633022

preeminent state research university designation pursuant to s. 1001.7065 may possess, test, transport, and lawfully dispose of marijuana for research purposes as provided by department rule.

(11) RULEMAKING.-

(a) The department and the applicable boards shall adopt emergency rules pursuant to s. 120.54(4) and this subsection necessary to implement this section. If an emergency rule adopted under this subsection is held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department and the applicable boards may adopt an emergency rule to replace the rule that has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an invalid exercise of delegated legislative authority and becomes void, the department and the applicable boards must follow the nonemergency rulemaking procedures of the Administrative Procedures Act to replace the rule that has become void.

(b) For emergency rules adopted under this subsection, the department and the applicable boards need not make the findings required by s. 120.54(4)(a). Emergency rules adopted under this subsection are exempt from ss. 120.54(3)(b) and 120.541. The department and the applicable boards shall meet the procedural requirements in s. 120.54(2)(a) if the department or the applicable boards have, before the effective date of this act, held any public workshops or hearings on the subject matter of the emergency rules adopted under this subsection. Challenges to emergency rules adopted under this subsection shall be subject to the time schedules provided in s. 120.56(5).

(c) Emergency rules adopted under this section are exempt

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from s. 120.54(4)(c) and shall remain in effect until replaced by rules adopted under the nonemergency rulemaking procedures of the Administrative Procedures Act. By January 1, 2018, the department and the applicable boards shall initiate nonemergency rulemaking pursuant to the Administrative Procedures Act by publishing a notice of rule development in the Florida Administrative Register. Except as provided in paragraph (a), after January 1, 2018, the department and applicable boards may not adopt rules pursuant to the emergency rulemaking procedures provided in this subsection.

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

And the title is amended as follows:

Between lines 56 and 57

insert:

providing that certain research institutions may possess, test, transport, and dispose of marijuana subject to certain conditions and as provided by department rule; providing for the use of emergency rulemaking procedures by the department;

731400

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
	.	
	.	
	.	

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

Senate Amendment

Delete line 952
and insert:
or substance abuse policy. Notwithstanding any other provision of law, this section does not require an employer to accommodate the ingestion of marijuana in any workplace or any employee working while under the influence of marijuana. Notwithstanding any other provision of law, this section does not create a cause of action against an employer for wrongful discharge or

731400

discrimination.

248940

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Between lines 1011 and 1012
insert:

Section 5. Section 1004.4351, Florida Statutes, is created to read:

1004.4351 Medical marijuana research and education.—

(1) SHORT TITLE.—This section shall be known and may be cited as the "Medical Marijuana Research and Education Act."

(2) LEGISLATIVE INTENT.—The Legislature finds that:

(a) The present state of knowledge concerning the use of marijuana to alleviate pain and treat illnesses is limited because permission to perform clinical studies on marijuana is difficult to obtain, with access to research-grade marijuana so restricted that little or no unbiased studies have been performed.

(b) Under the State Constitution, marijuana is available for the treatment of certain debilitating medical conditions.

(c) Additional clinical studies are needed to ensure that the residents of this state obtain the correct dosing, formulation, route, modality, frequency, quantity, and quality of marijuana for specific illnesses.

(d) An effective medical marijuana research and education program would mobilize the scientific, educational, and medical resources that presently exist in this state to determine the appropriate and best use of marijuana to treat illness.

(3) DEFINITIONS.—As used in this section, unless the context clearly indicates otherwise, the term:

(a) "Board" means the Medical Marijuana Research and Education Board.

(b) "Coalition" means the Coalition for Medical Marijuana Research and Education.

(c) "Marijuana"" has the same meaning as provided in s. 29, Art. X of the State Constitution.

(4) COALITION FOR MEDICAL MARIJUANA RESEARCH AND EDUCATION.—

(a) There is established within the H. Lee Moffitt Cancer Center and Research Institute, Inc., the Coalition for Medical Marijuana Research and Education. The purpose of the coalition

is to conduct rigorous scientific research, provide education, disseminate research, and to guide policy for the adoption of a statewide policy on ordering and dosing practices for the medicinal use of marijuana. The coalition shall be physically located at the H. Lee Moffitt Cancer Center and Research Institute, Inc.

(b) The Medical Marijuana Research and Education Board is established to direct the operations of the coalition. The board shall be composed of seven members appointed by the chief executive officer of the H. Lee Moffitt Cancer Center and Research Institute, Inc. Board members must have experience in a variety of scientific and medical fields, including, but not limited to, oncology, neurology, psychology, pediatrics, nutrition, and addiction. Members shall be appointed to 4-year terms and may be reappointed to serve additional terms. The chair shall be elected by the board from among its members to serve a 2-year term. The board shall meet no less than semiannually, at the call of the chair or, in his or her absence or incapacity, the vice chair. Four members constitute a quorum. A majority vote of the members present is required for all actions of the board. The board may prescribe, amend, and repeal a charter governing the manner in which it conducts its business. A board member shall serve without compensation but is entitled to be reimbursed for travel expenses by the coalition or the organization he or she represents in accordance with s. 112.061.

(c) The coalition shall be administered by a coalition director who shall be appointed by and serve at the pleasure of the board. The coalition director shall, subject to the approval

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of the board:

1. Propose a budget for the coalition.

2. Foster the collaboration of scientists, researchers, and other appropriate personnel in accordance with the coalition's charter.

3. Identify and prioritize the research to be conducted by the coalition.

4. Prepare the Medical Marijuana Research and Education Plan for submission to the board.

5. Apply for grants to obtain funding for research conducted by the coalition.

6. Perform other duties as determined by the board.

(d) The board shall advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medical marijuana research and education in this state. The board shall explore methods of implementing and enforcing medical marijuana laws in relation to cancer control, research, treatment, and education.

(e) The board shall annually adopt a plan for medical marijuana research, known as the "Medical Marijuana Research and Education Plan," which must be in accordance with state law and coordinate with existing programs in this state. The plan must include recommendations for the coordination and integration of medical, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions, research related to the treatment of such medical conditions, and education.

(f) By February 15 of each year, the board shall issue a report to the Governor, the President of the Senate, and the

Speaker of the House of Representatives on research projects, community outreach initiatives, and future plans for the coalition.

(5) RESPONSIBILITIES OF THE H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.—The H. Lee Moffitt Cancer Center and Research Institute, Inc., shall allocate staff, information, and assistance, as the coalition's budget permits, to assist the board in fulfilling its responsibilities.

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

And the title is amended as follows:

Between lines 56 and 57

insert:

creating s. 1004.4351, F.S.; providing a short title; providing legislative intent; defining terms; establishing the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.; providing a purpose for the coalition; establishing the Medical Marijuana Research and Education Board to direct the operations of the coalition; providing for the appointment of board members; providing for terms of office, reimbursement for certain expenses, and the conduct of meetings of the board; authorizing the board to appoint a coalition director; prescribing the duties of the coalition director; requiring the board to advise specified entities and officials regarding medical marijuana research and education in this state; requiring the board to annually adopt a Medical

Marijuana Research and Education Plan; providing requirements for the plan; requiring the board to issue an annual report to the Governor and the Legislature by a specified date; specifying responsibilities of the H. Lee Moffitt Cancer Center and Research Institute, Inc.;

By Senator Bradley

5-00443C-17 2017406__

A bill to be entitled

An act relating to compassionate use of low-THC cannabis and marijuana; amending s. 381.986, F.S.; defining and redefining terms; authorizing physicians to issue physician certifications to specified patients who meet certain conditions; authorizing physicians to make specific determinations in certifications; requiring physicians to meet certain conditions to be authorized to issue and make determinations in physician certifications; requiring written consent of a parent or legal guardian for the treatment of minors; requiring that certain physicians annually reexamine and reassess patients and update patient information in the compassionate use registry; revising criminal penalties; authorizing a distance learning format for a specified course and reducing the number of hours required for the course; providing that physicians who meet specified requirements are grandfathered for the purpose of specified education requirements; authorizing qualifying patients to designate caregivers; requiring caregivers to meet specified requirements; prohibiting a qualifying patient from designating more than one caregiver at any given time; providing exceptions; requiring the Department of Health to register caregivers meeting certain requirements on the compassionate use registry; revising the entities to which the compassionate use registry must be accessible; requiring the department to adopt certain rules by a specified date; authorizing the department to charge a fee for identification cards; requiring the department to begin issuing identification cards to qualified

5-00443C-17 2017406__

registrants by a specific date; providing requirements for the identification cards; requiring the department to register certain dispensing organizations as medical marijuana treatment centers by a certain date; requiring the department to register additional medical marijuana treatment centers in accordance with a specified schedule; deleting obsolete provisions; revising the operational requirements for medical marijuana treatment centers; authorizing the department to waive certain requirements under specified circumstances; requiring that certain receptacles be child proof; requiring that additional information be included on certain labels; requiring that a medical marijuana treatment center comply with certain standards in the production and dispensing of edible or food products; requiring a medical marijuana treatment center to enter additional information into the compassionate use registry; requiring a medical marijuana treatment center to keep a copy of a transportation manifest in certain vehicles at certain times; requiring the department to adopt rules related to ownership changes or changes in an owner's investment interest; providing applicability; conforming provisions to changes made by the act; amending ss. 381.987, 385.211, 499.0295, and 1004.441, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 381.986, Florida Statutes, is amended to read:

381.986 Compassionate use of low-THC ~~and medical~~ cannabis and marijuana.—

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

(a) "Cannabis delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana ~~low-THC cannabis or medical cannabis~~ into the human body.

(b) "Caregiver" has the same meaning as provided in s. 29, Art. X of the State Constitution.

(c) "Chronic nonmalignant pain" means pain that is caused by a debilitating medical condition or that originates from a debilitating medical condition and persists beyond the usual course of that debilitating medical condition.

(d) "Close relative" means a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half-blood, by marriage, or by adoption.

(e) ~~(b)~~ "Debilitating medical condition" has the same meaning as provided in s. 29, Art. X of the State Constitution ~~"Dispensing organization" means an organization approved by the department to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis pursuant to this section~~.

(f) ~~(c)~~ "Independent testing laboratory" means a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a medical marijuana treatment center ~~a dispensing organization~~.

(g) ~~(d)~~ "Legal representative" means the qualifying

~~qualified~~ patient's parent, legal guardian acting pursuant to a court's authorization as required under s. 744.3215(4), health care surrogate acting pursuant to the qualifying ~~qualified~~ patient's written consent or a court's authorization as required under s. 765.113, or an individual who is authorized under a power of attorney to make health care decisions on behalf of the qualifying ~~qualified~~ patient.

(h) ~~(c)~~ "Low-THC cannabis" means a plant of the genus *Cannabis*, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only by a medical marijuana treatment center ~~from a dispensing organization~~.

(i) ~~(f)~~ "Marijuana" has the same meaning as provided in s. 29, Art. X of the State Constitution ~~"Medical cannabis" means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a dispensing organization for medical use by an eligible patient as defined in s. 499.0295~~.

(j) "Medical marijuana treatment center" or "MMTC" has the same meaning as provided in s. 29, Art. X of the State Constitution.

(k) ~~(g)~~ "Medical use" has the same meaning as provided in s. 29, Art. X of the State Constitution ~~means administration of the ordered amount of low-THC cannabis or medical cannabis~~. The term

does not include the:

1. Possession, use, or administration of marijuana ~~low-THC cannabis or medical cannabis~~ by smoking.

2. Possession, use, or administration of marijuana that was not purchased or acquired from an MMTC registered with the Department of Health.

3.~~2.~~ Transfer of marijuana ~~low-THC cannabis or medical cannabis~~ to a person other than the qualifying ~~qualified~~ patient ~~for whom it was ordered~~ or the qualifying ~~qualified~~ patient's caregiver ~~legal representative~~ on behalf of the qualifying ~~qualified~~ patient.

4. Use or administration of any type or amount of marijuana not specified on the qualifying patient's physician certification.

5.~~3.~~ Use or administration of marijuana ~~low-THC cannabis or medical cannabis~~:

a. On any form of public transportation.

b. In any public place.

c. In a qualifying ~~qualified~~ patient's place of employment, if restricted by his or her employer.

d. In a state correctional institution as defined in s. 944.02 or a correctional institution as defined in s. 944.241.

e. On the grounds of a preschool, primary school, or secondary school.

f. On a school bus or in a vehicle, aircraft, or motorboat.

(l)~~(h)~~ "Qualifying ~~Qualified~~ patient" has the same meaning as provided in s. 29, Art. X of the State Constitution but also includes eligible patients, as that term is defined in s. 499.0295, and patients who are issued a physician certification

under subparagraph (2)(a)2. or subparagraph (2)(a)3. A patient is not a qualifying patient unless he or she is registered with the department and has been issued a compassionate use registry identification card ~~means a resident of this state who has been added to the compassionate use registry by a physician licensed under chapter 458 or chapter 459 to receive low-THC cannabis or medical cannabis from a dispensing organization~~.

(m)~~(i)~~ "Smoking" means burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer.

(2) PHYSICIAN CERTIFICATION ~~ORDERING~~.—

(a) A physician is authorized to issue a physician certification to:

1. A patient suffering from a debilitating medical condition, which allows the patient to receive marijuana for the patient's medical use;

2. A ~~order low-THC cannabis to treat a qualified~~ patient suffering from ~~cancer or~~ a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, which allows the patient to receive low-THC cannabis for the patient's medical use;

3. A patient suffering from chronic nonmalignant pain, if the physician has diagnosed an underlying debilitating medical condition as the cause of the pain, which allows the patient to receive marijuana for the patient's medical use ~~order low-THC cannabis~~ to alleviate the patient's pain ~~symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient~~; or

4. ~~order medical cannabis to treat~~ An eligible patient as defined in s. 499.0295, which allows the patient to receive marijuana for the patient's medical use.~~;~~

(b) In the physician certification, the physician may also specify one or more ~~or order a~~ cannabis delivery devices to assist with ~~device for~~ the patient's medical use of marijuana. ~~low-THC cannabis or medical cannabis,~~

(c) A physician may certify a patient and specify a delivery device under paragraphs (a) and (b) only if the physician:

1.~~(a)~~ Holds an active, unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459;

~~(b) Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;~~

2.~~(c)~~ Has successfully completed the course and examination required under paragraph (4)(a);

3. Has conducted a physical examination and made a full assessment of the medical history of the patient;

4. Has determined that, in the physician's professional opinion, the patient meets one or more of the criteria specified in paragraph (a);

5.~~(d)~~ Has determined that the medical use of marijuana would likely outweigh the potential health risks to ~~of treating the patient with low-THC cannabis or medical cannabis are reasonable in light of the potential benefit to~~ the patient~~. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record~~;

6.~~(e)~~ Registers as the patient's physician ~~orderer of low-THC cannabis or medical cannabis for the named patient~~ on the compassionate use registry maintained by the department and updates the registry to reflect ~~the contents of the order, including~~ the amount of marijuana ~~low-THC cannabis or medical cannabis~~ that will provide the patient with not more than a 90-day ~~45-day~~ supply and any ~~a~~ cannabis delivery device needed by the patient for the medical use of marijuana ~~low-THC cannabis or medical cannabis~~. If the physician's recommended amount of marijuana for a 90-day supply changes, the physician must ~~also~~ update the registry within 7 days after the ~~any~~ change is made ~~to the original order to reflect the change~~. The physician shall deactivate the registration of the patient ~~and the patient's legal representative~~ when the physician no longer recommends the medical use of marijuana for the patient ~~treatment is discontinued~~;

7.~~(f)~~ Maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the marijuana ~~low-THC cannabis or medical cannabis~~;

8.~~(g)~~ Submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of marijuana ~~low-THC cannabis and medical cannabis~~ on patients; and

9.~~(h)~~ Obtains the voluntary written informed consent of the patient or the patient's legal representative to treatment with marijuana ~~low-THC cannabis~~ after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with

marijuana ~~low-THC cannabis, the medically acceptable alternatives,~~ and the potential risks and side effects. If the patient is a minor, the patient's parent or legal guardian must consent to treatment in writing. If the patient is an eligible patient as defined in s. 499.0295, the physician must obtain written informed consent as defined in and required by s. 499.0295.~~,~~

(d) At least annually, a physician must recertify the qualifying patient pursuant to paragraph (c).

~~(i) Obtains written informed consent as defined in and required under s. 499.0295, if the physician is ordering medical cannabis for an eligible patient pursuant to that section; and~~

(e)~~(j)~~ A physician may not issue a physician certification if the physician is ~~not~~ a medical director employed by an MMTC ~~a dispensing organization~~.

(f) An order for low-THC cannabis or medical cannabis issued pursuant to former s. 381.986, Florida Statutes 2016 and registered with the compassionate use registry on the effective date of this act, shall be considered a physician certification issued pursuant to this subsection. The details and expiration date of such certification must be identical to the details and expiration date of the order as logged in the compassionate use registry. Until the department begins issuing compassionate use registry identification cards, all patients with such orders shall be considered qualifying patients, notwithstanding the requirement that a qualifying patient have a compassionate use registry identification card.

(3) PENALTIES.—

(a) A physician commits a misdemeanor of the first degree,

punishable as provided in s. 775.082 or s. 775.083, if the physician issues a physician certification for marijuana to ~~orders low-THC cannabis for~~ a patient in a manner other than as required in subsection (2) ~~without a reasonable belief that the patient is suffering from:~~

~~1. Cancer or A physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or~~

~~2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis~~.

~~(b) A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition as defined in s. 499.0295.~~

(b)~~(c)~~ A person who fraudulently represents that he or she has a debilitating medical condition ~~cancer~~, a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, chronic nonmalignant pain, or a terminal condition as defined in s. 499.0295 to a physician for the purpose of being issued a physician certification for marijuana ~~ordered low-THC cannabis, medical cannabis,~~ or a cannabis delivery device by such physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c)~~(d)~~ A qualifying patient ~~an eligible patient as defined in s. 499.0295~~ who uses marijuana ~~medical cannabis~~, and such

patient's caregiver ~~legal representative~~ who administers marijuana ~~medical cannabis~~, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(d) A qualifying patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than an MMTC commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(e) A caregiver who violates any of the applicable provisions of this section or applicable department rules commits, upon the first offense, a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083 and, upon the second and subsequent offenses, a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(f) ~~(e)~~ A physician who issues a physician certification for marijuana ~~orders low-THC cannabis, medical cannabis,~~ or a cannabis delivery device and receives compensation from an MMTC ~~a dispensing organization~~ related to issuing the physician certification for marijuana ~~the ordering of low-THC cannabis, medical cannabis,~~ or a cannabis delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before a physician may issue a physician certification pursuant to subsection (2) ~~ordering low-THC cannabis, medical cannabis, or a cannabis delivery device for medical use by a~~

~~patient in this state~~, the appropriate board shall require the ~~ordering~~ physician to successfully complete a 4-hour ~~an 8-hour~~ course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which ~~that~~ encompasses the clinical indications for the appropriate use of marijuana ~~low-THC cannabis and medical cannabis~~, the appropriate cannabis delivery devices, the contraindications for such use, and the relevant state and federal laws governing the issuance of physician certifications ~~ordering~~, as well as dispensing~~,~~ and possessing ~~of~~ these substances and devices. The course and examination shall be administered at least quarterly ~~annually~~. Successful completion of the course may be used by a physician to satisfy 4 hours ~~8 hours~~ of the continuing medical education requirements required by his or her respective board for licensure renewal. This course may be offered in a distance learning format, including an electronic, online format that is available on request. Physicians who have completed an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of marijuana and who are registered in the compassionate use registry on the effective date of this act, are deemed to meet the requirements of this paragraph.

(b) The appropriate board shall require the medical director of each MMTC ~~dispensing organization~~ to hold an active, unrestricted license as a physician under chapter 458 or as an osteopathic physician under chapter 459 and successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic

Medical Association which ~~that~~ encompasses appropriate safety procedures and knowledge of marijuana ~~low-THC cannabis, medical cannabis,~~ and cannabis delivery devices.

~~(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device each time such physician renews his or her license. In addition, successful completion of the course and examination specified in paragraph (b) is required for the medical director of each dispensing organization each time such physician renews his or her license.~~

(c) ~~(d)~~ A physician who fails to comply with this subsection and issues a physician certification for marijuana ~~who orders low-THC cannabis, medical cannabis,~~ or a cannabis delivery device may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

(5) CAREGIVERS.—

(a) During the course of registration with the department for inclusion on the compassionate use registry, or at any time while registered, a qualifying patient may designate an individual as his or her caregiver to assist him or her with the medical use of marijuana. The designated caregiver must be 21 years of age or older, unless the patient is a close relative of the caregiver; must agree in writing to be the qualifying patient's caregiver; may not receive compensation, other than actual expenses incurred, for assisting the qualifying patient with the medical use of marijuana unless the caregiver is acting pursuant to employment in a licensed facility in accordance with subparagraph (c)2.; and must pass a level 2 screening pursuant

to chapter 435, unless the patient is a close relative of the caregiver.

(b) A qualifying patient may have only one designated caregiver at any given time unless all of the patient's caregivers are his or her close relatives or legal representatives.

(c) A caregiver may assist only one qualifying patient at any given time unless:

1. All qualifying patients the caregiver is assisting are close relatives of each other and the caregiver is the legal representative of at least one of the patients; or

2. All qualifying patients the caregiver is assisting are receiving hospice services, or are residents, in the same assisted living facility, nursing home, or other licensed facility and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice or licensed facility; and the caregiver provides personal care or services directly to clients of the hospice or licensed facility as a part of his or her employment duties at the hospice or licensed facility.

(d) The department must register a caregiver on the compassionate use registry and issue him or her a caregiver identification card if he or she is designated by a qualifying patient pursuant to paragraph (a) and meets all of the requirements of this subsection and department rule.

(6) ~~(5)~~ DUTIES OF THE DEPARTMENT.—The department shall:

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, patients, and caregivers ~~the legal representatives of patients~~

as provided under this section. The registry must be accessible to:

1. Practitioners licensed under chapter 458 or chapter 459, to ensure proper care for patients requesting physician certifications;

2. Practitioners licensed to prescribe prescription drugs, to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana;

3. Law enforcement agencies, to verify the authorization of a qualifying patient or a patient's caregiver to possess marijuana or a cannabis delivery device; and

4. MMTCs, to ~~a dispensing organization to~~ verify the authorization of a qualifying patient or a patient's caregiver ~~legal representative~~ to possess marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device and to record the marijuana ~~low-THC cannabis, medical cannabis,~~ or cannabis delivery device dispensed.

The registry must prevent ~~an~~ active registration of a patient by multiple physicians.

(b) By July 3, 2017, adopt rules establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for patients and caregivers who are residents of this state. The department may charge a reasonable fee associated with the issuance and renewal of patient and caregiver identification cards. By October 3, 2017, the department shall begin issuing identification cards to adult patients who are residents of this state and who have a physician certification that meets the requirements of

subsection (2); minor patients who are residents of this state and who have a physician certification that meets the requirements of subsection (2) and the written consent of a parent or legal guardian; and caregivers registered pursuant to subsection (5). Patient and caregiver identification cards must be resistant to counterfeiting and tampering and must include at least the following:

1. The name, address, and date of birth of the patient or caregiver, as appropriate;

2. A full-face, passport-type, color photograph of the patient or caregiver, as appropriate, taken within the 90 days immediately preceding registration;

3. Designation of the cardholder as a patient or caregiver;

4. A unique numeric identifier for the patient or caregiver which is matched to the identifier used for such person in the department's compassionate use registry. A caregiver's identification number and file in the compassionate use registry must be linked to the file of the patient or patients the caregiver is assisting so that the caregiver's status may be verified for each patient individually;

5. The expiration date, which shall be 1 year after the date of issuance of the identification card or the date treatment ends as provided in the patient's physician certification, whichever occurs first; and

6. For caregivers who are assisting three or fewer qualifying patients, the names and unique numeric identifiers of the qualifying patient or patients that the caregiver is assisting.

(c) As soon as practicable after the effective date of this

act, update its records by registering each dispensing organization approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, as an MMTC with an effective registration date that coincides with that dispensing organization's date of approval as a dispensing organization. On the effective date of this act, all dispensing organizations approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, are deemed to be registered MMTCs. The department may not require a dispensing organization approved pursuant to chapter 2014-157, Laws of Florida, or chapter 2016-123, Laws of Florida, to submit an application and may not charge the dispensing organization an application or registration fee for the initial registration of that dispensing organization as an MMTC pursuant to this section. For purposes of the requirement that an MMTC comply with the representations made in its application pursuant to subsection (7), an MMTC registered pursuant to this paragraph shall continue to comply with the representations made in its application for approval as a dispensing organization, including any revision authorized by the department before the effective date of this act. After the effective date of this act, the department may grant variances from the representations made in a dispensing organization's application for approval pursuant to subsection (7). For purposes of the definition of the term "marijuana" in s. 29, of Art. X of the State Constitution, an MMTC is deemed to be a dispensing organization as that term is defined in former s. 381.986(1)(a), Florida Statutes 2014 ~~Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as~~

~~necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis, medical cannabis, or a cannabis delivery device under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida~~.

(d) Within 6 months after the registration of 250,000 active qualifying patients in the compassionate use registry, the department must register five additional MMTCs, including, but not limited to, an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) or *In re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011) and a member of the Black Farmers and Agriculturalists Association. Additionally, the department must register an additional five MMTCs within 6 months after the registration of each of the following totals of the number of patients in the compassionate use registry: 350,000 qualifying patients; 400,000 qualifying patients; 500,000 qualifying patients; and then the registration of each additional 100,000 qualifying patients above 500,000, if a sufficient number of MMTC applicants meet the registration requirements established in this section and by department rule.

(e) The department shall develop an application form for registration as an MMTC and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. To be registered as an MMTC, the ~~an~~ applicant ~~for approval as a dispensing organization~~ must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis and marijuana. ~~The applicant must possess a valid certificate of registration issued by the~~

~~Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.~~

2. The ability to secure the premises, resources, and personnel necessary to operate as an MMTC ~~a dispensing organization~~.

3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.

4. An infrastructure reasonably located to dispense low-THC cannabis and marijuana to registered qualifying patients statewide ~~or regionally as determined by the department~~.

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a $5 million performance bond. However, upon an MMTC ~~a dispensing organization's~~ serving at least 1,000 qualifying ~~qualified~~ patients, the MMTC ~~dispensing organization~~ is only required to maintain a $2 million performance bond.

6. That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director to supervise the activities of the MMTC ~~dispensing organization~~.

~~(c) Upon the registration of 250,000 active qualified patients in the compassionate use registry, approve three~~

~~dispensing organizations, including, but not limited to, an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association, which must meet the requirements of subparagraphs (b)2.-7. and demonstrate the technical and technological ability to cultivate and produce low-THC cannabis.~~

(f) ~~(d)~~ Allow an MMTC ~~a dispensing organization~~ to make a wholesale purchase of marijuana ~~low-THC cannabis or medical cannabis~~ from, or a distribution of marijuana ~~low-THC cannabis or medical cannabis~~ to, another MMTC ~~dispensing organization~~.

(g) ~~(e)~~ Monitor physician registration in the compassionate use registry and the issuance of physician certifications pursuant to subsection (2) ~~ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device~~ for ~~ordering~~ practices that could facilitate unlawful diversion or misuse of marijuana ~~low-THC cannabis, medical cannabis,~~ or ~~a~~ cannabis delivery devices ~~device~~ and take disciplinary action as indicated.

(7) ~~(6)~~ MEDICAL MARIJUANA TREATMENT CENTERS ~~DISPENSING ORGANIZATION~~.—Each MMTC must register with the department. A registered MMTC ~~An approved dispensing organization~~ must, at all times, maintain compliance with paragraph (6)(e), ~~the criteria demonstrated for selection and approval as a dispensing organization under subsection(5) and~~ the criteria required in this subsection, and all representations made to the department in the MMTC's application for registration. Upon request, the department may grant an MMTC one or more variances from the representations made in the MMTC's application. Consideration of

such a variance shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting MMTC can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application.

(a) When growing marijuana ~~low-THC cannabis or medical cannabis~~, an MMTC ~~a dispensing organization~~:

1. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

2. Must grow marijuana ~~low-THC cannabis or medical cannabis~~ within an enclosed structure and in a room separate from any other plant.

3. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days after a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures.

4. Must perform fumigation or treatment of plants, or the removal and destruction of infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

(b) When processing marijuana ~~low-THC cannabis or medical cannabis~~, an MMTC ~~a dispensing organization~~ must:

1. Process the marijuana ~~low-THC cannabis or medical cannabis~~ within an enclosed structure and in a room separate from other plants or products.

2. Test the processed marijuana ~~low-THC cannabis and medical cannabis~~ before it is ~~they are~~ dispensed. Results must be verified and signed by two MMTC ~~dispensing organization~~ employees. Before dispensing low-THC cannabis, the MMTC ~~dispensing organization~~ must determine that the test results indicate that the low-THC cannabis meets the definition of low-THC cannabis. Before dispensing marijuana, the MMTC must determine ~~and, for medical cannabis and low-THC cannabis,~~ that the marijuana ~~all medical cannabis and low-THC cannabis~~ is safe for human consumption and free from contaminants that are unsafe for human consumption. The MMTC ~~dispensing organization~~ must retain records of all testing and samples of each homogenous batch of marijuana ~~cannabis and low-THC cannabis~~ for at least 9 months. The MMTC ~~dispensing organization~~ must contract with an independent testing laboratory to perform audits on the MMTC's ~~dispensing organization's~~ standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana ~~low-THC cannabis or medical cannabis~~ meets the requirements of this section and that the marijuana ~~medical cannabis and low-THC cannabis~~ is safe for human consumption.

3. Package the marijuana ~~low-THC cannabis or medical cannabis~~ in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

4. Package the marijuana ~~low-THC cannabis or medical cannabis~~ in a child-proof receptacle that has a firmly affixed

and legible label stating the following information:

a. A statement that the marijuana ~~low-THC cannabis or medical cannabis~~ meets the requirements of subparagraph 2.;

b. The name of the MMTC ~~dispensing organization~~ from which the marijuana ~~medical cannabis or low-THC cannabis~~ originates; ~~and~~

c. The batch number and harvest number from which the marijuana ~~medical cannabis or low-THC cannabis~~ originates; and

d. The concentration of tetrahydrocannabinol and cannabidiol in the product.

5. Reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of testing pursuant to the audit required under subparagraph 2.

(c) When dispensing marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device, an MMTC ~~a dispensing organization~~:

1. May not dispense more than a 90-day ~~45-day~~ supply of marijuana ~~low-THC cannabis or medical cannabis~~ to a qualifying patient or caregiver ~~the patient's legal representative~~.

2. Must ensure its ~~have the dispensing organization's~~ employee who dispenses the marijuana ~~low-THC cannabis, medical cannabis,~~ or ~~a~~ cannabis delivery device enters ~~enter~~ into the compassionate use registry his or her name or unique employee identifier.

3. Must verify that the qualifying patient and the caregiver, if applicable, both have an active and valid compassionate use registry identification card and that the amount and type of marijuana dispensed matches the physician's certification in the compassionate use registry for that

qualifying patient ~~that a physician has ordered the low-THC cannabis, medical cannabis, or a specific type of a cannabis delivery device for the patient~~.

4. Must label the low-THC cannabis or marijuana with the recommended dose for the qualifying patient receiving the low-THC cannabis or marijuana.

5.~~4.~~ May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a ~~physician-ordered~~ cannabis delivery device required for the medical use of marijuana that is specified in a physician certification ~~low-THC cannabis or medical cannabis, while dispensing low-THC cannabis or medical cannabis~~. A registered MMTC may produce and dispense marijuana as an edible or food product but may not produce such items in a format designed to be attractive to children. In addition to the requirements of this section and department rule, food products produced by an MMTC must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of THC in each serving.

~~5. Must verify that the patient has an active registration in the compassionate use registry, the patient or patient's legal representative holds a valid and active registration card, the order presented matches the order contents as recorded in the registry, and the order has not already been filled.~~

6. Must, upon dispensing the marijuana ~~low-THC cannabis, medical cannabis,~~ or cannabis delivery device, record in the registry the date, time, quantity, and form of marijuana ~~low-THC cannabis or medical cannabis~~ dispensed; ~~and~~ the type of cannabis

delivery device dispensed; and the name and compassionate use registry identification number of the qualifying patient or caregiver to whom the marijuana or cannabis delivery device was dispensed.

(d) To ensure the safety and security of its premises and any off-site storage facilities, and to maintain adequate controls against the diversion, theft, and loss of marijuana ~~low-THC cannabis, medical cannabis,~~ or cannabis delivery devices, an MMTC ~~a dispensing organization~~ shall:

1.a. Maintain a fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detectors; pressure switches; and duress, panic, and hold-up alarms; or

b. Maintain a video surveillance system that records continuously 24 hours each day and meets at least one of the following criteria:

(I) Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of the premises. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms;

(II) Cameras are fixed in entrances and exits to the premises, which shall record from both indoor and outdoor, or ingress and egress, vantage points;

(III) Recorded images must clearly and accurately display the time and date; or

(IV) Retain video surveillance recordings for a minimum of 45 days, or longer upon the request of a law enforcement agency.

2. Ensure that the MMTC's ~~organization's~~ outdoor premises

have sufficient lighting from dusk until dawn.

3. Establish and maintain a tracking system approved by the department which ~~that~~ traces the marijuana ~~low-THC cannabis or medical cannabis~~ from seed to sale. The tracking system must ~~shall~~ include notification of key events as determined by the department, including when cannabis seeds are planted, when cannabis plants are harvested and destroyed, and when marijuana ~~low-THC cannabis or medical cannabis~~ is transported, sold, stolen, diverted, or lost.

4. Not dispense from its premises marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device between the hours of 9 p.m. and 7 a.m., but may perform all other operations and deliver marijuana ~~low-THC cannabis and medical cannabis~~ to qualifying ~~qualified~~ patients 24 hours each day.

5. Store marijuana ~~low-THC cannabis or medical cannabis~~ in a secured, locked room or a vault.

6. Require at least two of its employees, or two employees of a security agency with whom it contracts, to be on the premises at all times.

7. Require each employee or contractor to wear a photo identification badge at all times while on the premises.

8. Require each visitor to wear a visitor's pass at all times while on the premises.

9. Implement an alcohol and drug-free workplace policy.

10. Report to local law enforcement within 24 hours after it is notified or becomes aware of the theft, diversion, or loss of marijuana ~~low-THC cannabis or medical cannabis~~.

(e) To ensure the safe transport of marijuana ~~low-THC~~

~~cannabis or medical cannabis~~ to MMTC ~~dispensing organization~~ facilities, independent testing laboratories, or qualifying patients, the MMTC ~~dispensing organization~~ must:

1. Maintain a transportation manifest, which must be retained for at least 1 year. A copy of the manifest must be in the vehicle at all times when transporting marijuana.

2. Ensure only vehicles in good working order are used to transport marijuana ~~low-THC cannabis or medical cannabis~~.

3. Lock marijuana ~~low-THC cannabis or medical cannabis~~ in a separate compartment or container within the vehicle.

4. Require at least two persons to be in a vehicle transporting marijuana ~~low-THC cannabis or medical cannabis~~, and require at least one person to remain in the vehicle while the marijuana ~~low-THC cannabis or medical cannabis~~ is being delivered.

5. Provide specific safety and security training to employees transporting or delivering marijuana ~~low-THC cannabis or medical cannabis~~.

(8) ~~(7)~~ DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

(a) The department may conduct announced or unannounced inspections of MMTCs ~~dispensing organizations~~ to determine compliance with this section or rules adopted pursuant to this section.

(b) The department shall inspect an MMTC ~~a dispensing organization~~ upon complaint or notice provided to the department that the MMTC ~~dispensing organization~~ has dispensed marijuana ~~low-THC cannabis or medical cannabis~~ containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.

(c) The department shall conduct at least a biennial inspection of each MMTC ~~dispensing organization~~ to evaluate the MMTC's ~~dispensing organization's~~ records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.

(d) The department shall adopt by rule a process for approving changes in MMTC ownership or a change in an MMTC owner's investment interest. This process must include specific criteria for the approval or denial of an application for change of ownership or a change in investment interest and procedures for screening applicants' criminal and financial histories.

(e) ~~(d)~~ The department may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(f) ~~(c)~~ The department must make a list of all approved MMTCs, ~~dispensing organizations and qualified ordering~~ physicians who are qualified to issue physician certifications, and medical directors publicly available on its website.

~~(f) The department may establish a system for issuing and renewing registration cards for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must~~

~~require, at a minimum, the registration cards to:~~

~~1. Provide the name, address, and date of birth of the patient or legal representative.~~

~~2. Have a full-face, passport-type, color photograph of the patient or legal representative taken within the 90 days immediately preceding registration.~~

~~3. Identify whether the cardholder is a patient or legal representative.~~

~~4. List a unique numeric identifier for the patient or legal representative that is matched to the identifier used for such person in the department's compassionate use registry.~~

~~5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis or medical cannabis.~~

~~6. For the legal representative, provide the name and unique numeric identifier of the patient that the legal representative is assisting.~~

~~7. Be resistant to counterfeiting or tampering.~~

(g) The department may impose reasonable fines not to exceed $10,000 on an MMTC ~~a dispensing organization~~ for any of the following violations:

1. Violating this section, s. 499.0295, or department rule.

2. Failing to maintain qualifications for registration with the department ~~approval~~.

3. Endangering the health, safety, or security of a qualifying ~~qualified~~ patient.

4. Improperly disclosing personal and confidential information of a qualifying ~~the qualified~~ patient.

5. Attempting to procure MMTC registration with the

department ~~dispensing organization approval~~ by bribery, fraudulent misrepresentation, or extortion.

6. Any owner or manager of the MMTC being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which directly relates to the business of an MMTC ~~a dispensing organization~~.

7. Making or filing a report or record that the MMTC ~~dispensing organization~~ knows to be false.

8. Willfully failing to maintain a record required by this section or department rule.

9. Willfully impeding or obstructing an employee or agent of the department in the furtherance of his or her official duties.

10. Engaging in fraud or deceit, negligence, incompetence, or misconduct in the business practices of an MMTC ~~a dispensing organization~~.

11. Making misleading, deceptive, or fraudulent representations in or related to the business practices of an MMTC ~~a dispensing organization~~.

12. Having a license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of an MMTC ~~a dispensing organization~~ suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.

13. Violating a lawful order of the department or an agency of the state, or failing to comply with a lawfully issued

subpoena of the department or an agency of the state.

(h) The department may suspend, revoke, or refuse to renew an MMTC's registration with the department ~~a dispensing organization's approval~~ if the MMTC ~~a dispensing organization~~ commits a violation specified ~~any of the violations~~ in paragraph (g).

(i) The department shall renew an MMTC's registration with the department ~~the approval of a dispensing organization~~ biennially if the MMTC ~~dispensing organization~~ meets the requirements of this section and pays the biennial renewal fee.

(j) The department may adopt rules necessary to implement this section.

(9)~~(8)~~ PREEMPTION.—

(a) All matters regarding the regulation of the cultivation and processing of marijuana ~~medical cannabis or low-THC cannabis~~ by MMTCs ~~dispensing organizations~~ are preempted to the state.

(b) A municipality may determine by ordinance the criteria for the number and location of, and other permitting requirements that do not conflict with state law or department rule for, dispensing facilities of MMTCs ~~dispensing organizations~~ located within its municipal boundaries. A county may determine by ordinance the criteria for the number, location, and other permitting requirements that do not conflict with state law or department rule for all dispensing facilities of MMTCs ~~dispensing organizations~~ located within the unincorporated areas of that county.

(10)~~(9)~~ EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of

this section, a qualifying ~~qualified~~ patient, or a caregiver who has obtained a valid compassionate use registry identification card from the department, ~~and the qualified patient's legal representative~~ may purchase from an MMTC, and possess for the qualifying patient's medical use, up to the amount of marijuana in the physician's certification ~~low-THC cannabis or medical cannabis ordered for the patient~~, but not more than a 90-day ~~45-day~~ supply, and a cannabis delivery device specified in the physician's certification ~~ordered~~ for the qualifying patient.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a registered MMTC ~~an approved dispensing organization~~ and its owners, managers, contractors, and employees may manufacture, possess, sell, deliver, distribute, dispense, administer, and lawfully dispose of reasonable quantities, as established by department rule, of marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved independent testing laboratory may possess, test, transport, and lawfully dispose of marijuana ~~low-THC cannabis or medical cannabis~~ as provided by department rule.

(d) An approved MMTC ~~dispensing organization~~ and its owners, managers, contractors, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing,

dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of marijuana ~~low-THC cannabis, medical cannabis,~~ or a cannabis delivery device.

(e) ~~An approved dispensing organization that continues to meet the requirements for approval is presumed to be registered with the department and to meet the regulations adopted by the department or its successor agency for the purpose of dispensing medical cannabis or low-THC cannabis under Florida law. Additionally,~~ Exercise by an MMTC of the authority provided to MMTCs ~~a dispensing organization~~ in s. 499.0295 does not impair its registration with the department ~~the approval of a dispensing organization~~.

(f) This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of marijuana ~~low-THC cannabis or medical cannabis~~ or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

(g) This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy.

Section 2. Paragraph (b) of subsection (3) of section 381.987, Florida Statutes, is amended to read:

381.987 Public records exemption for personal identifying information in the compassionate use registry.—

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

(b) A medical marijuana treatment center ~~dispensing organization~~ approved by the department pursuant to s. 381.986

which is attempting to verify the authenticity of a physician's certification ~~order~~ for marijuana ~~low-THC cannabis~~, including whether the physician certification ~~order~~ had been previously filled and whether the physician certification ~~order~~ was written for the person attempting to have it filled.

Section 3. Subsection (1) of section 385.211, Florida Statutes, is amended to read:

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

(1) As used in this section, the term "low-THC cannabis" means "low-THC cannabis" as defined in s. 381.986 which ~~that~~ is dispensed only from a medical marijuana treatment center ~~dispensing organization~~ as defined in s. 381.986.

Section 4. Present paragraphs (b) and (c) of subsection (2) of section 499.0295, Florida Statutes, are redesignated as paragraphs (a) and (b), respectively, present paragraphs (a) and (c) of that subsection are amended, a new paragraph (c) is added to that subsection, and subsection (3) of that section is amended, to read:

499.0295 Experimental treatments for terminal conditions.—

(2) As used in this section, the term:

~~(a) "Dispensing organization" means an organization approved by the Department of Health under s. 381.986(5) to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices.~~

(b) ~~(c)~~ "Investigational drug, biological product, or device" means:

1. A drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not

been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration; or

2. Marijuana ~~Medical cannabis~~ that is manufactured and sold by an MMTC ~~a dispensing organization~~.

(c) "Medical marijuana treatment center" or "MMTC" means an organization registered with the Department of Health under s. 381.986.

(3) Upon the request of an eligible patient, a manufacturer may, or upon the issuance of a physician certification ~~a physician's order~~ pursuant to s. 381.986, an MMTC ~~a dispensing organization~~ may:

(a) Make its investigational drug, biological product, or device available under this section.

(b) Provide an investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986 to an eligible patient without receiving compensation.

(c) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, device, or cannabis delivery device as defined in s. 381.986.

Section 5. Subsection (1) of section 1004.441, Florida Statutes, is amended to read:

1004.441 Refractory and intractable epilepsy treatment and research.—

(1) As used in this section, the term "low-THC cannabis" means "low-THC cannabis" as defined in s. 381.986 which ~~that~~ is dispensed only from a medical marijuana treatment center

~~dispensing organization~~ as defined in s. 381.986.

Section 6. The Division of Law Revision and Information is directed to replace the phrase "the effective date of this act" wherever it occurs in this act with the date the act becomes a law.

Section 7. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: February 2, 2017

I respectfully request that **Senate Bill # 406**, relating to Compassionate Use of Low-THC Cannabis and Marijuana, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Rob Bradley
Florida Senate, District 5

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)

4/3/2017
Meeting Date

406
Bill Number (if applicable)

731400
Amendment Barcode (if applicable)

Topic MEDICAL CANNABIS - EMPLOYEE PROTECTION

Name GARY STEIN

Job Title

Address 7035 DELT LAWN LOOP
Street

WESLEY CHAPEL FL 33545
City *State* *Zip*

Phone (513) 305-8280

Email GSTEINMPH@ME.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

APPEARANCE RECORD

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

Meeting Date

406
Bill Number (if applicable)

Topic Medical Marijuana Employer Rights

731400
Amendment Barcode (if applicable)

Name David Daniel

Job Title Lobbyist

Address 311 East Park Ave
Street

Phone 850-224-2972

Tallahassee FL 32301
City State Zip

Email ddaniel@smithbryan
tnyer.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing FL Chamber

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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

731400
Amendment Barcode (if applicable)

Topic Medical Marijuana

Name Melissa Ramba

Job Title VP of Government Affairs

Address 227 S Adams St.
Street

Tallahassee FL 32301
City *State* *Zip*

Phone

Email Melissa@FRF.ORG

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Retail Federation

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)

4/3/17
Meeting Date

Bill Number (if applicable)

~~#5816~~

Amendment Barcode (if applicable)
882270

Topic Medical Cannabis

Name Josephine Cannella-Krehl

Job Title Licensed Medical Social Worker

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Street

Phone (850) 653-1428

City *State* *Zip*

Email jokrehl@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Patients

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)

4.3.17
Meeting Date

406
Bill Number (if applicable)

248940
Amendment Barcode (if applicable)

Topic MMJ

Name Jodi James

Job Title Executive Director

Address 1375 Cypress
Street

Melbourne FL 32935
City *State* *Zip*

Phone 321 890 7302

Email jjamesflorida@gmail.com

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

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

Representing Florida CAN

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

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3 Apr 17
Meeting Date

406
Bill Number (if applicable)

248940
Amendment Barcode (if applicable)

Topic Medical Marijuana

Name Barney Bishop

Job Title Pres & CEO

Address 204 S. Monroe St.
Street

Phone 850.510.9922

Tall | FL | 32301
City | *State* | *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Fla. Smart Justice 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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3 Apr 17
Meeting Date

406
Bill Number (if applicable)

Topic Medical Marijuana - Research Amend.

633022
Amendment Barcode (if applicable)

Name Barney Bishop

Job Title Pres & CEO

Address 204 S. Monroe
Street

Phone 850.510.9922

Tall — Fl — 32301
City — *State* — *Zip*

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Fla. Smart Justice 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.

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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)

11/3/17
Meeting Date

460
Bill Number (if applicable)

8608112
Amendment Barcode (if applicable)

Topic A2 SB460 860811 2

Name John H Gutower

Job Title Paralegal

Address 2507 Sweetbriar Dr
Street

Tallahassee FL 32312
City *State* *Zip*

Phone 8505190376

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing myself

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3 Apr 17
Meeting Date

406
Bill Number (if applicable)

905618
Amendment Barcode (if applicable)

Topic Medical Marijuana

Name Barney Bishop

Job Title Pres & CEO

Address 204 S. Monroe
Street

Phone 850.510.9922

Tall — FL — 32301
City — *State* — *Zip*

Email

Speaking: ☐ For ☐ Against ☑ Information

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

Representing Fla. Smart Justice 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.

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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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

905618
Amendment Barcode (if applicable)

Topic Medical Cannabis

Name David Custin

Job Title Lobbyist

Address 6401 SW 113 PL
Street

Phone 305-607-8576

Email CustinDR@DavidRCustin.com

City *State* *Zip*

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Eureka Vapors Inc & Kaycha Holdings LLC

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)

4/3/2017
Meeting Date

406
Bill Number (if applicable)

905618
Amendment Barcode (if applicable)

Topic Medical Cannabis

Name Gary J. Stein

Job Title

Address 7035 Bent Tree Loop
Street

Wesley Chapel FL 33545
City *State* *Zip*

Phone (813) 305-8280

Email GSTEINMPH@MS.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.

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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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

533696
Amendment Barcode (if applicable)

Topic MARIJUANA

Name Louis Rotundo

Job Title

Address 302 Pinestraw Circle
Street
Altamonte Springs FL 32714
City *State* *Zip*

Phone 407-699-9361

Email LCR5002@aol.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing CBSY inc

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/2/17
Meeting Date

SB 406
Bill Number (if applicable)

Topic MEDICAL MARIJUANA / PHYSICIANS REQUIREMENTS

(ON THE BILL)
Amendment Barcode (if applicable)

Name JAMES EATON

Job Title

Address P.O. BOX 1713
Street

Phone 850 224 6789

TALLAHASSEE FL 32302
City *State* *Zip*

Email jimeaton53@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing THREE BOYS FARM

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

406

Meeting Date | *Bill Number (if applicable)*

Topic _____ *Amendment Barcode (if applicable)*

Name DR. MARK MOORE

Job Title PHYSICIAN, MEDCAN

Address 1849 CAPITAL MEDICAL CT Phone 850-222-2222

Street

TALLAHASSEE FL 32308 Email _____

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against

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

Representing THE PATIENTS AND THE PEOPLE OF FLORIDA

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 406
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Medical Marijuana

Name Christopher Malek

Job Title

Address
Street

Phone

City *State* *Zip*

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Patients First

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)

4/3/17
Meeting Date

SB 406
Bill Number (if applicable)

Topic Medical Cannabis

Amendment Barcode (if applicable)

Name Josephine Gonella-Krehl

Job Title Licensed Medical Social Worker

Address 3784 Wentworth Way
Street

Tallahassee Fl. 32311
City *State* *Zip*

Phone (850)653-1928

Email jokrehl@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Patients

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 406
Bill Number (if applicable)

Topic Implementation of AX, 529, F.C.

Amendment Barcode (if applicable)

Name Ben Pollara

Job Title Executive Director, Florida for Care

Address 801 Arthur Godfrey Road #402A
Street

Miami Beach FL 33140
City *State* *Zip*

Phone

Email

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

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

Representing Florida for Care

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 406
Bill Number (if applicable)

Topic Medical Marijuana

Amendment Barcode (if applicable)

Name Shalah Romine

Job Title MMJ Coordinator

Address 608 W 16th St.
Street

Phone 904-651-1306

Saint Augustine FL 32080
City *State* *Zip*

Email Shalah@lucalawfirm.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Luca Law Firm, P.A.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

4/06
Bill Number (if applicable)

[redacted]
Amendment Barcode (if applicable)

Topic Licensure

Name Ron Watson

Job Title Lobbyist

Address 3738 Mundon Way
Street
Tallahassee FL
City *State* *Zip*

Phone 850 567-1202

Email watson.strategies@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AHMed

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/13/17
Meeting Date

406
Bill Number (if applicable)

Topic MEDICAL MARIJUANA

Amendment Barcode (if applicable)

Name Jeff SHARKEY

Job Title Mgr. CAPITOL ALLIANCE GROUP

Address 106 E College
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850 224 1660

Email jsharkey5@gmail.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing MEDICAL MARIJUANA BUSINESS ASSOCIATION of FLORIDA

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic Medical Cannabis

Amendment Barcode (if applicable)

Name Christopher Newcomb

Job Title MD, physician

Address 4840 Sweetbrade dr
Street

Sarasota FL 34241
City *State* *Zip*

Phone 941 685 2467

Email Hydrocmo@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing My patients

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-3-2017
Meeting Date

SB 506
Bill Number (if applicable)

Topic Amendment 2 implementation

Amendment Barcode (if applicable)

Name Alex Golden

Job Title Consultant

Address 11050 Wildlife Trail
Street

Phone 850-322-8253

Tallahassee, FL 32312
City *State* *Zip*

Email alexandergolden@comcast.net

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Thornton and Thornton PHARMS

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)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic SB 406, Amendment 2

Amendment Barcode (if applicable)

Name John Hightower

Job Title Paralegal

Address 2807 Sweetbriar Dr
Street

Phone 850-222-3363

Tallahassee FL 32312
City *State* *Zip*

Email johndhightower@gmail.com

Speaking: ☐ For ☐ Against ☑ Information

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

Representing Cannabis patients

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3 Apr 17
Meeting Date

406
Bill Number (if applicable)

Topic Medical Marijuana

Amendment Barcode (if applicable)

Name Barney Bishop

Job Title Pres & CEO

Address 204 S. Monroe
Street

Tall Fl 32301
City *State* *Zip*

Phone 850.510.9922

Email

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Fla. Smart Justice 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.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3 APR 2017
Meeting Date

406
Bill Number (if applicable)

Topic Medical Marijuana

Amendment Barcode (if applicable)

Name Bill Cody

Job Title Disabled Veteran

Address 1554 Oakhill RD
Street

Phone 856-693-2132

Gulf Breeze FL 32563
City *State* *Zip*

Email wildbill53e@gmail.com

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

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

Representing

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

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

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

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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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic Amendmet 2

Amendment Barcode (if applicable)

Name Melissa Lozano

Job Title

Address 109 Sinclair Dr
Street

Tallahassee FL 32312
City *State* *Zip*

Phone 8502842090

Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic Medical Marijuana System

Amendment Barcode (if applicable)

Name Michael Patterson

Job Title CEO - US Cannabis Pharmaceutical Research + Dev.

Address 1469 Tipperary Drive
Street
Melbourne FL 32940
City *State* *Zip*

Phone 321-960-9699

Email Mpatterson@uscprd.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing The people 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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic MARIJUANA

Amendment Barcode (if applicable)

Name LOUIS ROTUNDO

Job Title

Address 302 Riverstone Circle
Street

Altamonte Springs 32714
City *State* *Zip*

Phone 407-697-9361

Email LCR5002@aol.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing CBS4 IWC

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4·3·2017
Meeting Date

SB 406
Bill Number (if applicable)

Topic COMPASSIONATE USE

Amendment Barcode (if applicable)

Name DENNIS DECKERHOFF

Job Title PATIENT ADVOCATE

Address 5704 VICTOR BROWN TRL.
Street

TALL. FL. 32303
City *State* *Zip*

Phone 850·567-0405

Email dennis@deckerhoff.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing BARRETT DECKERHOFF + PATIENTS IN 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)

4-3-17
Meeting Date

406
Bill Number (if applicable)

Topic MMJ

Amendment Barcode (if applicable)

Name Bianca Chang Gentile

Job Title Disabled Patient

Address 3405E 3 PL
Street

Deerfield Bch FL 33441
City *State* *Zip*

Phone 561 346 9207

Email wonderingmom@gmail.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.

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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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic Medical Cannabis

Amendment Barcode (if applicable)

Name Bridgit Kirouac

Job Title

Address 7505 SE Bay Cedar Circle
Street

Phone 772-210-2322

Hobe Sound, FL 33455
City *State* *Zip*

Email

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.

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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)

4/3/17
Meeting Date

406
Bill Number (if applicable)

Topic Implementation Amend 2

Amendment Barcode (if applicable)

Name Heather S. Preysz

Job Title CEO

Address 635 Pullman Circle
Street
St. Augustine, FL 32084
City *State* *Zip*

Phone 9043336728

Email Heather@BudsforVets.org

Speaking: ☐ For ☒ Against ☐ Information Edible, High THC Vape, Waive Speaking: ☐ In Support [redacted] Against
(The Chair will read this information into the record.)

Representing Veterans, We need smokable, Natural Medical Marijuana reciprocity.

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)

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THE FLORIDA SENATE

APPEARANCE RECORD

4-3-17
Meeting Date

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

406
Bill Number (if applicable)

Topic AMENDMENT 2

Amendment Barcode (if applicable)

Name MARC RESSLER

Job Title

Address 176 CROSSROAD LAKES DR.
Street

POMPANO BEACH FL 33082
City *State* *Zip*

Phone 904 - 321-9556

Email MARCRESSLER@AOL.COM

Speaking: ☑ For ☑ Against ☐ Information

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

Representing MYSELF

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 732
INTRODUCER:	Heath Policy Committee and Senator Steube
SUBJECT:	Physician Assistant Workforce Surveys
DATE:	April 4, 2017
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 732 requires a physician assistant (PA) to complete a workforce survey for license renewal under ch. 458, or ch. 459, F.S. The Department of Health (DOH) must report the data collected from the PA workforce surveys to the boards every 2 years.

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

II. Present Situation:

Physician Assistants

Regulation of PAs - The Boards and the Council

Chapter 458, F.S., sets forth the provisions for the regulation of the practice of allopathic medicine by the Board of Medicine (BOM). Chapter 459, F.S., sets forth the provisions for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine (BOOM). PAs are regulated by either the BOM or the BOOM, as applicable. Licensure of PAs is overseen jointly by the boards through the Council on Physician Assistants.

Supervision of PAs

PAs are trained and required by statute to work under the supervision and control of allopathic physicians or osteopathic physicians.[1] The BOM and the BOOM have adopted rules that set out the general principles a supervising physician must use in developing the scope of practice of the PA under both direct[2] and indirect[3] supervision. These principles are required to recognize the diversity of both specialty and practice settings in which PAs are used.[4]

PAs may perform services delegated by a supervising physician in accordance with the PA's education and training unless expressly prohibited under ch. 458, F.S., ch. 459, F.S., or by rules adopted under either chapter.[5] A supervising physician's decision to permit a PA to perform a task or procedure under direct or indirect supervision must be based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. The supervising physician must be certain that the PA is knowledgeable and skilled in performing the tasks and procedures assigned.[6] Each physician or group of physicians supervising a licensed PA must be qualified in the medical areas in which the PA is to practice and must be individually and collectively responsible and liable for the acts and omissions of the PA.[7]

Licensure as a PA requires that the individual:

- Is at least 18 years of age;
- Has passed a proficiency examination with an acceptable score established by the National Commission on Certification of Physician Assistants (NCCPA);[8]
- Has completed the DOH application form, remitted an application fee, and included the following:
  - A certificate of completion of a BOM or BOOM approved PA program;
  - Acknowledgment of any prior felony convictions;
  - Acknowledgement of any revocations or denials of licensure in any state; and
  - A copy of PA training course descriptions and transcripts in pharmacotherapy, if prescribing privileges are desired.[9]

Renewal of a PA's license is biennial and contingent upon completion of a certain type and quantity of continuing medical education requirements. A PA with delegated prescribing authority must submit a signed affidavit that he or she has completed a minimum of ten

[1] Sections 458.347(4) and 459.022(4), F.S.
[2] "Direct supervision" requires the physician to be on the premises and immediately available. (*See* Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.).
[3] "Indirect supervision" refers to the easy availability of the supervising physician to the PA, which includes the ability to communicate by telecommunications, and requires the physician to be within reasonable physical proximity. (*See* Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.)
[4] Sections 458.347(4)(a) and 459.002(4)(a), F.S.
[5] Section 458.347(4)(h) and 459.022(4)(g), F.S.
[6] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[7] Sections 458.347(3) and 459.022(3), F.S.
[8] If an applicant does not hold a current certificate issued by the NCCPA, and has not actively practiced within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the NCCPA to be eligible for licensure.
[9] Section 458.347(7)(a), F.S. and s. 459.022(7)(a), F.S.

continuing medical education hours in the specialty practice in which the PA has prescriptive privileges.[10]

Workforce Surveys

There is currently no statutory requirement for the DOH to develop or administer, or for a PA to complete, a survey before he or she can renew his or her license. However, physicians licensed under the same chapters as PAs are required to complete a survey at licensure renewal.[11] The DOH may issue a nondisciplinary citation if the physician does not complete the survey at least 90 days after renewal. The citation must notify the physician that his or her license will not be renewed in any subsequent renewal period, unless the survey is completed.[12]

III. Effect of Proposed Changes:

PA Workforce Survey as a Renewal Requirement

CS/SB 732 requires a PA, as a condition of licensure renewal, to complete a workforce survey which will be administered in the same manner as the physician's survey[13] and must contain, the following:[14]

- Licensee information, including, but not limited to:
  - Frequency and geographic location of practice within the state;
  - Practice setting;
  - Percentage of time spent in direct patient care;
  - Anticipated change to license or practice status; and
  - Areas of specialty or certification.

- Availability and trends relating to critically needed services, including, but not limited to:
  - Obstetric care and services, including incidents of deliveries;
  - Radiological services, particularly performance of mammograms and breast-imaging services;
  - Physician services for hospital emergency departments and trauma centers, including on-call hours; and
  - Other critically needed specialty areas, as determined by the department.

The information submitted must include a statement that the information provided is true and accurate to the best of the PA's knowledge and the submission does not contain any knowingly false information.[15]

The bill requires the DOH to administer the PA survey in the same manner as the physician survey. Accordingly, the DOH must:

- Include in PA license renewals a notice that the PA survey must be completed prior to license renewal; and that the DOH may not renew the license until the survey s completed;

[10] Section 458.347(4)(e)3., F.S., and s. 459.022(4)(e)3., F.S.
[11] *See* s. 458.3191, F.S.
[12] Sections 458.3191 and 459.0081, F.S.
[13] See 458. 319, and 459.0081, F.S.
[14] Id.
[15] Id.

- Issue a nondisciplinary citation to PAs who do not complete the survey within 90 days after filing an application for renewal; and
- Include in the nondisciplinary citation notice that PA's license will not be renewed unless the survey is completed.

Beginning July 1, 2018, and every 2 years thereafter, the DOH must report the survey data to the applicable boards. The DOH has been granted rulemaking authority to implement the survey process.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

CS/SB 732 may require the DOH to incur additional expenses to develop, administer, and enforce the PA survey.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires PAs licensed under ch. 458, F.S., and ch. 459, F.S., to provide personal identifying information without making that information confidential and exempt from disclosure. A public records exception exists for records containing personal identifying

information that the DOH receives from physicians in response to their mandatory workforce survey.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.347 and 459.022.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

CS by Health Policy on April 3, 2017

The CS:

- Deletes specific components of a PA survey; and instead requires the PA workforce survey to contain the same information required by physicians, and administered in the same manner;
- Deletes reference to designated supervising physician or PAs; and
- Deletes changes to the composition of the Council on Physician Assistants

B. Amendments:

None.

230990

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraph (b) of subsection (7) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b)1. The license must be renewed biennially. Each renewal must include:

230990

a.~~1.~~ A renewal fee not to exceed $500 as set by the boards.

b.~~2.~~ Acknowledgment of no felony convictions in the previous 2 years.

c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. 458.3191 and must contain the same information required in s. 458.3191(1) and (2).

2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.

3. The department shall adopt rules to implement this paragraph.

Section 2. Paragraph (b) of subsection (7) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b)1. The licensure must be renewed biennially. Each renewal must include:

a.~~1.~~ A renewal fee not to exceed $500 as set by the boards.

b.~~2.~~ Acknowledgment of no felony convictions in the previous 2 years.

c. A completed physician assistant workforce survey, which shall be administered in the same manner as the physician survey established in s. 458.3191 and must contain the same information required in s. 458.3191(1) and (2).

2. Beginning July 1, 2018, and every 2 years thereafter, the department shall report the data collected from the physician assistant workforce surveys to the boards.

3. The department shall adopt rules to implement this

230990

paragraph.

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

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; requiring that a physician assistant license renewal include the submission of a physician assistant workforce survey; requiring the Department of Health to report the data collected from such surveys to the boards; providing rulemaking authority; providing an effective date.

678364

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
	.	
	.	
	.	

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

Senate Amendment to Amendment (230990)

In title, delete lines 48 - 49
and insert:
An act relating to physician assistant workforce surveys; amending ss. 458.347 and 459.022, F.S.; requiring that a physician

By Senator Steube

23-01487-17 2017732__

A bill to be entitled

An act relating to physician assistants; amending s. 458.347, F.S.; requiring that a physician assistant license renewal include the submission of a physician assistant survey; requiring the Department of Health to create a physician assistant survey that includes specified information; revising requirements of appointees to the Council on Physician Assistants; providing an effective date.

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

Section 1. Paragraphs (b) and (d) of subsection (7) and paragraphs (a) and (b) of subsection (9) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b)1. The license must be renewed biennially. Each renewal must include:

a.~~1.~~ A renewal fee not to exceed $500 as set by the boards.

b.~~2.~~ Acknowledgment of no felony convictions in the previous 2 years.

c. A completed physician assistant survey as provided in subparagraph 2.

2. The department shall create a standardized physician assistant survey, which must include, but is not limited to, the following:

a. Licensee information, including:

(I) Frequency and geographic location of practice within the state;

(II) Name of accredited physician assistant training program where the physician assistant received his or her

23-01487-17 2017732__

education and training, year of his or her graduation, and number of years of practice in this state;

(III) Practice setting;

(IV) Percentage of time spent in direct patient care;

(V) Areas of specialty;

(VI) Current salary; and

(VII) Ownership of practice, in part or in full.

b. Questions regarding availability and trends relating to critically needed services, as determined by the department.

c. A statement submitted by the physician assistant that the information provided is true and accurate to the best of his or her knowledge and the submission does not contain any knowingly false information.

3. The department shall issue a nondisciplinary citation to any physician assistant licensed under this chapter or chapter 459 who fails to complete the survey within 90 days after he or she has filed an application for the renewal of his or her license to practice as a physician assistant. The citation must notify the physician assistant that his or her license will not be renewed unless the physician assistant completes the survey.

4. In conjunction with issuing the license renewal notice required by s. 456.038, the department shall notify each physician assistant licensed under this chapter or chapter 459 who has failed to complete the survey, at the licensee's last known address of record, that the physician assistant survey must be completed before the department renews his or her license.

5. The department shall adopt rules to implement this paragraph.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment or after any subsequent changes in the supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. Any subsequent change in the designated supervising physician shall be reported to the department within 30 days after the change. Assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of physicians other than the designated supervising physician.

2. The designated supervising physician must be a physician designated by the facility or the practice to be the primary contact and supervising physician for the physician assistants in a practice in which physician assistants are supervised by multiple supervising physicians. The designated supervising physician shall maintain a list of all approved supervising physicians at the practice or facility, which includes the name of each supervising physician and the physician's area of practice. The list must be kept up to date with additions and terminations and be provided to the department in a timely manner upon written request.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of five members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint one member ~~three members~~ who is a physician ~~are physicians~~ and a

member ~~members~~ of the Board of Medicine. ~~One of~~ The physician ~~physicians~~ must supervise a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and a member of the Board of Osteopathic Medicine. The physician must supervise a physician assistant in the physician's practice.

3. The State Surgeon General or his or her designee shall appoint three ~~a~~ fully licensed physician assistants ~~assistant~~ licensed under this chapter or chapter 459.

(b) ~~Two of the members appointed to the council must be physicians who supervise physician assistants in their practice.~~ Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Judiciary, *Chair*
Banking and Insurance, *Vice Chair*
Agriculture
Appropriations Subcommittee on Finance and Tax
Regulated Industries

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GREG STEUBE
23rd District

February 17, 2017

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

Dear Senator Young,

I am writing this letter because my bill, SB 732: Physicians Assistants, has been referred to the Senate Health Policy Committee. I am respectfully requesting that you place the bill on your committee's calendar for the next committee week.

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

Very respectfully yours,

W. Gregory Steube, District 23

REPLY TO:
❒ 722 Apex Road, Unit A, Sarasota, Florida 34240 (941)342-9162
❒ 326 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5023

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

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

732
Bill Number (if applicable)

Topic Physician Assistants

Amendment Barcode (if applicable)

Name Corinne Mixon

Job Title Lobbyist

Address 119 S. Monroe St. (*Street*)
Tallahassee FL 32301 (*City / State / Zip*)

Phone 766-5795

Email corinnemixon@gmail.com

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

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

Representing Florida Academy of Physician Assistants

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

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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4/3/17
Meeting Date

SB 732
Bill Number (if applicable)

Topic PAs

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title Gen. Counsel

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Street

Tall FL 32308
City *State* *Zip*

Phone 850-224-6496

Email JScott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FMA

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)

4:00pm
412 K

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

732
Bill Number (if applicable)

Topic Physician Assistants

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr.
Street

Phone 878-7364

Tallahassee FL 32301
City *State* *Zip*

Email winnsr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 782
INTRODUCER:	Senators Mayfield and Young
SUBJECT:	High School Graduation Requirements
DATE:	March 31, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Androff	Graf	ED	**Favorable**
2.	Lloyd	Stovall	HP	**Favorable**
3.			RC	

I. Summary:

SB 782 revises the high school graduation requirements for satisfying the mandatory one-credit requirement in physical education. Specifically, the bill deletes the requirement for students who participate in two full seasons of an interscholastic sport to pass a competency test on personal fitness in order to satisfy the physical education credit required for graduation with a standard high school diploma.

The bill takes effect July 1, 2017.

II. Present Situation:

Florida law specifies the requirements for students to obtain a standard high school diploma.

Credits Required to Earn a Standard High School Diploma

To graduate from high school with a standard high school diploma, a student must successfully complete 24 credits, an International Baccalaureate curriculum, or an Advanced International Certificate of Education curriculum.[1]

A student must successfully complete 24 credits in the following subject areas:[2]

- Four credits in English Language Arts (ELA) I, II, III, and IV.
- Four credits in mathematics, including one each in Algebra I and Geometry. Industry certifications earned by students may substitute for up to two mathematics credits, except for Algebra I and Geometry.

[1] Section 1003.4282(1)(a), F.S.
[2] *Id.* at (3).

- Three credits in science, including one credit in Biology I and two credits in equally rigorous courses.[3] Industry certifications earned by students may substitute for one science credit except for Biology I.
- Three credits in social studies, including one credit each in U.S. history and World history; one-half in credit in economics, which must include financial literacy; and one-half credit in U.S. Government.
- One credit in fine or performing arts, speech and debate, or practical arts that incorporates artistic content and techniques of creativity, interpretation, and imagination.
- One credit in physical education that must include the integration of health.
- Eight credits in electives. School districts are required to develop and offer coordinated electives to enable a student to develop knowledge and skills in his or her area of interest and these electives must include opportunities for students to earn college credit.

Physical Education Credit

Florida law requires a student to earn one credit in physical education, of the mandatory 24 credits, to graduate with a standard high school diploma.[4] Currently, students that participate in an interscholastic sport at the junior varsity or varsity level for two full seasons can satisfy the one-credit requirement in physical education if the student passes a competency test on personal fitness with a score of "C" or better.[5] In 1998, the Legislature raised the physical education credit requirement from one to two seasons of interscholastic sports and added the personal fitness competency test.[6]

Currently, students who complete one semester with a grade of "C" or better in a marching band class, in a physical activity class that requires participation in marching band activities as an extracurricular activity, or in a dance class can satisfy one-half credit in physical education.[7] Additionally, students who complete 2 years in a Reserve Officer Training Corps (ROTC) class, a significant component of which is drills, satisfy the one-credit requirement in physical education and the one-credit requirement in performing arts.[8] There is no requirement that such students complete a personal fitness competency exam.

III. Effect of Proposed Changes:

SB 782 revises the high school graduation requirements for satisfying the mandatory one-credit requirement in physical education. Specifically, the bill deletes the requirement for students who participate in two full seasons of an interscholastic sport to pass a competency test on personal fitness in order to satisfy the physical education credit required for graduation with a standard high school diploma.

The bill takes effect July 1, 2017.

[3] Two of the three science credits must have a laboratory component. *See* section 1003.4282(3)(c), F.S.
[4] Section 1003.4282(9)(b)6., F.S.
[5] *Id.* at (3)(f).
[6] Chapter 1998-421, s. 40, Laws of Fla.
[7] Section 1003.4383(3)(f), F.S.
[8] *Id.*

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

At the local school level, according to the Florida Department of Education (DOE), the elimination of the competency test on personal fitness may create savings in supplies that the school currently supplies, such as paper, printing, and the portion of salary used for the administration and grading of such tests.[9] However, any such savings are indeterminable because the current expenditures related to the competency test at the school level are currently unknown.[10]

According to the DOE, the elimination of the competency test on personal fitness may save the DOE costs for personnel to update the test, and any mailing or other costs associated with making the test available to the school districts.[11] The update to the personal fitness exam is currently expected to cost $1,427. Additionally, there is expected to be approximately $372.52 in expenditures related to the distribution of the updated material.[12]

VI. Technical Deficiencies:

None.

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[9] Florida Department of Education, *Senate Bill 782 Analysis* (Jan. 1, 2017), p. 3, (on file with the Senate Committee on Health Policy).
[10] *Id.*
[11] *Id.* at 4.
[12] *Id.*

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 1003.4282 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 Mayfield

17-00968-17 2017782__

A bill to be entitled

An act relating to high school graduation requirements; amending s. 1003.4282, F.S.; removing a requirement that a student participating in an interscholastic sport pass a competency test on personal fitness to satisfy the physical education credit requirement for high school graduation; conforming a provision; providing an effective date.

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

Section 1. Paragraph (f) of subsection (3) of section 1003.4282, Florida Statutes, is amended to read:

1003.4282 Requirements for a standard high school diploma.—

(3) STANDARD HIGH SCHOOL DIPLOMA; COURSE AND ASSESSMENT REQUIREMENTS.—

(f) *One credit in physical education.*—Physical education must include the integration of health. Participation in an interscholastic sport at the junior varsity or varsity level for two full seasons shall satisfy the one-credit requirement in physical education ~~if the student passes a competency test on personal fitness with a score of "C" or better~~. ~~The competency test on personal fitness developed by the Department of Education must be used.~~ A district school board may not require that the one credit in physical education be taken during the 9th grade year. Completion of one semester with a grade of "C" or better in a marching band class, in a physical activity class that requires participation in marching band activities as an extracurricular activity, or in a dance class shall satisfy one-half credit in physical education or one-half credit in performing arts. This credit may not be used to satisfy the personal fitness requirement or the requirement for adaptive

Florida Senate - 2017 **SB 782**

17-00968-17 2017782__

physical education under an individual education plan (IEP) or 504 plan. Completion of 2 years in a Reserve Officer Training Corps (R.O.T.C.) class, a significant component of which is drills, shall satisfy the one-credit requirement in physical education and the one-credit requirement in performing arts. This credit may not be used to satisfy the personal fitness requirement or the requirement for adaptive physical education under an IEP or 504 plan.

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

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Education, *Vice Chair*
Appropriations Subcommittee on the Environment and Natural Resources
Appropriations Subcommittee on General Government
Banking and Insurance
Judiciary

JOINT COMMITTEE:
Joint Legislative Auditing Committee, *Alternating Chair*

SENATOR DEBBIE MAYFIELD
17th District

March 29, 2017

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

Re: SB 782

Dear Chair Young,

I am respectfully requesting Senate Bill 782, a bill relating to the High School Graduation Requirements, be placed on the agenda for your Health Policy comittee.

I appreciate your consideration of this bill and I look forward to working with you and the Health Policy committee in the future. If there are any questions or concerns, please do not hesitate to call my office at 850-487-5017.

Thank you,

Deb

Senator Debbie Mayfield
District 17

Cc: Sandra Stovall, Celia Georgiades, Brian McManus

REPLY TO:
☐ 900 E. Strawbridge Avenue, Melbourne, Florida 32901 (321) 409-2025
☐ 1801 27th Street, Vero Beach, Florida 32960 (772) 226-1970
☐ 324 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5017

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)

4/3/17
Meeting Date

782
Bill Number (if applicable)

Topic High School Graduation Requirements

Amendment Barcode (if applicable)

Name Fely Curva, Ph.D.

Job Title Partner, Curva & Associate LLC

Address 1212 Piedmont Dr.
Street

Phone (850) 508-2256

Tallahassee FL 32312
City *State* *Zip*

Email fely.curva@gmail.com

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Society of Health & Physical Educators (SHAPE) 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)

4-3-2017
Meeting Date

(782)
? 1314
Bill Number (if applicable)

Topic Educational options

Amendment Barcode (if applicable)

Name Shawn Frost

Job Title President

Address 113 S. Monroe St #101
Street

Tallahassee FL 32301
City *State* *Zip*

Phone

Email info@FCSBM.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Coalition of School Board Members

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 800
INTRODUCER:	Banking and Insurance Committee and Senator Broxson and others
SUBJECT:	Medication Synchronization
DATE:	March 29, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.	Lloyd	Stovall	HP	**Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 800 establishes coverage and payment requirements relating to medication synchronization. Medication synchronization is a process where a pharmacist coordinates or synchronizes refills for a patient who is taking multiple covered prescriptions, allowing them to be filled on the same day each month. Partial fills for less than the standard refill amount are often required in order to align all patient medications to the same refill date. Medication synchronization can be used as a tool to increase medication adherence.

The bill requires health insurers and health maintenance organizations (HMOs) that provide prescription drug coverage to offer insureds or members the option to align the refill dates of their prescription drugs through a network pharmacy at least once during the plan year. Controlled substances, prescription drugs dispensed in an unbreakable package, or a multidose unit of a prescription may not be partially filled for the purpose of aligning refill dates.

The bill requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy unless otherwise agreed to by the plan and the network pharmacy. The health insurer or HMO must prorate cost-sharing obligations of the insured for each partial refill of a covered prescription drug dispensed to align refill dates.

The fiscal impact of the bill on the Division of State Group Insurance is indeterminate.

The effective date of the bill is January 1, 2018.

II. Present Situation:

Medication synchronization is a process where a pharmacist coordinates or synchronizes refills for a patient who is taking multiple covered prescriptions, allowing them to be filled on the same day each month. This model is sometimes also referred to as the "appointment based model" as the patient has made a set appointment each month to pick up all of their prescriptions. Pharmacy staff will usually call the patient ahead of their appointment day to confirm that there have been no changes to the medications and that each prescription should be refilled.[1] Partial fills for less than the standard refill amount are often required initially in order to align all patient medications to the same refill date.

Medication synchronization can be used as a tool to increase medication adherence. Poor adherence to medication refills is most often an issue among individuals who suffer from chronic diseases. A Robert Wood Johnson Foundation study found that over 50 percent of all Americans suffer from at least one chronic disease, including such chronic diseases as cancer, diabetes, heart disease, hypertension, stroke, mental disorders, or pulmonary conditions.[2] The National Community Pharmacists Association estimates the cost of medication non-adherence to be in excess of $290 billion annually.[3]

Federal Health Care and Access to Prescription Drugs

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[4] established a voluntary, outpatient, prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug plans (MA-PDs) that offer coverage as part of broader, managed care plans. The Centers for Medicare and Medicaid Services currently requires health plans administering Medicare Part D plans to prorate copayments associated with refill synchronization.[5] A Medicare enrollee may request less than a one month's supply and pay and required copayment or coinsurance based on the quantity actually received.[6]

Patient Protection and Affordable Care Act

On March 23, 2010, the federal Patient Protection and Affordable Care Act (PPACA) was signed into law.[7] The PPACA requires health insurers to make coverage available to all individuals and

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[1] American Pharmacists Association, *Appointment Based Model*, http://www.pharmacist.com/appointment-based-model (last visited Mar. 29, 2017).
[2] National Community Pharmacists Association, *Pharmacists Advancing Medication Adherence - Moving Forward on A Solid Foundation: Year One Progress Report*, p.3, *available at* http://www.ncpa.co/pdf/smm/PAMA2012annualreport.pdf (July 2011 - June 2012) (last visited Mar. 29, 2017).
[3] *Id*.
[4] Pub. L. No. 108-173.
[5] Medicare.gov, *Copayment/coinsurance in drug plans* https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html (last visited Mar. 29, 2017).
[6] *Id*.
[7] The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.

employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates required essential health benefits,[8] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.[9]

The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide 10 categories of essential health benefits (EHB), which includes prescription drugs.[10] To be certified as a QHP, the insurer must also submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.[11] The deadline for insurers and HMOs to submit 2018 rates and forms to the Florida Office of Insurance Regulation (OIR) is May 3, 2017.

The QHPs must provide access to prescription drug benefits. An individual or small group health plan[12] providing QHPs must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless a drug is subject to restricted distribution by the U.S. Food and Drug Administration; or a drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under 45 CFR 156.135. The health plans retain the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy. While this provision requires coverage of a drug at a network, retail pharmacy, for plans that do not have a network, the enrollee may go to any pharmacy to access his prescription drug benefit. In those situations, those plans would be deemed in compliance with this standard.

The issuers need only provide enrollees with the option to access drugs that are not exempted under 45 CFR s. 156.122(e), at a network retail pharmacy. The federal Department of Health and Human Services (HHS) notes that there are instances in which obtaining a drug through a mail-order pharmacy may not be a viable option, such as when an individual does not have a stable living environment and does not have a permanent address, or when a retail pharmacy option better ensures that consumers can access their EHB prescription drug benefit on short notice.[13]

According to the HHS final rules, certain drugs have a Risk Evaluation and Mitigation Strategy (REMS) that includes Elements to Assure Safe Use that may require that pharmacies,

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[8] 42 U.S.C. s.18022.
[9] President Trump, Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and (Jan. 20, 2017). President Trump issued an executive order indicating that it is the intent of his administration to seek the prompt repeal of PPACA. (last viewed Mar. 30, 2017).
[10] See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Mar. 30, 2017) for Florida's benchmark plan.
[11] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last viewed Mar. 30, 2017).
[12] The Patient Protection and Affordable Care Act (Pub. L. 111–148). This regulation would not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.
[13] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10820, 10821 (Feb. 27, 2015).

practitioners, or health care settings that dispense the drug be specially certified and that may limit access to the drugs to certain health care settings.[14] If the health plan finds it necessary to restrict access to a drug for either of the reasons listed above, it must indicate this restricted access on the formulary drug list that plans must make publicly available under 45 CFR s. 156.122(d).

Medication Synchronization

Medication synchronization is a tool that can improve adherence when patients are on a regular medication regimen. Medication synchronization can also reduce the administrative burden on patients who take multiple medications by reducing the number of refill dates. A retail or mail order pharmacy would coordinate all of a patient's prescription medications so that the drugs have the same refill date each month. The pharmacist initially performs a comprehensive review of the patient's medication regimen to determine the appropriateness of each therapy.

A partial fill can be required to align the patient's medications to a single refill date. Currently, some plans may not provide coverage for a refill for less than a 30-day supply. Patients may be required to pay a full month's copayment or coinsurance for less than a month's supply of medications. In some cases, pharmacies trying to submit a claim for adjusted quantities, will receive a "refill too soon" rejection, and the plan will deny coverage altogether, resulting in the patient paying out of pocket to cover the cost for the amount of medication needed to align their refills. Contingent on the plan, some plans will allow a limited number of overrides per year for special circumstances, such as a vacation supply, replacement of lost medication, or medication synchronization. In regard to dispensing fees, some plans will prorate the dispensing fee payment to the pharmacy that reflects a partial refill of a prescription.

Staff conducted a limited survey of states and found that approximately 23 states[15] have considered medication synchronization legislation.[16] Some states place restriction on the types of drugs that may be eligible for synchronization or limited synchronization to those with chronic conditions. For example, Ohio requires that the medication must meet the following criteria:

- Cannot have quantity limits, dose optimization criteria, or other requirements that would be violated if synchronized;
- Not have special handling or sourcing needs, as determined by the policy, contract, or agreement, that require a single, designated pharmacy to fill or refill the prescription;
- Be formulated so that the quantity or amount dispensed can be effectively divided in order to achieve synchronization;
- Not be a schedule II controlled substance, opiate, or benzodiazepine.[17]

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[14] FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain drugs to ensure that the benefits of a drug or biological product outweigh its risks. The FDA's list of currently approved REMS is available at: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last viewed Mar. 30, 2017).

[15] See National Conference of State Legislators database available at http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx (last viewed Mar. 30, 2017).

[16] See http://www.ncpanet.org/newsroom/ncpa's-blog---the-dose/2015/06/18/states-take-the-lead-in-making-med-synchronization-easier (last viewed Mar. 30, 2017).

[17] See 2015 Ohio Act at https://custom.statenet.com/public/resources.cgi?id=ID:bill:OH2015000H116&ciq=ncsldc3&client_md=af8c8e805f456317976bcd68b3cfee7e&mode=current_text (last viewed Mar. 21, 2017).

Likewise, Kentucky law provides that a synchronized medication may not be a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.[18] Nevada law states that the synchronization provisions do not apply to unit-of-use packaging for which synchronization is not practicable or to a controlled substance.[19] In Maine, prescriptions for solid oral doses of antibiotics and solid oral doses that are dispensed in their original container as indicated in the federal Food and Drug Administration prescribing information or are customarily dispensed in their original packaging to assist a patient with compliance are excluded from the medication synchronization requirements.[20]

Regulation of Insurance in Florida

The Florida Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[21] The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S.[22] Before receiving a certificate of authority from the OIR, an HMO must obtain a Health Care Provider Certificate from the agency.

Florida's State Group Health Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group health insurance program under a cafeteria plan.[23] To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, insured HMOs, and a pharmacy benefits manager (PBM), CaremarkPCS Health, L.L.C. (CVS/Caremark) for the state employees' self-insured prescription drug program.

III. Effect of Proposed Changes:

Sections 1 and 2 require health insurers and health maintenance organizations (HMOs) that provide prescription drug coverage to offer insureds or members the option to align the refill dates of their prescription drugs through a network pharmacy at least once in a plan year. Controlled substances, prescription drugs dispensed in an unbreakable package, or a multidose unit may not be partially filled for the purpose of aligning refill dates.

The bill requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy unless otherwise agreed to by the plan and the network pharmacy. The health insurer or HMO must prorate cost-sharing obligations of the insured for each partial refill of a covered prescription drug dispensed to align refill dates.

The provisions of these sections apply to policies or contracts issued on or after January 1, 2018.

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[18] See KRS 304.17A-165.
[19] Chapter 689A.330 of NRS.
[20] See http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0284&item=3&snum=127 (last viewed Mar. 30, 2017).
[21] Section 20.121(3)(a), F.S.
[22] Section 641.21(1), F.S.
[23] 26 U.S.C. s. 125.

Section 3 provides that this act takes effect January 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:

Implementation of medication synchronization may improve medication adherence for patients, particularly patients with chronic conditions who are on multiple-medication regimens.

According to DMS, for a preferred provider organization enrollee filling maintenance medications at a retail pharmacy, any partial fill would count as one of their three 30-day fills at retail before being required to use 90-day retail or 90-day mail order.[24] Insurers and HMOs may incur additional costs associated with full dispensing fees associated with partial refills of covered drugs.

C. Government Sector Impact:

Local governments may experience an indeterminate increase in pharmacy dispensing fees if they are required to pay full dispensing fees for partial refills.

DMS/Division of State Group Insurance

Currently, the program does not allow for the synchronization of medication, if that synchronization requires an early refill. The fiscal impact on the program is unknown.[25]

[24] Department of Management Services, *Senate Bill 800 Analysis* (Mar. 16, 2017) (on file with the Senate Committee on Health Policy).
[25] *Id.*

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates section 627.64196 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 March 27, 2017:
The CS:

- Requires health insurers and HMOs that provide covered prescription drugs to offer insureds or members the option to use medication synchronization at least once in a plan year at a network pharmacy.
- Requires such health insurer and HMO to implement a process for dispensing drugs for the purpose of aligning the refill dates of such drugs.
- Requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy for each partial refill of a covered drug dispensed to align refill dates, unless otherwise agreed to by the plan and the network pharmacy at the time of the insured or member requests medication synchronization.
- Excludes certain prescription drugs from being partially filled for the purpose of aligning refill drugs.
- Applies to policies or contracts renewed or entered into on or after January 1, 2018.

B. Amendments:

None.

By the Committee on Banking and Insurance; and Senators Broxson and Mayfield

597-02936-17 2017800c1

A bill to be entitled

An act relating to medication synchronization; creating s. 627.64196, F.S., and amending s. 641.31, F.S.; requiring health insurers and health maintenance organizations, respectively, which issue or deliver certain policies or contracts to offer medication synchronization to allow insureds and subscribers to align refill dates for certain drugs at least once in a plan year; requiring such insurers and health maintenance organizations to implement a process for aligning such dates; authorizing medical synchronization only through a network pharmacy; providing exceptions from partial filling for the purpose of aligning refill dates; requiring such insurers and health maintenance organizations to pay, except under certain circumstances, the full dispensing fee for a partial refill to align refill dates; requiring such insurers and health maintenance organizations to prorate certain cost-sharing obligations; providing applicability; providing an effective date.

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

Section 1. Section 627.64196, Florida Statutes, is created to read:

627.64196 Medication synchronization.—A health insurer issuing or delivering in this state an individual or a group health insurance policy that provides prescription drug coverage

597-02936-17 2017800c1

shall offer medication synchronization to allow an insured to align at least once in a plan year the refill dates for prescription drugs covered by the policy. The insurer shall implement a process for dispensing prescription drugs to an insured for the purpose of aligning the refill dates of such drugs, and such medication synchronization may be available only through a network pharmacy. A controlled substance, a prescription drug dispensed in an unbreakable package, or a multidose unit of a prescription drug may not be partially filled for the purpose of aligning refill dates. The insurer shall pay a full dispensing fee to the network pharmacy for each partial refill of a covered prescription drug dispensed to align refill dates, unless otherwise agreed to by the plan and the network pharmacy at the time an insured requests medication synchronization. The insurer shall prorate the cost-sharing obligations of the insured for each partial refill of a covered prescription drug dispensed to align refill dates. This section applies to policies renewed or entered into on or after January 1, 2018.

Section 2. Subsection (44) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(44) A health maintenance organization issuing or delivering in this state a health maintenance contract that provides prescription drug coverage shall offer medication synchronization to allow a subscriber to align at least once in a plan year the refill dates for prescription drugs covered by the health maintenance contract. The health maintenance organization shall implement a process for dispensing

prescription drugs to a subscriber for the purpose of aligning the refill dates of such drugs, and such medication synchronization may be available only through a network pharmacy. A controlled substance, a prescription drug dispensed in an unbreakable package, or a multidose unit of a prescription drug may not be partially filled for the purpose of aligning refill dates. The health maintenance organization shall pay a full dispensing fee to the network pharmacy for each partial refill of a covered prescription drug dispensed to align refill dates, unless otherwise agreed to by the plan and the network pharmacy at the time a subscriber requests medication synchronization. The health maintenance organization shall prorate the cost-sharing obligations of the subscriber for each partial refill of a covered prescription drug dispensed to align refill dates. This subsection applies to policies renewed or entered into on or after January 1, 2018.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Military and Veterans Affairs, Space, and Domestic Security, *Vice Chair*
Appropriations Subcommittee on General Government
Appropriations Subcommittee on Pre-K - 12 Education
Children, Families, and Elder Affairs
Communications, Energy, and Public Utilities

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight, *Alternating Chair*

SENATOR DOUG BROXSON
1st District

March 29, 2017

Senator Dana Young

316 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Chairman Young,

I respectfully request that Senate Bill 800 be placed on the Health Policy Committee agenda at your earliest convenience.

Thank you for your consideration and I look forward to discussing this good bill with you, and the members of the committee.

Respectfully,

Doug Broxson
State Senator

REPLY TO:
❒ 418 West Garden Street, 4th Floor, Room 403, Pensacola, Florida 32502 (850) 595-1036
❒ 311 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5001

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)

4/3/17
Meeting Date

800
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Mand

Job Title _____

Address 1000 Riverside Ave #240
Street

Jacksonville, FL 32204
City *State* *Zip*

Phone 904-233-3051

Email _____

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Chapter, American College of Physicians

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

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4/03/17
Meeting Date

SB 800
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Medication Synchronization

Name Dorene Barker

Job Title Associate State Director

Address 200 W. College Ave, Ste 304
Street

Tall FL 32301
City *State* *Zip*

Phone 850 228-6387

Email doBarker@aarp.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing AARP

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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4/3/17
Meeting Date

800
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Med Sync

Name Melissa Ramba

Job Title VP Government Affairs

Address 227 S Adams St
Street

Tallahassee Fl. 32301
City *State* *Zip*

Phone

Email Melissa@FRF.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Retail Federation

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)

Meeting Date

802
Bill Number (if applicable)

Topic MEDICATION Synch.

Amendment Barcode (if applicable)

Name BETH LABASKY

Job Title Consultant

Address 1400 Village Sq Blvd
Street

Phone 850 322 7335

Tallahassee Fla 32312
City State Zip

Email bethlabasky@aol.com

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Alpha One Foundation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

4:00pm
412 K

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

800
Bill Number (if applicable)

Topic Medication Synchronization

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr.
Street

Phone 878-7364

Tallahassee FL 32301
City *State* *Zip*

Email winnsr@earthlink.net

~~Speaking:~~ ☒ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

April 3, 2017
Meeting Date

SB 800
Bill Number (if applicable)

Topic Medication Asynchronization

Amendment Barcode (if applicable)

Name Doug Bell

Job Title

Address 101 N. Monroe St
Street

TLH FL
City *State* *Zip*

Phone 681-3241

Email douglas.bell@bipc.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Chapter American Academy of Pediatrics

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 802
Bill Number (if applicable)

Topic Medication Sync.

Amendment Barcode (if applicable)

Name Jeff Scott

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Email JScott@medicalr

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FMA

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)

4/3
Meeting Date

SB 800
Bill Number (if applicable)

Topic Medication Synchronization

Amendment Barcode (if applicable)

Name Aimee Diaz Lyon

Job Title

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Street

Phone 850-200-9000

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City *State* *Zip*

Email aimee.diazlyon@mhdfirm.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Academy of Family Physicians / American Lung Association of 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.

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)

4-3-17
Meeting Date

SB800
Bill Number (if applicable)

Topic Medication Synchronization

Amendment Barcode (if applicable)

Name Joy Ryan

Job Title

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Speaking: ☐ For ☒ Against ☐ Information

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

Representing Americas Health Insurance Plans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/2017
Meeting Date

CS/SB 800
Bill Number (if applicable)

Topic MEDICATION SYNCHRONIZATION

Amendment Barcode (if applicable)

Name MICHAEL JACKSON

Job Title EXECUTIVE VICE PRESIDENT & CEO

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Street

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TALLAHASSEE FL 32301
City *State* *Zip*

Email MJACKSON@PHARMFLA.COM

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

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

Representing FLORIDA PHARMACY ASSOCIATION

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

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

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

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)

4/3
Meeting Date

800
Bill Number (if applicable)

Topic Support SB 800 MedSynch

Amendment Barcode (if applicable)

Name Chris Hansen

Job Title Ballard Partners

Address _____ Phone 577-0444
Street

Tallahassee FL 32301 Email Chansen@ballardfl.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Walgreens

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 840
INTRODUCER:	Health Policy Committee and Senator Clemens
SUBJECT:	Prescription Drug Monitoring Program
DATE:	April 5, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Fav/CS**
2.			GO	
3.			RI	
4.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 840 limits an initial prescription of opioids for acute pain to a quantity not to exceed 5 days. "Acute pain" is defined as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

The bill requires dispensers that must report the dispensing of a controlled substance to the Prescription Drug Monitoring Program database (PDMP) to report by the close of the next business day, rather than 7 days, after the controlled substance is dispensed. This expedited timeframe for reporting is effective January 1, 2018. Reporting must be through the electronic system approved by the Department of Health (DOH or department).

The bill clarifies an exemption from reporting for rehabilitative hospitals, assisted living facilities, or nursing homes dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician by requiring the dispensing to occur while the patient is present and receiving care.

An employee of the U.S. Department of Veterans Affairs, who is authorized to prescribe controlled substances, may access the PDMP for the purpose of reviewing his or her patient's controlled substance prescription history.

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

II. Present Situation:

The Prescription Drug Monitoring Program

Starting in the early 2000s, Florida began experiencing a marked increase in deaths resulting from prescription drug abuse. In 2010, the former Florida Office of Drug Control (FODC) identified prescription drug abuse as "the most threatening substance abuse issue in Florida."[1] According to the FODC, between 2003 and 2009, the number of deaths caused by at least one prescription drug increased by 102 percent (from 1,234 to 2,488).[2] The FODC remarked that these numbers translated into seven Floridians dying from prescription drug overdoses per day.[3]

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the PDMP; and stricter regulation on selling, distributing, and dispensing controlled substances.[4]

Chapter 2009-197, L.O.F., established the PDMP in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.[5] The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[6] Dispensers have reported over 198 million controlled substance prescriptions to the PDMP since its inception.[7] Health care practitioners began accessing the PDMP on October 17, 2011.[8] Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[9]

Dispensers of controlled substances listed in Schedule II, Schedule III, or Schedule IV of s. 893.03, F.S., must report specified information to the PDMP database within seven days after dispensing, each time the controlled substance is dispensed. The information required to be reported includes:[10]

- Name of the dispenser [pharmacy], Drug Enforcement Administration registration number, and address of the pharmacy;

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[1] Executive Office of the Governor, *Florida Office of Drug Control 2010 Annual Report*, p. 8 (on file with the Senate Committee on Health Policy).
[2] *Id.*
[3] *Id.*
[4] *See* chs. 2009-197, 2010-211, and 2011-141, Laws of Fla.
[5] Section 893.055(2)(a), F.S.
[6] Florida Dep't of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (December 1, 2013), p. 2, *available at* http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited on Mar. 29, 2017).
[7] Florida Dep't of Health, *2015-2016 Prescription Drug Monitoring Program Annual Report* (December 1, 2016), p. 4, *available at* http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited on Mar. 29, 2017).
[8] *Supra* note 6.
[9] *Supra* note 6.
[10] The specific information reported depends upon the whether the reporter is a pharmacy or practitioner.

- Name of the prescribing practitioner and his or her Drug Enforcement Administration registration number, National Provider Identification, or other applicable identifier, and the date of the prescription;
- Date the prescription is dispensed;
- Name, address, and date of birth of the person to whom the controlled substance is dispensed; and
- Name, national drug code, quantity, and strength of the controlled substance dispensed.[11]

Personally identifying information in the PDMP is confidential and exempt from the public records laws and State Constitution. Specified persons or entities are authorized either direct or indirect[12] access to certain protected information in the PDMP.[13]

Current law exempts certain acts of dispensing or administering from PDMP reporting:

- A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- A practitioner when administering a controlled substance in the emergency room of a licensed hospital.
- A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.
- A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.
- A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician.[14]

A dispenser must submit the required dispensing information in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.[15] Rule 64K-1.004, F.A.C., requires all

[11] *See* s. 893.055(3), F.S.
[12] Indirect access requires submitting a request to the PDMP program manager for specific information each time information is needed which may be released once the requester and request is verified as authentic and authorized. *See* ss. 893.055(7)(c) and 893.0551(3), F.S.
[13] *See* s. 893.0551, F.S.
[14] *See* s. 893.055(5), F.S.
[15] *See* s. 893.055(4), F.S.

dispensers to electronically report the dispensing information.[16] The DOH allows five electronic data delivery methods.[17]

On average, each month 6,546 dispensers report controlled substance dispensing information to the PDMP, and 96 percent of dispensers complied with the mandated 7-day timeframe for reporting. Of those dispensers, 66 percent reported the information within 24 hours.[18]

PDMP Reporting in Other States

Data reporting frequency varies from state to state. Oklahoma is the only state that requires its dispensers to report controlled substance dispensing data at the point of sale, real time. Thirty-five states require data to be uploaded within 1 day, three states require data to be uploaded within 3 days, 11 states require data to be uploaded within 7 days, and one state requires data to be uploaded within 14 days.[19]

Guidelines for Prescribing Opioids

Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. From 2000 to 2015 more than half a million people died from drug overdoses. Ninety-one Americans die every day from an opioid overdose.[20]

In March 2016, the Centers for Disease Control and Prevention (CDC) issued Guidelines for Prescribing Opioids for Chronic Pain.[21] The guidelines is a series of recommendations that focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.[22] However, among the 12 recommendations is one relating to prescribing short durations for acute pain. This recommendation is summarized as follows:

---

[16] The DOH may grant a dispenser a waiver of the electronic submission requirement for good cause. "Good cause" includes financial hardship and lack of an automated recordkeeping system. The dispenser must notify the DOH in writing by completing an electronic reporting waiver form provided by the DOH. The DOH will work with the dispenser to determine the format, method, and frequency of the alternative non-electronic submissions. *See* E-FORCSE Dispenser's Implementation Guide ASAP 4.2 (July 2015) DH8013-PDMP, p. 7, *available at* https://www.flrules.org/gateway/reference.asp?No=Ref-06459 and click on the DH8013-PDMP (01.15) 64K-1.004 (v2).pdf link, (last visited on Mar. 29, 2017).

[17] *Id.*, p. 21.

[18] *Supra* note 7, p.5.

[19] Department of Health, *Senate Bill 840 Analysis* (February 13, 2017) (on file with the Senate Committee on Health Policy).

[20] Centers for Disease Control and Prevention, *Opioid Overdose, Understanding the Epidemic* (updated December 16, 2016) *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited April 4, 2017).

[21] Dowell D. Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1): 1-49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501el *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr650el.htm (last visited April 4, 2017).

[22] Centers for Disease Control and Prevention, *Opioid Overdose, CDC Guidelines for Prescribing Opioids for Chronic Pain* (updated March 15, 2017) *available at* https://www.cdc.gov/drugoverdose/prescribing/guideline.html (last visited April 4, 2017).

> Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.[23]

A number of states have enacted legislation or otherwise limited the initial duration of prescriptions for opioids for acute pain. On February 15, 2017, Governor Chris Christie of New Jersey signed legislation, reported as the strictest in the nation, limiting initial opioid prescriptions to a 5-day supply.[24] Over the past year, Connecticut, Delaware, Maine, Massachusetts, New York, Pennsylvania, Rhode Island, and Vermont, have enacted laws or adopted rules for imposing 7-day limits for initial opioid prescriptions, mostly for acute pain.[25] Bills to restrict opioid prescriptions are pending in Georgia, Hawaii, Indiana, Kentucky, Montana, Oregon, and Washington.[26]

III. Effect of Proposed Changes:

The bill amends the general provisions for prescribing controlled substances, to limit an initial prescription of opioids for the treatment or alleviation of acute pain to a quantity not to exceed 5 days. "Acute pain" is defined as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

Effective January 1, 2018, dispensers of controlled substances that are required to report the dispensing of a controlled substance to the PDMP must report no later than the close of the next business day after the controlled substance is dispensed. The DOH may grant an extension to this timeframe for cause as determined by rule. The bill requires the submission via the department-approved electronic system; eliminating other approved formats that may include being on a disc or submitting by regular mail.

The bill clarifies an exemption from reporting to the PDMP that was enacted during the 2016 Regular Session[27] for rehabilitative hospitals, assisted living facilities, or nursing homes dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician. The bill limits application of the exemption such that the controlled substance must be dispensed to a patient while the patient is present and receiving care in the facility. This ensures that the controlled substance is dispensed and administered[28] at the facility to conform with the other exemptions.

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[23] Centers for Disease Control and Prevention, Opioid Overdose, Guidelines at a Glance, (updated February 9, 2017), *available at* https://www.cdc.gov/drugoverdose/ (last visited April 4, 2017).
[24] Christine Vestal, *New Jersey Enacts Nation's Strictest Opioid Prescribing Limit* (February 16, 2017), *available at* http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/02/16/new-jersey-enacts-nations-strictest-opioid-prescribing-limit (last visited April 4, 2017).
[25] Association of State and Territorial Health Officials, *A Look at State Legislation Limiting Opioid Prescriptions* (February 23, 2017), *available at* http://astho.org/StaatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/?terms=acute+pain (last visited April 4, 2017).
[26] *Id.*
[27] Chapter 2016-177, Laws of Fla.
[28] Dispense means to transfer possession and administer means to inject, inhale, or ingest. *See* s. 893.02, F.S.

The bill also authorizes an employee of the U.S. Department of Veterans Affairs, who provides health care services pursuant to that employment and is authorized to prescribe controlled substances, to access the PDMP only for the purpose of reviewing his or her patient's controlled substance prescription history.

A conforming cross-reference is made to s. 463.0055, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Some dispensers may incur additional costs, such as software updates, to develop electronic reporting capabilities and being able to submit within the next business day reporting timeframe. The effective date of January 1, 2018, for meeting the submission timeframe may ease the transition.

C. Government Sector Impact:

The DOH indicates it will incur non-recurring costs for rulemaking, which can be absorbed within existing resources.[29]

VI. Technical Deficiencies:

None.

[29] *Supra* note 19.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.44, 463.0055, and 893.055.

IX. Additional Information:

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

CS by Health Policy on April 3, 2017:
The committee substitute:

- Limits an initial prescription for controlled substances for "acute pain" (associated with surgery, trauma, or acute illness) to a 5-day supply.
- Revises reporting to the PDMP to: the close of the next business day and via the department-approved electronic system. The bill as filed provided for reporting within 24 hours and via the Internet.
- Authorizes a prescriber of controlled substances with the U.S. Department of Veterans Affairs access to the PDMP.
- Includes a conforming cross-reference within ch. 463, F.S., relating to optometrists.
- Changes the title of the bill from the Prescription Drug Monitoring Program.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Paragraphs (a) through (g) of subsection (1) of section 456.44, Florida Statutes, are redesignated as paragraphs (b) through (h), respectively, a new paragraph (a) is added to that subsection, and subsection (4) is added to that section, to read:

456.44 Controlled substance prescribing.—

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

(a) "Acute pain" means the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

(4) INITIAL PRESCRIPTION QUANTITY.—For the initial prescription of opioids for the treatment or alleviation of acute pain, the prescription must be limited to a quantity not to exceed 5 days.

Section 2. Subsection (4), paragraph (g) of subsection (5), and paragraphs (a) and (b) of subsection (7) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but no later than the close of the next business day ~~not more than 7 days~~ after the day ~~date~~ the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the department-approved electronic system ~~providing~~ the required information concerning each controlled substance that it dispensed ~~in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail~~.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

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(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic ~~or other~~ method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b) A pharmacy, prescriber, or dispenser, or the designee of a pharmacy, prescriber, or dispenser, shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. An employee of the United States Department of Veterans Affairs who provides health care services pursuant to such employment and has the authority to prescribe controlled substances shall have access to the information in the program's database in a manner established by the department. Such access is limited to the information that relates to a patient of such employee and may only be accessed for the purpose of reviewing the patient's controlled substance

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prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

Section 3. The requirement in s. 893.055(4), Florida Statutes, as amended by this act, that the dispensing of a controlled substance be reported to the Department of Health no later than the next business day shall take effect January 1, 2018.

Section 4. Paragraph (b) of subsection (4) of section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ocular

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pharmaceutical agents.—

(4) A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for an ocular pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon. A certified optometrist may not administer or prescribe:

(b) A controlled substance for the treatment of chronic nonmalignant pain as defined in s. 456.44 ~~456.44(1)(c)~~.

Section 5. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to controlled substance prescribing; amending s. 456.44, F.S.; defining the term "acute pain"; limiting the quantity of opioids that may be prescribed for acute pain in certain circumstances; amending s. 893.055, F.S.; revising requirements for reporting the dispensing of controlled substances; limiting an exception to reporting requirements for certain facilities that dispense controlled substances; authorizing certain employees of the United States Department of Veterans Affairs access to certain information in the prescription drug monitoring program's database; specifying when a revised reporting requirement takes effect; amending

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s. 463.0055, F.S.; conforming a cross-reference;
providing effective dates.

By Senator Clemens

31-01147-17 2017840__

A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; revising requirements for reporting the dispensing of controlled substances; limiting an exception to reporting requirements for certain facilities dispensing controlled substances; specifying when a revised reporting requirement takes effect; providing effective dates.

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

Section 1. Subsection (4) and paragraph (g) of subsection (5) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 24 hours ~~7 days~~ after ~~the date~~ the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the Internet ~~providing~~ the required information concerning each controlled substance that it dispensed ~~in a department-approved, secure methodology and format~~. ~~Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.~~

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled

31-01147-17 2017840__

substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

Section 2. The requirement that the dispensing of a controlled substance be reported to the Department of Health within 24 hours in s. 893.055(4), Florida Statutes, as amended by this act, shall take effect January 1, 2018.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Community Affairs, *Vice Chair*
Appropriations Subcommittee on Criminal and Civil Justice
Appropriations Subcommittee on Higher Education
Communications, Energy, and Public Utilities
Criminal Justice

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR JEFF CLEMENS
Democratic Whip
31st District

March 8, 2017

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

Chair Young:

I respectfully request that SB 840—Prescription Drug Monitoring Program be added to the agenda for the next Senate Committee on Health Policy meeting.

SB 840 will help combat Florida's ongoing opioid epidemic by modernizing the prescription drug monitoring program and shortening reporting time to better identify drug abuse. The bill would shorten the reporting time to the close of the next business day and require reporting to be handled exclusively via the electronic system.

Please feel free to contact me with any questions. Thank you for your consideration.

Sincerely,

Senator Jeff Clemens
Florida Senate District 31

REPLY TO:
❒ 508 Lake Avenue, Unit C, Lake Worth, Florida 33460 (561) 540-1140 FAX: (561) 540-1143
❒ 210 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5031

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)

4-3-17
Meeting Date

840
Bill Number (if applicable)

Topic Prescription Drug Monitoring Program

Amendment Barcode (if applicable)

Name Jill Gran

Job Title Policy Director

Address 2868 Mahan Dr
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 8508782194

Email jill@myfbha.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Behavioral Health Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1056
INTRODUCER:	Senator Garcia
SUBJECT:	Home Health Care Agency Licenses
DATE:	March 31, 2017
REVISED:	

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

I. Summary:

SB 1056 removes a prohibition on the Agency for Health Care Administration (AHCA) issuing an initial home health agency license to an applicant that shares common controlling interests with another licensed home health agency that is located in the same county and within 10 miles of the applicant.

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

II. Present Situation:

Home Health Agencies (HHA)

An HHA is an organization that provides home health services and staffing services.[1] Home health services provided by an HHA include health and medical services and medical supplies provided to an individual in his or her home, such as nursing care, physical and occupational therapy, and home health aide services.[2,3]

Home health agencies are regulated by the AHCA pursuant to part III of ch. 400, F.S., and the general licensing provisions in part II of ch. 408, F.S. As of March 31, 2017, there are 1950 licensed HHAs in the state.[4]

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[1] Section 400.462(12), F.S.
[2] Section 400.462(14), F.S. Additional services may include dietetics and nutrition practice and nutrition counseling.
[3] Home health aide services may include hands-on personal care, simple procedures as an extension of therapy or nursing services, assisting in ambulation or exercises, and assisting with the self-administration of medication. *See* s. 400.462(15), F.S.
[4] Agency for Health Care Administration, FloridaHealthFinder.gov, search on home health agencies, available at: http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited March 31, 2017),

A license is required to operate as an HHA unless an exemption applies.[5] Numerous exemptions exist and the most common exemptions apply to an HHA operated by the federal government or home health services provided by a state agency, licensed health care practitioner operating under his or her professional license, or other licensed health care facility.[6]

An HHA must designate a geographic service area (one or more counties within an AHCA district) in which the HHA will operate. These counties are identified on the license. An HHA may apply to amend the geographic service area to expand within the AHCA district under the same license.[7]

A licensed HHA may also operate satellite offices under the main HHA license. A satellite office must be located in the same geographic service area as the HHA's main office and share administration, fiscal management, supervision, and service provision with the main office. Supplies and records may be stored at a satellite office and signs and advertisements can notify the public of the satellite office location. If an HHA wants to open an office outside of the geographic services area where the main licensed office is located, it must obtain a separate license.[8]

Section 400.471(7), F.S., prohibits the AHCA from issuing an initial license to an applicant for an HHA license if the applicant shares common controlling interest with another licensed HHA that is located within 10 miles of the applicant and is in the same county. This restriction was enacted in ch. 2008-246, Laws of Fla.

"Controlling interest" means:[9]

- The applicant or license or
- A person or entity that serves as an officer of, is on the board of directors of, or has a five percent or greater ownership interest in the
  - Applicant or licensee or
  - Management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider.

Medicare and Medicaid Fraud

The HHA industry in Florida has been marred with years of uncontrolled growth and health care fraud. The Florida Senate studied HHAs in Florida in 2007, issuing an interim report[10] that outlined unusually rapid growth in licensed HHAs, particularly in South Florida, and indications of possible quality-of-care problems and Medicaid fraud. Numerous regulatory reforms were enacted in 2008 and 2009 which focused on fraud and abuse prevention in the HHA industry.[11]

[5] Section 400.464, F.S.
[6] Section 400.464(5), F.S.
[7] Rule 59A-8.007, F.A.C. The AHCA reviews the HHA's previous history of survey results and administrative action to assess the HHA's ability to provide quality services within the requested expanded area.
[8] Rule 59A-8.003(7), F.A.C.
[9] Section 408.803(7), F.S.
[10] The Florida Senate, *Review Regulatory Requirements for Home Health Agencies*, November 2007, http://archive.flsenate.gov/data/Publications/2008/Senate/reports/interim_reports/pdf/2008-135hr.pdf (last viewed March 30, 2017)
[11] *See* chs. 2008-246, 2009-193, and 2009-223, Laws of Fla.

Ongoing monitoring and Medicare and Medicaid fraud enforcement action continues. Most recently, in fiscal year 2015-2016, 24 HHAs were terminated from participation in the Medicaid program as a result of fraud and abuse,[12] and 26 HHAs were denied enrollment or reenrollment in the Medicaid program because of suspected fraud and abuse.[13]

In addition, the Centers for Medicare and Medicaid Services (CMS) has imposed a federal moratoria on new HHAs in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) in order to target fraud in Florida.[14]

- In July 2013, CMS implemented a moratorium on the enrollment of new HHAs in the Miami area.
- CMS extended the moratorium in 2014 to the metropolitan areas of Fort Lauderdale. The moratoria have since been extended at 6-month intervals and remain in place in both Miami and Ft. Lauderdale.
- Effective July 29, 2016, CMS expanded the moratoria statewide and made it applicable to Medicare, Medicaid, and the CHIP.[15]

There is no indication at this point as to the duration of the CMS imposed moratoria. The CMS has created a Provider Enrollment Moratoria Access Waiver Demonstration (PEWD) which is designed to provide exceptions to the moratoria to ensure that beneficiary access to care is not adversely impacted.[16]

III. Effect of Proposed Changes:

The bill removes a prohibition on the agency issuing an initial home health agency license to an applicant that shares common controlling interests with another licensed home health agency that is located in the same county and within 10 miles of the applicant. The bill also removes the directive for the agency to return the application and fees to the applicant.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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[12] Joint Report by the AHCA and the Medicaid Fraud Control Unit with the Office of the Attorney General, The State's Efforts to Control Medicaid Fraud and Abuse FY 2015-16, December 16, 2016, page 57, available at: http://ahca.myflorida.com/Executive/Inspector_General/docs/Medicaid_Fraud_Abuse_Annual_Reports/2015-16_MedicaidFraudandAbuseAnnualReport.pdf (last viewed March 30, 2017).

[13] *Id.* at page 58.

[14] CMS *Provider Enrollment Moratorim*, available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html (last viewed March 30, 2017).

[15] The moratoria was imposed statewide to address problems in the effectiveness of the earlier moratorium because those did not prevent providers outside the moratoria area from billing for servicing beneficiaries within that area.

[16] *Supra*, note 13.

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:

Applicants for an initial HHA license with common controlling interests with a currently licensed HHA will be able to obtain a new license within close proximity to the currently licensed HHA. A new license will enable the HHA to do business under a different license authority.

C. Government Sector Impact:

Indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 400.471 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 Garcia

36-00455A-17 20171056__

A bill to be entitled

An act relating to home health care agency licenses; amending s. 400.471, F.S.; removing a prohibition against the issuance of an initial home health agency license to an applicant who shares common controlling interests with another licensed home health agency located within 10 miles of the applicant and in the same county; providing an effective date.

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

Section 1. Subsection (7) of section 400.471, Florida Statutes, is amended to read:

400.471 Application for license; fee.—

~~(7) The agency may not issue an initial license to an applicant for a home health agency license if the applicant shares common controlling interests with another licensed home health agency that is located within 10 miles of the applicant and is in the same county. The agency must return the application and fees to the applicant.~~

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

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

The Florida Senate

State Senator René García
36th District

Please reply to:

District Office:

1490 West 68 Street
Suite # 201
Hialeah, FL. 33014
Phone# (305) 364-3100

March 10th, 2017

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

Dear Senator Young,

Please have this letter serve as my formal request to have **SB 1056: Home Health Care Agency Licenses** be heard during the next scheduled Health Policy Committee Meeting. Should you have any questions or concerns, please do not hesitate to contact my office.

Sincerely,

State Senator René García
District 36

CC: Sandra Stovall
Celia Georgiades

THE FLORIDA SENATE

APPEARANCE RECORD

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

4-3-17
Meeting Date

1056
Bill Number (if applicable)

Topic Home Health Ten mile rule

Amendment Barcode (if applicable)

Name Bobby Lolley

Job Title Executive Director

Address 2236 NE Capital Circle
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850-567-1951

Email BLolley@HomeCareFla.org

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

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

Representing Home Care Association of Florida

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 Committee on Health Policy

BILL:	CS/SB 1354
INTRODUCER:	Health Policy Committee and Senators Young and Mayfield
SUBJECT:	Medical Specialists
DATE:	April 4, 2017
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1354 establishes an additional process by which physicians may obtain formal recognition as a board-certified specialist in a particular area within the practice of medicine or osteopathic medicine; and obtain re-certification without undergoing periodic testing, proprietary self-assessment, or peer evaluation. The Department of Health (DOH) must issue a certificate authorizing a recognizing agency to grant an allopathic or osteopathic physician recognition as a specialist upon submission of an application meeting certain criteria.

The bill authorizes a physician to hold himself or herself out as a board-certified specialist if he or she has received formal recognition as a specialist from the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), the Accreditation Council on Graduate Medical Education (ACGME), or from an recognizing agency that has received a certificate from the DOH under this new process.

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

II. Present Situation:

Licensure and Regulation of Physicians

The DOH regulates health care practitioners.[1] It works with 22 boards and six councils to license and regulate more than 40 health care professions, including Medical Doctors (allopathic

[1] Section 456.001(4), F.S., defines health care practitioners to include: acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists,

physicians) and Doctors of Osteopathic Medicine (osteopathic physicians).[2] Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the DOH. Allopathic physicians are regulated by ch. 458, F.S., and Osteopathic Physicians are regulated by ch. 459, F.S.

Allopathic Physician Licensure and Continuing Medical Education (CME)

Chapter 458, F.S., delineates two main paths for a person to obtain an unrestricted Florida license as an allopathic physician: licensure by examination and licensure by endorsement.

An individual seeking to be licensed by examination as an allopathic physician must, among other things:

- Complete certain undergraduate college education courses;
- Meet the medical school education and college postgraduate training requirements; and
- Obtain a passing score on the U.S. Medical Licensing Examination (USMLE) or other approved examinations.[3]

An individual who holds an active license to practice allopathic medicine in another jurisdiction may seek licensure by endorsement to practice in Florida.[4] The applicant must meet the same requirements for licensure by examination and submit evidence of his or her licensed active practice of medicine in another jurisdiction for at least 2 of the preceding 4 years, or evidence of successful completion of either a board-approved postgraduate training program within 2 years preceding the filing of an application, or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

Allopathic physician licenses are renewed biennially.[5] Within each biennial licensure renewal period, a physician must complete 40 hours of CME courses approved by the allopathic Board of Medicine (BOM). A licensee must also complete, as a part of the 40 hours of CME, the following:

- A 2-hour course regarding domestic violence every third biennial;[6]
- A 1-hour course addressing the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome before the first biennial renewal;[7] and
- 2 hours of CME relating to the prevention of medical errors.[8]

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midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.

[2] Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2014-2015*, p 3, *available at* http://mqawebteam.com/annualreports/1415/#6 (last visited Mar. 17, 2017).

[3] Section 458.311(1), F.S.

[4] Section 458.313, F.S.

[5] Rule 64B8-3.003, F.A.C. If a practitioner dispenses medicinal drugs, an additional fee of $100 must be paid at the time of renewal.

[6] Section 456.031, F.S.

[7] Section 456.033, F.S.

[8] Section 456.013(7), F.S.

The DOH may not renew a license until a licensee complies with all CME requirements.[9] The BOM may also take action against a license for failure to comply with CME requirements.

Osteopathic Physician Licensure and Continuing Medical Education (CME)

An individual seeking to be licensed in Florida as an osteopathic physician must, among other things:[10]

- Graduate from a medical college recognized and approved by the American Osteopathic Association (AOA);
- Successfully complete an approved resident internship; and
- Obtain a passing score on all parts of the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the osteopathic board, no more than 5 years prior to applying for licensure.[11]

If an applicant for a license to practice osteopathic medicine is licensed in another state, the applicant must have actively practiced osteopathic medicine within the 2 years prior to applying for licensure in Florida.

Osteopathic physician licenses are renewed biennially.[12] Each biennial licensure renewal period, an osteopathic physician must complete 40 hours of approved CME courses. As a part of the 40 hours of CME, a licensee must also complete the following:

- A 2-hour course on domestic violence every third biennial;[13]
- A 1-hour course on the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) before the first biennial renewal;[14]
- 2 hours of CME relating to the prevention of medical errors;[15]
- A 1-hour course on professional and medical ethics; and
- A 1-hour course on the federal and state laws on prescribing of controlled substances.[16]

The DOH may not renew a license until a licensee complies with all CME requirements.[17] The osteopathic board may also take action against a license for failure to comply with CME requirements.[18]

[9] Section 456.013, F.S.
[10] Section 459.0055(1), F.S.
[11] However, if an applicant has been actively licensed in another state, the initial licensure in the other state must have occurred no more than 5 years after the applicant obtained the passing score on the licensure examination. *See* s. 459.055(1)(m), F.S.
[12] Section 459.008, F.S.
[13] Section 456.013, F.S.
[14] Section 456.033, F.S.
[15] Section 456.013(7), F.S.
[16] Rule 64B15-13.001, F.A.C.
[17] Section 456.031, F.S.
[18] Section 459.015, F.S.

Board Certification of Physicians

Medical licensure of physicians sets the minimum competency requirements to diagnose and treat patients; it is not specialty specific.[19] Medical specialty certification is a voluntary process that gives a physician a way to develop and demonstrate expertise in a particular specialty or subspecialty.[20]

Board Certification by the American Board of Medical Specialties (ABMS)

When a physician is board certified by an ABMS specialty board, it means he or she has met the standards[21] and requirements for certification in a specialty or subspecialty of one or more of the 24 ABMS Member Boards.[22]

Board Certifications Offered by ABMS Member Boards:[23]

Member Board	General Certification(s)	Subspecialty Certification(s)
American Board of Allergy and Immunology	Allergy and Immunology	No Subspecialties
American Board of Anesthesiology	Anesthesiology	Critical Care Medicine Hospice and Palliative Medicine Pain Medicine Pediatric Anesthesiology Sleep Medicine
American Board of Colon and Rectal Surgery	Colon and Rectal Surgery	No Subspecialties
American Board of Dermatology	Dermatology	Dermatopathology Pediatric Dermatology
American Board of Emergency Medicine	Emergency Medicine	Anesthesiology Critical Care Medicine Emergency Medical Services Hospice and Palliative Medicine Internal Medicine-Critical Care Medicine Medical Toxicology Pain Medicine Pediatric Emergency Medicine Sports Medicine

[19] American Board of Family Medicine, "*What does board-certified mean?" available at* https://www.theabfm.org/diplomate/certified.aspx, (last visited Mar. 17, 2017).
[20] Id.
[21] *See* American Board of Medical Specialties, *A Trusted Credential*, *available at* http://www.abms.org/board-certification/a-trusted-credential/ (last visited Mar. 17, 2017).
[22] American Board of Medical Specialties, *Standards for Initial Certification* (2016), *available at* http://www.abms.org/media/119927/abms-standards-for-initial-certification.pdf (last visited Mar. 17, 2017).
[23] American Board of Medical Specialties, *Specialty and Subspecialty Certificates*, *available at* http://www.abms.org/member-boards/specialty-subspecialty-certificates/ (last visited Mar. 17, 2017).

Member Board	General Certification(s)	Subspecialty Certification(s)
		Undersea and Hyperbaric Medicine
American Board of Family Medicine	Family Medicine	Adolescent Medicine Geriatric Medicine Hospice and Palliative Medicine Pain Medicine Sleep Medicine Sports Medicine
American Board of Internal Medicine	Internal Medicine	Adolescent Medicine Adult Congenital Heart Disease Advanced Heart Failure and Transplant Cardiology Cardiovascular Disease Clinical Cardiac Electrophysiology Critical Care Medicine Endocrinology, Diabetes and Metabolism Gastroenterology Geriatric Medicine Hematology Hospice and Palliative Medicine Infectious Disease Interventional Cardiology Medical Oncology Nephrology Pulmonary Disease Rheumatology Sleep Medicine Sports Medicine Transplant Hepatology
American Board of Medical Genetics and Genomics	Clinical Biochemical Genetics Clinical Cytogenetics and Genomics Clinical Genetics and Genomics Clinical Molecular Genetics and Genomics	Medical Biochemical Genetics Molecular Genetic Pathology
American Board of Neurological Surgery	Neurological Surgery	No Subspecialties
American Board of Nuclear Medicine	Nuclear Medicine	No Subspecialties

Member Board	General Certification(s)	Subspecialty Certification(s)
American Board of Obstetrics and Gynecology	Obstetrics and Gynecology	Critical Care Medicine Female Pelvic Medicine and Reconstructive Surgery Gynecologic Oncology Hospice and Palliative Medicine Maternal and Fetal Medicine Reproductive Endocrinology/Infertility
American Board of Ophthalmology	Ophthalmology	No Subspecialties
American Board of Orthopaedic Surgery	Orthopaedic Surgery	Orthopaedic Sports Medicine Surgery of the Hand
American Board of Otolaryngology	Otolaryngology	Neuroethology Pediatric Otolaryngology[24] Plastic Surgery Within the Head and Neck[25] Sleep Medicine
American Board of Pathology	Pathology Anatomic/Pathology-Clinical Pathology – Anatomic Pathology - Clinical	Blood Banking/Transfusion Medicine Clinical Informatics Cytopathology Dermatopathology Hematopathology Neuropathology Pathology – Chemical Pathology – Forensic Pathology – Medical Microbiology Pathology – Molecular Genetic Pathology – Pediatric
American Board of Pediatrics	Pediatrics	Adolescent Medicine Child Abuse Pediatrics Developmental-Behavioral Pediatrics Hospice and Palliative Medicine Medical Toxicology Neonatal-Perinatal Medicine Pediatric Cardiology Pediatric Critical Care Medicine Pediatric Emergency Medicine Pediatric Endocrinology Pediatric Gastroenterology Pediatric Hematology-Oncology Pediatric Hospital Medicine[26]

[24] Subspecialty has been approved by the American Board of Otolaryngology, but not yet issued.
[25] Id.
[26] Subspecialty has been approved by the American Board of Pediatrics, but not yet issued.

Member Board	General Certification(s)	Subspecialty Certification(s)
		Pediatric Infectious Diseases Pediatric Nephrology Pediatric Pulmonology Pediatric Rheumatology Pediatric Transplant Hepatology Sleep Medicine Sports Medicine
American Board of Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation	Brain Injury Medicine Hospice and Palliative Medicine Neuromuscular Medicine Pain Medicine Pediatric Rehabilitation Medicine Spinal Cord Injury Medicine Sports Medicine
American Board of Plastic Surgery	Plastic Surgery	Plastic Surgery Within the Head and Neck[27] Surgery of the Hand
American Board of Preventive Medicine	Aerospace Medicine Occupational Medicine Public Health and General Preventive Medicine	Addiction Medicine[28] Clinical Informatics Medical Toxicology Undersea and Hyperbaric Medicine
American Board of Psychiatry and Neurology	Psychiatry Neurology Neurology with Special Qualification in Child Neurology	Addiction Psychiatry Brain Injury Medicine Child and Adolescent Psychiatry Clinical Neurophysiology Epilepsy Forensic Psychiatry Geriatric Psychiatry Hospice and Palliative Medicine Neurodevelopmental Disabilities Neuromuscular Medicine Pain Medicine Psychosomatic Medicine Sleep Medicine Vascular Neurology

[27] Subspecialty has been approved by the American Board of Plastic Surgery, but not yet issued.
[28] Subspecialty has been approved by the American Board of Preventative Medicine, but not yet issued.

Initial Allopathic Board Certification

Allopathic board certification occurs soon after completion of a residency.[29] To receive initial board certification in a specialty from one of the ABMS boards, the physician must first:

- Finish 4 years of premedical education;
- Earn a medical degree (MD) from an ABMS accredited medical school;
- Complete three to 5 years of a residency program accredited by the ACGME;
- Provide letters of attestation from the program director or faculty;
- Obtain an unrestricted medical license to practice in the U.S. or Canada; and
- Pass a written and an oral examination given by the ABMS Member Board.[30]

The standards for initial certification consist of four general standards:

- Each ABMS Member Board's Standards for Initial certification will incorporate all six ABMS/ACGME Core Competencies: [31]
  - Practice-Based Learning and Improvement;
  - Patient Care and Procedural Skills;
  - Systems-based Practice;
  - Medical Knowledge;
  - Interpersonal and Communication Skills; and
  - Professionalism;
- The Member Board and programs in a specialty share the responsibility for assessing a candidate's suitability;[32]
- Each ABMS Member Board will determine criteria for eligibility and the expiration date for the eligibility period;[33] and
- Each ABMS Member Board will work to maintain high standards in the initial certification program to reflect advances in medicine.[34]

The standards for initial certification also include standards of professionalism; education and training; and assessment of knowledge, judgment, and skills.[35]

Candidates who have passed the exam and completed all other requirements are considered certified as a specialist and a diplomat of their specialty board.[36]

Subspecialty Allopathic Board Certification

A similar eligibility process to the initial board certification is followed for certifying physicians seeking subspecialty certification. In order to obtain a subspecialty board certification, the physician must have an initial certification in the general specialty from the ABMS Member

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[29] American Board of Medical Specialties, *ABMS Guide to Medical Specialties*, p-7 (2017), *available at* http://www.abms.org/media/114634/guide-to-medicalspecialties_04_2016.pdf, (last visited Mar. 17, 2017).
[30] American Board of Medical Specialties, *Steps Toward Initial Certification and MOC*, *available at* http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/ (last visited Mar. 12, 2017).
[31] *Supra* note 22, at 3.
[32] *Supra* note 22, at 4.
[33] *Id.*
[34] *Id.*
[35] Supra note 22, at 5-7.
[36] *Supra* note 22, at 7.

Board.[37] Subspecialty board certification requires additional training or the completion of a fellowship program and the passing of another examination given by the ABMS Member Board.[38]

ABMS Maintenance of Certification (MOC)

Physicians maintain their board certification by participating in a professional development program called the ABMS Program for MOC.[39] The MOC program provides physicians a structured approach for enhancing patient care and improving patient outcomes through focused assessment and improvement activities. The ABMS Program for MOC involves ongoing measurement of six core competencies defined by ABMS and ACGME:

- Practice-based Learning and Improvement;
- Patient Care and Procedural Skills;
- Systems-based Practice;
- Medical Knowledge;
- Interpersonal and Communication Skills; and
- Professionalism.[40]

These competencies, which are the same ones used in the ACGME's Next Accreditation System, are measured in the ABMS Program for MOC within a four-part framework:

- Professionalism and Professional Standing;
- Lifelong Learning and Self-Assessment;
- Assessment of Knowledge, Judgment, and Skills; and
- Improvement in Medical Practice.[41]

All Programs for MOC implemented by the Member Boards measure the same six competencies within the same four-part framework.[42] While these elements are consistent across all Member Boards, the specific activities used to measure these competencies may vary according to the specialty.[43]

Initial Board Certification by the AOA

The AOA's Department of Certifying Board Services administers board certification for osteopathic physicians in 29 primary specialties and 77 subspecialties.[44]

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[37] Supra note 23, at 11.
[38] *Id.*
[39] *Supra* note 30.
[40] American Board of Specialties, *Based on Core Competencies, available at* http://www.abms.org/board-certification/a-trusted-credential/based-on-core-competencies/ (last visited Mar. 17, 2017).
[41] American Board of Medical Specialties, *Assessed Through a Four-Part Framework, available at* http://www.abms.org/board-certification/a-trusted-credential/assessed-through-a-four-part-framework/ (last visited Mar. 17, 2017).
[42] *Supra* note 22.
[43] Id.
[44] American Osteopathic Association, *AOA Specialty Certified Boards and Conjoint Examination Committees, available at* https://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/aoa-specialty-boards.aspx (last visited Mar. 17, 2017).

***Board Certifications Offered by AOA Boards*[45]**

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
American Osteopathic Board of Anesthesiology	Anesthesiology	Critical Care Pain Management Pediatric Anesthesiology
American Osteopathic Board of Dermatology	Dermatology	Dermatopathology MOHS Micrographic Surgery Pediatric Dermatology
American Osteopathic Board of Emergency Medicine	Emergency Medicine	Emergency Medical Services Medical Toxicology Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Family Physicians[46]	Family Practice and Osteopathic Manipulative Treatment [47] Family Practice and Osteopathic Manipulative Treatment with OCC Special Emphasis in Hospital Medicine	Geriatric Medicine Hospice and Palliative Medicine Pain Medicine Sleep Medicine Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Internal Medicine	Internal Medicine Internal Medicine with OCC Special Emphasis in Hospital Medicine	Addiction Medicine Adult and Pediatric Allergy and Immunology Clinical Cardiac Electrophysiology Cardiology Correctional Medicine

[45] American Osteopathic Association, *AOA Specialties & Subspecialties, available at* http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/specialty-subspecialty-certification.aspx (last visited Mar. 17, 2017).
[46]) The AOA Board of Family Physicians uses the term "Certification of Added Qualifications" to describe a subspecialty certification obtained under its jurisdiction.
[47] Effective after July 1, 1999, general certification issued from AOBFP will be, *Family Practice and Osteopathic Manipulative Treatment.* Physicians who have general certification in family practice and whose certificates are dated before July 1, 1999, have the option of requesting reissuance of their certificates with the new nomenclature. In July 2011, the Board of Trustees of the AOA approved a change in the name of general certification in family practice from the American Osteopathic Board of Family Practice (AOBFP) to *Family Medicine and Osteopathic Manipulative Treatment*.

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
		Critical Care Medicine[48] Endocrinology Gastroenterology Geriatric Medicine Hematology Hospice and Palliative Medicine Infectious Diseases Interventional Cardiology Nephrology Oncology Pain Medicine Pulmonary Diseases Rheumatology Sleep Medicine Sports Medicine Undersea and Hyperbaric Medicine
American Osteopathic Board of Neurology and Psychiatry	Neurology Psychiatry	Addiction Medicine Child Neurology Child Psychiatry Geriatric Psychiatry Hospice and Palliative Medicine Neurology & Psychiatry* Neurophysiology Pain Medicine Sleep Medicine
American Osteopathic Board of Neuromusculoskeletal Medicine	Neuromusculoskeletal Medicine and OMM	Pain Medicine Sports Medicine
American Osteopathic Board of Nuclear Medicine	No longer offered	
American Osteopathic Board of Obstetrics and Gynecology	Obstetrics and Gynecology	Female Pelvic Medicine/ Reconstructive Surgery

[48] Available to diplomats of other AOA boards.

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
		Gynecologic Oncology Maternal and Fetal Medicine Reproductive Endocrinology
American Osteopathic Board of Ophthalmology and Otolaryngology-HNS	Ophthalmology Otolaryngology and Facial Plastic Surgery	Otolaryngic Allergy Sleep Medicine
American Osteopathic Board of Orthopedic Surgery	Orthopedic Surgery	Hand Surgery
American Osteopathic Board of Pathology	Anatomic Pathology Laboratory Medicine	Dermatopathology Forensic Pathology
American Osteopathic Board of Pediatrics	Pediatrics	Adolescent Medicine Adult and Pediatric Allergy and Immunology Neonatology Pediatric Endocrinology Pediatric Pulmonology* Sports Medicine
American Osteopathic Board of Physical Medicine and Rehabilitation	Physical Medicine and Rehabilitation	Hospice and Palliative Medicine Pain Medicine Sports Medicine
American Osteopathic Board of Preventive Medicine	Preventive Medicine-Aerospace Medicine Preventive Medicine-Occupational/Environmental Medicine Preventive Medicine-Public Health	Correctional Medicine Occupational Medicine[49] Sports Medicine* Undersea and Hyperbaric Medicine
American Osteopathic Board of Proctology	Proctology	None offered
American Osteopathic Board of Radiology	Diagnostic Radiology Radiation Oncology	Neuroradiology Pediatric Radiology

[49] Id.

Specialty Board	Primary Certification(s)	Subspecialty Certification(s)
		Vascular and Interventional Radiology
American Osteopathic Board of Surgery	Cardiothoracic Surgery General Vascular Surgery Neurological Surgery Plastic and Reconstructive Surgery Surgery (general)	Surgical Critical Care[50]

Primary Board Certification

Primary board certification is conferred on diplomats who meet the requirements in a specified field of medical practice under the jurisdiction of a certifying board.[51] Primary certification represents a distinct and well-defined field of osteopathic medical practice.[52] Unlike the Member Boards of the AMBS, which are all subject to the same basic criteria for board certification, each of the certifying specialty boards of the AOA have their own eligibility for board certification.

Regardless of specialty board, there are certain requirements that apply to all osteopathic physicians seeking board certification. The physicians seeking certification must:

- Be a graduate of an AOA-accredited college of osteopathic medicine;
- Hold an unrestricted license to practice in a state or territory;
- Be a member in good standing of the AOA for a set time prior to the date of certification;
- Have satisfactorily completed residency training in the relevant specialty; and
- Pass written, oral, and clinical examinations.[53]

Osteopathic Subspecialty Certification

Osteopathic subspecialty certification is conferred by a certifying board in a specific subspecialty area.[54] A subspecialty certification requires prior attainment of general certification; however, there are certain subspecialty certifications that are considered specialized enough to not require maintenance of the primary board certification after a physician has become subspecialty certified.[55] Such subspecialty certifications, which require longer than the standard 1 year of additional training, indicate the possession of knowledge, skill, training and successful

[50] Id.
[51] American Osteopathic Association, *Definitions of Certifications, available at* http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/certification-definitions.aspx, (last visited Mar. 19, 2017).
[52] Id.
[53] *See* American Osteopathic Board of Anesthesiology, *Primary Certification in Anesthesiology, available at* http://www.aobanes.com/services.html,(last visited Mar. 19, 2017)*;* American Osteopathic Board of Internal Medicine, *Regulations, Requirements and Procedures* (October 2016), *available at* http://www.aobim.org/WebPageStatic/PDF/IM_Regs_Req_Proced.pdf (last visited Mar. 19, 2017); and American Osteopathic Board of Orthopedic Surgery 2017, *Handbook for Candidates for Board Certification* (February 2017), *available at* http://www.aobos.org/mm/files/Candidate-Handbook-Master.pdf (last visited Mar. 19, 2017).
[54] *Id*.
[55] *Supra* note 51.

examination in a subspecialty field over and above that required for primary certification.[56] For example, Cardiology is a limited area within the field of Internal Medicine for which physicians may earn a subspecialty certification that does not require them to maintain their primary certification in Internal Medicine, after they have become subspecialty certified in Cardiology.[57]

Osteopathic Continuous Certification (OCC)

Each specialty certifying board developed OCC requirements implemented as of January 1, 2013.[58] A physician with a time-limited[59] board certification is required to participate in the five components of the OCC process to maintain osteopathic board certification.[60] The five components of OCC are:

- Active Licensure;
- Lifelong Learning/Continuing Medical Education;
- Cognitive Assessment;
- Practice Performance Assessment and Improvement; and
- Continuous AOA Membership, including participation in relevant specialty-specific educational activities.[61]

Credentialing of Physicians by Health Plans and Insurers

Credentialing is the process of collecting and verifying a provider's professional qualifications, including academic background, relevant training and experience, licensure, and certification or registration to practice in a particular health care field.[62] Health plans and insurers use credentialing to determine whether to include a provider in the plan's or insurer's network; that is, to contract with the provider to provide services to enrollees and policyholders. Credentialing is a required element for health plan accreditation by the National Commission for Quality Assurance.[63] Health plans and insurers may require board-certified physicians to maintain board certification as a condition of participating in the network.[64]

Admitting Privileges Credentialing

Health care facilities, hospitals and ambulatory surgical centers, also use the credentialing process to confer admitting privileges. An admitting privilege is the right of a physician to admit

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[56] *Id*.
[57] *Id*.
[58] American Osteopathic Association, *Osteopathic Continuous Certification*, *available at* http://www.osteopathic.org/inside-aoa/development/aoa-board-certification/Pages/osteopathic-continuous-certification.aspx (last visited Mar. 19, 2017).
[59] Certificates issued prior to 1993 are not time-limited and therefore are valid for life.
[60] *Supra* note 58.
[61] *Id*.
[62] *See* Aetna, *Health care professionals: Joining the Network FAQs*, *available at* https://www.aetna.com/faqs-health-insurance/health-care-professionals-join-network.html, (last visited March 19, 2017); Florida Blue, *Manual for Physicians and Providers* (2017), *available at* https://www.floridablue.com/providers/tools-resources/provider-manual (last visited Mar. 12, 2017); United Health Care, *Physician Credentialing and Recredentialing Frequently Asked Questions*, *available at* https://www.uhccommunityplan.com/content/dam/communityplan/healthcareprofessionals/providerinformation/KS-Provider-Information/KS_Credentialing_FAQ.pdf, (last visited Mar. 19, 2017).
[63] NCQA, *CR Standards & Guidelines*, *available at* http://www.ncqa.org/tabid/404/Default.aspx (last visited Mar. 19, 2017).
[64] See Aetna, *Health care professionals: Joining the Network FAQs*, *available at* https://www.aetna.com/faqs-health-insurance/health-care-professionals-join-network.html, (last visited Mar. 19, 2017)

patients to a particular hospital, and to provide specific services in that facility.[65] Admitting privileges are different from clinical privileges, which are the privileges granted to a physician or other licensed health care practitioner to render patient care services in a hospital, but which do not include the privilege of admitting patients.[66]

Board Certification and Florida Licensure

The DOH does not license physicians by specialty or subspecialty based upon board certification; however, ch. 458, F.S., and ch. 459, F.S., limit which physicians may hold themselves out as board-certified specialists. An allopathic physician licensed under ch. 458, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has received formal recognition as a specialist from the ABMS or other recognizing agency[67] approved by the BOM.[68] Additionally, an allopathic physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the BOM.[69]

Similarly, an osteopathic physician licensed under ch. 459, F.S., may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the AOA or the ACGME and is certified as a specialist by a certifying agency[70] approved by the board.[71] The limitations on advertising are set out in Rules 64B8-11.001 and 64-B15-14.001 of the Florida Administrative Code, for allopathic and osteopathic physicians, respectively.

III. Effect of Proposed Changes:

CS/SB 1354 creates s. 456.0291, F.S., *Recognizing agency certificate.* The bill requires the DOH to issue certificates to recognizing agencies to grant physicians formal recognition as board-certified specialists in a particular medical practice area. The bill requires the recognizing agency to submit a registration application containing the following:

- The agency's legal name, mailing address, telephone number, and business location;
- The particular practice area in which the agency will recognize a physician as a specialist;
- The requirements the agency will impose for a physician to be eligible to receive formal recognition as a specialist; and
- The amount of any fee charged to a physician to apply for, receive, and maintain, formal recognition as a specialist.

[65] In order for a physician to be granted privileges, a hospital generally checks the individual's medical credentials, license and malpractice history. Many hospitals also require physicians to admit a minimum number of patients to the hospital each year before they will grant or renew privileges. Others require the doctor to live within a minimum distance of the hospital.
[66] Section 395.002(5), F.S.
[67] The allopathic board has approved the specialty boards of the ABMS as recognizing agencies. *See* Rule 64B8-11.001(1)(f), F.A.C.
[68] Section 458.3312, F.S.
[69] Id.
[70] The osteopathic board has approved the specialty boards of the ABMS and AOA as recognizing agencies. *See* Rule 64B15-14.001(h), F.A.C.
[71] Section 459.0152, F.S.

The DOH must approve an application for a recognizing agency certificate within 60 business days after receipt of the completed application, if the agency meets all of the following:

- Is an independent body that certifies members as having advanced qualifications in a particular medical specialty through peer-reviewed demonstrations of competence in the specialty;
- Requires successful completion of a comprehensive examination administered by the recognizing agency pursuant to written procedures that ensure adequate security and appropriate grading standards;
- Has been determined by the Internal Revenue Service to be a legitimate nonprofit pursuant to s. 501(c)(3), I.R.C.;
- Has full-time administrative staff housed in dedicated office space that is appropriate for the agency's program and sufficient for responding to consumer or regulatory inquiries;
- Has written by-laws, a code of ethics to guide the practice of its members, and an internal review and control process, including budgetary practices, to ensure effective use of resources;
- Does not mandate that physicians who receive initial certification from the recognizing agency undergo a maintenance of certification process that involves a periodic testing regimen, proprietary self-assessment, or peer evaluation in order to retain certification, other than the continuing medical education hours required for recertification;
- Does not charge more than $500 every two years for recertification;
- Requires, at a minimum, a specified number of continuing medical education hours in the physician's specialty for recertification; and
- Has a practice improvement program, that the physician is required to participate in, to encourage continued improvement within medical practice. The program must focus on the following:
  - Recent scientific developments;
  - Improved patient safety;
  - Improved patient or population health outcomes;
  - Improved access to health care;
  - Improved patient experience; and
  - Increased value to the health care system.

The BOM and the Board of Osteopathic Medicine may adopt rules to implement this section. These rules may impose additional requirements on applicants for a recognizing agency certificate.

A physician who holds a current board certification from a recognizing agency approved by the board, pursuant to DOH rule, may advertise himself or herself as a board-certified specialist.

The bill prohibits an allopathic physician from holding himself or herself out as a board-certified specialist unless the physician has received formal recognition as a specialist from a specialty board of the ABMS or other recognizing agency that has received a recognizing agency certificate.

Similarly, an osteopathic physician may not hold himself or herself out as a board-certified specialist unless he or she has successfully completed the requirements for certification by the

AOA, ACGME, or is certified as a specialist by a recognizing agency that has received a recognized agency certificate.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians initially certified in a medical specialty may be able to maintain a specialty recognition through a recognized agency certification, thereby avoiding the cost and time associated with other maintenance of certification processes.

C. Government Sector Impact:

Similarly, the cost and time savings may be available to physicians in the public sector.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 458.3113 and 459.0056.

IX. Additional Information:

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

CS by Health Policy on April 3, 2017:
The bill adds another method of medical specialty certification, rather than replacing the ABMS, AOA or ACGME methods, for a physician to obtain, and maintain, a medical specialty board certification. The re-certification process requires a specific number of CEUs in the specialty area. A physician may hold himself or herself out as a board-certified specialist if he or she has received formal specialty recognition from the ABMS, the AOA, the ACGME, or a recognizing agency that has received a certificate from the DOH under this new process.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
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The Committee on Health Policy (Young) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 456.0291, Florida Statutes, is created to read:

456.0291 Recognizing agency certificate.—

(1) The department shall issue a certificate authorizing a recognizing agency to grant physicians licensed under chapters 458 and 459 formal recognition as specialists in a particular

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area within the practice of medicine, if the recognizing agency submits a complete registration application containing the recognizing agency's legal name, mailing address, telephone number, and business location; the particular area within the practice of medicine in which the agency will recognize a physician as a specialist; the requirements the agency will impose for a physician to be eligible to receive formal recognition as a specialist; and the amount of any fee charged to a physician to apply for, receive, and maintain formal recognition as a specialist from the agency.

(2) The department shall approve an application for a recognizing agency certificate within 60 business days after receipt of the completed application if the recognizing agency meets all of the following requirements:

(a) It is an independent body that certifies members as having advanced qualifications in a particular allopathic or osteopathic medical specialty through peer-reviewed demonstrations of competence in the specialty being recognized.

(b) It requires successful completion of a comprehensive examination administered by the recognizing agency pursuant to written procedures that ensure adequate security and appropriate grading standards.

(c) It has been determined by the Internal Revenue Service of the United States to be a legitimate nonprofit entity pursuant to s. 501(c)(3) of the Internal Revenue Code.

(d) It has full-time administrative staff housed in dedicated office space that is appropriate for the agency's program and sufficient for responding to consumer or regulatory inquiries.

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(e) It has written by-laws, a code of ethics to guide the practice of its members, and an internal review and control process, including budgetary practices, to ensure effective use of resources.

(f) It does not mandate that physicians who receive initial certification from the recognizing agency undergo a maintenance of certification process that involves a periodic testing regimen, proprietary self-assessment, or peer evaluation in order to retain certification, other than the continuing medical education hours required for recertification under paragraph (h).

(g) It does not charge more than $500 every 2 years for recertification.

(h) It requires only a specified number of continuing medical education hours for recertification.

(3) The Board of Medicine and the Board of Osteopathic Medicine may adopt rules to implement this section. These rules may impose additional requirements on applicants for a recognizing agency certificate.

Section 2. Section 458.3312, Florida Statutes, is amended to read:

458.3312 Specialties.—A physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the physician has received formal recognition as a specialist from a ~~specialty board of the American Board of Medical Specialties or other~~ recognizing agency that has received a certificate issued ~~been approved~~ by the department in accordance with s. 456.0291 ~~board~~. However, a physician may indicate the services offered and may state that his or her

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practice is limited to one or more types of services when this accurately reflects the scope of practice of the physician. A physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the Board of Medicine.

Section 3. Section 459.0152, Florida Statutes, is amended to read:

459.0152 Specialties.—An osteopathic physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless he or she ~~the osteopathic physician has successfully completed the requirements for certification by the American Osteopathic Association or the Accreditation Council on Graduate Medical Education and~~ is certified as a specialist by a recognizing ~~certifying~~ agency that has received a certificate issued ~~approved~~ by the department in accordance with s. 456.0291 ~~board~~. However, an osteopathic physician may indicate the services offered and may state that his or her practice is limited to one or more types of services when this accurately reflects the scope of practice of the osteopathic physician.

Section 4. 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 medical specialties; creating s.

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456.0291, F.S.; requiring the Department of Health to issue a certificate authorizing recognizing agencies to grant certain licensed physicians formal recognition as specialists in a particular area if the recognizing agency submits a completed application to the department and meets specified requirements; authorizing the Board of Medicine and the Board of Osteopathic Medicine to adopt rules to implement the certificate process; amending ss. 458.3312 and 459.0152, F.S.; providing that a physician may not hold himself or herself out as a board-certified specialist unless the physician has received formal recognition as a specialist from a recognizing agency that has received a certificate issued by the department; providing an effective date.

620084

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
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The Committee on Health Policy (Young) recommended the following:

Senate Amendment to Amendment (148648) (with title amendment)

Delete lines 53 - 82
and insert:
(h) It requires, at a minimum, a specified number of continuing medical education hours in the physician's area of specialty for recertification.
(i) It has a practice improvement program to encourage continued improvement within medical practice. The program must

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focus on recent scientific developments, improved patient safety, improved patient or population health outcomes, improved access to health care, improved patient experience, and increased value to the health care system. The program must require physician participation in practice improvement programs within the context of the health care team and system of practice.

(3) The Board of Medicine and the Board of Osteopathic Medicine may adopt rules to implement this section. These rules may impose additional requirements on applicants for a recognizing agency certificate.

(4) A physician who holds a current board certification from a recognizing agency approved by the board pursuant to department rules may advertise himself or herself as a board-certified specialist.

Section 2. Section 458.3312, Florida Statutes, is amended to read:

458.3312 Specialties.—A physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless the physician has received formal recognition as a specialist from a specialty board of the American Board of Medical Specialties or other recognizing agency that has received a certificate issued ~~been approved~~ by the department in accordance with s. 456.0291 ~~board~~. However, a physician may indicate the services offered and may state that his or her practice is limited to one or more types of services when this accurately reflects the scope of practice of the physician. A physician may not hold himself or herself out as a board-certified specialist in dermatology unless the recognizing

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agency, whether authorized in statute or by rule, is triennially reviewed and reauthorized by the Board of Medicine.

Section 3. Section 459.0152, Florida Statutes, is amended to read:

459.0152 Specialties.—An osteopathic physician licensed under this chapter may not hold himself or herself out as a board-certified specialist unless he or she ~~the osteopathic physician~~ has successfully completed the requirements for certification by the American Osteopathic Association or the Accreditation Council on Graduate Medical Education or ~~and~~ is

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

And the title is amended as follows:

Delete line 106

and insert:

certificate process; providing that a physician who meets certain criteria may advertise himself or herself as a board-certified specialist; amending ss. 458.3312 and

By Senator Young

18-00951-17 20171354__

A bill to be entitled

An act relating to maintenance of certification; creating ss. 458.3113 and 459.0056, F.S.; providing definitions; providing legislative intent; prohibiting the Boards of Medicine and Osteopathic Medicine, respectively, and the Department of Health, health care facilities, and insurers from requiring certain certifications as conditions of licensure, reimbursement, employment, or admitting privileges; providing construction; providing an effective date.

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

Section 1. Section 458.3113, Florida Statutes, is created to read:

458.3113 Conditions of licensure, reimbursement, employment, or admitting privileges.—

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

(a) "Maintenance of certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by a recognizing agency approved by the board pursuant to rule 64B8-11.001, Florida Administrative Code.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification in a subspecialty by a recognizing agency approved by the board pursuant to rule 64B8-11.001, Florida Administrative Code.

(2) It is the intent of the Legislature to further improve

18-00951-17 20171354__

the efficiency of the health care market and eliminate unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require maintenance of certification or recertification as a condition of licensure, reimbursement, employment, or admitting privileges for a physician who practices medicine and has achieved initial board certification in a subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education pursuant to rule 64B8-13.001, Florida Administrative Code.

Section 2. Section 459.0056, Florida Statutes, is created to read:

459.0056 Conditions of licensure, reimbursement, employment, or admitting privileges.—

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

(a) "Maintenance of certification" means a periodic testing regimen, proprietary self-assessment requirement, peer evaluation, or other requirement imposed by a recognizing agency approved by the board pursuant to rule 64B15-14.001, Florida Administrative Code.

(b) "Recertification" means a subsequent recognition or certification of educational or scholarly achievement beyond initial board certification in a subspecialty by a recognizing agency approved by the board pursuant to rule 64B15-14.001, Florida Administrative Code.

(2) It is the intent of the Legislature to further improve the efficiency of the health care market and eliminate

unnecessary administrative and regulatory requirements.

(3) Notwithstanding any other provision of law, the board, the department, a health care facility licensed under chapter 395, or an insurer as defined in s. 624.03 may not require maintenance of certification or recertification as a condition of licensure, reimbursement, employment, or admitting privileges for an osteopathic physician who practices medicine and has achieved initial board certification in a subspecialty pursuant to this chapter.

(4) This section may not be construed to prohibit the board from requiring continuing medical education pursuant to rule 64B15-13.001, Florida Administrative Code.

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

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/2017
Meeting Date

1354
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic MAINTENANLE OF CERTIFICATION

Name Dr. Carolyn Geis MD

Job Title Physician

Address 380 Old Bridge Way
Street

Ormond Beach,
City *State* *Zip*

Phone 386-212-1308

Email carolyn.geis@halifax.org

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Myself!

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

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)

4/3/2017
Meeting Date

1354
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic Maintenance of Certification

Name Rebecca L. Johnson, MD

Job Title CEO, American Board of Pathology

Address 4830 W. Kennedy Blvd
Street

Tampa FL 33609
City *State* *Zip*

Phone 813-286-2444

Email rljohnson@abpath.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Am. Board of Pathology

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)

4/3/2017
Meeting Date

SB 1354
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic Maintenance of Certification

Name THOMAS GRANATIR

Job Title SR VICE PRESIDENT, POLICY & EXT. AFFAIRS, ABMS

Address 353 N. CLARK ST Suite 1400
Street

CHICAGO IL 60654
City *State* *Zip*

Phone 312-436-2683

Email tgranatir@abms.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Board of Medical Specialties

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)

4/3/2017
Meeting Date

1354
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic MAINTENANCE OF CERTIFICATION

Name DR. JEDD ROE, MD, FAAFP

Job Title EMERGENCY PHYSICIAN

Address 1910 OCEAN FRONT
Street

Phone 904-772-4622

NEPTUNE BEACH FL 32266
City *State* *Zip*

Email JROE3@AOL.COM

Speaking: ☐ For ☒ Against ☐ Information

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

Representing MYJSEF

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

4-3-17
Meeting Date

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

SB 1054
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic Maintenance of Certification

Name Chris Newing

Job Title MD physician

Address 4840 Sweetshade dr
Street

Sarasota FL 34241
City *State* *Zip*

Phone 941 685-2963

Email Hydrocmo.smith.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 1354
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic MOC

Name Jeff Scott

Job Title General Counsel

Address 1430 Piedmont Dr. E
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 850-224-6496

Email JScott@flmedical.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing FMA

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)

4-3-17
Meeting Date

SB 554
Bill Number (if applicable)

148648
Amendment Barcode (if applicable)

Topic Maintenance of Certification

Name David McKalip, M.D.

Job Title President - Florida Association of American Physicians and Surgeons

Address 1455 1st Ave N #101
Street
St. Petersburg, FL 33713
City *State* *Zip*

Phone 727-822-3500

Email DMCKALIP@NEURO.NET

Speaking: ☐ For ☒ Against ☐ Information (oppose as substitute - support original)

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

Representing Florida Chapter AAPS

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

1354
Bill Number (if applicable)

1020084
Amendment Barcode (if applicable)

Am to Am

Topic Maintenance of Certification

Name Crystal Stickle

Job Title VP Gov Affairs

Address 306 E College Ave
Street

TLH
City *State* *Zip*

Phone

Email Crystals@fha.org

Speaking: ☒ For ☐ Against ☐ Information

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

Representing Florida Hospital Association

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

SB 1359

4-3-17
Meeting Date

~~626084~~
Bill Number (if applicable)

Topic Maintenance of Certification (EI) 626084
Amendment Barcode (if applicable)

Name DAVID MCKAIG, M.D. (Late filed Amendment)

Job Title President - FL AAPS

Address 1955 1st Ave. N #101
Street
St. Petersburg, FL 33713
City *State* *Zip*

Phone 727-822-3500

Email DMCKAIG@NEO.RR.COM

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Florida Chapter Assoc. of American Physicians and Surgeons

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

SB 1354
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title _____

Address 1430 Piedmont Dr. E.
Street

City *State* *Zip*

Phone 850 224-6496

Email jscott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

1354
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title _____

Address 1000 Riverside Ave #240
Street
Jacksonville, FL 32204
City *State* *Zip*

Phone 904-233-3051

Email nulandlaw@aol.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Chapter, American College of Physicians

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)

4:00pm
412 K

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/17
Meeting Date

1354
Bill Number (if applicable)

Topic Maintenance of Certification

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr.
Street

Phone 878-7364

Tallahassee FL 32301
City *State* *Zip*

Email winnsr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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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)

4-3-2017
Meeting Date

1354
Bill Number (if applicable)

Topic Maintenance of Certification

Amendment Barcode (if applicable)

Name Marnie George

Job Title Sr. Advisor, Buchanan, Ingersoll & Rooney

Address 101 N. Monroe Street, Suite 1090 *Street*

Phone 850-510-8866

Tallahassee FL 32301
City *State* *Zip*

Email Marnie.george@bipc.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL. Chapter, American College of Cardiology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

4/3/2017 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1354

Meeting Date *Bill Number (if applicable)*

Topic MAINTENANCE OF CERTIFICATION *Amendment Barcode (if applicable)*

Name Rebecca L. Johnson, MD

Job Title CEO, American Board of Pathology

Address 4380 W. Kennedy Blvd, Suite 690 Phone 813-286-2444
Street

Tampa FL 33609 Email rljohnson@abpath.org
City *State* *Zip*

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

Representing American Board of Pathology

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)

Meeting Date

1354
Bill Number (if applicable)

Topic SB 1354

Amendment Barcode (if applicable)

Name Peggy Gossett-Seidman

Job Title Sportswriter, Freelance Marketing Rep.

Address 4312 Intracoastal Drive (Street)

Phone 561-271-5050

Highland Beach (City) FL (State) 33487 (Zip)

Email p7eg@earthlink.net

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Dr. Barry Seidman M.D.

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

4/3/2017 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1354

Meeting Date *Bill Number (if applicable)*

Topic MAINTENANCE OF CERTIFICATION *Amendment Barcode (if applicable)*

Name THOMAS GRANATIR

Job Title SR VICE PRESIDENT, POLICY & EXT AFFAIRS

Address 353 N. CLARK ST. Ste 1400 Phone 312 436 - 2683
Street

CHICAGO IL 60654 Email tgranatir@abms.org
City *State* *Zip*

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

Representing American Board of Medical Specialties

Appearing at request of Chair: ☐ Yes ☐ No Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/3/2017
Meeting Date

1354
Bill Number (if applicable)

Topic MAINTENANCE OF CERTIFICATION

Amendment Barcode (if applicable)

Name Dr. JOHN ROE, MD, FACEP

Job Title EMERGENCY PHYSICIAN

Address 1910 OCEAN FRONT
Street

Phone 904-772-4622

NEPTUNE BEACH FL 32266
City *State* *Zip*

Email JROE3@AOL.COM

Speaking: ☐ For ☒ Against ☐ Information

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

Representing MYSELF

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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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)

4/3/17
Meeting Date

1354
Bill Number (if applicable)

Topic Maintenance of Certification

Amendment Barcode (if applicable)

Name Dr. Carolyn Geis, MD

Job Title Physician

Address 380 Old Bridge Way
Street

Ormond Beach
City *State* *Zip*

Phone 386-212-1308

Email carolyn.geis@halifax.org

Speaking: ☐ For ☑ Against ☐ Information

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

Representing Myself

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

4/3/17 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1354

Meeting Date *Bill Number (if applicable)*

Topic Maintenance of Certification *Amendment Barcode (if applicable)*

Name Brewster Bevis

Job Title Vice President

Address 516 N. Adams st. Phone 224-7173

Street

Tallahassee FL 32301 Email BBevis@aif.com

City *State* *Zip*

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)

4-3-17
Meeting Date

SB 1354
Bill Number (if applicable)

Topic Maintenance of Certification

Amendment Barcode (if applicable)

Name David McKalip, M.D.

Job Title President

Address 1955 1st Ave N #101
Street

St. Petersburg FL 33713
City *State* *Zip*

Phone 727-822-3500

Email DMCKALIP@NAVICOS.NET

Speaking: ☒ For ☐ Against ☐ Information (original language)

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

Representing Florida Chapter AAPS

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

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	SB 1446
INTRODUCER:	Senator Rouson
SUBJECT:	Pay-for-success Contracts
DATE:	March 31, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peacock	Ferrin	GO	**Favorable**
2.	Lloyd	Stovall	HP	**Favorable**
3.			AP	
4.			RC	

I. Summary:

SB 1446 authorizes a state agency, contingent upon authorization in the General Appropriations Act (GAA), to negotiate and enter into a pay-for-success contract with a private entity. The bill defines the terms "pay-for-success contract," "private entity," and "success payment."

The bill specifies the duties of the state agency for a pay-for-success contract. An independent evaluator must determine whether the outcome measures have been met under the contract, and the private entity must report annually to the state agency. Funding obtained under this program is not considered a procurement item under s. 287.057, F.S.

Contingent upon authorization in the GAA, the Department of Health (DOH) is authorized to implement the Nurse-Family Partnership (NFP) pay-for-success contract as an evidence-based practice model or provider.

The bill provides a nonrecurring appropriation of $850,000 from the General Revenue Fund for the fiscal year 2017-2018 to the DOH, to support existing infrastructure and implementation of the NFP model in designated Healthy Start Coalitions and federally qualified health centers (FQHCs).

By December 1, 2017, the Department of Management Services (DMS) must prescribe the procedures to be used by state agencies in connection with pay-for-success contracts.

The bill takes effect on July 1, 2017.

II. Present Situation:

Pay-for-Success Contract Program

A pay-for-success program allows a governmental entity to enter into contracts with private non-profit organizations to provide targeted services. Initial funding for these services is provided by private investors. When a performance measure outcome identified in the contract is achieved, as recognized by an independent evaluator, the governmental entity makes a "success payment." The amount of the success payment is specified in the contracts, but presumably covers the costs of the services plus some level of return on the initial investment made by private investors.[1]

Nurse-Family Partnership of Florida

The Nurse-Family Partnership of Florida (NFP) is an evidence-based, community health program that serves low-income, high-risk women pregnant with their first child.[2] Each mother is partnered with a registered nurse early in her pregnancy and receives ongoing nurse visits that continue through her child's second birthday.

The NFP goals[3] are to improve:

- Pregnancy outcomes by helping women engage in good preventive health practices, including thorough prenatal care from their healthcare providers, improving their diets, and reducing their use of cigarettes, alcohol and illegal substances;
- Childhood health and development by helping parents provide responsible and competent care; and
- Economic self-sufficiency of the family by helping parents develop a vision for their own future, plan future pregnancies, and continue their education and find work.

The NFP began serving its first Florida clients in Palm Beach County in 2008 and in Pinellas County in 2011.[4] The NFP also serves clients in Broward, Collier, Duval, Gadsden, Hendry, Hillsborough, Lee, Miami-Dade, and Orange counties.[5]

The NFP of Florida reports that of the clients served under its program, the following positive outcomes were achieved through June 30, 2014:

- 89 percent of babies were born full term;
- 86 percent of mothers initiated breastfeeding; and
- 94 percent of children received all recommended immunizations by 24 months old.[6]

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[1] *See* http://www.payforsuccess.org/learn/basics/ (last visited on March 28, 2017).
[2] *See* https://www.nursefamilypartnership.org/assets/PDF/Communities/State-profiles/FL_State_Profile.aspx (last visited on March 28, 2017).
[3] *Id*.
[4] *See* http://www.nursefamilypartnership.org/locations/Florida (last visited on March 28, 2017).
[5] See http://www.nursefamilypartnership.org/locations/Florida/find-a-local-agency (last visited on March 28, 2017).
[6] *Supra* note 2.

Department of Health

The Department of Health was created in 1996,[7] and its purpose is to protect and promote the health of all residents and visitors in the state through organized state and community efforts, including cooperative agreements with counties.[8] One of the DOH's duties is to provide or ensure the provision of quality health care and related services to identified populations in the state.[9]

The 2016-2017 GAA provided a total of $681,250 in non-recurring funds to the DOH to integrate the NFP home visiting model in designated Healthy Start Coalitions and FQHCs.[10] The NFP, coalitions, and FQHCs were to provide intensive nurse visitation services for women and their infants. The DOH contracted with the Florida Association of Healthy Start Coalitions to implement the NFP model at five additional clinic sites located in Brevard, Hillsborough, Miami-Dade (two sites), and Orange counties through sub-contracts (Contract period of September 1, 2016 – June 30, 2017).[11]

This appropriation also authorized $10,000 for the DOH to contract with the NFP National Service Office for process and outcome data identification, management, analysis, training, and programmatic support (Contract period of September 16, 2016 – June 30, 2017).[12]

Chapter 287, Florida Statutes

Chapter 287, F.S., regulates state agency[13] procurement of personal property and services.[14] Agencies may use a variety of procurement methods, depending on the cost and characteristics of the needed good or service, the complexity of the procurement, and the number of available vendors. These include the following:

- "Single source contracts," which are used when an agency determines that only one vendor is available to provide a commodity or service at the time of purchase;
- "Invitations to bid," which are used when an agency determines that standard services or goods will meet needs, wide competition is available, and the vendor's experience will not greatly influence the agency's results;
- "Requests for proposals," which are used when the procurement requirements allow for consideration of various solutions and the agency believes more than two or three vendors exist who can provide the required goods or services; and

[7] Section 20.43, F.S.
[8] Section 20.43(1), F.S.
[9] Section 20.43(1)(e), F.S.
[10] Chapter 2016-66, s. 3, Line 467, Laws of Fla.
[11] E-mail from Bryan P. Wendel, Government Analyst II, Office of Legislative Planning, Department of Health (March 17, 2017) (on file with the Senate Committee on Governmental Oversight).
[12] *Id*.
[13] As defined in s. 287.012(1), F.S., "agency" means any of the various state officers, departments, boards, commissions, divisions, bureaus, and councils and any other unit of organization, however designated, of the executive branch of state government. "Agency" does not include the university and college boards of trustees or the state universities and colleges.
[14] Local governments are not subject to the provisions of ch. 287, F.S. Local governmental units may look to the chapter for guidance in the procurement of goods and services, but many have local policies or ordinances to address competitive solicitations.

- "Invitations to negotiate," which are used when negotiations are determined to be necessary to obtain the best value and involve a request for high complexity, customized, mission-critical services, by an agency dealing with a limited number of vendors.[15]

Contracts for commodities or contractual services in excess of $35,000 must be procured using a competitive solicitation process.[16] However, some specified contractual services and commodities are not subject to competitive-solicitation requirements.[17]

The DMS assists state agencies and eligible users by providing uniform commodity and contractual service procurement policies, rules, procedures, and forms.[18]

State and Federal Audit Requirements

Any agency agreements funded with state or federal assistance to a nonstate recipient or a subrecipient are subject to the requirements of ss. 215.97 and 215.971, F.S. The Florida Single Audit Act, s. 215.97, F.S., provides for an audit of a nonstate entity's financial statements and state financial assistance conducted in accordance with the auditing standards as stated in the rules of the Auditor General.[19] Under the Single Audit Act, there is an audit threshold which is triggered when a nonstate entity expends a total amount of state financial assistance equal to or in excess of $750,000 in any fiscal year.[20] A nonstate entity under the act is defined as a local government entity, higher education entity, nonprofit organization, or for-profit organization that receives state financial assistance.[21]

Additionally, for agreements funded with federal or state assistance, s. 215.971, F.S., requires specific deliverables and a provision that describes the scope of work, that deliverables be related to the scope of work, completion of a minimum level of work before payments; consequences for unmet obligations including the return of unobligated funds, and a final reconciliation report. Each agreement must also have a designated contract manager who is a certified contract manager through DMS and DFS.

Under s. 216.3475, F.S., agencies must maintain records to support a cost analysis, which includes a detailed budget submitted by any entity awarded funding on a noncompetitive basis and the agency's documented review of individual cost elements from the submitted budget for allowability, reasonableness, and necessity. Funds that are awarded on a noncompetitive basis to a person or entity specifically designated through the GAA to provide services through funds designated in the GAA may not receive payment in excess of the competitive prevailing rate for those services unless expressly authorized in the GAA.

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[15] *See* ss. 287.012(6) and 287.057, F.S.
[16] Section 287.057(1), F.S., requires all projects that exceed the Category Two ($35,000) threshold contained in s. 287.017, F.S., to be competitively bid. As defined in s. 287.012(6), F.S., "competitive solicitation" means the process of requesting and receiving two or more sealed bids, proposals, or replies submitted by responsive vendors in accordance with the terms of a competitive process, regardless of the method of procurement.
[17] *See* s. 287.057(3)(e), F.S.
[18] Section 287.032(2), F.S.
[19] Section 215.97(2)(x), F.S.
[20] Section 215.97(2)(a), F.S.
[21] Section 215.97(2)(n), F.S.

Federal regulations also govern allowable costs with state agency contracts with nonstate entities where federal funds will be paid out under 2 C.F.R. Part 200. Costs must meet the following general criteria in order to be allowable under federal awards:

- Be necessary and reasonable for the performance of the federal award and be allocable thereto in order to be allowable under these principles;
- Conform to any limitations or exclusions set forth in these principles or in the federal award as to types or amount of cost items;
- Be consistent with policies and procedures that apply uniformly to both federally financed and other activities of the non-federal entity;
- Be accorded consistent treatment. A cost may not be assigned to a federal award as a direct cost if any other cost incurred for the same purpose in like circumstances has been allocated to the federal award as an indirect cost;
- Be determined in accordance with generally accepted accounting principles (GAAP), except for state and local governments and Indian tribes only, as otherwise provided in this part;
- Not be included as a cost or used to meet cost sharing or matching requirements of any other federally-financed program in either the current or a prior period; and
- Be adequately documented.[22]

The federal regulations also define reasonable costs, how to classify direct and indirect costs, and which items are allowable costs under federal grants and agreements.

III. Effect of Proposed Changes:

Section 1 provides definitions necessary to implement the pay-for-success contracts.

The term "pay-for-success contract" or "contract" is defined as a contract between a state agency and a private entity to fund a program, as specified in the GAA, to address a critical public problem with historically poor outcomes.

The term "private entity" is defined as a private, not-for-profit organization, or a subsidiary or an affiliate thereof, exempt from federal income taxation pursuant to s. 501(c)(3) of the Internal Revenue Code of 1986, which enters into a pay-for-success contract with a state agency and subcontracts with one or more entities to provide the actual services.

The term "success payment" is defined as the amount paid to a private entity when performance outcome measures established in the pay-for-success contract are met, or as otherwise set forth in the pay-for-success contract.

Under the pay-for-success concept, the private entity must secure initial funding for the services provided under the contract from private-sector investors and enter into separate subcontracts with entities providing the services for the identified program.

Contingent upon authorization in the GAA, a state agency may negotiate and enter into a pay-for-success contract with a private entity. This contract may be initiated in one fiscal year, may

[22] 2 C.F.R. § 200.403.

continue into subsequent fiscal years, and may be paid from appropriations authorized in any of those fiscal years.

The state agency is required to:
- Determine performance outcome measures to be included in the contract in consultation with the private entity and provider.
- Determine the data to be included in an annual report filed by a private entity.
- Select an independent, nationally recognized evaluator through competitive solicitation procedures to evaluate the performance outcome measures specified in the contract.
- Ensure that subcontractors share participant data and sign an acknowledgment that the data may be shared with an independent evaluator for research and evaluation purposes, and maintain documentation of the required acknowledgements.

A pay-for-success contract must meet all of the following requirements:
- Be limited to programs specified in the GAA.
- Require the private entity to underwrite or secure upfront capital from private funders, such as foundations, banks, businesses, or individuals to fund the services provided under the subcontracts.
- Require an independent evaluator to determine whether the specified performance outcomes have been achieved.
- Require a success payment, consistent with the GAA, if the specified performance outcome measures are achieved.
- Prohibit the private entity from receiving or viewing any personally identifiable participant information.

The bill requires a private entity to annually report to the state agency for the duration of the contract period. In addition, the bill specifies that funding for a program under this bill is not considered a procurement item under s. 287.057, F.S.

The bill also requires the DMS to prescribe the procedures to be used by state agencies in connection with pay-for-success contracts by December 1, 2017.

Section 2 provides that, contingent upon authorization in the GAA, the DOH is authorized to implement the NFP pay-for-success contract as an evidence-based practice model or provider. All subsequent models or providers funded under this program are subject to the same requirements provided under s. 287.05715, F.S., as created by this bill.

Section 3 appropriates the nonrecurring sum of $850,000 from the General Revenue Fund for fiscal year 2017-2018, to the DOH to support existing infrastructure and implementation of the NFP model in designated Healthy Start Coalitions and FQHCs as provided in Specific Appropriation 467 of the 2016-2017 GAA, in preparation for participation in the pay-for-success contract program established under s. 287.05715, F.S., as created by this bill.

Section 4 provides an effective date of July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Indeterminate. Investors who fund the private providers of services could potentially lose their investments if the service provider did not meet the outcome measures whereby the state would not be required to make payment for the services provided. However, if the performance and outcome measures are met, the investors receive their investment back, plus a small return on their investment. The amount of that return would depend upon the individual terms of the contract between the private entity and the state entity.

Additionally, private providers are used to deliver the services under these contracts. As more pay-for-success contracts are awarded, the more private providers across the state will be involved in the opportunity to achieve performance payments and assist the state achieve positive outcomes.

C. Government Sector Impact:

Section 2 of the bill addresses funding specifically for the DOH's implementation of the NFP pay-for-success contract. Non-recurring General Revenue funding of $850,000 is provided to the DOH to support existing infrastructure and the implementation of the NFP model in designated Healthy Start Coalitions and FQHCs. Funding for new pay-for-success contracts is contingent upon a specific authorization in the GAA.

The DMS is tasked with prescribing the procedures to be used by state agencies in connection with pay-for-performance contracts. These procedures have not yet been developed. As of publication of the analysis, the DMS has not provided an estimate of the impact.

The Department of Financial Services (DFS), Bureau of Auditing audits and settles obligations that are requested for the State of Florida. Most payments for vendors are

paid with a voucher schedule through the Bureau of Auditing and are paid based on the terms of the contractual agreement. The term "success payment" could be in conflict with the contract payment terms and audit requirements under s. 215.97, F.S., and 2 C.F.R. Part 200, according to DFS.

In addition, if the contract is awarded on a non-competitive basis, then a cost analysis by the DOH and the vendor would need to be performed in accordance with s. 216.3475, F.S.[23]

VI. Technical Deficiencies:

Lines 100-101 of the bill provide, "Funding obtained for a program under this section is not a procurement item under s. 287.057, F.S." It is unclear whether this provision is intended to deem the private entity's efforts to obtain private investment not to be subject to the competitive procurement process. If this is the intent, the provision is most likely unnecessary.

VII. Related Issues:

The bill requires the private entity to report annually; however, in two places, "success payments" are required to be made when performance measures are met or achieved, or as otherwise set forth in the contract. It is unclear if the annual report later contains information that shows that measures were not met, if the state can recoup funds or if reporting can occur at the same time that payment is requested.

VIII. Statutes Affected:

This bill creates section 287.05715 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.

[23] Florida Department of Financial Services, *House Bill 1187 Analysis (Identical to SB 1446)* (Mar. 8, 2017) (on file with the Senate Committee on Health Policy).

By Senator Rouson

19-01317B-17 20171446__

A bill to be entitled

An act relating to pay-for-success contracts; creating s. 287.05715, F.S.; defining terms; authorizing a state agency to negotiate and enter into a pay-for-success contract with a private entity, subject to authorization in the General Appropriations Act; requiring a state agency to take certain actions if participating in the program; prescribing requirements for a pay-for-success contract; requiring a contracted private entity to annually report to the appropriate state agency for the length of the contract; specifying an exclusion from competitive solicitation requirements; requiring the Department of Management Services to prescribe procedures by a specified date; authorizing the Department of Health to implement the Nurse-Family Partnership pay-for-success program; providing an appropriation; providing an effective date.

WHEREAS, the Legislature finds that there are numerous prevention-focused social service programs and services for health care which can result in positive impacts and outcomes for individuals and families that use government resources more efficiently, and

WHEREAS, because government resources are limited, the state is often unable to fund these critical programs or services, and

WHEREAS, new and innovative financing models, like pay-for-success initiatives, are emerging throughout the country which

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authorize nongovernmental entities to invest their funds to provide support for these programs and services, and

WHEREAS, such financing models enable governmental entities to shift away from a traditional model of paying service providers for a defined quantity of services to a model where governmental entities only pay upon the successful achievement of agreed-upon outcomes, and

WHEREAS, the Legislature further finds that the establishment of a pay-for-success contract program will foster partnerships between the public, private, and philanthropic sectors while also emphasizing accountability in the rendering of services and encouraging the use of sophisticated program evaluations, NOW, THEREFORE,

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

Section 1. Section 287.05715, Florida Statutes, is created to read:

287.05715 Pay-for-success contracts.—

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

(a) "Pay-for-success contract" or "contract" means a contract between a state agency and a private entity to fund a program, as specified in the General Appropriations Act, to address a critical public problem with historically poor outcomes.

(b) "Private entity" means a private, not-for-profit organization, or a subsidiary or an affiliate thereof, exempt from federal income taxation pursuant to s. 501(c)(3) of the Internal Revenue Code of 1986 which enters into a pay-for-

success contract with a state agency and subcontracts with one or more entities to provide the actual services.

(c) "Success payment" means the amount paid to a private entity when performance outcome measures established in the pay-for-success contract are met, or as otherwise set forth in the pay-for-success contract.

(2) Contingent upon authorization in the General Appropriations Act, a state agency may negotiate and enter into a pay-for-success contract with a private entity. The contract may be initiated in 1 fiscal year, may continue into subsequent fiscal years, and may be paid from appropriations authorized in any of those fiscal years. The state agency shall:

(a) Determine performance outcome measures to be included in the contract in consultation with the private entity and provider.

(b) Determine the data to be included in an annual report filed by a private entity pursuant to subsection (4).

(c) Select an independent, nationally recognized evaluator through competitive solicitation procedures to evaluate the performance outcome measures specified in the contract.

(d) Ensure that subcontractors share participant data and sign an acknowledgment that the data may be shared with an independent evaluator for research and evaluation purposes, and maintain documentation of the required acknowledgements.

(3) A pay-for-success contract must meet all of the following requirements:

(a) Be limited to programs specified in the General Appropriations Act.

(b) Require the private entity to underwrite or secure

upfront capital from private funders, such as foundations, banks, businesses, or individuals to fund the services provided under the subcontracts.

(c) Require an independent evaluator to determine whether the specified performance outcomes have been achieved.

(d) Require a success payment, consistent with the General Appropriations Act, if the specified performance outcome measures are achieved.

(e) Prohibit the private entity from receiving or viewing any personally identifiable participant information.

(4) The private entity shall annually report to the state agency for the duration of the contract term.

(5) Funding obtained for a program under this section is not considered a procurement item under s. 287.057.

(6) By December 1, 2017, the department shall prescribe procedures to be used by state agencies in connection with pay-for-success contracts which are consistent with this section.

Section 2. Contingent upon authorization in the General Appropriations Act, the Department of Health is authorized to implement the Nurse-Family Partnership pay-for-success contract as an evidence-based practice model or provider. All subsequent models or providers funded under this program are subject to the same requirements provided under s. 287.05715, Florida Statutes, as created by this act.

Section 3. For the 2017-2018 fiscal year, the nonrecurring sum of $850,000 is appropriated from the General Revenue Fund to the Department of Health to support existing infrastructure and implementation of the Nurse-Family Partnership model in designated healthy start coalitions and federally qualified

health centers as provided in Specific Appropriation 467 of the 2016-2017 General Appropriations Act in preparation for participation in the pay-for-success contract program established under s. 287.05715, Florida Statutes, as created by this act.

Section 4. This act shall take effect July 1, 2017.

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

The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: March 23, 2017

I respectfully request that **Senate Bill #1446**, relating to Pay-for-Success Contracts , be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Darryl Rouson
Florida Senate, District 19

Cc: Kathleen Passidomo, VC; Sandra Stovall, SD; Celia Georgiades, AA

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)

04/03/2017
Meeting Date

1446
Bill Number (if applicable)

Topic Relating to Pay-for-success Contracts

Amendment Barcode (if applicable)

Name Gabrielle Bargerstock

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Phone 321-261-1454

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Nurse-Family Partnership

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1550
INTRODUCER:	Health Policy Committee and Senator Artiles
SUBJECT:	Health Information Transparency
DATE:	April 5, 2017
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1550 requires the Agency for Health Care Administration (AHCA) to contract with a vendor to evaluate health information technology in the state and report to the Legislature by December 31, 2017, on the development of systems that will use existing public and private health care data sources to provide health care providers with real-time access to information about their patients' health records, ensure that health care services are clinically appropriate, and ensure cost avoidance by eliminating duplicative and overused services.

The bill also amends sections of the Florida Statutes related to Medicaid third party liability to clarify who is a third party, extend the time frame for the AHCA to file a claim of lien, require an entity to respond to a claim by the AHCA within 90 days, require an entity to either pay or deny a claim within 140 days, and to repeal language that requires the AHCA to enter into cooperative agreements with the Office of Insurance Regulation (OIR) and the Department of Revenue (DOR) for information sharing related to third party liability.

The bill takes effect July 1, 2017.

II. Present Situation:

Florida Center for Health Information and Transparency

The Florida Center, housed within the AHCA, collects, compiles, coordinates, analyzes, indexes, and disseminates health-related data and statistics.[1] The information and data it collects include:

- Health resources, including licensed health care practitioners, by specialty and type of practice;
- Health service inventories, acute care, long-term care, and other institutional care facilities and specific services provided by hospitals, nursing homes, home health agencies, and other licensed health care;
- Service utilization for licensed health care facilities;
- Health care costs and financing, including trends in health care prices and costs, the sources of payment for health care services, and federal, state, and local expenditures for health care;
- The extent of public and private health insurance coverage in this state; and
- Specific quality-of-care initiatives involving various health care providers available to the public.[2]

The Florida Center makes all information available to the public through www.FloridaHealthFinder.gov.

Electronic Health Records

An electronic health record (EHR) is a record of a person's medical treatment which is created by a licensed health care practitioner and stored in an interoperable accessible digital format.[3] The Health Insurance Portability and Accountability (HIPPA) Security Rule establishes national standards for the security and privacy of personal health information (PHI) that a covered entity creates, receives, maintains, or transmits in electric form.[4] A covered entity must:

- Ensure the confidentiality, integrity, and availability of all electronic PHI it creates, receives, maintains, or transmits;
- Identify and protect against reasonably anticipated threats to security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance of its workforce.[5]

The Florida Electronic Health Records Exchange Act

Section 408.051, F.S., establishes the Florida Health Records Exchange Act. The act requires a healthcare provider that receives an authorization form containing a request for the release of an

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[1] Section 408.05(1), F.S.
[2] Section 408.05(2), F.S.
[3] Section 408.051(2)(a), F.S.
[4] HHS.gov, "The Security Rule," available https://www.hhs.gov/hipaa/for-professionals/security/index.html(last visited March 29, 2017). Covered entities include health care practitioners, health plans, and health care clearinghouses, as well of the business associates of these entities.
[5] HHS.gov, "Summary of the HIPAA Security Rule," available at https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html (last visited March 29, 2017).

identifiable health record to accept the form as a valid authorization to release the record.[6] Any release of health information after the receipt of an authorization form completed and submitted as prescribed by the Agency for Health Care Administration (AHCA) creates a rebuttable presumption that the release was appropriate.[7] Additionally, the act shields a health care provider that acts in good faith to release or access an identifiable health record without the patient's consent for the use in treatment of an emergency medical condition when the health care provider is unable to obtain the patient's or the patient's representative's consent when the patient requires immediate medical attention.[8]

In addition to the provisions contained within the Florida Electronic Health Records Exchange Act, s. 408.062(5), F.S., requires the AHCA to develop and implement a strategy for the adoption and use of electronic health records, including the development of an electronic health information network for the sharing of electronic health records among health care facilities, health care providers, and health insurers.

Federal Requirements for the Meaningful Use of EHR

In order to qualify for EHR Incentive Programs[9] offered by the Federal Centers for Medicare and Medicaid Services (CMS) hospitals and eligible professionals[10] (EP) must attest to demonstrating the meaningful use of EHR. Meaningful use is defined as using EHR to:

- Improve quality, safety, efficiency, and reduce health disparities;
- Engage patients and family;
- Improve care coordination, and population and public health; and
- Maintain privacy and security of patient health information.

Meaningful use sets specific objectives that EPs and hospitals must achieve to qualify for incentives and these objectives have evolved in three stages over five years:

- Stage 1, from 2011-2012, included data capture and sharing;
- Stage 2, in 2014-2015, included advanced clinical processes; and
- Stage 3, in 2016, included improved outcomes.[11]

Health Information Databases

A number of commercial products provide a health care practitioner with real time patient eligibility information, centralized claim filings, preauthorization services, and medical necessity

[6] Section 408.051(4)(c), F.S.
[7] Section 408.051(4)(e), F.S.; however, pursuant to s. 408.051(4)(d), F.S., the use of the form adopted by the AHCA is not required to authorize release of protected health information.
[8] Section 408.051(3), F.S.
[9] For a description of the EHR Incentive Programs, see https://www.healthit.gov/providers-professionals/ehr-incentive-programs, (last visited on March 30, 2017).
[10] Eligible professionals are doctors of medicine, osteopathy, dental surgery, dental medicine, podiatry, and optometry and chiropractors. See https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/eligibility.html, (last visited on March 30, 2017)
[11] See https://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives, (last visited on March 30, 2017). For more details on the specific on the objectives see https://www.healthit.gov/providers-professionals/how-attain-meaningful-use, (last visited on March 30, 2017).

validation.[12] However, the availability of such databases varies depending on geographic location, and the participating health insurers vary. The NORC at the University of Chicago[13] is an independent research organization that performs ongoing work in health care delivery and financing, including access to insurance, payment, and delivery system reform, and offers expertise in acquiring and analyzing health care claims data and national health-related datasets.[14] However, there is not a publicly accessible database that provides information on patient eligibility, claims data, and information regarding the clinical indications for the provision of specific medical services to a specific patient.

Medicaid Third Party Liability

Medicaid

Medicaid is a medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with costs of nursing facility care and other medical expenses. The AHCA is the single state agency responsible for administering the Florida Medicaid Program, which is funded by state and federal funds. The statutory authority for the Medicaid program is contained in ch. 409, F.S.

In 2011, the Legislature enacted Part IV of ch. 409, F.S., which requires all Medicaid beneficiaries to enroll in a managed care plan unless they are specifically exempt.[15] The statewide Medicaid managed care program includes the long-term care managed care program and the managed care medical assistance program.

Responsibility for Third Party Recovery

Federal law requires that a state, in the administration of its Medicaid program, take reasonable measures to determine the legal liability of third parties to pay for any medical assistance provided, and seek recovery from a third party for any claims that have been paid for which a third party is liable.[16] When a state identifies probable third party liability (TPL), it uses one of two methods to ensure that Medicaid is the payer of last resort: cost avoidance and pay-and-chase.[17] Cost avoidance is the method used to avoid payment when other insurance resources are available to the beneficiary. Federal regulations generally require states to use cost avoidance when probable TPL is established.[18] In contrast, the pay-and-chase method is used when a state

[12] For example, see Ability Network, (https://abilitynetwork.com/about/); Transunion, Inc. (https://www.transunion.com/product/insurance-eligibility-verification?utmsource=Google&utmmedium=ppc&utmkeyword=%252Bhealthcare%2520%252Beligibility&utm_source=Google&utm_medium=cpc&utm_content=%252Bhealthcare%2520%252Beligibility&utm_campaign=628735576&gclid=CMHM4ryhz9ICFY4vgQodrzYBgQ); and SSI Group, Inc. (http://thessigroup.com/access-management/) (last visited March 29, 2017).

[13] NORC at University of Chicago was originally founded as the National Opinion Research Center. Since the original name no longer reflected its mission and the global nature of its work, the business name was established as NORC (not an acronym) in 2010. See NORC at the University of Chicago, "About Our Name," available at http://www.norc.org/Pages/about-our-name.aspx (last visited March 29, 2017).

[14] NORC at the University of Chicago, "Health Care," available at http://www.norc.org/Research/Departments/Pages/health-care.aspx (last visited March 10, 2017).

[15] Chapter 2011-134, Laws of Fla. Full implementation occurred in 2014.

[16] 42 U.S.C. s. 1396a(a)(25). States are not required to seek reimbursement if is not cost-effective to do so.

[17] The state may contract with a vendor to fulfill this responsibility.

[18] 42 CFR s. 433.139(b).

pays health care service providers for submitted claims and then attempts to recover payments from liable third parties.[19] This usually occurs when TPL is later identified.

In 2005, Congress passed the Deficit Reduction Act (DRA)[20] that, among other things, clarified a state's duties to pursue reimbursement from third parties for medical assistance provided by Medicaid. Specifically, the DRA:

- Clarified the specific entities considered "third parties" and "health insurers" that may be liable for payment;
- Prohibited third parties and health insurers from discriminating against individuals on the basis of Medicaid eligibility; and
- Required that states pass laws requiring health insurers to:
  - Provide the state with eligibility and coverage information needed to identify potentially liable third parties;
  - Accept the assignment to the state of the Medicaid beneficiary's right to payment by such insurers for health care items or services for which Medicaid has paid;
  - Respond to any inquiry regarding a claim for payment of any health care item or service that is submitted within three years after the date of service; and
  - Agree not to deny such assignment or refuse to pay claims by Medicaid based on procedural reasons, if the claim is submitted within three years of the date of service and any action to enforce the state's right with respect to such claim is commenced within six years of the state's submission of the claim.

Florida Medicaid Third Party Liability Act

Under the Medicaid Third Party Liability Act,[21] Medicaid is the payor of last resort for medically necessary goods and services furnished to Medicaid beneficiaries. All other sources of payment are primary to Medicaid. If third party benefits are discovered or become available after medical assistance is provided by Medicaid, state law requires Medicaid to be paid in full and prior to any other person, program, or entity.[22]

An individual who is eligible for Medicaid assigns his or her right to third party benefits or payments to AHCA by applying for or accepting Medicaid benefits.[23] A Medicaid lien is automatically applied when a beneficiary receives services paid by Medicaid for which a third

[19] Under 42 U.S.C. s. 1396a(a)(25), a state must also pay and chase for prenatal care, preventive pediatric care, or if the coverage is through a parent whose obligation to pay support is enforced by the state's child support enforcement agency.
[20] Pub. Law No. 109-171.
[21] Section 409.910, F.S.
[22] Id. Florida Medicaid contracts with Health Management Systems, which subcontracts to Conduent Payment Integrity Solutions to pursue these reimbursements. See http://flmedicaidtplrecovery.com/tortcasualty/ (last visited April 5, 2017). For recipients enrolled in the statewide Medicaid managed care program, the managed care organization is responsible for TPL collections. See AHCA, SMMC Model Contract, Core Contract Provisions, available at http://www.fdhc.state.fl.us/medicaid/statewide_mc/pdf/Contracts/2017-02-01/02-01-17_Attachment_II.pdf (last visited April 5, 2017).
[23] Section 409.910(6), F.S.

party may be liable. A verified claim of lien may be filed with the clerk of the circuit court in the beneficiary's last known county of residence.[24]

III. Effect of Proposed Changes:

CS/SB 1550 amends s. 408.05, F.S., to require that the AHCA contract with a vendor to evaluate health information technology in the state and report to the Legislature on best practices in for the development of systems that will leverage existing public and private health care data sources in order to:

- Provide health care providers with real-time access to information about their patients' health records.
- Methods to increase interoperability across delivery systems and geographic locations, including a review of public and private insurance eligibility, to ensure that health care services, including Medicaid services, are clinically appropriate;
- Ensure cost avoidance through elimination of duplicative services and overutilization of services.

The bill requires that the AHCA submit the report to the Legislature by December 31, 2017.

The bill also amends ss. 409.901 and 409.910, F.S., relating to the Medicaid Third Party Liability Program, to bring the statutes into conformity with the federal DRA and improve efficiencies. The bill:

- Includes within the definition of "third party" a health insurer; self-insured plan; group health plan, as defined in s. 607(1) of the Employee Retirement Income Security Act of 1974; service benefit plan; managed care organization; liability insurance, including self-insurance; no-fault insurance; workers' compensation laws or plans; or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.
- Extends the amount of time the AHCA has to file a TPL lien from one year to three years after last payment for medical care, date of the AHCA's discovery of third party liability, or date of the discovery of a cause of action.
- Requires an entity to respond to a claim within 90 days with payment, a written request for more information, or a written denial of the claim stating a reason for denial.
- Establishes an uncontestable obligation to pay the claim if the entity fails to pay or respond to a claim within 140 days.
- Repeals provisions requiring the AHCA to enter into cooperative agreements with OIR and DOR to adopt rules for information sharing related to third party liability.
- Clarifies that a beneficiary may contest the amount of reimbursement from a recovered medical expense by filing a petition with the Division of Administrative Hearings only if amount of the recovery is limited by federal law.[25]

[24] Section 409.910(6)(c)2., F.S. A lack of a properly filed claim of lien will not affect AHCA's assignment rights or the existence of the lien, but only the effective date of notice.

[25] Federal law prohibits a Medicaid agency from recovering more than the amount of a recovery that is attributable to past and future medical needs. If a recovery does not provide an allocation, AHCA may recover 50 percent of the remaining recovery after payment of attorney fees and costs, up to the total amount of medical assistance provided. Therefore, the beneficiary may argue that the medical assistance provided is less than the remaining 50 percent of the recovery or that

The bill's provisions take effect on July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1550 may have an impact on the private sector if the AHCA recovers funds from the person or entity through TPL action beyond the current timeframe or if funds that would have been contestable but have become uncontestable through inaction of the person or entity are recovered through the TPL program.

C. Government Sector Impact:

CS/SB 1550 may have an indeterminate negative fiscal impact to the AHCA for contracting with a vendor to develop the report required in the bill.

CS/SB 1550 may have an indeterminate positive fiscal impact on the AHCA if the AHCA is able to recover more funds through TPL.

VI. Technical Deficiencies:

The title for CS/SB 1550 is "An act relating to the health information transparency." Sections two and three of the bill amend provisions related to TPL and do not appear to amend provisions related to health information transparency. As such, the current title of the bill may not be broad enough to incorporate all of the substantive provisions of the bill. The title should be amended so that it incorporates all substantive provisions. A title such as "An act relating to health care costs" may be sufficient.

AHCA's calculation of the amount that should have been allocated as past and future medical expenses is incorrect. 42 U.S.C. s. 1396a(a)(25).

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 408.05, 409.901, and 409.910.

IX. Additional Information:

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

CS by Health Policy on March 3, 2017:
The CS:

- Amends current bill language to:
  - Require the report be delivered by December 31, 2017;
  - Remove the automatic repeal date.
- Adds new language that:
  - Amends the definition of "third party" in part III of ch. 409, F.S., (related to Medicaid) to specifically include health insurers; self-insured plans, group health plan;, service benefit plans; managed care organizations; liability insurance; workers' comp laws or plans; or other parties that are legally responsible for payment of a claim for a health care item or service by statute, contract, or agreement.
  - Extends the time for AHCA to file a claim of lien from one year to three years after last payment for medical care, date of AHCA's discovery of third party liability; or date of the discovery of a cause of action.
  - Requires an entity to respond to a claim within 90 days with payment, a written request for more information, or a written denial of the claim stating a reason for denial. Failure to pay or respond to a claim within 140 days creates an uncontestable obligation to pay the claim.
  - Repeals provisions requiring the AHCA to enter into cooperative agreements with OIR and DOR to adopt rules for information sharing related to third party liability.
  - Clarifies that a beneficiary may contest the amount of reimbursement from a recovered medical expense by filing a petition with the DOAH only if amount of the recovery is limited by federal law.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2017	.	
	.	
	.	
	.	

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

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Present paragraphs (d) through (j) of subsection (3) of section 408.05, Florida Statutes, are redesignated as paragraphs (e) through (k), respectively, and a new paragraph (d) is added to that subsection, to read:

408.05 Florida Center for Health Information and Transparency.—

(3) HEALTH INFORMATION TRANSPARENCY.—In order to disseminate and facilitate the availability of comparable and uniform health information, the agency shall perform the following functions:

(d) Contract with a vendor to evaluate health information technology activities within the state. The vendor shall identify best practices for developing data systems which will leverage existing public and private health care data sources to provide health care providers with real-time access to their patients' health records. The evaluation shall identify methods to increase interoperability across delivery systems regardless of geographic location and include a review of eligibility for public programs or private insurance to ensure that health care services, including Medicaid services, are clinically appropriate. The evaluation shall address cost-avoidance through the elimination of duplicative services or overutilization of services. The agency shall submit a report of the vendor's findings and recommendations to the President of the Senate and the Speaker of the House of Representatives by December 31, 2017.

Section 2. Subsection (27) of section 409.901, Florida Statutes, is amended to read:

409.901 Definitions; ss. 409.901-409.920.—As used in ss. 409.901-409.920, except as otherwise specifically provided, the term:

(27) "Third party" means an individual, entity, or program, excluding Medicaid, that is, may be, could be, should be, or has been liable for all or part of the cost of medical services related to any medical assistance covered by Medicaid. A third

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party includes a third-party administrator; ~~or a~~ pharmacy benefits manager; health insurer; self-insured plan; group health plan, as defined in s. 607(1) of the Employee Retirement Income Security Act of 1974; service benefit plan; managed care organization; liability insurance, including self-insurance; no-fault insurance; workers' compensation laws or plans; or other parties that are, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

Section 3. Subsection (4), paragraph (c) of subsection (6), paragraph (h) of subsection (11), subsection (16), paragraph (b) of subsection (17), and subsection (20) of section 409.910, Florida Statutes, are amended to read:

409.910 Responsibility for payments on behalf of Medicaid-eligible persons when other parties are liable.—

(4) After the agency has provided medical assistance under the Medicaid program, it shall seek ~~recovery of~~ reimbursement from third-party benefits to the limit of legal liability and for the full amount of third-party benefits, but not in excess of the amount of medical assistance paid by Medicaid, as to:

(a) Claims for which the agency has a waiver pursuant to federal law; or

(b) Situations in which the agency learns of the existence of a liable third party or in which third-party benefits are discovered or become available after medical assistance has been provided by Medicaid.

(6) When the agency provides, pays for, or becomes liable for medical care under the Medicaid program, it has the following rights, as to which the agency may assert independent

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principles of law, which shall nevertheless be construed together to provide the greatest recovery from third-party benefits:

(c) The agency is entitled to, and has, an automatic lien for the full amount of medical assistance provided by Medicaid to or on behalf of the recipient for medical care furnished as a result of any covered injury or illness for which a third party is or may be liable, upon the collateral, as defined in s. 409.901.

1. The lien attaches automatically when a recipient first receives treatment for which the agency may be obligated to provide medical assistance under the Medicaid program. The lien is perfected automatically at the time of attachment.

2. The agency is authorized to file a verified claim of lien. The claim of lien shall be signed by an authorized employee of the agency, and shall be verified as to the employee’s knowledge and belief. The claim of lien may be filed and recorded with the clerk of the circuit court in the recipient’s last known county of residence or in any county deemed appropriate by the agency. The claim of lien, to the extent known by the agency, shall contain:

a. The name and last known address of the person to whom medical care was furnished.

b. The date of injury.

c. The period for which medical assistance was provided.

d. The amount of medical assistance provided or paid, or for which Medicaid is otherwise liable.

e. The names and addresses of all persons claimed by the recipient to be liable for the covered injuries or illness.

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3. The filing of the claim of lien pursuant to this section shall be notice thereof to all persons.

4. If the claim of lien is filed within 3 years ~~1 year~~ after the later of the date when the last item of medical care relative to a specific covered injury or illness was paid, or the date of discovery by the agency of the liability of any third party, or the date of discovery of a cause of action against a third party brought by a recipient or his or her legal representative, record notice shall relate back to the time of attachment of the lien.

5. If the claim of lien is filed after 3 years ~~1 year~~ after the later of the events specified in subparagraph 4., notice shall be effective as of the date of filing.

6. Only one claim of lien need be filed to provide notice as set forth in this paragraph and shall provide sufficient notice as to any additional or after-paid amount of medical assistance provided by Medicaid for any specific covered injury or illness. The agency may, in its discretion, file additional, amended, or substitute claims of lien at any time after the initial filing, until the agency has been repaid the full amount of medical assistance provided by Medicaid or otherwise has released the liable parties and recipient.

7. No release or satisfaction of any cause of action, suit, claim, counterclaim, demand, judgment, settlement, or settlement agreement shall be valid or effectual as against a lien created under this paragraph, unless the agency joins in the release or satisfaction or executes a release of the lien. An acceptance of a release or satisfaction of any cause of action, suit, claim, counterclaim, demand, or judgment and any settlement of any of

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the foregoing in the absence of a release or satisfaction of a lien created under this paragraph shall prima facie constitute an impairment of the lien, and the agency is entitled to recover damages on account of such impairment. In an action on account of impairment of a lien, the agency may recover from the person accepting the release or satisfaction or making the settlement the full amount of medical assistance provided by Medicaid. Nothing in this section shall be construed as creating a lien or other obligation on the part of an insurer which in good faith has paid a claim pursuant to its contract without knowledge or actual notice that the agency has provided medical assistance for the recipient related to a particular covered injury or illness. However, notice or knowledge that an insured is, or has been a Medicaid recipient within 1 year from the date of service for which a claim is being paid creates a duty to inquire on the part of the insurer as to any injury or illness for which the insurer intends or is otherwise required to pay benefits.

8. The lack of a properly filed claim of lien shall not affect the agency's assignment or subrogation rights provided in this subsection, nor shall it affect the existence of the lien, but only the effective date of notice as provided in subparagraph 5.

9. The lien created by this paragraph is a first lien and superior to the liens and charges of any provider, and shall exist for a period of 7 years, if recorded, after the date of recording; and shall exist for a period of 7 years after the date of attachment, if not recorded. If recorded, the lien may be extended for one additional period of 7 years by rerecording the claim of lien within the 90-day period preceding the

expiration of the lien.

10. The clerk of the circuit court for each county in the state shall endorse on a claim of lien filed under this paragraph the date and hour of filing and shall record the claim of lien in the official records of the county as for other records received for filing. The clerk shall receive as his or her fee for filing and recording any claim of lien or release of lien under this paragraph the total sum of $2. Any fee required to be paid by the agency shall not be required to be paid in advance of filing and recording, but may be billed to the agency after filing and recording of the claim of lien or release of lien.

11. After satisfaction of any lien recorded under this paragraph, the agency shall, within 60 days after satisfaction, either file with the appropriate clerk of the circuit court or mail to any appropriate party, or counsel representing such party, if represented, a satisfaction of lien in a form acceptable for filing in Florida.

(11) The agency may, as a matter of right, in order to enforce its rights under this section, institute, intervene in, or join any legal or administrative proceeding in its own name in one or more of the following capacities: individually, as subrogee of the recipient, as assignee of the recipient, or as lienholder of the collateral.

(h) Except as otherwise provided in this section, actions to enforce the rights of the agency under this section shall be commenced within 6 ~~5~~ years after the date a cause of action accrues, with the period running from the later of the date of discovery by the agency of a case filed by a recipient or his or


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her legal representative, or of discovery of any judgment, award, or settlement contemplated in this section, or of discovery of facts giving rise to a cause of action under this section. Nothing in this paragraph affects or prevents a proceeding to enforce a lien during the existence of the lien as set forth in subparagraph (6)(c)9.

(16) Any transfer or encumbrance of any right, title, or interest to which the agency has a right pursuant to this section, with the intent, likelihood, or practical effect of defeating, hindering, or reducing reimbursement to ~~recovery by~~ the agency for ~~reimbursement of~~ medical assistance provided by Medicaid, shall be deemed to be a fraudulent conveyance, and such transfer or encumbrance shall be void and of no effect against the claim of the agency, unless the transfer was for adequate consideration and the proceeds of the transfer are reimbursed in full to the agency, but not in excess of the amount of medical assistance provided by Medicaid.

(17)

(b) If federal law limits the agency to reimbursement from the recovered medical expense damages, a recipient, or his or her legal representative, may contest the amount designated as recovered medical expense damages payable to the agency pursuant to the formula specified in paragraph (11)(f) by filing a petition under chapter 120 within 21 days after the date of payment of funds to the agency or after the date of placing the full amount of the third-party benefits in the trust account for the benefit of the agency pursuant to paragraph (a). The petition shall be filed with the Division of Administrative Hearings. For purposes of chapter 120, the payment of funds to

the agency or the placement of the full amount of the third-party benefits in the trust account for the benefit of the agency constitutes final agency action and notice thereof. Final order authority for the proceedings specified in this subsection rests with the Division of Administrative Hearings. This procedure is the exclusive method for challenging the amount of third-party benefits payable to the agency. In order to successfully challenge the amount designated as recovered medical expenses ~~payable to the agency~~, the recipient must prove, by clear and convincing evidence, that the ~~a lesser~~ portion of the total recovery that should be allocated as ~~reimbursement for~~ past and future medical expenses is less than the amount calculated by the agency pursuant to the formula set forth in paragraph (11)(f). Alternatively, the recipient must prove by clear and convincing evidence ~~or~~ that Medicaid provided a lesser amount of medical assistance than that asserted by the agency.

(20)(a) Entities providing health insurance as defined in s. 624.603, health maintenance organizations and prepaid health clinics as defined in chapter 641, and, on behalf of their clients, third-party administrators, ~~and~~ pharmacy benefits managers, and any other third parties, as defined in s. 409.901(27), which are legally responsible for payment of a claim for a health care item or service as a condition of doing business in the state or providing coverage to residents of this state, shall provide such records and information as are necessary to accomplish the purpose of this section, unless such requirement results in an unreasonable burden.

(b) An entity must respond to a request for payment with


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payment on the claim, a written request for additional information with which to process the claim, or a written reason for denial of the claim within 90 working days after receipt of written proof of loss or claim for payment for a health care item or service provided to a Medicaid recipient who is covered by the entity. Failure to pay or deny a claim within 140 days after receipt of the claim creates an uncontestable obligation to pay the claim.

~~(a) The director of the agency and the Director of the Office of Insurance Regulation of the Financial Services Commission shall enter into a cooperative agreement for requesting and obtaining information necessary to effect the purpose and objective of this section.~~

~~1. The agency shall request only that information necessary to determine whether health insurance as defined pursuant to s. 624.603, or those health services provided pursuant to chapter 641, could be, should be, or have been claimed and paid with respect to items of medical care and services furnished to any person eligible for services under this section.~~

~~2. All information obtained pursuant to subparagraph 1. is confidential and exempt from s. 119.07(1). The agency shall provide the information obtained pursuant to subparagraph 1. to the Department of Revenue for purposes of administering the state Title IV-D program. The agency and the Department of Revenue shall enter into a cooperative agreement for purposes of implementing this requirement.~~

~~3. The cooperative agreement or rules adopted under this subsection may include financial arrangements to reimburse the reporting entities for reasonable costs or a portion thereof~~

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~~incurred in furnishing the requested information. Neither the cooperative agreement nor the rules shall require the automation of manual processes to provide the requested information.~~

~~(b) The agency and the Financial Services Commission jointly shall adopt rules for the development and administration of the cooperative agreement. The rules shall include the following:~~

~~1. A method for identifying those entities subject to furnishing information under the cooperative agreement.~~

~~2. A method for furnishing requested information.~~

~~3. Procedures for requesting exemption from the cooperative agreement based on an unreasonable burden to the reporting entity.~~

Section 4. This act shall take effect July 1, 2017.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to health information transparency; amending s. 408.05, F.S.; requiring the Agency for Health Care Administration to contract with a vendor to evaluate health information technology activities to identify best practices and methods to increase interoperability; requiring a report to the Legislature by a specified date; amending s. 409.901, F.S.; revising the definition of the term "third party" for purposes of liability for payment of

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certain medical services covered by Medicaid; amending s. 409.910, F.S.; revising provisions relating to responsibility for Medicaid payments in settlement proceedings; extending the period of time for filing a claim of lien filed for purposes of third-party liability; extending the period of time within which the agency is authorized to pursue certain causes of action; revising procedures for a recipient to contest the amount payable to the agency when federal law limits reimbursement under certain circumstances; requiring certain entities responsible for payment of claims to provide certain records and information and respond to requests for payment of claims within a specified timeframe as a condition of doing business in the state; providing circumstances under which such parties are obligated to pay claims; deleting provisions relating to cooperative agreements between the agency, the Office of Insurance Regulation, and the Department of Revenue; providing an effective date.

By Senator Artiles

40-01536-17 20171550__

A bill to be entitled

An act relating to the Florida Center for Health Information and Technology; amending s. 408.05, F.S.; requiring the Agency for Health Care Administration to contract with a vendor relating to development of systems to leverage existing public and private health care data sources for specified purposes; requiring the agency to submit a report to the Legislature by a specified date; providing an effective date.

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

Section 1. Present paragraphs (d) through (j) of subsection (3) of section 408.05, Florida Statutes, are redesignated as paragraphs (e) through (k), respectively, and a new paragraph (d) is added to that subsection, to read:

408.05 Florida Center for Health Information and Transparency.—

(3) HEALTH INFORMATION TRANSPARENCY.—In order to disseminate and facilitate the availability of comparable and uniform health information, the agency shall perform the following functions:

(d)1. Contract with a vendor to investigate and report to the Legislature on opportunities for, and best practices in, the development of systems that will leverage existing public and private health care data sources, in order to:

a. Provide health care providers with real-time access to information about their patients' health records, including public program or private insurance eligibility, across delivery

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systems and geographic locations;

b. Ensure that health care services, including Medicaid services, are clinically appropriate; and

c. Ensure cost avoidance through elimination of duplicative services or overutilization of services.

2. The agency shall submit the report to the Legislature by March 1, 2018.

3. This paragraph is repealed July 1, 2018.

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

The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 15, 2017

I respectfully request that **Senate Bill #1550**, relating to Florida Center for Health Information and Technology, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Senator Frank Artiles
Florida Senate, District 40

File signed original with committee office

S-020 (03/2004)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

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

BILL:	CS/SB 1578
INTRODUCER:	Health Policy Committee and Senator Gibson
SUBJECT:	Diabetes Educators
DATE:	April 4, 2017
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1578 establishes a new regulated health care practitioner profession in Florida, the diabetes educator. The bill provides definitions and requirements for registration. It prohibits an unregistered person from certain activities relating to diabetes self-management training, and provides exceptions. The Department of Health (DOH) must implement these provisions by July 1, 2018.

The bill provides an effective date of July 1, 2017.

II. Present Situation:

Diabetes -What is it?

Diabetes is a group of diseases in which the body produces too little insulin,[1] is unable to use insulin efficiently, or both. When diabetes is not controlled, glucose and fats remain in the blood and eventually cause damage to vital organs.

The most common forms of diabetes are: [2]

[1] Insulin is a hormone that allows glucose (sugar) to enter cells and be converted to energy. Merriam-Webster, *available at* http://www.merriam-webster.com/dictionary/insulin (last visited Mar. 29, 2017).

[2] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Diabetes Report Card* (2014), p. 4, *available at* http://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2014.pdf (last visited Mar. 29, 2017).

- **Type 1**: (juvenile diabetes). Type 1 diabetes is usually first diagnosed in children and adolescents and accounts for about 5 percent of all diagnosed cases. Type 1 diabetes is an autoimmune disease in which the body's own immune system destroys cells in the pancreas that produce insulin. Type 1 diabetes may be caused by genetic, environmental, or other risk factors. At this time, there are no methods to prevent or cure type 1 diabetes, and treatment requires the use of insulin by injection or pump.
- **Type 2**: (adult-onset diabetes). Type 2 diabetes accounts for about 95 percent of diagnosed diabetes in adults and is usually associated with older age, obesity, lack of physical activity, family history, or a personal history of gestational diabetes. Studies have shown that healthy eating, regular physical activity, and weight loss can prevent or delay the onset of type 2 diabetes or eliminate the symptoms and effects post-onset.
- **Gestational diabetes**: This type of diabetes is diagnosed during pregnancy. The cause of gestational diabetes is unknown. Some women with gestational diabetes are overweight before getting pregnant or have diabetes in the family. From 1 in 50 to 1 in 20 pregnant women have gestational diabetes. It is more common in Native American, Alaskan Native, Hispanic, Asian, and Black women, but it is also found in White women.[3] Gestational diabetes can cause health problems during pregnancy for both the child and mother. Children whose mothers have gestational diabetes have an increased risk of developing obesity and type 2 diabetes.

Complications of diabetes include: heart disease, stroke, high blood pressure (hypertension), blindness and other eye problems, kidney disease, nervous system disease, vascular disorders, and amputations. Death rates for heart disease and the risk of stroke are about two to four times higher among adults with diabetes than among those without diabetes. Diabetes and its potential health consequences can be managed through physical activity, diet, self-management training, and, when necessary, medication.[4]

People with "pre-diabetes" are at high risk of developing type 2 diabetes, heart disease, and stroke. Their blood glucose levels are higher than normal, but not high enough to be classified as diabetes. Although an estimated 33 percent of adults in the United States have pre-diabetes, less than 10 percent of them report having been told they have the condition. Thus, awareness of the risk is low. People with pre-diabetes who lose 5 to 7 percent of their body weight and get at least 150 minutes per week of moderate physical activity can reduce the risk of developing type 2 diabetes by 58 percent.[5]

Risk factors for diabetes include:[6]

- Being over the age of 45;
- Overweight;
- Having a parent or sibling with diabetes;

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[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Diabetes and Pregnancy, Gestational Diabetes, available at* https://www.cdc.gov/pregnancy/documents/Diabetes_and_Pregnancy508.pdf,(last visited Mar. 29, 2017).

[4] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Diabetes Latest, available at* http://www.cdc.gov/features/diabetesfactsheet/, (last visited Mar. 29, 2017).

[5] *Supra* note 3, at 4.

[6] Florida Department of Health, *Diabetes, Warning Signs and Risk Factors, available at* http://www.floridahealth.gov/diseases-and-conditions/diabetes/warning-signs.html, (last visited Mar. 29, 2017).

- Having a minority family background;
- Developing diabetes while pregnant, gave birth to a baby weighing 9 pounds or more; and
- Being physically active less than three times per week.

Persons with any of the above risk factors are also at risk of developing pre-diabetes. Individuals with pre-diabetes are 5 to 15 times more likely to develop type 2 diabetes, heart disease, and stroke.[7] The Centers for Disease Control (CDC) estimates that as many as one out of every three American adults has pre-diabetes and half of all Americans aged 65 years and older have pre-diabetes.[8]

In 2013, the American Diabetes Association (ADA)[9] released a report updating its earlier studies (2002, 2007) estimating the economic burden of diagnosed diabetes. In 2012, the total estimated cost of diagnosed diabetes in the United States was $245 billion, including $176 billion in direct medical costs and $69 billion in reduced productivity. This represents a 41 percent increase over the 2007 estimate. The largest components of medical expenditures are:

- Hospital inpatient care (43 percent of the total medical cost);
- Prescription medications to treat complications of diabetes (18 percent);
- Anti-diabetic agents and diabetes supplies (12 percent); and
- Physician office visits (9 percent), and nursing/residential facility stays (8 percent).

People with diagnosed diabetes incur average medical costs of about $13,700 per year, of which about $7,900 is attributed to diabetes. Care for people with diagnosed diabetes accounts for more than one in five dollars spent on health care in the United States, and more than half of that is directly attributable to diabetes. Overall, average medical expenses for a person with diabetes are 2.3 times higher than they are for a person without diabetes.[10]

Diabetes in Florida

Diabetes was the seventh leading cause of death in 2014 in Florida. In 2014, there were 5,324 Florida deaths due to diabetes.[11] As a percentage of total deaths in the state, diabetes accounted for 2.9 percent of all deaths, and over a 3-year period (2012 - 2014), diabetes had an age adjusted death rate per 100,000 of 19.7 or 15,597 deaths.[12]

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[7] Florida Department of Health, *Prediabetes, What is Prediabetes? available at* http://www.floridahealth.gov/diseases-and-conditions/diabetes/prediabetes.html, (last visited Mar. 29, 2017).
[8] *Id.*
[9] The ADA was founded in 1940 by 26 physicians. It remained an organization for health care professionals during its first 30 years. In 1970, the Association welcomed general members. In the years since, it has grown to include a network of more than 1 million volunteers. See American Diabetes Association, *75 Years of Progress, available at* http://www.diabetes.org/about-us/75th-anniversary/, (last visited Mar. 29, 2017).
[10] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2012*, Diabetes Care 36: 1033 – 1046, 2013, *available at* http://care.diabetesjournals.org/content/36/4/1033.full.pdf+html, (last visited Mar. 29, 2017).
[11] Florida Diabetics Advisory Council, *2017 Florida Diabetes Report*, p. 31 (January 10, 2017), *available at* http://www.floridahealth.gov/provider-and-partner-resources/dac/_documents/dac-report-january2017.pdf, (last visited Mar. 29, 2017).
[12] Florida Department of Health, *Florida Charts: Diabetes Deaths - Three Year Trends, available at* http://www.floridacharts.com/charts/DataViewer/DeathViewer/DeathViewer.aspx?indNumber=0090, (last visited Mar. 29, 2017).

Florida's Diabetes Advisory Council (DAC)

The DAC was created over 40 years ago to guide statewide policy on diabetes prevention, diagnosis, education, care, treatment, impact, and costs. The DAC has 26 members who have experience related to diabetes and serve in an advisory capacity to the DOH, other agencies, and the public. Twenty-one members represent a broad range of health and public health related interests. The remaining five members are representatives of the general public of which at least three are affected by diabetes. The council meets annually with the State Surgeon General to make recommendations regarding the public health aspects of the prevention and control of diabetes.[13]

In 2015, the Legislature added a requirement that the DAC issue a report on the public health consequences and financial impact of diabetes and its complications in Florida by January 10 of each odd-numbered year, and submit the report to Governor, the President of the Senate, and the Speaker of the House of Representatives. In January 2017, the Council issued its first report describing the public health consequences and financial impact diabetes, and its complications, have in Florida. The council reviewed data collected by the DOH, Agency for Health Care Administration, and Division of State Group Insurance, about diabetes and state programs that address diabetes, as well as developed an action plan to reduce the impact of diabetes. The report includes data on the scope and cost of diabetes in Florida; how each partner is addressing diabetes prevention and control for their population; how partners are coordinating efforts; recent successes; and recommendations for actions to reduce the impact of diabetes. Funding recommendations are also provided, and anticipated outcomes described, for funding at optimal, intermediate, and current levels.[14]

The 2017, DAC report includes specific recommendations to change state policy to reduce the impact of all types of diabetes by the passage of statewide changes to reimburse Certified Diabetes Educators (CDEs) and Board Certified-Advanced Diabetes Management (BC-ADM) educators for providing diabetes self-management education (DSME) through increased reimbursement for DSME from Medicare; and requiring all state employee health insurance plans to cover CDC-recognized diabetes prevention programs (DPP) for employees who are eligible. The DAC report does not address whether state regulation of CDE's or BC-ADMs is required.[15]

Diabetes Educators

The American Diabetes Association (ADA) defines a "diabetes educator" as, "a health care professional who teaches people who have diabetes how to manage their diabetes."[16] Diabetes educators are found in hospitals, physician offices, managed care organizations, home health care, and other settings.[17]

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[13] Section 385.203, F.S. *See also* Florida Diabetics Advisory Council, *2017 Florida Diabetes Report* (Jan. 10, 2017), *available at* http://www.floridahealth.gov/provider-and-partner-resources/dac/_documents/dac-report-january2017.pdf, (last visited Mar. 29, 2017).
[14] Id.
[15] Id. at pp. 64-66.
[16] *See* American Diabetes Association, Diabetes Basics, *Common Terms*, *available at* http://www.diabetes.org/diabetes-basics/common-terms/?loc=db-slabnav (Last visited Mar. 29, 2017).
[17] *Id.*

The State of Florida does not currently license or regulate diabetes educators. At least 28 professions in Florida currently include patient or client diabetes education within their scope of practice.[18]

Kentucky enacted a diabetes educator law in 2013,[19] and Indiana in 2014.[20] Both are under the respective state's board of medicine. Kentucky provides three paths for individuals to become licensed as diabetes educators. An individual must file an application, pay a fee, and demonstrate completion of any one of the following:

- A board-approved course in diabetes education with supervised experience in the care of people with diabetes under supervision that meets requirements specified in administrative regulations promulgated by the board;21
- The credentialing program of the American Association of Diabetes Educators (AADE) or the National Certification Board for Diabetes Educators (NCDBE); or
- An equivalent credentialing program as determined by the board.

Indiana's law is similar to Kentucky's and requires an applicant to demonstrate completion of one of the following:

- The AADE core concepts course[22] with demonstrable experience in the care of individuals with diabetes under supervision that meets requirements specified in rules adopted by the board;
- The credentialing program of the AADE;
- The credentialing program of the NCBDE; or
- An equivalent credentialing program as determined by the board.

The AADE was founded in 1973, as a multi-disciplinary professional membership organization dedicated to improving diabetes care through education. It has more than 14,000 members

[18] The professions that include diabetes education in their scope of practice include: Physicians, PAs, Podiatrists, Chiropractors, Dentists, Podiatrists, Chiropractors, Dentists, Pharmacists, ARNPs, CNSs, CRNAs, LPNs, RNs, Dental Hygienists, Paramedics, EMTs, Dietitian/Nutritionists, Orthotists, Acupuncturists, Athletic Trainers, Physical Therapists; Massage Therapists, Prosthetists, Midwives, Opticians, Optometrists, School Psychologists, Orthotic Fitters, Mental Health Counselors, Clinical Psychologists, and Clinical Social Workers.

[19] The Kentucky Board of Licensed Diabetes Educators, *Laws and Regulations Relating to Licensed Diabetes Educators*, s. 309.335, K.R.S., p. 7, *available at* http://bde.ky.gov/Documents/Laws%20and%20Regulations.pdf, (last visited Mar. 29, 2017).

[20] See IC 25-14.3-3-3, (2015), *available at* http://www.in.gov/pla/files/2015_Medical_Compilation.pdf, (last visited Mar. 29, 2017).

[21] 201 KAR 45:110 (2015), requires the apprentice diabetes educator to accumulate at least 750 hours of supervised work experience in 5 years with 250 of the hours being obtained in the 12 months preceding licensure application. The apprentice is required to interact with the supervisor at least 2 hours quarterly, 1 hour of which must be in person. A supervisor shall not supervise more than four apprentices at a time. The supervision process shall focus on: (a) Identifying strengths, developmental needs, and providing direct feedback to foster the professional development of the apprentice diabetes educator; (b) Identifying and providing resources to facilitate learning and professional growth; (c) Developing awareness of professional and ethical responsibilities in the practice of diabetes education; and (d) Ensuring the safe and effective delivery of diabetes education services and fostering the professional competence and development of the apprentice diabetes educator.

[22] American Association of Diabetes Educators, *CORE Concepts Course On Line*, is available for a cost of between $386 - $586, *available at* https://www.diabeteseducator.org/education-career/online-courses/ccc-online, (last visited Mar. 29, 2017).

including nurses, dietitians, pharmacists and others. The AADE offers the Board Certified-Advanced Diabetes Management (BC-ADM) credential.[23]

Healthcare professionals who hold BC-ADM certification, if within their scope of practice, are trained to:

- Adjust medications;
- Treat and monitor complications and other comorbidities;
- Council patents on lifestyle modifications;
- Address psychosocial issues; and
- Participate in research and mentoring.

Certification as a BC-ADM requires a current active licensure/registration as a registered nurse, dietitian, pharmacist, physician or physician assistant, a master's or higher level degree, and 500 clinical practice hours within 48 months prior to taking the certification exam.[24]

The NCBDE was established in 1986 as an independent organization that promotes the interests of diabetes educators and the public by granting certification to qualified health professionals. The NCBDE offers the Certified Diabetes Educator (CDE) credential. Individuals holding the CDE credential educate people affected by diabetes to manage the condition and promote self-management in order to optimize health outcomes.[25]

Certification as a CDE requires active licensure/registration as a psychologist, registered nurse, occupational therapist, optometrist, pharmacist, physical therapist, physician, podiatrist, dietitian with a Commission on Dietetic Registration (CDR), or a health professional with a master's degree or higher in social work. Professional practice experience, continuing education and an examination are also required.[26]

The CDC has also established the CDC National Diabetes Recognition Program (NDRP) as part of the National Diabetes Prevention Program (NDPP).[27] The NDPP is a partnership of public and private organizations working to reduce the growing problem of lack of public education on prediabetes and type 2 diabetes.[28] A key part of the NDPP is the lifestyle change program to prevent or delay type 2 diabetes. Hundreds of in-person, and online, lifestyle change programs nationwide teach participants to make CDC approved lasting lifestyle changes, like eating healthier, adding physical activity into a daily routine, and improving coping skills. To ensure high quality, the CDC recognizes lifestyle change programs that meet certain standards and show they can achieve results. These standards include following an approved curriculum, facilitation

[23] The American Association of Diabetes Educators, *About AADE*, *available at* https://www.diabeteseducator.org/about-aade (last visited Mar. 29, 2017).
[24] Id.
[25] National Certification Board for Diabetes Educators, *History*, *available at* http://www.ncbde.org/about/history/ (last visited Mar. 2017).
[26] Id.
[27] U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *Diabetes Prevention Recognition Program, Standards and Operating Procedures* (January 1, 2015), *available at* http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf (last visited Mar. 29, 2017).
[28] U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *What Is the National DPP?* (updated January 14, 2016), *available at* http://www.cdc.gov/diabetes/prevention/about/index.html (last visited Mar. 29, 2017).

by a trained lifestyle coach, and submitting data each year to show that the program is having an impact. The NDPP must use a lifestyle coach to deliver the program to participants. Many lifestyle coaches are registered dieticians or registered nurses, but no credentials are required;[29] and the CDC has a free lifestyle coach facilitator training guide available on its website.[30]

The AADE also offers NDPP diabetes lifestyle coach training based on the curriculum of the CDC in a 2-day, in person, course for $750 - $850 to acquire all necessary skills to deliver a successful CDC NDRP/NDPP Program.[31]

The Sunrise Act and Sunrise Questionnaire

The Sunrise Act (the act), codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The legislative intent in the act provides that:

- No profession or occupation be subject to regulation unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the state's police power be exercised only to the extent necessary for that purpose; and
- No profession or occupation be regulated in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the services to the public.

The Legislature must review all legislation proposing regulation of a previously unregulated profession or occupation and make a determination for regulation based on consideration of the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The act requires the proponents of legislation for the regulation of a profession or occupation to provide specific information in writing to the state agency that is proposed to have jurisdiction

[29] *Supra* note 20, at 25.
[30] U.S. Department of Health and Human Services, Center for Disease Control and Prevention, *National Diabetes Prevention Program, Life Coach Facilitation Guide, available at* http://www.cdc.gov/diabetes/prevention/pdf/curriculum_intro.pdf, (last visited Mar. 2017).
[31] American Association of Diabetes Educators, *AADE Diabetes Prevention Program Lifestyle Coach Training, available at* https://www.diabeteseducator.org/practice/diabetes-prevention-program/lifestyle-coach-training, (last visited Mar. 29, 2017).

over the regulation and to the legislative committees of reference.[32] This required information is traditionally compiled in a "Sunrise Questionnaire."

The Florida Senate Sunrise Questionnaire (questionnaire) has been provided to the Senate Health Policy Committee.[33] The responsive comments to the questionnaire indicate that unregistered and incompetent diabetes self-management training practitioners create a danger to public health and safety in Florida through inaccurate information, that effects the prevalence of the disease and associated complications; and that registration to establish minimum practice standards is necessary to protect the public. The questionnaire also indicates that the number of individuals who will qualify for, or pursue registration is unknown.

III. Effect of Proposed Changes:

The bill creates part XVII of ch. 468, F.S., entitled "Diabetes Educators," to establish a new regulated profession in Florida; and amends the definition of a health care practitioner in ch. 456, F.S., to include diabetes educators.

The bill expresses a finding that unregistered and incompetent diabetes self-management training practitioners create a danger to public health and safety in Florida; and that to protect the public it is necessary to require practitioner registration to establish minimum standards of practice for Florida diabetes educators.

The bill defines the following terms:

- "Diabetes educator" as a registered health care practitioner who has demonstrated a comprehensive knowledge of and experience in prediabetes, diabetes prevention, and diabetes education and who provides diabetes self-management training.
- "Diabetes self-management training" is the assessment and development of a care plan for a person with diabetes whereby that person gains knowledge and the necessary skills to modify behavior and successfully self-manage the disease in line with the national standards published by the ADA.

The bill prohibits a person providing diabetes self-management training, or holding himself or herself out as a diabetes educator, unless he or she is registered with the DOH.

However, the bill specifically delineates that it does not restrict or prohibit a person:

- From engaging in his or her listed profession if licensed by the DOH;[34] or
- Employed by the federal government from discharging his or her official duties.

Registration as a diabetes educator under the bill requires the person to submit to the DOH an application, registration fee and proof of the following:

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[32] *See* s. 11.62(4)(a)-(m), F.S.

[33] Florida Sunset Review Questionnaire, *Diabetes Educator*, (received March 30, 2017) (on file with the Senate Committee on Health Policy).

[34] The listed professions include the following: doctors (allopathic, osteopathic and podiatric); Physician Assistants; optometrists; opticians; nurses (ARNP, RN, LPN); pharmacists; pharmacy technicians; dentists; dental hygienist; dental laboratory personnel; medical physicists; occupational therapists; dieticians; nutritionists; clinical laboratory personnel; physical therapists; and psychologists.

- Certification as a CDE or a BC-ADM, or
- Proof of 250 practice hours of diabetes education, of which 100 hours must have been earned in the proceeding calendar year, and proof of passing an NCBDE[35] examination; and
  - Proof of licensure by the DOH under one of the listed professions;[36]
  - Proof of certification as a clinical exercise physiologist or Registered Clinical Exercise Physiologist by the American College of Sports Medicine; or
  - Proof of a master's degree in social work from an accredited U.S. college or university.

The DOH may take disciplinary action pursuant to s. 456.072, F.S., against an applicant or registrant and may deny, revoke, or suspend registration or registration renewal for a violation of this section.

Renewal of a diabetes educator registration is required biennially. The DOH must establish by rule the fees for registration and renewal for the newly created profession, which must be adequate to implement and administer the profession, including:

- A nonrefundable application fee, not exceeding $100;
- An initial registration fee, not exceeding $100;
- A biennial renewal fee, not exceeding $80; and
- A fee for reactivation of an inactive registration, not exceeding $135.

The DOH must implement the provisions of this bill by July 1, 2018.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[35] In order to sit for the NCBDE examination a candidate must have a current unrestricted active license or registration as a clinical psychologist, registered nurse, occupational therapist, optometrist, pharmacist, physical therapist, physician, podiatrist, master certified health education specialist, certified clinical exercise physiologist, registered clinical exercise physiologist, registered dietitian, dietitian, nutritionist, or registered physician assistant; or hold a minimum of a master's degree in social work from a U.S. college or university accredited by a nationally recognized regional accrediting body. If the candidate does not have these credentials he or she may investigate the NCBDE's Unique Pathway which requires a degree, 2 calendar years of practice experience within the last 4 years since receiving the license, registration or advanced degree; 1000 hours of practice experience in DSME within the last 4 years of which 40 percent (400 hours) must have been accrued in the last year; and 15 hours of continuing education applicable to diabetes within the past 2 years. *See* National Certification Board for Diabetes Educators, *2016 Certification Examination for Diabetes Educators* (rev. November 20, 2015), *available at* http://www.ncbde.org/assets/1/7/Handbook_Current.pdf (last visited Mar. 30, 2017).

[36] *See* note 34.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 1578 may have a chilling effect on health care volunteers and home health aides reinforcing diabetes education, as it may potentially subject them to regulatory sanctions.

C. Government Sector Impact:

The DOH may incur costs associated with regulating a new profession.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not include diabetes educators (CDE or BC-ADM) in:

- Currently, multiple DOH licensed professions are able to provide diabetes education under their scope of practice, including: Physicians, Chiropractic Physicians, Podiatric Physicians, Naturopathic Physicians, PAs, ARNPs, RNs, LPNs, Paramedics, EMTs, Dietitian/Nutritionists, Orthoptists, Prosthetists, Acupuncturists, Athletic Trainers, Physical Therapists, Massage Therapists, Midwives, School Psychologists, Orthotic Fitters and Mental Health Counselors. Not all of these professions are exempt from registration.
- The group of health care practitioners subject to emergency suspension orders for being convicted of, or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, certain felony and misdemeanor convictions related to Medicaid fraud and drug crimes in s. 456.074, F.S.
- The health care practitioner registry for disasters and emergencies in s. 456.38, F.S.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 468.931, 468.932, 468.933, 468.934, and 468.935.
This bill amends section 456.001, of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on April 3, 2017:
The committee substitute:

- Amends ch. 456, F.S., to add diabetes educator to definition of a health care practitioner.
- Requires the DOH to implement diabetes educator registration by July 1, 2018.
- Requires the hours of diabetes education for a person not certified to be 'practice' hours of diabetes education.
- Removes the exemptions from registration for persons:
  - Employed by, or acting under the supervision of, certain licensed health care practitioners; and
  - Registered outside Florida.
- Revises the fees.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/03/2017	.	
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The Committee on Health Policy (Gibson) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

456.001 Definitions.—As used in this chapter, the term:

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;

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chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, ~~or~~ part XIV, or part XVII of chapter 468; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 2. Part XVII of chapter 468, Florida Statutes, consisting of sections 468.931 through 468.935, Florida Statutes, is created to read:

PART XVII

DIABETES EDUCATORS

468.931 Legislative intent; implementation.—

(1) The Legislature finds that the provision of diabetes self-management training by unregistered and incompetent practitioners presents a danger to the public health and safety. Therefore, it is the intent of the Legislature to prohibit diabetes educators who fall below minimum competency standards or who otherwise present a danger to the public health and safety from providing diabetes self-management training in this state.

(2) The Department of Health must implement the provisions of this part by July 1, 2018.

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

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

(2) "Diabetes educator" means a health care practitioner registered under this part who has demonstrated a comprehensive knowledge of and experience in prediabetes, diabetes prevention, and diabetes education and who provides diabetes self-management training.

(3) "Diabetes self-management training" means the assessment and development of a plan of care for a person with

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diabetes through a collaborative process through which such person gains the knowledge and skills necessary to modify behavior and successfully self-manage the disease as provided for in the national standards published by the American Diabetes Association.

468.933 Requirements for registration; registration renewal.—

(1) The department shall issue a registration to an applicant who has submitted to the department:

(a) A completed application in a form prescribed by the department.

(b) A registration fee, pursuant to s. 468.934.

(c)1. Proof of certification as a Certified Diabetes Educator by the National Certification Board for Diabetes Educators or certification in Board Certified—Advanced Diabetes Management by the American Association of Diabetes Educators; or

2. Proof of completion of at least 250 practice hours of diabetes education, of which at least 100 practice hours are earned in the calendar year immediately preceding application, and proof of passing the registration examination administered by the National Certification Board for Diabetes Educators; and

a. Proof of licensure under chapter 456, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part III or part X of this chapter, chapter 483, part I of chapter 484, chapter 486, chapter 490, or s. 491.0145;

b. Proof of certification as a clinical exercise physiologist or Registered Clinical Exercise Physiologist by the American College of Sports Medicine; or

c. Proof of a master’s degree or higher in social work from

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an accredited United States college or university.

(2) The department shall renew a registration under this section upon receipt of a renewal application and biennial renewal fee from a registrant. The department shall adopt rules establishing a procedure for the biennial renewal of registrations under this section.

468.934 Fees.—The department shall establish, by rule, the following fees to be paid by a person seeking registration or registration renewal as a diabetes educator, which must be adequate to implement and administer this part:

(1) A nonrefundable application fee, which may not exceed $100.

(2) An initial registration fee, which may not exceed $100.

(3) A biennial renewal fee, which may not exceed $80.

(4) A fee for reactivation of an inactive registration, which may not exceed $135.

468.935 Prohibited acts; exemptions.—

(1) A person may not provide diabetes self-management training, or represent himself or herself as being a diabetes educator, unless he or she is registered pursuant to this part.

(2) This section does not prohibit or restrict:

(a) A person licensed under chapter 456, chapter 458, chapter 459, chapter 461, chapter 463, part I of chapter 464, chapter 465, chapter 466, part III or part X of this chapter, chapter 483, part I of chapter 484, chapter 486, or chapter 490 from engaging in the profession or occupation for which he or she is licensed.

(b) A person employed by the federal government or any bureau, division, or agency of the federal government from

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discharging his or her official duties.

(3) The department may take disciplinary action pursuant to s. 456.072 against an applicant or registrant and may deny, revoke, or suspend registration or registration renewal for a violation of this section.

(4) The department may adopt rules to implement and administer this section.

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

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to diabetes educators; amending s. 456.001, F.S.; redefining the term "health care practitioner" to include diabetes educators; creating part XVII of ch. 468, F.S., entitled "Diabetes Educators"; providing legislative findings and intent; requiring implementation by a specified date; providing definitions; providing requirements for registration as a diabetes educator; requiring the Department of Health to renew a registration under certain circumstances; requiring the department to adopt rules for biennial renewal of registrations; requiring the department to establish specified fees; prohibiting an unregistered person from certain activities relating to diabetes self-management training; providing exemptions; authorizing the

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department to take disciplinary action against an applicant or registrant for specified violations; authorizing rulemaking; providing an effective date.

By Senator Gibson

6-01191B-17 20171578__

A bill to be entitled

An act relating to diabetes educators; creating part XVII of ch. 468, F.S., entitled "Diabetes Educators"; providing legislative findings and intent; providing definitions; providing requirements for registration as a diabetes educator; requiring the Department of Health to renew a registration under certain circumstances; requiring a registrant to notify the department of specified changes; requiring the department to establish specified fees; requiring the department to adopt rules for biennial renewal of registration; prohibiting an unregistered person from certain activities relating to diabetes self-management training; providing exemptions; authorizing the department to take disciplinary action against an applicant or registrant for specified violations; authorizing rulemaking; providing an effective date.

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

Section 1. Part XVII of chapter 468, Florida Statutes, consisting of sections 468.931 through 468.935, Florida Statutes, is created to read:

PART XVII

DIABETES EDUCATORS

468.931 Legislative intent.—The Legislature finds that the provision of diabetes self-management training by unregistered and incompetent practitioners presents a danger to the public health and safety. Therefore, it is the intent of the

6-01191B-17 20171578__

Legislature to prohibit diabetes educators who fall below minimum competency standards or who otherwise present a danger to the public health and safety from providing diabetes self-management training in this state.

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

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

(2) "Diabetes educator" means a health care practitioner registered under this part who has demonstrated a comprehensive knowledge of and experience in prediabetes, diabetes prevention, and diabetes education and who provides diabetes self-management training.

(3) "Diabetes self-management training" means the assessment and development of a plan of care for a person with diabetes through a collaborative process through which such person gains the knowledge and skills necessary to modify behavior and successfully self-manage the disease as provided for in the national standards published by the American Diabetes Association.

468.933 Requirements for registration; registration renewal.—

(1) A person may not receive compensation for providing diabetes self-management training, or hold himself or herself out as a diabetes educator, unless he or she is registered in accordance with this part.

(2) The department shall issue a registration to an applicant who has submitted to the department:

(a) A completed application in a form prescribed by the department.

(b) A registration fee, pursuant to s. 468.934.

(c)1. Proof of certification as a Certified Diabetes Educator by the National Certification Board for Diabetes Educators or certification in Board Certified—Advanced Diabetes Management by the American Association of Diabetes Educators; or

2. Proof of completion of at least 250 hours of diabetes education, of which at least 100 hours are earned in the calendar year immediately preceding application, and proof of passing a registration examination administered by the National Certification Board for Diabetes Educators; and

a. Proof of licensure under chapter 456, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part III or part X of this chapter, chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491;

b. Proof of certification as a clinical exercise physiologist or Registered Clinical Exercise Physiologist by the American College of Sports Medicine; or

c. Proof of graduation with a master's degree or higher with a major course of study in social work from an institution of higher learning that is, or at the time the applicant was enrolled and graduated was, accredited by an accrediting agency recognized by the Council for Higher Education Accreditation or its successor or the United States Department of Education.

(3) The department shall renew a registration under this section upon receipt of a renewal application and biennial renewal fee from a registrant. The department shall adopt rules establishing a procedure for the biennial renewal of registrations under this section.

(4) A registrant shall notify the department, in a form prescribed by the department, within 10 days after a

registrant's change in address or certification status required pursuant to paragraph (2)(c).

468.934 Fees.—The department shall establish, by rule, the following fees to be paid by a person seeking registration or registration renewal as a diabetes educator, which must be adequate to implement and administer this part:

(1) A nonrefundable application fee, which may not exceed $100.

(2) An initial registration fee, which may not exceed $100.

(3) A biennial renewal fee, which may not exceed $50.

(4) A fee for reactivation of an inactive registration, which may not exceed $50.

(5) Additional fees for verification, recordmaking, and recordkeeping.

468.935 Prohibited acts; exemptions.—

(1) A person may not provide diabetes self-management training, or represent himself or herself as being a diabetes educator, unless he or she is registered pursuant to this part.

(2) This section does not prohibit or restrict:

(a) A person licensed under chapter 456, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part III or part X of this chapter, chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491 from engaging in the profession or occupation for which he or she is licensed.

(b) A person employed by and performing tasks or activities under the supervision of a person licensed under chapter 456, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part III or part X of this chapter,

chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491 from rendering services within the scope of the profession or occupation of the licensee.

(c) A person employed by the federal government or any bureau, division, or agency of the federal government from discharging his or her official duties.

(d) A person who is a diabetes educator registered in another state, district, or territory of the United States, or another country, if the department determines that the criteria for issuance of such registration are substantially equivalent to or more stringent than those of this state, from providing diabetes self-management training.

(3) The department may take disciplinary action pursuant to s. 456.072 against an applicant or registrant and may deny, revoke, or suspend registration or registration renewal for a violation of this section.

(4) The department may adopt rules to implement and administer this section.

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

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 Legislative Auditing Committee

March 16, 2017

Senator Dana Young, Chair
Committee on Health Policy
530 Knott Building
404 South Monroe Street
Tallahassee, Florida 32399-1100

Chair Young:

I respectfully request that SB 1578, relating to diabetes educators, be placed on the next committee agenda.

SB 1578, provides requirements for registration as a diabetes educator and prohibits an unregistered person from certain activities relating to diabetes self-management training. The bill also requires the department to adopt rules for biennial registration renewal.

Thank you for your time and consideration.

Sincerely,

Audrey Gibson
State Senator
District 6

REPLY TO:
❒ 101 E. Union Street, Suite 104, Jacksonville, Florida 32202 (904)359-2553 FAX: (904) 359-2532
❒ 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

APPEARANCE RECORD

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

4/3/17
Meeting Date

1578
Bill Number (if applicable)

Topic Diabetes Educaters

Amendment Barcode (if applicable)

Name Alisa LaPolf

Job Title Lobbyist

Address PO Box 1344
Street

TLH FL 32302
City *State* *Zip*

Phone 850-443-1319

Email alisa@gofopsail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida Nurses 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)

4/3/2017
Meeting Date

1578
Bill Number (if applicable)

Topic Diabetes Educators

Amendment Barcode (if applicable)

Name Melanie Bostick

Job Title Vice President

Address 113 E. College Ave.
Street

Tallahassee FL 32301
City *State* *Zip*

Phone (850) 841-1726

Email melanie@libertypartnersfl.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Association of Diabetes Educators

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Senate Committee on Health Policy **Judge:**

Started: 4/3/2017 4:07:33 PM
Ends: 4/3/2017 5:58:09 PM Length: 01:50:37

4:07:46 PM	Meeting Called to order
4:07:50 PM	Quorum present
4:08:24 PM	Pledge of Allegiance
4:08:39 PM	Tab 1 SB 406
4:09:31 PM	Sen Bradley explains
4:09:49 PM	Amend 941824
4:10:50 PM	Sen Bradley explains
4:11:14 PM	Chair calls for questions and debate
4:11:26 PM	Sen Bradley waives close on Amend
4:11:35 PM	Amend 941824 adopted
4:11:48 PM	Amend 758850
4:11:53 PM	Sen Bradley explains
4:12:17 PM	Questions on Amend
4:12:52 PM	Amend adopted
4:12:56 PM	Amend 601680
4:13:15 PM	Sen Bradley explains
4:13:31 PM	Sen Powell question
4:13:51 PM	Sen Bradley response
4:14:28 PM	Chair calls for debate
4:14:39 PM	Sen Bradley waives close
4:14:46 PM	Amend 601680 approved
4:15:09 PM	A 905618
4:15:16 PM	Sen Bradley explains
4:16:32 PM	Sen Benaquisto question
4:17:36 PM	Sen Bradley explains
4:18:34 PM	Sen Benaquisto question
4:18:46 PM	Sen Bradley response
4:18:53 PM	Sen Benaquisto
4:19:25 PM	Chair Young
4:19:32 PM	Sen Powell question
4:20:02 PM	Sen Bradley response
4:20:24 PM	Sen Powell follow up question
4:21:06 PM	Sen Bradley
4:22:05 PM	Sen Montford question
4:22:36 PM	Sen Bradley
4:22:41 PM	Sen Montford follow up
4:23:10 PM	Sen Bradley
4:25:30 PM	Sen Montford follow up
4:26:57 PM	Sen Bradley response
4:27:55 PM	BC 533696
4:28:37 PM	Chair Young explains
4:29:26 PM	Vice Chair calls for questions
4:29:39 PM	Sen Benaquisto question
4:29:51 PM	Chair Young response
4:29:56 PM	Sen Benaquisto follow up
4:30:03 PM	Chair Young response
4:30:23 PM	Sen Montford question
4:31:28 PM	Chair Young comments
4:31:48 PM	Sen Montford follow up
4:32:06 PM	Sen Powell question
4:32:26 PM	Chair Young response
4:33:27 PM	Louis Rotundo, CBSY Inc, speaking in in favor of the A 533696

4:34:43 PM Vice Chair calls for debate
4:34:58 PM Sen Bradley comments on the amendment
4:37:25 PM Vice Chair calls for debate
4:37:31 PM Sen Benaquisto comments
4:38:33 PM Chair Young closes on the amendment to the amendment
4:39:07 PM Chair Young withdraws the amendment
4:39:51 PM Vice Chair Passidomo questions on the amendment
4:40:14 PM Gary Stein, speaking in opposition to Amend 905618
4:42:59 PM David Custin, Eureka Vaporrs Inc, speaking in favor of the amendment
4:44:06 PM Bareny Bishop, Smart Justice Alliance, speaking in support of A 905618
4:45:36 PM Sen Powell debate on the Amendment
4:47:26 PM Sen Montford comments
4:48:17 PM Sen Bradley closes on the amendment
4:51:31 PM Amend 905618 adopted
4:51:42 PM Amend BC 393994
4:51:50 PM Sen Bradley explains
4:52:35 PM Vice Chair calls for questions
4:52:45 PM Sen Montford question
4:53:14 PM Sen Bradley response
4:53:42 PM A 393994 adopted
4:54:04 PM Amend 868112
4:54:11 PM Sen Bradley explains
4:54:37 PM John Hightower, self respresentative, speaking in favor
4:55:34 PM Sen Bradley comments
4:56:11 PM Amend 868112 adopted
4:56:33 PM Amend 633022
4:56:43 PM Sen Bradley explains
4:57:26 PM Barney Bishop, waives in support
4:57:40 PM Sen Bradley waive close
4:57:46 PM Amend 633022 adopted
4:57:54 PM Amend 248940
4:57:59 PM Sen Bradley explains
4:58:45 PM Barney Bishop waives in support
4:59:18 PM Jodi James, Florida CAN, speaking in support
5:00:15 PM Sen Bradley waives close
5:00:21 PM Amed 248940 adopted
5:00:28 PM Amend 882270
5:00:38 PM Sen Bradley explains
5:00:54 PM Question
5:01:04 PM Josephine Canella , Florida patients, speaking in support
5:02:04 PM Amen 882720 adopted
5:02:26 PM BC 415864
5:02:33 PM Sen Bradley explains
5:02:43 PM Sen Bradley waives close
5:02:51 PM Amend aodopted
5:03:00 PM BC 731400
5:03:06 PM Sen Bradley explains
5:03:17 PM Melissa Ramba, Florida Retail Federation, waives in support
5:03:33 PM David Daniel, waives in support
5:03:51 PM Sen Bradley waives close
5:04:50 PM Amend adopted
5:04:55 PM Amend 737584
5:05:05 PM Amend withdrawn
5:05:38 PM BC 185250
5:05:47 PM Sen Powell explains
5:06:20 PM Amend withdrawn
5:06:47 PM Questions on bill as amended
5:07:16 PM Sen Powell question
5:07:44 PM Sen Bradley
5:08:24 PM Sen Powell question
5:08:47 PM Sen Bradley response
5:09:27 PM Question withdrawn

5:09:37 PM Sen Benaquisto motion
5:09:59 PM Motion adopted to extend testimony to 5:25
5:10:20 PM Romain
5:10:32 PM lobbyist waives in support
5:10:41 PM marijuana
5:10:45 PM Newcome wis
5:10:52 PM John Hightower, speaks in support
5:11:35 PM Barney Bishop waives in support
5:11:46 PM Bill Cody, retired veteran, speaking in support
5:11:51 PM Melissa Lozono, speaking in support
5:11:56 PM Michael Patterson, speaking to inform
5:15:00 PM Dennis Deckerhoff, patients of Florida, speaking in opposition
5:16:28 PM Mark Ressler, speaking in opposition
5:17:00 PM Christopher Mack, waives in favor
5:17:34 PM Bianca Gentkene, waives in opposition
5:18:40 PM healther Preysz, speaking in opposition
5:19:56 PM Sen Powell debate
5:21:32 PM james Eaton support
5:21:42 PM Marc Moore agains
5:21:47 PM Christoprher Florda paitents in favor
5:21:56 PM Josephine in favor
5:22:15 PM Chair Young waives close
5:22:36 PM Roll Call by AA SB 406
5:22:45 PM SB 406 reported favorably
5:23:08 PM Tab 2 SB 732
5:23:33 PM Strike all 230990
5:23:38 PM Sen Steube explains
5:23:51 PM BC 678364
5:23:56 PM Sen Steube explains
5:24:08 PM Steven Wyinn wis
5:24:30 PM Jeff Scott wis
5:24:35 PM Sen Steube waives close
5:24:50 PM AA Roll Call
5:24:56 PM SB 732 reported favorably
5:25:13 PM SB 782
5:25:36 PM Sen Young explains the bill
5:26:00 PM Fely Curva, Society of Halth and P.E. educators, speaking in opposition
5:26:38 PM Sen Young waives close
5:26:51 PM Roll Call SB 782
5:27:03 PM SB 782 reported favorbly
5:27:17 PM CS/SB 800 Sen Broxson
5:27:41 PM Sen Broxson explains
5:28:43 PM Questions on the bill
5:28:53 PM Chris Nuland waives in support
5:29:06 PM Doreen Barker, AARP, waives in support
5:29:17 PM Melissa Ramba waives in support
5:29:25 PM Alpah one waives in support
5:29:31 PM Doug Bell waives in support
5:29:38 PM Jeff Scott waives in support
5:29:42 PM Amy Lion waives in support
5:29:46 PM Joy Ryan, speaking in support
5:30:22 PM Michael Jackson wis
5:30:27 PM Chris Hansen, Walgreens, waives in support
5:30:45 PM Roll Call AA
5:30:57 PM CS/SB 800 reportred favorably
5:31:16 PM Tab 8 SB 1446 Sen Rouson
5:31:33 PM Sen Rouson explains
5:32:46 PM Gabrielle Bargerstock, Nurse Family Partnership, waives in support
5:33:10 PM Sen Rouson waives close
5:33:19 PM Roll Call on SB 1446
5:33:39 PM Sb 1446 reported favorably
5:33:47 PM Tab 5 SB 840

5:33:58 PM	Sen Clemens explains
5:34:30 PM	Delete all amend 547330
5:34:49 PM	Sen Clemens waives close
5:34:58 PM	Jill Grand waives in support
5:35:09 PM	Roll call AA
5:35:16 PM	SB 840 reported favorably
5:35:41 PM	Tab 6 SB 1056
5:35:56 PM	Sen Garcia explains
5:36:13 PM	Sen Powell question
5:36:19 PM	Sen Garcia explains
5:37:27 PM	Sen Powell follow up
5:37:31 PM	Sen Garcia
5:38:11 PM	Bobby Lolley, Home Care Association of Florida, waives in support
5:38:30 PM	AA roll call
5:38:35 PM	SB 1056 reported favorably
5:38:44 PM	Tab 9 SB 1550
5:38:57 PM	Sen Artiles explains
5:40:42 PM	Delete all adopted
5:40:56 PM	Sen Artiles waives close
5:41:07 PM	AA roll call
5:41:10 PM	SB 1550 reported favorably
5:41:20 PM	Tab 10 SB 1578
5:41:51 PM	Sen Gibson explains
5:43:58 PM	Strike All amend adopted
5:44:15 PM	Bill as Amended
5:44:25 PM	Alisa Lapolt, Florida Nurses Association provides information
5:44:54 PM	Melanie Bostic, Diabetes Educator, waives in support
5:45:11 PM	Sen Gibson waives to close
5:45:19 PM	SB 1578 Roll Call by AA
5:45:28 PM	SB 1578 reported favorably
5:45:46 PM	Tab 7 SB 1354
5:46:06 PM	Sen Young explains
5:47:22 PM	Sen Young explains strike all amendments
5:47:51 PM	Sen Passidomo question
5:47:54 PM	Sen Young response
5:48:06 PM	BC 00284
5:49:05 PM	Sen Young explains
5:49:29 PM	Dr. Carolyn Guiess, speaking in opposition
5:50:49 PM	Sen Hudson motion
5:51:11 PM	Rebecca Johnson speaking in opposition
5:52:53 PM	thomas Grant waives in oppositon
5:53:08 PM	Chris Nucome waives in oppsiiton
5:53:18 PM	Jeff Scott waives in oppositon
5:53:48 PM	Doctor speaking in support
5:54:39 PM	Chris Stickle waives in support
5:55:00 PM	Sen Young waives close
5:55:10 PM	Jeff Scott waives in support
5:55:46 PM	Chris Nuland waives in support
5:55:51 PM	Steven Winn waives in support
5:55:58 PM	Rbecca Johnson waives in oppostion
5:56:11 PM	thomas Branteer waives in oppositon
5:56:21 PM	Caroly Guies waives in oppositon
5:56:32 PM	Sen Young closes on the bill
5:56:49 PM	CS/SB 1354
5:57:14 PM	CS/SB reported favorably
5:57:34 PM	Sen Passidomo favorably votes.
5:57:51 PM	Meeting adjourned