Tab 2	**SB 778** by **Baxley**; (Compare to CS/H 01123) Program of All-Inclusive Care for the Elderly					
712346	A	S	RCS	AHS, Baxley	Delete L.108 - 172:	04/04 02:54 PM
Tab 3	**CS/SB 434** by **HP, Harrell**; Ambulatory Surgical Centers					
246860	A	S		AHS, Harrell	Delete L.41:	04/03 02:59 PM
Tab 4	**SB 7078** by **HP**; (Compare to CS/H 00007) Health Care					
195108	A	S	RCS	AHS, Harrell	Delete L.119 - 407:	04/10 09:06 AM
~~169096~~	A	S	WD	AHS, Harrell	Delete L.308 - 316:	04/10 09:06 AM
310648	A	S	RCS	AHS, Harrell	Delete L.479:	04/10 09:06 AM
224512	A	S	RCS	AHS, Harrell	btw L.495 - 496:	04/10 09:06 AM
870336	A	S	RCS	AHS, Harrell	Delete L.583 - 609:	04/10 09:06 AM
Tab 5	**CS/SB 1528** by **HP, Bean (CO-INTRODUCERS) Gruters**; (Compare to CS/H 00019) Canadian Prescription Drug Importation Program					
872890	A	S	RCS	AHS, Bean	Delete L.116 - 281:	04/09 08:43 PM
104102	A	S	RCS	AHS, Bean	Delete L.321 - 339:	04/09 08:43 PM
Tab 6	**CS/SB 646** by **CF, Book (CO-INTRODUCERS) Rader**; (Similar to CS/H 00823) Child Welfare					
Tab 7	**CS/SB 732** by **HP, Flores**; (Similar to CS/H 00933) Clinics and Office Surgery					
359744	A	S	RS	AHS, Flores	Delete L.414 - 624:	04/09 06:30 PM
978476	SD	S	RCS	AHS, Flores	Delete everything after	04/09 06:31 PM
868332	AA	S	RCS	AHS, Flores	Delete L.166:	04/09 06:31 PM
Tab 8	**SB 1300** by **Benacquisto**; (Identical to H 06047) Florida ABLE Program					
Tab 9	**SB 1436** by **Gibson**; (Compare to H 01045) Closing the Gap Grant Proposals					
174138	A	S	RCS	AHS, Gibson	Delete L.26 - 32:	04/04 03:12 PM
Tab 10	**CS/SB 1460** by **HP, Book (CO-INTRODUCERS) Powell**; (Compare to CS/H 00993) Stroke Centers					
538518	A	S	RCS	AHS, Book	Delete L.43 - 49:	04/09 08:44 PM
835638	A	S	RCS	AHS, Book	Delete L.119:	04/09 08:44 PM

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

APPROPRIATIONS SUBCOMMITTEE ON HEALTH AND HUMAN SERVICES
Senator Bean, Chair
Senator Harrell, Vice Chair

MEETING DATE: Thursday, April 4, 2019
TIME: 12:30—2:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Harrell, Vice Chair; Senators Book, Diaz, Farmer, Flores, Hooper, Passidomo, Rader, and Rouson

TAB	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION
	Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointments to the offices indicated.		
	Secretary of Health Care Administration		
1	Mayhew, Mary C. (Tallahassee)	Pleasure of Governor	Recommend Confirm Yeas 6 Nays 3

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
2	**SB 778** Baxley (Compare CS/H 1123)	Program of All-Inclusive Care for the Elderly; Authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to approve entities applying to deliver Program of All-Inclusive Care for the Elderly (PACE) services in the state; requiring prospective PACE organizations that are granted initial state approval to submit a complete application to the agency and the Federal Government within a certain timeframe; exempting PACE organizations from specified provisions; specifying requirements for the agency in paying contractors providing services to eligible applicants, etc. HP 03/04/2019 Favorable AHS 03/13/2019 Temporarily Postponed AHS 04/04/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
3	**CS/SB 434** Health Policy / Harrell	Ambulatory Surgical Centers; Revising the definition of the term “ambulatory surgical center”; requiring the Agency for Health Care Administration, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules that establish requirements related to the delivery of surgical care to children in ambulatory surgical centers, in accordance with specified standards, etc. HP 02/19/2019 Fav/CS AHS 04/04/2019 Not Considered AP	Not Considered

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 7078** Health Policy (Compare CS/H 7, CS/CS/H 319, CS/H 559, CS/H 813, CS/H 843, CS/H 935, H 1035, CS/S 1520, S 1560, Linked CS/S 7080)	Health Care; Requiring a service provider to furnish and provide access to clinical records within a specified timeframe after receiving a request for such records; requiring a licensed facility to furnish and provide access to patient records within a specified timeframe after receiving a request for such records; requiring a nursing home facility to furnish and provide access to records within a specified timeframe after receiving a request; requiring a licensed hospital to provide specified information and data relating to patient safety and quality measures to a patient under certain circumstances or to any person upon request, etc. AHS 04/04/2019 Fav/CS AP	Fav/CS Yeas 5 Nays 4
5	**CS/SB 1528** Health Policy / Bean (Compare CS/H 19, S 1452)	Canadian Prescription Drug Importation Program; Requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program, etc. HP 03/25/2019 Fav/CS AHS 04/04/2019 Not Considered AP	Not Considered
6	**CS/SB 646** Children, Families, and Elder Affairs / Book (Similar CS/H 823)	Child Welfare; Specifying the rights of children and young adults in out-of-home care; requiring the Florida Children's Ombudsman to serve as an autonomous entity within the department for certain purposes; requiring that a case plan be developed in a face-to-face conference with a caregiver of a child under certain circumstances; requiring a caseworker to provide information about subsidies provided by early learning coalitions to caregivers of certain children; providing additional requirements for the licensure and operation of family foster homes, residential child-caring agencies, and child-placing agencies, etc. CF 03/04/2019 Fav/CS AHS 04/04/2019 Not Considered AP	Not Considered

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
7	**CS/SB 732** Health Policy / Flores (Similar CS/H 933)	Clinics and Office Surgery; Revising the definition of the term “clinic”; requiring a clinic to provide proof of its financial responsibility to pay certain claims and costs along with its application for licensure to the Agency for Health Care Administration; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility, etc. HP 03/11/2019 Fav/CS AHS 04/04/2019 Not Considered AP	Not Considered
8	**SB 1300** Benacquisto (Identical H 6047)	Florida ABLE Program; Repealing provisions relating to the scheduled reversion of provisions related to the distribution of funds in an ABLE account upon the death of a designated beneficiary, etc. CF 03/18/2019 Favorable AHS 04/04/2019 Favorable AP	Favorable Yeas 10 Nays 0
9	**SB 1436** Gibson (Compare H 1045)	Closing the Gap Grant Proposals; Removing provisions related to Front Porch Florida Communities; adding a priority area that may be addressed in a Closing the Gap grant proposal, etc. HP 03/25/2019 Favorable AHS 04/04/2019 Fav/CS AP	Fav/CS Yeas 10 Nays 0
10	**CS/SB 1460** Health Policy / Book (Compare CS/H 993)	Stroke Centers; Revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; revising provisions relating to the statewide stroke registry to conform to changes made by the act; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act, etc. HP 03/18/2019 Fav/CS AHS 04/04/2019 Not Considered AP	Not Considered
	Other Related Meeting Documents		

35

STATE OF FLORIDA
DEPARTMENT OF STATE
Division of Elections

I, Laurel M. Lee, Secretary of State,
do hereby certify that

Mary C. Mayhew

is duly appointed

Secretary,
Agency for Health Care Administration

for a term beginning on the Twenty-Second day of January, A.D., 2019, to serve at the pleasure of the Governor and is subject to be confirmed by the Senate during the next regular session of the Legislature.

Given under my hand and the Great Seal of the State of Florida, at Tallahassee, the Capital, this the Fifth day of March, A.D., 2019.

Secretary of State

DSDE 99 (3/03)

RON DESANTIS
GOVERNOR

January 13, 2019

Secretary Michael Ertel
Department of State
R.A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, FL 32399-0250

Dear Secretary Ertel:

Please be advised I have made the following appointment under the provisions of Section 20.42 Florida Statutes:

Ms. Mary Mayhew

as the Secretary of Health Care Administration, subject to confirmation by the Senate. This appointment is effective January 22, 2019, for a term ending at the pleasure of the Governor.

Sincerely,

Ron DeSantis
Governor

RD/mm

THE CAPITOL
TALLAHASSEE, FLORIDA 32399 • (850) 717-9249

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

2019 FEB 11 PM 12:07

STATE OF FLORIDA

County of LEON

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

SECRETARY of AGENCY for HEALTH CARE ADMINISTRATION

(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." *See* § 92.52, Fla. Stat.]

Mary C. Mayhew

Signature

Sworn to and subscribed before me this 8th *day of* February 2019.

Mary Gay Templeton

Signature of Officer Administering Oath or of Notary Public

Mary Gay Templeton

Print, Type, or Stamp Commissioned Name of Notary Public

MARY GAY TEMPLETON
Commission # FF 928124
Expires October 15, 2019
Bonded Thru Troy Fain Insurance 800-385-7019

Personally Known ☑ ***OR*** *Produced Identification* ☐

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: ☐ Home ☑ Office

2727 Mahan Drive, Mail Stop 1
Street or Post Office Box

Tallahassee, Florida 32308
City, State, Zip Code

Mary C. Mayhew
Print Name

Mary C. Mayhew
Signature

DS-DE 56 (Rev. 11/16)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

Mary C. Mayhew

Secretary of Health Care Administration

NOTICE OF HEARING

TO: Secretary Mary C. Mayhew

YOU ARE HEREBY NOTIFIED that the Appropriations Subcommittee on Health and Human Services of the Florida Senate will conduct a hearing on your executive appointment on Thursday, April 4, 2019, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 12:30 p.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 1st day of April, 2019

Appropriations Subcommittee on Health and Human Services

Senator Aaron Bean
As Chair and by authority of the committee

cc: Members, Appropriations Subcommittee on Health and Human Services
Office of the Sergeant at Arms

TABLE OF CONTENTS

Mr. Dennis Dean
9 Highpointe Circle
Kittery, ME 03904

March 28, 2019

The Honorable Bill Galvano
President
Florida Senate
305 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Senator Galvano,

I am writing regarding Mary Mayhew's nomination as Secretary of the Florida Agency for Heathcare Administration. I am the Dad of two adults with Intellectual Disabilities.

I first met Ms. Mayhew in a meeting at the Maine Governor's Office which she attended in her capacity as the Commissioner of the Department of Health and Human Services. My wife and I requested that meeting as we were concerned about the support services that were increasingly difficult to access and the long waiting list that existed for those services. I should add that Commissioner Mayhew "inherited" that list from a prior administration and was working with the Governor and the Legislature to clear it. They ultimately did clear all of the individuals classified as Priority One from the list –this was no small undertaking! It required strong budgetary skills, the ability to work with diverse groups, and demonstrated her concern for the safety and well-being of those she was charged to care for.

Because she shares our passion for helping our citizens that just need a little extra help, we remained in contact. She encouraged us to follow our vision of a new way to provide support services. She stood in the pouring rain with me and opened our County Special Olympics meet. When my son moved into his first apartment, she visited with him there to congratulate him, and I believe that she encouraged her senior staff to work with us as well, as her Director of Aging and Disability Services travelled to meet with us on multiple occasions during the establishment of our non-profit. At one of them he expressed that "I am here to be sure that everyone in my division is doing whatever they can to help you".

I am here to tell you as a parent, a long-time advocate for our citizens with disabilities, and a taxpayer that in my opinion, Mary Mayhew balanced her roles well in Maine – she managed the largest budget in the state while carefully considering the needs of our citizens with disabilities. I had hoped that she would be our Governor, but that was not to be. Thankfully, she has remained in human services and I have no doubt that when confirmed, she will lead in Florida as she did in Maine – with integrity and compassion. Please feel free to reach out to me at any time if I can provide more information.

Sincerely,

Dennis Dean
ddcrna@comcast.net
(207) 451-7469

Honorable Deborah J. Sanderson
64 Whittier Drive
Chelsea, ME 04330
(207) 376-7515
deb.sanderson2010@gmail.com

February 16, 2019

President Bill Galvano
Office of the Senate President
404 South Monroe St.
Suite 409 Capitol
Tallahassee, FL 32399

Dear President Galvano,

It is with great pleasure I submit this letter in strong support of Mary Mayhew to serve the state of Florida as Secretary of the Agency for Healthcare Administration.

In January 2011, Mary Mayhew was offered as a nominee by Governor LePage to lead Maine's Department of Health and Human Services. At that time, I served in the Maine Legislature on the Joint Standing Health and Human Services and Criminal Justice and Public Safety Committees. Sadly, serving on both of those committees provided a glaring backdrop to how services within our DHHS had failed a high number of Maine citizens suffering from mental illness and drug addiction who, with proper services in place, may have been able to receive critical care vs. entering the criminal justice system.

Faced with a department that continually ran over budget by hundreds of millions of dollars, a lack of prioritization of services to Maine's most vulnerable, and federal investigations into how previous administrations had inappropriately used federal Medicaid dollars, Mary Mayhew had her work cut out for her. Despite resistance from both the myriad of agencies that had been a strong voice for many of our ineffective programs and policies and Maine's media outlets, which were unceasingly negative toward the administration, Mary persevered throughout her tenure as Commissioner to shape Maine's DHHS into an agency that operated within its budget and finally began prioritizing services.

As our new commissioner, Mary immediately began reaching out to staff across the state; she gathered input and information. She directed her staff to tear down the outdated service delivery system within the DHHS that worked in silos and, instead, implemented an information sharing process that connected different offices for a more efficient delivery of service. She developed our "Health Home" model; focusing first on the individuals who had high ER use, often diagnosed with co-occurring mental health/substance use disorders. By transitioning these individuals into a Health Home service delivery model, wrapping primary care providers in with others to address co-occurring needs, we immediately began seeing a reduction of costs coupled with better health outcomes.

Working with Maine's governor, Paul LePage, Mary partnered with the Department of Education and the Department of Labor. Together, they developed a three-pronged system of assessment to determine work-readiness of welfare support recipients. Collaboration between the three independent state departments, directly focusing on a "welfare to work" model, provided a warm handoff for people that previously had not been available. Despite vigorous opposition, Mary confidently moved forward to co-locate the DHHS office into the same building as the Department of Labor in the greater Portland area; the path to employment became just a short walk down the hall. Federal work requirements were enforced for SNAP recipients. Her partnership with the Maine Revenue Services showed a 114 percent increase in personal income with the vast majority of people who transitioned off supplemental benefits and went to work. Mary strongly believes that a person's sense of self-worth and value is bolstered by independence and self-sufficiency. Maine's shrinking welfare rolls and rising income numbers support that belief.

These are just a few examples of the positive changes implemented by Mary Mayhew as our DHHS Commissioner. I would be remiss if I didn't mention that she also discovered: hundreds of contracts with independent nonprofit service agencies being automatically renewed without an RFP process and no measures of accountability, thousands of elderly and disabled people languishing on waiver wait-lists not receiving critical support, and fraudulent Medicaid billing practices…the list goes on.

Mary became very unpopular with those who wanted to maintain the status quo but, with grace, dignity and determination, she continued her quest to realign our Medicaid programs to serve those for whom it was originally intended, and for the first time in many years, Maine's DHHS ceased reeling from one budget crisis to another.

For seven years, I worked closely with Mary Mayhew and her staff. Her vision for reform was indeed aggressive, some would say impossible. However, with stalwart determination, a vision of prosperity for all Maine citizens and a strong belief in the human spirit, she made an enormous contribution to the State of Maine. I have every confidence she will serve the State of Florida just as well and without reservation, offer my unwavering support and endorsement for Mary Mayhew for the position of Secretary of the Agency for Healthcare Administration.

Sincerely,

Hon. Deborah J. Sanderson

February 15, 2019

President Bill Galvano
Office of the Senate President
404 South Monroe St.
Suite 409 Capitol
Tallahassee, FL 32399

Dear President Galvano,

This letter is submitted in strong support of Mary Mayhew for the position of Secretary of the Agency for Health Care Administration.

Beginning in 2011, Mary Mayhew served as Maine's Commissioner for the Department of Health and Human Services. At the time, I served in the Maine legislature as a state representative on the Joint Standing Committees on Health and Human Services and Appropriations and Financial Affairs. In my legislative capacity on these two committees, I observed first-hand Ms. Mayhew's leadership, expertise and calm resolve. Able to rise above the negative, ceaseless media attention, Mary was vital to Maine's successful transition from staggering debt and ongoing financial crises to balanced books, while simultaneously guiding out-of- work Mainers back to the work force.

As commissioner, Mary Mayhew inherited a department that was drowning in red ink. She tackled decades of mismanagement and misguided priorities. Mary discovered thousands of disabled people lingering on wait lists, while childless, able bodied individuals went to the front of the line. Under her stewardship, priorities were reset. The highest priority wait lists were eliminated and people in need finally received vital services. Many Mainers owe her a debt of gratitude.

Working together with Gov. Paul LePage, $750 million in long overdue hospital Medicaid debt was paid; this is an exorbitant amount of money for a poor, rural state. Concurrently, Mary concentrated on human services that helped people enter and re-enter the work force; she deserves credit for her under-recognized role in Maine's impressive economic recovery.

As a person, Mary as is always polite, cool under pressure, hard-working, honest, kind and smart; she is also a visionary. As a team player, Governor DeSantis and his administration will be well -served by Mary Mayhew, a true public servant. I wholeheartedly and unreservedly endorse her nomination.

Sincerely,

Heather Sirocki
32 Glenndale Circle
Scarborough, Maine 04074
207-730-6602

First Atlantic HealthCare

The Honorable Bill Galvano, President
Florida Senate
409, The Capitol
404 South Monroe Street
Tallahassee, FL 332399-1100

February 28, 2019

Re: Mayhew Recommendation Letter

Dear Senator Galvano:

The nomination of Mary Mayhew for Florida's Agency for Health Care Administration has my wholehearted endorsement. I've known Mary for at least 15 years including her time with Maine's Hospital Association as well as Maine's DHHS Commissioner.

A long list of attributes could be offered describing Mary: smart, tireless, strong communicator, secure in bearing yet approachable, Federal Medicaid regulation expert – the list could go on and on.

For seven plus years my occupation brought me into contact with Mary on many occasions. In addition, I spoke regularly with people who worked for Mary. After her role as Commissioner of DHHS and as I considered helping her pursue her career interests further, I asked a few questions of those I knew, knew her best. From memory, here is what I recall a small number of those individuals saying of her.

"Mary is always prepared for meetings and expects us to be also." "Mary never shied away from difficult issues, she never made one of us the fall guy". "I favor opposite politics usually, but I'd work for her again – I came to realize her priorities were good for our state, good for our clients and despite a few early on differences politically, we all came to admire and be inspired by her leadership."

She was a central figure in the LePage administration and unequivocally the best commissioner of his cabinet. Early on, she solved several, inherited "back-office" issues plaguing providers and clients. She applied CDC data to inform policy when an Ebola exposed nurse returned to Maine. She balanced the department's books year after year. Her advice pivotal as our Governor pursed his policy objectives.

She has demonstrated her ability to lead complex organizations, set priorities and knows the important roles of responsibility, authority and accountability that when mixed with strong, determined leadership coalesce into high performance results.

The great state of Florida will be well served by Ms. Mayhew's leadership, we only request that you see her as on loan.

Sincerely,

Kenneth W. Bowden, CEO
First Atlantic HealthCare

100 Waterman Drive • Suite 401 • South Portland, Maine 04106 • *phone:* (207) 874-2700 *fax:* (207) 874-2706

Hon. Paul B. Chace, R.Ph
Past Maine State Representative, House#46
31 Colonial Dr.
Durham, ME. 04222
February 15, 2019

Senator Galvano
President
Florida Senate
409, The Capitol
404 South Monroe St.
Tallahassee, FL 332399-1100

Re: Confirmation for Mary Mayhew, Secretary of the Florida Agency for Health Care Administration

Dear Senator Galvano:

My name is Paul Chace, and I am a recent past 2 term legislator in the Maine House of Representatives. I served on the Health and Human Services committee as well as deeply involved with other health care related bills for the citizens of Maine. I have also been a licensed pharmacist for nearly 30 years as of next year.

I feel strongly compelled to offer my support to former Maine DHHS Commissioner Mary Mayhew for her nomination as Secretary of the Florida Agency for Health Care Administration. Suffice to say, in my 30 years in Maine healthcare and familiarity with our Medicaid Program, there has NEVER been a commissioner as qualified and successful in that position. She closed a nearly billion dollar deficit. Maine owed the hospitals in the state nearly 750 million dollars. She ended yearly supplemental budget necessity. She reformed MaineCare (Medicaid), essentially getting 65,000 Maine residents good jobs and off of social programs. All of this was successful without shorting other programs of necessity. We made tremendous gains on helping curb the opiate problem in Maine, and results from her past administration is showing lower opioid deaths in Maine for the first year in probably 5 or 10 years. Wait lists for children and adults with mental health and cognitive issues were addressed and significantly reduced. Her focus on seniors and moving for helping our seniors to "age in place" was well positioned. I am sure you have a resume of her successes, and not one line item of it is a superficial entry.

I witnessed her professionalism, articulation of programs with the utmost care for the success and care of the residents of our state. As a member of the HHS committee in Maine, I saw her perform on everything from the largest state budget item, down to the most important human

resource functions and assessment and care of Maine citizens. I believe she was outstanding on every aspect and again in my career, I cannot find any comparison in any past commissioner in Maine. I regret that she is not still currently our commissioner, and even better yet, our governor. Our loss is certain to be your gain.

My sincere appreciation for your service, and thank you for taking time to review this letter, I have absolute admiration and respect for your time.

Sincerely,

Hon. Paul B. Chace, R.Ph
Former Maine Legislator
pchace@pbcrx.com
207-240-9300

MHCA

Maine Health Care Association

February 26, 2019

The Honorable Bill Galvano, President
Florida Senate
409, The Capitol
404 South Monroe Street
Tallahassee, FL 332399-1100

Dear President Galvano:

It is with pleasure that I share with you my experience working with Mary Mayhew, who I first met in 2001, when she was with the Maine Hospital Association. I admired her for her knowledge of health policy issues then and learned much from her in my first few years with the Maine Health Care Association. I would add that she was deeply respected by state officials during this time.

It was during her tenure as Commissioner of the Maine Department of Health and Human Services that I saw firsthand her leadership skills, as she oversaw a department of well over 3,000 employees. When she began these duties, the Department had been running at a deficit for several years. We had come to expect that our state legislature would be facing a Medicaid shortfall every year when they returned to Augusta.

Mary had inherited quite a financial mess. I remember her telling me that the amount of money that was transferred between programs, and the way that these were carried out, made it nearly impossible to track previous years' spending. This did not surprise me, as we had seen some of this within the state's nursing home and assisted living line items. Mary and her staff worked tirelessly to get to the bottom of this. The result was a transparent budget that was balanced year in and year out. There were no gimmicks required. Even advocates who didn't generally agree with Mary's policies and priorities grew to appreciate the job she did, and there was relief that we were no longer starting each legislative session in a one hundred million dollar hole.

Mary worked long hours to accomplish this. Whether I drove past her office in the early morning or late evening, her car would invariably be there. But she also motivated and inspired her team to do more. I spent a great deal of time with her key staff members and it was obvious that they admired her work ethic and held her in high esteem.

317 State Street
Augusta, Maine 04330

As an advocate for Maine's elder services, I saw that she cared deeply about providing the best possible services for this population. She made difficult budget decisions and established priorities, which of course, didn't always earn her plaudits. She handled it well though, and came to meetings fully prepared with the facts. I don't think I ever saw her get caught flat footed in that setting.

Mary left Maine's Department of Health and Human Services in much stronger shape than she found it, largely because she made decisions that had been avoided by others. She proved herself to be a talented administrator and a strong leader. I wish her the best in this new role.

Yours truly,

Richard A. Erb
President and Chief Executive Officer

317 State Street
Augusta, Maine 04330

Florida Health Care Association

February 15, 2019

The Honorable Bill Galvano
President
Florida Senate
305 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

RE: Endorsement of Mary Mayhew's confirmation as Secretary of the Agency for Health Care Administration

Dear President Galvano,

The Florida Health Care Association (FHCA) fully endorses Mary Mayhew to be confirmed as the Secretary of the Agency for Health Care Administration (AHCA). FHCA is Florida's leading long term care organization, representing over 82% of our state's nursing centers and the caregivers they employ who deliver exceptional care and services to our state's seniors.

As you know, FHCA has a close working relationship with AHCA. The individual serving in the role of Secretary is of great importance to our members. The ability to deliver high-quality care to residents is greatly enhanced by a strong working relationship and open lines of communication between AHCA and FHCA.

FHCA's members and staff have met with Secretary Mayhew multiple times since she assumed the leadership role at AHCA, including a meeting on her second day in this new position. She has taken time to learn more about our quality initiatives and goals to improve residents' health outcomes and our process for emergency preparedness and keeping residents safe. She has been willing to listen to our concerns and has been very straightforward about what she envisions and expects of nursing homes and regulators in Florida to ensure residents receive the best possible care. Her perspective on policy development is driven by incentivizing and measuring methods for providers to deliver exceptional care. She wants our long term care centers to continue being leaders in quality among the 50 states. We agree.

Her depth of knowledge about how FHCA members function and fit in the overall picture of health care for Floridians gives us the confidence that she is the right person for the job.

Please accept this endorsement, and feel free to contact me if you have any further questions.

Sincerely,

J. Emmett Reed

Emmett Reed, CAE
Executive Director

T: (850) 224-3907
F: (850) 681-2075
www.fhca.org

Street Address:
307 West Park Avenue
Tallahassee, FL 32301

Mail To:
P.O. Box 1459
Tallahassee, FL 32302

LeadingAge® Florida

February 26, 2019

The Honorable Bill Galvano
President
Florida Senate
305 Senate Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Senator Galvano:

On behalf of LeadingAge Florida and the more than 500 senior living facilities we represent, I am pleased to offer our support for the confirmation of Mary Mayhew as Secretary of the Agency for Health Care Administration.

In the short time that we have had the opportunity to work with Ms. Mayhew, she has been accessible to us and our members, meeting with me and my staff within her first two weeks in Florida, and already having traveled to visit our members' senior living communities seeking a deeper understanding of their challenges and opportunities. Moreover, I am encouraged by her willingness to discuss with us the critical issues that face Florida senior living providers, including reimbursement, certification, staffing, and disaster preparedness, to name only a few.

I am grateful for the opportunity to offer LeadingAge Florida's support of Ms. Mayhew in this process, and we look forward to her successful confirmation.

Sincerely,

Steve Bahmer
President & CEO

cc: Senator Dennis Baxley

1812 Riggins Road | Tallahassee, Florida 32308
P 850.671.3700 | F 850.671.3790 | www.LeadingAgeFlorida.org

SNHAF Safety Net Hospital Alliance of Florida

February 25, 2019

The Honorable Bill Galvano
President, Florida Senate
305 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399

Dear Senate President Galvano:

The Safety Net Hospital Alliance of Florida writes to offer our support for the nomination of Mary Mayhew as Secretary of the Agency for Health Care Administration (AHCA). Secretary Mayhew has a distinguished career in both the public and private sectors and has a deep understanding of Medicaid and healthcare policy, having served as the head of a state health and human services agency and, most recently, as the head of the federal Center for Medicaid and CHIP Services.

Our organization strongly shares Secretary Mayhew's commitment to Florida's health care safety net, a commitment she has already expressed in appearances before legislative committees. Our organization represents 14 non-profit hospital systems throughout the state and includes public hospitals, teaching hospitals, children's hospitals, and Regional Perinatal Intensive Care Centers. Together, these systems treat a disproportionate share of low income patients in Florida, particularly Medicaid patients and the uninsured, regardless of low (or even no) reimbursement. Moreover, our hospitals see the majority of Florida's most critically ill patients — in fact, the more critical the patient, the more likely the patient is to be seen by one of our member hospitals.

There are 27 hospitals (out of a total of roughly 250 hospitals in the state) that receive Critical Care Funding via the Florida Medicaid program's budget, with our members being the most prominent among them. Together, these hospitals provide care for 72% of Medicaid's most critical newborn patients, 73% of the most critical Medicaid pediatric patients, and 33% of the most critical adult Medicaid patients. These hospitals also perform 82% of Medicaid's pediatric transplants and 45% of its adult transplants, all while training 48% of Florida's future doctors. We applaud the continuance of this vital funding in Governor DeSantis's "Bold Vision for a Brighter Future" 2019-2020 budget and we look forward to working with Secretary Mayhew to maintain Florida's commitment to serving our state's most vulnerable residents.

Our member hospitals also provide the highest quality of care in the state. Indeed, we are proud to represent 14 member systems that have 10 hospitals on the recent US News and World Report's "30 Best Hospitals in Florida" list, which means that all Floridians have access to world class care regardless of their ability to pay. We look forward to working with Secretary Mayhew to improve access through innovation and transparency so that

Florida's most affordable and accessible hospitals continue to provide the highest quality of care available in the state.

As Secretary Mayhew knows, the state of Florida is adding over 800 people a day. This rapid growth means our healthcare system – and especially our hospitals – must be able to meet the growing demands of patients while still providing the highest quality care at the most affordable price. We look forward to working with her and Governor DeSantis to ensure that Florida maintains and builds upon its successful healthcare investments, particularly in supporting Florida's safety net providers.

Like Secretary Mayhew and Governor Ron DeSantis, we are constantly focused on providing high-quality health care to all – regardless of a patient's ability to pay or to afford private insurance. Every life matters and every Floridian deserves access to the highest level of care at the most affordable price. It is because of the Secretary's shared focus on this mission that we are pleased to support Mary Mayhew's nomination and are hopeful she will be quickly confirmed.

Sincerely,

Justin M. Senior
Chief Executive Officer

cc: The Honorable Ron DeSantis, Governor, State of Florida
Mary Mayhew, Secretary, Agency for Health Care Administration

February 15, 2019

The Honorable Bill Galvano
President
Florida Senate
305 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear President Galvano,

On behalf of the Florida Hospital Association's 220 member hospitals and health systems, I am writing to express our strong support for Mary Mayhew to be confirmed as Secretary of the Agency for Health Care Administration (AHCA). We believe Ms. Mayhew has the skills, expertise and commitment to care for Florida's most vulnerable citizens.

In the short time that she has been on the job, Ms. Mayhew has made a point of meeting with stakeholders including the FHA. During those meetings, she has listened well and conveyed clearly her priorities for improving quality and access to services for people who are insured through Florida's Medicaid program. Her interest in increasing access to mental health and substance abuse services demonstrates her understanding of Florida's health care challenges.

We were particularly encouraged by the insight and expertise Ms. Mayhew brings to her position. She is knowledgeable regarding payment methodologies, managed care practices and challenges facing other states around the country. Those insights will greatly enhance her ability to improve the accountability, efficiency and effectiveness of Florida's Medicaid program.

We look forward to working closely with Ms. Mayhew and her team at AHCA to achieve our shared goals of improving access and quality of care provided to Florida's citizens covered through the Medicaid program. We are pleased to endorse Ms. Mayhew's confirmation. Contact me at any time if you have questions or require additional information.

Sincerely,

Bruce Rueben
President

ASSOCIATED INDUSTRIES OF FLORIDA
The Voice of Florida Business Since 1920

February 28, 2019

The Honorable Bill Galvano
President
Florida Senate
305 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

RE: Endorsement of Mary Mayhew's Confirmation as Secretary of the Agency for Health Care Administration

Dear President Galvano,

On behalf of the Associated Industries of Florida (AIF), a state trade association representing a broad spectrum of industries, we are writing to express our full endorsement of Mary Mayhew for confirmation as Secretary of the Agency for Health Care Administration (AHCA).

We believe that her deep-rooted knowledge of the health care industry will be beneficial in helping bring down health care costs on Florida's employers. As you know, out-of-control health care costs are a huge issue for businesses here and controlling these costs will help our current businesses flourish, while also attracting new companies to our state.

AIF's members have had the opportunity to listen to Ms. Mayhew and were impressed with her knowledge of the issues they face and are confident that she is the right person to lead this very important agency. We look forward to her swift confirmation through the Florida Senate.

Please accept this endorsement and feel free to contact me if you have any further questions.

Sincerely,

Thomas C. Feeney
President & CEO

516 North Adams Street • Post Office Box 784 • Tallahassee, Florida 32302-0784 • Phone: (850) 224-7173 • Fax: (850) 224-6532 • Email: aif@aif.com • www.aif.com

The Florida Senate

COMMITTEE RECOMMENDATION ON EXECUTIVE APPOINTMENT

COMMITTEE: Appropriations Subcommittee on Health and Human Services
MEETING DATE: Thursday, April 4, 2019
TIME: 12:30—2:00 p.m.
PLACE: Pat Thomas Committee Room, 412 Knott Building

TO: The Honorable Bill Galvano, President

FROM: Appropriations Subcommittee on Health and Human Services

The committee was referred the following executive appointment subject to confirmation by the Senate:

Office: Secretary of Health Care Administration

Appointee: Mayhew, Mary C.

Term: 1/22/2019-Pleasure of Governor

After inquiry and due consideration, the committee recommends that the Senate **confirm** the aforesaid executive appointment made by the Governor.

THE FLORIDA SENATE

APPEARANCE RECORD

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

April 4 2019
Meeting Date

Bill Number (if applicable)

Topic Mayhew Confirmation

Amendment Barcode (if applicable)

Name Bruce Rueben

Job Title President - Florida Hospital Association

Address _____ Phone 222-9800
Street

_____ Email _____
City *State* *Zip*

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

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)

4/4/19
Meeting Date

Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Confirmation Secretary Mayhew

Name Tom Parker

Job Title Director of Reimbursement

Address 307 W Park Ave
Street

Phone 850-224-3907

Tallahassee FL 32309
City *State* *Zip*

Email tparker@fHCA.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Health Care Administration

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)

4/4/19
Meeting Date

Bill Number (if applicable)

Topic Sec. Mahon Confirmation

Amendment Barcode (if applicable)

Name Barbara Palmer

Job Title Director, Agency for Persons with Disabilities

Address 4030 Esplanade Way
Street

Tall FL 32399
City *State* *Zip*

Phone 850-488-1558

Email barbara.palmer@apdcares.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing APD

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)

4/4/19
Meeting Date

Bill Number (if applicable)

Topic CONFIRMATION

Amendment Barcode (if applicable)

Name Mary Mayhew

Job Title Secretary

Address 2727 MAHAN DR. Phone 412-3660
Street

TALLAHASSEE FL 32308 Email mary.mayhew@ahca.myflorida.com
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Agency For Health Care Administration

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)

4/4/19
Meeting Date

Bill Number (if applicable)

Topic Question for Ms. Mayhew

Amendment Barcode (if applicable)

Name Greg Pound

Job Title

Address 9166 Sonrise
Street

Phone

Email

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/4/19
Meeting Date

Confirmation
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Confirmation AHCA Secretary

Name Karen Woodall

Job Title Exec. Director

Address 579 E. Call St.
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850-321-9386

Email fcfep@yahoo.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Center for Fiscal & Economic Policy

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)

4/14
Meeting Date

Bill Number (if applicable)

Topic Confirmation AHCA Secretary

Amendment Barcode (if applicable)

Name Justin Senior

Job Title CEO

Address 101 W. Gadsden
Street

Phone

Tallahassee FL
City *State* *Zip*

Email

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

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

Representing SNHAF

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)

4.4.19
Meeting Date

Bill Number (if applicable)

Topic Mary Mayhew AHCA Secretary

Amendment Barcode (if applicable)

Name Peter Lohrengel

Job Title Executive Director

Address 1400 Village Sq Blvd 3-175 Phone 850 222 3000
Street

Tallahassee FL 32312 Email peter@fascmember.org
City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Society of Ambulatory Surgical Centers

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	PCS/SB 778 (559118)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services and Senator Baxley
SUBJECT:	Program of All-Inclusive Care for the Elderly
DATE:	April 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Favorable**
2.	McKnight	Kidd	AHS	**Recommend: Fav/CS**
3.			AP	

I. Summary:

PCS/SB 778 codifies the Program of All-Inclusive Care for the Elderly (PACE) in s. 430.84, F.S. First authorized in 1998, the PACE became operational in Miami-Dade County in 2003, but has not yet been codified in state law. With almost 2,000 Medicaid managed care eligible recipients already enrolled in seven counties, the bill establishes a statutory process for the review, approval, and oversight of future and current PACE organizations, including:

- Requiring PACE organizations to enroll participants at levels funded by the General Appropriations Act (GAA);
- Requiring each PACE organization to annually submit information to the Agency for Health Care Administration (AHCA) that reflect its reasonable capacity for growth to meet demonstrated community needs;
- Requiring the AHCA to include in its annual legislative budget request the amount of funding estimated by the Social Services Estimating Conference;
- Providing notification requirements for PACE organization applications;
- Requiring the AHCA to provide monitoring and oversight of PACE organizations; and
- Providing other eligibility guidelines and requirements for Medicaid recipients enrolled in PACE organizations.

The bill exempts all PACE organizations from the requirements of chapter 641, which regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

The bill has no fiscal impact on state revenues or expenditures.

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

II. Present Situation:

Program of All-Inclusive Care for the Elderly

The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit model authorized by the federal Balanced Budget Act of 1997 (BBA)[1] that features a comprehensive service delivery system and integrated federal Medicare and state Medicaid financing. The model, which was tested through the federal Centers for Medicare and Medicaid Services (CMS) demonstration projects beginning in the mid-1980s,[2] was developed to address the needs of long-term care clients, providers, and payers. The PACE operates as a three-way agreement between the federal government, the state administering agency, and a PACE organization. In Florida, the PACE is a Florida Medicaid long-term care managed care plan option providing comprehensive long-term and acute care services which support Medicaid and Medicare enrollees who would otherwise qualify for Medicaid nursing facility services.[3]

The PACE is a unique federal/state partnership. The BBA established the PACE model of care as a permanent entity within the Medicare program and enabled states to provide PACE services to Medicaid beneficiaries as an optional state plan service without a Medicaid waiver.

The federal government established the PACE organization requirements and application process, however, the state is responsible for oversight of the application process, which includes reviewing the initial application and providing an on-site readiness review before a PACE organization can be authorized to serve patients. An approved PACE organization must sign a contract with the CMS and the state Medicaid agency.

The PACE is administered by the Department of Elder Affairs (DOEA) in consultation with the Agency for Health Care Administration (AHCA). The DOEA oversees the contracted PACE organizations, but is not a party to the contract between the CMS, the AHCA, and the PACE organizations.[4] The DOEA, the AHCA, and the CMS must approve any applications for new PACE organizations if expansion is authorized by the Legislature through the necessary appropriation of the state matching funds.

A PACE organization must be part of either a city, county, state, or tribal government; a private not-for-profit 501(c)(3) organization; or for-profit entity that is primarily engaged in providing PACE services and must also:

- Have a governing board that includes participant representation;
- Be able to provide the complete service package regardless of frequency or duration of services;

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[1] Specifically, services under the PACE program are authorized under Section 1905(a)(26) of the Social Security Act.
[2] United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, *CMS Manual System: Pub. 100-11 Programs of All-Inclusive Care for the Elderly (PACE) Manual* (issued June 9, 2011), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pace111c01.pdf (last visited March 5, 2019).
[3] Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), p. 3, *available at* http://ahca.myflorida.com/docs/PACE_Evaluation_2014.pdf (last visited March 5, 2019).
[4] *Id.*

- Have a physical site to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
- Have a defined service area;
- Have safeguards against conflicts of interest;
- Have a demonstrated fiscal soundness;
- Have a formal participant bill of rights; and
- Have a process to address grievances and appeals.[5]

Eligibility and Benefits

PACE participants must be at least 55 years of age, live in the PACE center service area, meet eligibility requirements for nursing home care, pursuant to a Comprehensive Assessment and Review for Long-Term Care Services (CARES) pre-admission screening, and be able to live safely in the community. The PACE becomes the sole source of services for these Medicare and Medicaid eligible enrollees. Additionally, by electing to enroll in the PACE, the participant agrees to forgo other options for medical services and receive all of their services through the PACE organization.[6]

Under the PACE, an interdisciplinary team consisting of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all services, including acute care and nursing facility services when necessary, which are integrated to provide a seamless delivery model. In most cases, a PACE organization provides social and medical services in a health center with supplemental services through in-home and referral services as necessary. The PACE service package must include all Medicare and Medicaid covered services and other services determined necessary by the multidisciplinary team for the care of the PACE participant.[7]

Before being approved to operate and deliver services, PACE organizations are required to provide evidence of the necessary financial capital to deliver the benefits and services, which include a combined adult day care center and primary care clinic, transportation, and full range of clinical and support staff with the interdisciplinary team of professionals.[8]

By federal law, the first three contract years for a PACE organization are considered a trial period, and the PACE organization is subject to annual reviews to ensure compliance.[9] The site visit reviews include:

- A comprehensive assessment of an organization's fiscal soundness;
- A comprehensive assessment of the organization's capacity to provide all PACE services to all enrolled participants;
- A detailed analysis of the PACE organization's substantial compliance with all the federal statutory requirements and accompanying federal regulations; and

[5] *Supra* note 2.
[6] *Id.*
[7] *Id.*
[8] *Supra* note 3, at 4.
[9] *See* 42 U.S.C. s. 1395eee(e)(4)(A)(2019).

- Compliance with any other elements the Secretary of the United States Department of Health and Human Services (secretary) or the state's administering agency considers necessary and appropriate.[10]

Review of the PACE organization may continue after the trial period by the secretary or the administering state agency as appropriate, depending upon the PACE organization's performance and compliance with requirements and regulations.

No deductibles, copayments, coinsurance, or other cost-sharing can be charged by a PACE organization. No other limits relating to amount, duration, or scope of services that might otherwise apply in Medicaid are permitted.[11] The PACE enrollee must accept the PACE center physician as his or her new Medicare primary care physician, if enrolled in Medicare.[12]

Quality of Care Requirements

Each PACE organization is required to develop, implement, maintain, and evaluate an effective data-driven Quality Assurance and Performance Improvement (QAPI) program. The program must incorporate all aspects of the PACE organization's operations, which allows for the identification of areas that need performance improvement. The organization's written QAPI plan must be reviewed by the PACE organization's governing body at least annually. At a minimum, the plan should address the following areas:

- Utilization of services in the PACE organization, especially in key services;
- Participant and caregiver satisfaction with services;
- Data collected during patient assessments to determine if individual and organizational-level outcomes were achieved within a specified time period;
- Effectiveness and safety of direct and contracted services delivered to participants; and
- Outcomes in the organization's non-clinical areas.[13]

Florida PACE

The Florida PACE project was initially authorized in ch. 98-327, Laws of Florida, under the administration of the DOEA operating in consultation with the AHCA.[14] Florida's first PACE organization, located in Miami-Dade County, began serving enrollees in February 2003 with a total of 150 slots. Since then, the Legislature has approved additional slots either as part of the General Appropriations Act (GAA) or general law. Currently, PACE organizations with funded slots exist in 13 Florida counties: Baker, Broward, Charlotte, Clay, Collier, Duval, Lee, Martin, Miami-Dade, Nassau, Palm Beach, Pinellas, and St. John's.

In 2011, the Legislature moved administrative responsibility for the PACE program from the DOEA to the AHCA as part of the expansion of Medicaid managed care into the Statewide

[10] *Id.*
[11] *Supra* note 2.
[12] Department of Elder Affairs and Agency for Health Care Administration, *Program of All-Inclusive Care for the Elderly and Statewide Medicaid Managed Care Long-term Care Program Comparison Report* (January 14, 2014), *available at* http://ahca.myflorida.com/docs/PACE_Evaluation_2014.pdf (last visited March 5, 2019).
[13] *Id.*
[14] Chapter 2011-135, s. 24, L.O.F., repeals s. 430.707, F.S., effective October 1, 2013, as part of the expansion of Medicaid managed care.

Medicaid Managed Care (SMMC) program.[15] Participation by the PACE in the SMMC program is not subject to the procurement requirements or regional plan number limits normally applicable to SMMC plans. Instead, PACE plans may continue to provide services to individuals at such levels and enrollment caps as authorized by the GAA.[16]

The 2013 Legislature also directed the AHCA and the DOEA to provide a comprehensive report describing the PACE's organizational structure, scope of services, utilization, and costs, comparing those findings with similar information for managed long-term care, and evaluating alternative methods for integrating PACE with SMMC Long-Term Care (LTC).[17] The report's findings noted a difference in the average age (81.1 years in SMMC LTC versus 75.5 in PACE),[18] prevalence of severe emotional problems (PACE enrollees are more likely to report), and affliction with cognitive impairments such as dementia (higher in SMMC LTC).[19]

The current PACE approval process requires any entity interested in becoming a PACE organization to submit a comprehensive PACE application to the AHCA, which sets forth details about the adult day care center, staffing, provider network, financial solvency and pro forma financial projections, and policies and procedures, among other elements. The application is similar in detail to the provider applications submitted by managed care plans seeking to provide medical care to Medicaid recipients. Providers operating in the same geographic region must establish that there is adequate demand for services so that each provider will be viable. The application requires that documentation be submitted demonstrating that neither provider is competing for the same potential enrollees.

The AHCA and the DOEA review the application and, when the entity has satisfied all requirements, conduct an on-site survey of the entity's readiness to serve PACE enrollees. Once all requirements are met, including full licensure of the center, staffing for key positions, and signed provider network contracts, the AHCA certifies to the CMS that the PACE site is ready. At that time, the CMS reviews the application and readiness certification and, if all requirements are satisfied, executes a three-way agreement with the PACE provider and the AHCA. The PACE provider may then begin enrolling members, subject to an appropriation to fund the slots.

Enrollment and Organizational Slots

Slots are authorized by the Legislature for a specific PACE area, however, slots may not always be fully funded in the same year the program is authorized. Some PACE providers need additional time to complete the application process, obtain necessary licensures, or to finalize operations. The chart below summarizes the current status of approved PACE organizations.

[15] Chapter 2011-135, s. 24, L.O.F., repeals s. 430.707, F.S., effective October 1, 2013.
[16] Section 409.981(4), F.S.
[17] Chapter 2013-40, L.O.F., line 424.
[18] Department of Elder Affairs, *Supra* note 2, at 20.
[19] *Id* at 19.

SUMMARY OF PACE PROGRAMS[20]					
PACE ORGANIZATION			SLOT INFORMATON		
Area	**Year**	**Organization**	**Auth. Slots**	**Funded Slots**	**Current Enrollment[21] (Jan. 2019)**
Broward	2014	Florida PACE	150	125	65
Charlotte	2010	Hope Select	150	150	66
Collier	2010	Hope Select	120	120	37
Desoto, Manatee, and Sarasota	NA	Tidewell	150	0	0
Gadsden, Jefferson, Leon and Wakulla	NA	Elder Care Services	300	0	0
Hillsborough	2011	Suncoast Neighborly PACE	150	0	0
Lee	2010	Hope Select	380	380	213
Martin	2018	Morse PACE	150	75	0
Miami-Dade	2003	Miami-Dade	809	809	759
Northeast Florida *(Clay, Duval, St. Johns, Baker, Nassau)*	2018	Northeast Florida PACE	300	100	0
Orange, Osceola, Lake and Sumter	NA	Cornerstone PACE	150	0	0
Palm Beach	2013	Morse PACE	656	656	493
Panhandle	NA	Covenant	100	100	0
Pinellas	2009	Suncoast Neighborly PACE	325	325	316
Seminole	NA	Cornerstone PACE	150	0	0
Total Enrollees - Statewide:			4,040	2,740	1,949

Funding and Rates

Each year since the PACE's inception, the Legislature has appropriated funds for PACE organizations through proviso language in the GAA or through one of the appropriation implementing or conforming bills.[22] These directives provide specific slot increases or decreases by county or authorization for a county to implement a new program. In 2013, Governor Scott vetoed all county allocations with exception of Palm Beach County, noting that the state's focus should be on the implementation of the SMMC and that effectiveness and the need for additional PACE slots should be re-evaluated after that transition was completed.[23]

PACE organizations receive a capitated Medicaid payment for each enrolled Medicaid long-term care recipient and an enhanced Medicare payment for Medicare enrollees for acute care services

[20] Agency for Health Care Administration and Department of Elder Affairs, *SPB 7124 - Relating to the Program of All-Inclusive Care for the Elderly (PACE) Bill Analysis and Background Information* (March 28, 2014) on file with the Senate Health Policy Committee.
[21] Agency for Health Care Administration, *Florida Statewide Medicaid Monthly Enrollment Report Program Enrollment by Region* (January 2019) *available at* http://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited March 5, 2019).
[22] Chapter 2013-40, L.O.F.
[23] Governor Rick Scott, *Veto Message - SB 1500* (May 20, 2013), p. 28, *available at* http://www.flgov.com/wp-content/uploads/2013/05/Message1.pdf (last visited March 5, 2019).

from the federal government. The payment amount is established in the GAA and is based on estimates that have been forecast by the Social Services Estimating Conference (SSEC) for the PACE. The SSEC principals from the Office of Economic and Demographic Research, the Governor's Office of Planning and Budget, and the budget staff of the House of Representatives and the Florida Senate, seek a consensus on an appropriate risk-adjusted rate for the program which takes into account the current membership, any statutory or regulatory changes that may affect health care utilization, and any other changes that may impact costs positively or negatively.

The current cost per eligible per month for the PACE is $2,681.76.[24] In comparison, according to a 2016 survey by Genworth Financial, the national average cost for nursing home care cost $92,000 per year for a private room or $82,125 for a semi-private room.[25]

Medicaid

Medicaid is the health care safety net for low-income Floridians. The Florida Medicaid Program serves approximately 3.9 million individuals, with over half of those being children and adolescents 19 years of age or younger.[26] Medicaid is a partnership between the federal and state governments where the federal government establishes the structure for the program and pays a share of the cost. Each state operates its own Medicaid program under a state plan that must be approved by the CMS. The plan outlines current Medicaid eligibility standards, policies, and reimbursement methodologies.

To qualify for nursing home care under Medicaid, both an individual's income and assets are reviewed. Additionally, a personal needs allowance is applied as part of the eligibility determination process.[27] The current standard income limit in Florida for institutional care or services under the home and community based services waiver is $2,313 for an individual and $4,626 for a couple. There is also an asset limit for either category of $2,000 for an individual or $3,000 for a couple.[28]

In Florida, the Medicaid program is administered by the AHCA. The AHCA, however, delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Agency for Persons with Disabilities (APD), and the DOEA. The AHCA has overall responsibility for the program and qualifies providers, sets payment levels, and pays for services.

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[24] Office of Economic and Demographic Research, *Social Services Estimating Conference –Long Term Medicaid Services and Expenditures Forecast* (December 2018), p. 22, http://edr.state.fl.us/Content/conferences/medicaid/medltexp.pdf (last visited March 5, 2019).
[25] Emily Mullin and Lisa Esposito, *How to Pay for Nursing Home Costs,* U.S. NEWS AND WORLD REPORT (November 16, 2016) *available at* https://health.usnews.com/wellness/articles/2016-11-16/how-to-pay-for-nursing-home-costs (last visited March 5, 2019).
[26] Social Services Estimating Conference, Medicaid Caseloads and Expenditures, November 18, 2018 and December 10, 2018--Executive Summary http://edr.state.fl.us/Content/conferences/medicaid/execsummary.pdf (last visited March 6, 2019).
[27] The personal needs allowance (PNA) of an individual is defined as that portion of an individual's income that is protected to meet the individual's personal needs while in an institution. *See* Department of Children and Families, *Glossary (Chapter 4600) "Personal Needs Allowance," pg. 19,* http://www.dcf.state.fl.us/programs/access/docs/esspolicymanual/4600.pdf (last visited March 5, 2019).
[28] Department of Children and Families, *SSI-Related Program-Financial Eligibility Standards: January 2019,* http://www.dcf.state.fl.us/programs/access/docs/esspolicymanual/a_09.pdf (last visited March 5, 2019).

The DCF is responsible for determining financial eligibility for Medicaid recipients. The APD operates one of the larger waiver programs under Medicaid, the Home and Community Based (HCBS) Waiver program serving individuals with developmental disabilities.

The DOEA assesses Medicaid recipients to determine if they require nursing home care. Specifically, the DOEA determines whether an individual:

- Requires nursing home placement as evidenced by the need for medical observation throughout a 24-hour period and requires medically complex care to be performed on a daily basis under the direct supervision of a health professional because of mental or physical incapacitation;
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires care to be performed on a daily basis under the supervision of a health professional because of mental or physical incapacitation; or
- Requires or is at imminent risk of nursing home placement as evidenced by the need for observation throughout a 24-hour period and requires limited care to be performed on a daily basis under the supervision of a health professional because of mild mental or physical incapacitation.

Floridians who need nursing home care, but do not qualify for Medicaid, must pay from their own funds or through insurance.

Long-Term Care Managed Care

In 2011, HB 7107[29] was signed into law, increasing the use of managed care in Medicaid. The law required both Medicaid LTC services and Managed Medical Assistance (MMA) services to be provided through managed care plans.

LTC Managed Care plans participating in SMMC are required to provide minimum benefits that include nursing home care as well as home and community based services. The minimum benefits include:

- Nursing home care;
- Services provided in assisted living facilities;
- Hospice;
- Adult day care;
- Medical equipment and supplies, including incontinence supplies;
- Personal care;
- Home accessibility adaptation;
- Behavior management;
- Home delivered meals;
- Case management;
- Therapies, including physical, respiratory, speech, and occupational;
- Intermittent and skilled nursing;

[29] Chapter 2011-134, L.O.F.

- Medication administration;
- Medication management;
- Nutritional assessment and risk reduction;
- Caregiver training;
- Respite care;
- Transportation; and
- Personal emergency response system

III. Effect of Proposed Changes:

Section 1 creates s. 430.84, F.S., and codifies the PACE. Currently, the program does not have an implementing statute and has been operationalized through annual appropriations, proviso, or bills designed to implement the state budget or conform statute to provisions of the state budget.

Definitions

The bill creates the following definitions for the PACE:
- Agency;
- Applicant;
- CMS;
- Department;
- PACE organization; and
- Participant;

Program Creation

The bill authorizes the AHCA, in consultation with the DOEA, to approve entities that have submitted the required application and data to the CMS as PACE organizations pursuant to 42 U.S.C. s. 1395eee (2019). Applications, as required by the CMS, will be reviewed by the AHCA on an ongoing basis, in consultation with the DOEA for initial approval as PACE organizations. Notice of applications must also be published in the Florida Administrative Register.

A prospective PACE organization must submit an application to the AHCA before submitting a request for program funding. An applicant for a PACE program must meet the following requirements:
- Provide evidence that the applicant can meet all of the federal regulations and requirements established by the CMS by the proposed implementation date;
- Provide market studies which include an estimate of the potential number of participants and which show the geographic area the applicant proposes to serve;
- Develop a business plan of operation, including pro forma financial statement and projections based on the planned implementation date;
- Show evidence of regulatory compliance and meet market studies requirements, if the applicant is an existing PACE organization which seeks to expand to an additional service area; and
- Implement the program within 12 months after date of initial state approval if granted authorization as a prospective PACE organization or the approval of the application is void.

Funding and Enrollment

The bill requires PACE organizations to enroll participants at the levels funded each fiscal year in the GAA. Each PACE organization is required to annually submit information to the AHCA that reflects its reasonable capacity for growth to meet demonstrated community needs and consistent with financial statements and projections or projections of PACE census and demand growth. Further, the bill requires the AHCA to include in its legislative budget request the amount of funding estimated by the SSEC needed to fund demonstrated growth in community needs which is consistent with PACE census and demand growth.

The bill also permits the use of funds within any PACE organization's authorized geographic area, regardless of county lines. The DOEA is required to notify individuals who are determined eligible for nursing level of care under Medicaid that the PACE organization is an available service option and that enrollment in the PACE is voluntary. The AHCA is required to notify individuals eligible for Managed LTC that the PACE is available as a choice for a managed care plan in statewide MMC regions where a PACE organization operates.

Quality and Reporting

All PACE organizations are required to meet specific quality and performance standards established by the CMS and the AHCA for the PACE program. The AHCA has the responsibility to oversee and monitor Florida's PACE and the contracted organizations through the data and reports submitted periodically to the AHCA and the CMS.

The bill exempts all PACE organizations from the requirements of chapter 641, the chapter of Florida law which regulates health maintenance organizations, prepaid health clinics, and other health care service programs.

Section 2 amends s. 409.981, F.S., relating to eligible LTC plans in the Medicaid program, particularly the PACE. The bill modifies this section of law to provide a cross reference to the new section of law created by Section 1 of the bill and to change the language from permissive participation in the Medicaid managed care program to mandatory participation in the program.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

PCS/SB 778 has no fiscal impact on state revenues or expenditures.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill amends section 409.981 of the Florida Statutes.

This bill creates section 430.84 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.)

Recommended CS by Appropriations Subcommittee on Health and Human Services on April 4, 2019:
The committee substitute:

- Amends funding and enrollment criteria to require PACE organizations to enroll participants at the levels funded each fiscal year in the GAA.
- Removes provisions that appeared to require funding in the General Appropriations Act that reflects "a reasonable growth of capacity sufficient to meet community needs" and consistent with information submitted by PACE organizations.

- Removes provisions requiring the AHCA, in consultation with the DOEA and the SSEC, to submit an annual report to the Legislature regarding funding for prospective PACE participants.
- Requires each PACE organization to annually submit information to the AHCA that reflects its reasonable capacity for growth to meet demonstrated community needs; requires such information be reviewed by the Social Services Estimating Conference, and requires the AHCA to include in its legislative budget request the amount of funding estimated by the Social Services Estimating Conference needed to fund demonstrated growth in PACE census and demand growth.
- Clarifies that all PACE organizations are required to meet quality and performance standards established not only by the CMS, but the AHCA as well, for the PACE program.
- Removes provision that permitted retroactive enrollment at a PACE organization's discretion.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Baxley) recommended the following:

Senate Amendment (with title amendment)

Delete lines 108 - 172

and insert:

(a)1. PACE organizations shall enroll participants at the levels funded each fiscal year in the General Appropriations Act.

2. Each PACE organization shall annually submit information to the agency which reflects its reasonable capacity for growth to meet demonstrated community needs and which must be

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consistent with the pro forma or other projections submitted pursuant to paragraph (3)(a) or other projections of PACE census and demand growth. The agency, in consultation with the department, shall submit a report to the Social Services Estimating Conference summarizing such information.

3. The agency shall include in its legislative budget request submitted pursuant to chapter 216 the amount of funding estimated by the Social Services Estimating Conference needed to fund demonstrated growth in community needs which is consistent with PACE census and demand growth.

(b) Funds may be used within any PACE organization's authorized geographic service area, regardless of county lines.

(c) The department shall notify individuals who are determined to need the level of care required under the state Medicaid plan for coverage of nursing facility services that the PACE program is a service plan option and that enrollment in the PACE program is voluntary.

(d) The agency shall notify individuals who are determined eligible for managed long-term care that the PACE program is available as a choice for a managed care plan pursuant to s. 409.969 in statewide Medicaid managed care regions wherein a PACE organization operates.

(5) ACCOUNTABILITY.—All PACE organizations must meet specific quality and performance standards established by the CMS and the agency for the PACE program. The agency shall oversee and monitor the PACE program and organizations based upon data and reports PACE organizations submit periodically to the agency and the CMS. A PACE organization is exempt from the requirements of chapter 641.

712346

Section 2. Subsection (4) of section 409.981, Florida Statutes, is amended to read:

409.981 Eligible long-term care plans.—

(4) PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY.—Participation by the Program of All-inclusive Care for the Elderly (PACE) shall be pursuant to a contract with the agency and not subject to the procurement requirements or regional plan number limits of this section. PACE organizations shall ~~plans may continue to~~ provide services to participants ~~individuals~~ at such levels ~~and enrollment caps~~ as authorized by the General Appropriations Act pursuant to s. 430.84.

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

And the title is amended as follows:

Delete lines 16 - 39

and insert:

Government within a certain timeframe; requiring PACE organizations to enroll participants at certain levels; requiring PACE organizations to annually submit certain information to the agency; requiring the agency to submit a report to the Social Services Estimating Conference; requiring the agency to include certain information in its legislative budget request; providing that funds may be used within any PACE organization's authorized geographic service area; requiring the department and the agency to provide certain notices to certain individuals; requiring PACE organizations to meet certain standards; requiring the agency to oversee and monitor the PACE program based

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on certain information; exempting PACE organizations from the requirements of ch. 641, F.S.; amending s. 409.981, F.S.; conforming a provision to changes made by the act; providing an effective date.

By Senator Baxley

12-01151A-19 2019778__

A bill to be entitled

An act relating to the Program of All-Inclusive Care for the Elderly; creating s. 430.84, F.S.; defining terms; authorizing the Agency for Health Care Administration, in consultation with the Department of Elderly Affairs, to approve entities applying to deliver Program of All-Inclusive Care for the Elderly (PACE) services in the state; requiring the agency, in consultation with the department, to review and consider applications; requiring that notice of such applications be published in the Florida Administrative Register; specifying application requirements; requiring prospective PACE organizations that are granted initial state approval to submit a complete application to the agency and the Federal Government within a certain timeframe; specifying funding and enrollment requirements for PACE organizations; requiring the agency, in consultation with the department and the Social Services Estimating Conference, to submit a certain report to the Legislature; requiring the agency and department to provide certain notices to certain individuals; requiring PACE organizations to meet certain standards; requiring the agency to oversee and monitor the PACE program based on certain information; exempting PACE organizations from ch. 641, F.S.; amending s. 409.981, F.S.; conforming a provision to changes made by the act; providing that specified individuals may be enrolled in the PACE program under

12-01151A-19 2019778__

certain circumstances; requiring the Comprehensive Assessment and Review for Long-Term Care Services program to determine a PACE applicant's eligibility within a certain timeframe; requiring the Department of Children and Families to determine a PACE applicant's financial eligibility; specifying requirements for the agency in paying contractors providing services to eligible applicants; authorizing certain actions by a contractor with respect to certain applicants; providing an effective date.

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

Section 1. Section 430.84, Florida Statutes, is created to read:

430.84 Program of All-Inclusive Care for the Elderly.—

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

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

(b) "Applicant" means an entity that has filed an application with the agency for consideration as a Program of All-Inclusive Care for the Elderly (PACE) organization.

(c) "CMS" means the Centers for Medicare and Medicaid Services within the United States Department of Health and Human Services.

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

(e) "PACE organization" means an entity under contract with the agency to deliver PACE services.

(f) "Participant" means an individual receiving PACE

services who the department has determined needs the level of care required under the state Medicaid plan for coverage of nursing facility services.

(2) PROGRAM CREATION.—The agency, in consultation with the department, may approve entities that have submitted the application the CMS requires to the agency for review and consideration. An entity must submit the data and information required in subsection (3) to provide benefits pursuant to the PACE program as established in 42 U.S.C. s. 1395eee and in accordance with the requirements set forth in this section.

(3) PACE ORGANIZATION SELECTION.—The agency, in consultation with the department, shall review and consider on a continuous basis applications the CMS requires for PACE which have been submitted to the agency by entities seeking initial state approval to become PACE organizations. Notice of such applications must be published in the Florida Administrative Register.

(a) A prospective PACE organization shall submit application documents to the agency before requesting program funding. Application documents submitted to and reviewed by the agency, in consultation with the department, must include all of the following:

1. Evidence that the applicant is able to meet all of the applicable federal regulations and requirements established by the CMS for participation as a PACE organization by the proposed implementation date.

2. Market studies, including an estimate of the number of potential participants and the geographic service area the applicant proposes to serve.

3. A business plan of operation, including pro forma financial statements and projections, based on the proposed implementation date.

(b) Each applicant must propose to serve a unique and defined geographic service area without duplication of services or target populations. No more than one PACE organization may be authorized to provide services within any unique and defined geographic service area.

(c) An existing PACE organization seeking authority to serve an additional geographic service area not previously authorized by the agency or Legislature must meet the requirements set forth in paragraphs (a) and (b).

(d) A prospective PACE organization granted initial state approval by the agency, in consultation with the department, shall submit its complete federal PACE application, in accordance with the application process and guidelines established by the CMS, to the agency and the CMS within 12 months after the date of initial state approval, or such approval is void.

(4) FUNDING AND ENROLLMENT.—

(a) PACE organizations shall enroll participants at such levels as funded by the General Appropriations Act, which must reflect a reasonable growth of capacity sufficient to meet community needs and which must be consistent with the pro forma or other projections submitted pursuant to paragraph (3)(a) or projections of PACE census and demand growth that are periodically submitted by PACE organizations. The agency, in consultation with the department and the Social Services Estimating Conference, shall submit a report to the Legislature

requesting the amount of funding necessary for prospective PACE participants to have access to PACE services as a program service option in all authorized geographic service areas.

(b) Funds may be used within any PACE organization's authorized geographic service area, regardless of county lines.

(c) The department shall notify individuals who are determined to need the level of care required under the state Medicaid plan for coverage of nursing facility services that the PACE program is a service plan option and that enrollment in the PACE program is voluntary.

(d) The agency shall notify individuals who are determined eligible for managed long-term care that the PACE program is available as a choice for a managed care plan pursuant to s. 409.969 in statewide Medicaid managed care regions wherein a PACE organization operates.

(5) ACCOUNTABILITY.—All PACE organizations must meet specific quality and performance standards established by the CMS for the PACE program. The agency shall oversee and monitor the PACE program and organizations based upon data and reports PACE organizations submit periodically to the agency and the CMS. A PACE organization is exempt from the requirements of chapter 641.

Section 2. Subsection (4) of section 409.981, Florida Statutes, is amended to read:

409.981 Eligible long-term care plans.—

(4) PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY.—

(a) Participation by the Program of All-inclusive Care for the Elderly (PACE) shall be pursuant to a contract with the agency and not subject to the procurement requirements or

regional plan number limits of this section. PACE organizations shall ~~plans may continue to~~ provide services to participants ~~individuals~~ at such levels ~~and enrollment caps~~ as authorized by the General Appropriations Act pursuant to s. 430.84.

(b) A prospective participant who applies for the PACE program and has been determined by the Comprehensive Assessment and Review for Long-Term Care Services (CARES) program to be medically eligible but has not been determined financially eligible for Medicaid by the Department of Children and Families, or who has been determined financially eligible for Medicaid by the Department of Children and Families but has not been determined medically eligible by the CARES program, may be enrolled in the PACE program if contractors elect to provide services to PACE program applicants pending final determination of eligibility. The CARES program shall determine each applicant's medical eligibility within 21 days after receiving the complete application packet. The Department of Children and Families shall determine each applicant's financial eligibility according to federal and state requirements. If the applicant is determined eligible, the Agency for Health Care Administration shall pay the contractor that provided the services the applicable Medicaid rate, retroactive to the first day of the month following the CARES program eligibility determination. If the applicant is not eligible for the PACE program with Medicaid as the payor, the contractor may continue to provide services as a private-pay PACE participant or terminate services and seek reimbursement from the applicant.

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

THE FLORIDA SENATE

SENATOR DENNIS BAXLEY
12th District

COMMITTEES:
Ethics and Elections, *Chair*
Appropriations Subcommittee on Education
Education
Finance and Tax
Health Policy
Judiciary

JOINT COMMITTEE:
Joint Legislative Auditing Committee

March 7, 2019

The Honorable Chair Aaron Bean
405 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399

Dear Chairman Bean,

I would like to request that SB 778 Program of All-Inclusive Care for the Elderly (PACE) be heard in your next committee meeting.

This bill codifies the Program of All-Inclusive Care for the elderly (PACE). PACE was first authorized in 1998 and became operational in Miami-Dade County, but has not been codified in state law.

With almost 2,000 Medicaid managed care eligible recipients already enrolled in seven counties, the bill establishes a statutory process for the review, approval, and oversight of future and current PACE organizations.

I appreciate your favorable consideration.

Onward & Upward,

Senator Dennis Baxley
Senate District 12

DKB/dd

cc: Tonya Kidd, Staff Director

320 Senate Office Building, 404 South Monroe St, Tallahassee, Florida 32399-1100 • (850) 487-5012
Email: baxley.dennis@flsenate.gov

Bill Galvano
President of the Senate

David Simmons
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date	Bill Number (if applicable)
	778

Topic SB 778 - Information Only

Amendment Barcode (if applicable)

Name Matt Hudson

Job Title Exec Director Florida PACE Providers Assoc

Address 9470 Healthpark Cir Phone 2394259711

Street

Ft Myers FL 33908 Email

City State Zip

Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against

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

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 434
INTRODUCER:	Health Policy Committee and Senator Harrell
SUBJECT:	Ambulatory Surgical Centers
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Fav/CS**
2.	McKnight	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 434 amends s. 395.002, F.S., to allow a patient to stay in an ambulatory surgical center (ASC) for 24 hours, thus allowing a patient to stay overnight, rather than requiring a patient be admitted and discharged on the same working day.

The bill also amends s. 395.1005, F.S., to require the Agency for Health Care Administration (AHCA), in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill has an indeterminate fiscal impact on the Florida Medicaid Program. See Section V. Fiscal Impact Statement.

The bill takes effect on July 1, 2019.

II. Present Situation:

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a licensed facility not part of a hospital with the primary purpose of providing elective surgical care in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[1]

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. As of January 2019, there are 458 ASCs and 308 licensed hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital-based outpatient surgical services.[2]

Between April 2017 and March 2018, there were 3,049,558 visits to ASCs in Florida.[3] Hospital outpatient facilities accounted for 1,419,020 visits (46.5 percent) and freestanding ASCs accounted for 1,622,013 visits (53.5 percent). Freestanding ASC average charges range from $3,516 to $9,347 and hospital-based ASC average charges range from $10,522 to $34,291 for the same time period.[4] According to 2017 utilization data submitted to the Agency for Health Care Administration (AHCA), less than five percent of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).[5]

Age Group	Visits	% of Visits
Age 0 (Less than 1 year old)	10,348	0.34%
1 – 4 years	48,802	1.60%
5 – 9 years	37,398	1.22%
10 – 14 years	25,958	0.85%
15 – 17 years	24,992	0.82%
Total Pediatrics	147,498	4.83%
Total All Ages	3,056,789	100%

Licensure

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.[6] Applicants for ASC licensure are required to submit certain information to the AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- The applicant's zoning certificate or proof of compliance with zoning requirements.[7]

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[1] Section 395.002(3), F.S.
[2] Agency for Health Care Administration, *Senate Bill 434 Analysis* (January 24, 2019) (on file with the Senate Committee on Health Policy).
[3] Agency for Health Care Administration, *Florida Health Finder*, http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx (last viewed March 4, 2019).
[4] *Id.*
[5] *Id.* note 4.
[6] Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.
[7] Rule 59A-5.003(4), F.A.C.

Upon receipt of an initial ASC application, the AHCA is required to conduct a survey to determine compliance with all laws and rules. Applicants are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules, and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- A comprehensive emergency management plan.[8]

Florida Administrative Rules

Pursuant to s. 395.1055, F.S., the AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals, but the rules for all hospitals and ASCs are required to include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.

Rule 59A-5 of the Florida Administrative Code (F.A.C.) implements the minimum standards for ASCs. Those rules require policies and procedures to ensure the protection of patient rights.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, laboratory services, and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A qualified person responsible for the daily functioning and maintenance of the surgical suite;
- An anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician, or an anesthesiologist assistant under the direct supervision of an anesthesiologist, who must be in the center during the anesthesia and post-anesthesia recovery period until all patients are cleared for discharge;
- A registered professional nurse who is responsible for coordinating and supervising all nursing services;
- A registered professional circulating nurse for a patient during that patient's surgical procedure; and
- A registered professional nurse who must be in the recovery area at all times when a patient is present.[9]

[8] Rule 59A-5.003(5), F.A.C.
[9] Rule 59A-5.0085, F.A.C.

Infection Control Program

ASCs are required to establish an infection control program involving members of the medical, nursing, and administrative staff. The program must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating, and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation, and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.[10]

Emergency Management Plan

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.[11]

Accreditation

ASCs may seek voluntary accreditation by an accrediting organization whose standards are determined by the AHCA to be comparable to state licensure requirements. The AHCA is required to conduct a licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.[12]

The AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[13]

Medicare Requirements

ASCs are required to have an agreement with the federal Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and for whom the expected duration of services would not exceed 24 hours following an admission.[14]

[10] Rule 59A-5.011, F.A.C.
[11] Rule 59A-5.018, F.A.C.
[12] Rule 59A-5.004, F.A.C.
[13] *Id.*
[14] 42 C.F.R. s. 416.2

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency and if the CMS determines that such accreditation or licensure provides reasonable assurance that the conditions for coverage are met.[15] All of the CMS conditions for coverage requirements are specifically required in Rule 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have a:

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

American College of Surgeons: Optimal Resources for Children's Surgical Care v. 1

In 1913, the American College of Surgeons (ACS) was founded on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With these principles in mind, the ACS Children's Surgery Verification Committee was created in 2015 to continue, on a permanent basis within the ACS, the work of the ad hoc Task Force for Children's Surgical Care. This group was first convened in 2012. The recommendations of this task force are contained in the ACS' Standards Manual entitled, "Optimal Resources for Children's Surgical Care v. 1."[16]

Specific to ASCs, the report found that:

> Children's ambulatory surgical centers must have treatment protocols for resuscitation, transfer protocols, and data reporting and must participate in systems for performance improvement. Children's ambulatory centers must have good working relationships and be fully integrated with a Level I, II, or III inpatient children's surgical center[17] to be verified in this program… It is essential for the children's ambulatory surgical center to

[15] 42 C.F.R. s. 416.26(a)(1)

[16] American College of Surgeons, *Optimal Resources for Children's Surgical Care v.1*, (released in 2015) *available at* https://www.facs.org/~/media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx (last visited on March 27, 2019).

[17] The report details such relationship on page 19. "*Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, a Level II center may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a Level III center may be the only resource for miles. Ambulatory surgical centers are considered separately but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II, or III children's inpatient facilities.*" *Id.*

> have the involvement of one or more committed and appropriately trained pediatric health care providers to provide leadership and sustain the integration with other relevant components of an integrated children's health care system.[18]

III. Effect of Proposed Changes:

The bill amends s. 395.002, F.S., to allow a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day. This change complies with the CMS requirements for an ASC.[19]

The bill also amends s. 395.1005, F.S., to require the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 Standards Manual entitled "Optimal Resources for Children's Surgical Care."

The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

The bill takes effect on July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

[18] *Id.*
[19] 42 C.F.R. s. 416.2.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 434 may have an indeterminate positive fiscal impact on patients seeking surgical services if such patients are able to obtain the surgical services at an ASC for lower costs than the costs of receiving comparable services at a hospital.

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

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the Florida Medicaid program.

ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed for an overnight stay. If ASCs are authorized to bill for an overnight stay through the EAPG system, there could potentially be an increase in the volume of ASC claims and therefore, a potential increase in ASC expenditures. However, a potential increase in claim volumes and expenditures may be offset due to a decrease in claims and expenditures for services provided in the outpatient or inpatient hospital setting.[20]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

[20] *Supra* note 2.

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 February 19, 2019:
The CS revises the bill's requirement for the AHCA to adopt rules related to pediatric care in ASCs and eliminates the requirement that the AHCA adopt rules regulating practitioners providing such care. Additionally the CS eliminates specified items that the rules must address.

B. Amendments:

None.

246860

LEGISLATIVE ACTION

Senate . House

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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment

Delete line 41

and insert:

effective delivery of surgical care to children kept past midnight in ambulatory

By the Committee on Health Policy; and Senator Harrell

588-02473-19 2019434c1

A bill to be entitled

An act relating to ambulatory surgical centers; amending s. 395.002, F.S.; revising the definition of the term "ambulatory surgical center"; amending s. 395.1055, F.S.; requiring the Agency for Health Care Administration, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules that establish requirements related to the delivery of surgical care to children in ambulatory surgical centers, in accordance with specified standards; specifying that ambulatory surgical centers may provide certain procedures only if authorized by agency rule; providing an effective date.

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

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

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours ~~the same working day and is not permitted to stay overnight~~, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry may not be construed to be an ambulatory surgical center, provided that any facility or

588-02473-19 2019434c1

office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003.

Section 2. Present subsections (3) through (12) of section 395.1055, Florida Statutes, are redesignated as subsections (4) through (13), respectively, and a new subsection (3) is added to that section, to read:

395.1055 Rules and enforcement.—

(3)(a) The agency, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, shall adopt rules that establish requirements to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 standards document entitled "Optimal Resources for Children's Surgical Care" and must establish minimum standards for pediatric patient care in ambulatory surgical centers.

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

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Health Policy, *Chair*
Appropriations Subcommittee on Health and Human Services, *Vice Chair*
Appropriations Subcommittee on Criminal and Civil Justice
Children, Families, and Elder Affairs
Military and Veterans Affairs and Space

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GAYLE HARRELL
25th District

March 9, 2019

Senator Aaron Bean
405 Senate Building
404 South Monroe Street
Tallahassee, FL 32399

Chair Bean,

I respectfully request that **SB 434 – Ambulatory Surgical Centers** be placed on the next available agenda for the Appropriations Subcommittee on Health and Human Services Committee Meeting.

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

Thank you,

Gayle

Senator Gayle Harrell
Senate District 25

Cc: Tonya Kidd, Staff Director
Robin Jackson, Committee Administrative Assistant

REPLY TO:
❒ 215 SW Federal Highway, Suite 203, Stuart, Florida 34994 (772) 221-4019
❒ 310 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5025

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

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	PCS/SB 7078 (192902)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services and Health Policy Committee
SUBJECT:	Health Care
DATE:	April 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	Williams, et al	Brown		**HP Submitted as Committee Bill**
1.	Loe	Kidd	AHS	**Recommend: Fav/CS**
2.			AP	

I. Summary:

PCS/SB 7078 addresses a variety of health care and health insurance issues, including:

- Access to medical records;
- Transparency of hospital quality information;
- Access to primary and specialist care in a hospital setting;
- Patient notification of hospital observation status;
- Expansion of the duties of the Pediatric Cardiac Technical Advisory Panel;
- Expansion of direct health care agreements;
- Consumer-friendly protections to prescription drug step-therapy protocols;
- Price transparency for services covered by health insurance; and
- Authorization for Florida to participate in the Interstate Medical License Compact.

The bill has an indeterminate fiscal impact on state revenues and state expenditures. The increase in state expenditures related to the expanded duties of the Pediatric Cardiac Technical Advisory Panel is addressed in SB 2500, First Engrossed, the Senate's proposed General Appropriations Bill for the 2019-2020 fiscal year.

The bill has an effective date of July 1, 2019, except as otherwise provided in the bill.

II. Present Situation:

Access to Medical and Clinical Records

Federal Law

The Health Insurance Portability and Accountability Act

The federal Health Insurance Portability and Accountability Act (HIPAA) Health Insurance Portability and Accountability Act establishes standards to protect an individual's medical and clinical records and other personal health information (PHI).[1] The HIPAA provides that, except in certain circumstances,[2] individuals have the right to view and inspect – at no charge – or request to obtain a copy of their protected health information [3] in a covered entity's[4] designated record set.[5] If an individual requests a copy of his or her PHI, or a summary or explanation of such information, covered entities may impose reasonable, cost-based fees for the cost of labor, supplies, copying, postage, and preparation of the summary or explanation of the PHI.[6] A covered entity must disclose the approximate amount of a fee to be assessed to an individual or other requesting entity prior to completing a request for medical and clinical records.[7] The HIPAA prohibits certain costs from being included in the fee charged by the covered entity, even if such costs are authorized by state law.[8] A covered entity may charge a fee on a per-page basis when the PHI is maintained in paper format and the individual requests a paper copy of the PHI or asks that the paper PHI be scanned into electronic format.[9] A covered entity may charge individuals a flat fee – not to exceed $6.50 – for all requests for electronic copies of PHI maintained electronically, inclusive of all labor, supplies, and postage, if applicable.[10]

A covered entity must provide access – within 30 days of a request – to an individual's medical and clinical records and other PHI in the format requested by the individual or requesting entity

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[1] Pub. L. No. 104-191 (1996). *See also* U.S. Department of Health and Human Services, Office for Civil Rights, Summary of the HIPAA Privacy Rule, (last rev. May 2003), available at: https://www.hhs.gov/sites/default/files/privacysummary.pdf. (last visited March 28, 2019).

[2] *Id.* The HIPAA excepts from the right of access the following protected health information: psychotherapy notes, information compiled for legal proceedings, laboratory results to which the Clinical Laboratory Improvement Act (CLIA) prohibits access, or information held by certain research laboratories. Additionally, a covered entity may deny an individual access in certain specified situations, such as when a health care professional believes access could cause harm to the individual or another. In such situations, the individual must be given the right to have such denials reviewed by a licensed health care professional for a second opinion.

[3] *Id.* "Protected Health Information" includes all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.

[4] *Id.* "Covered entities" include health plans, health care providers, health care clearinghouses, and business associates of any of the aforementioned covered entities.

[5] *Id.* The "designated record set" is that group of records maintained by or for a covered entity that is used, in whole or part, to make decisions about individuals, or that is a provider's medical and billing records about individuals or a health plan's enrollment, payment, claims adjudication, and case or medical management record systems.

[6] U.S. Department of Health and Human Services, Individuals' Right under HIPAA to Access their Health Information 45 C.F.R. § 164.524, available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/#maximumflatfee (last visited March 28, 2019).

[7] *Id.*

[8] *Id.*

[9] *Id.* Per page fees for copies of PHI maintained electronically are not considered reasonable under HIPAA.

[10] *Id.*

if such records are readily producible in the requested format.[11] An individual must provide written authorization to a covered entity when requesting the disclosure of PHI; however, a covered entity may release records without such authorization under certain circumstances.[12]

HIPAA privacy rules typically preempt any state law that is contrary to its provisions; however, the state law applies if it is more stringent than, and not contrary to, HIPAA privacy rules.[13]

Florida Law

In addition to federal HIPAA requirements, Florida law establishes requirements for the disclosure, production, and inspection of a patient's or resident's medical and clinical records in various health care facility licensure acts;[14] however, these requirements vary amongst facility types.

Mental Health Records

Any facility[15] or private mental health practitioner providing mental health services authorized by the Baker Act[16] is required to maintain clinical records for a patient that includes specific information deemed confidential and exempt from the provisions of section 119.07(1), Florida Statutes, unless:

- Waived by express and informed consent by the patient or the patient's guardian or guardian advocate; or
- If the patient is deceased, by the patient's personal representative or the family member who stands next in line of intestate succession.[17]

The confidential status of a patient's clinical record must be maintained in circumstances where release of such records to a person, organization, or agency is either mandatory or permissive.[18] Any facility or private mental health practitioner who acts in good faith when lawfully releasing information from a patient's clinical record is not subject to civil or criminal liability for such release.[19]

The aforementioned requirements pertaining to the confidentiality of a patient's clinical record does not prohibit the parent or next of kin of a patient who is held in, or treated under a mental health facility or program, from requesting and receiving information limited to a summary of

[11] *Id.*
[12] *Supra* Note 1. PHI may be released without a patient's written authorization for certain public health activities, law enforcement purposes, or for certain victims of abuse, neglect, or domestic violence.
[13] 45 C.F.R. § 160.203.
[14] *See* ss. 394.4615, F.S. (mental health facilities); 395.3025 (hospitals and ambulatory surgical centers); 397.501 (substance abuse service providers); and 400.145 (nursing homes), F.S.
[15] *See* section 394.455(16), F.S. A "facility" is defined as any hospital, community facility, public or private facility, or receiving or treatment facility providing for the evaluation, diagnosis, care, treatment, training, or hospitalization of persons who appear to have or who have been diagnosed as having a mental illness or substance abuse impairment. The term "facility" does not include a program or an entity licensed under chapters 400 or 429, F.S.
[16] Chapter 71-131, Laws of Fla.; the Baker Act is contained in ch. 394, F.S.
[17] Section 394.4615(1), F.S.
[18] Section 394.4615(2)-(7), F.S.
[19] Section 394.4615(8), F.S.

such patient's treatment plan and current physical and mental condition.[20] Patients are entitled to reasonable access to their mental health clinical records unless such access is determined by the patient's physician to be harmful to the patient.[21] A decision by a facility to restrict a patient's right to inspect his or her mental health clinical record expires after seven days, but may be renewed for a subsequent seven days.[22]

A facility or private mental health practitioner is not required under state law to release requested clinical records within a certain timeframe. There is no standardized fee structure established in statute to limit the amount a facility or private mental health practitioner may charge to produce requested records.

Hospital and Ambulatory Surgical Center Records

Hospitals and ambulatory surgical centers (ASCs) are required to furnish records in a timely manner, without delays for legal review, to a patient or the patient's representative[23] but only after the patient has been discharged from the hospital or ASC.[24] A hospital or ASC may charge up to $1 per page of paper records or up to $2 in total for non-paper records regardless if the records are furnished by the hospital, the ASC, or a copy service. A hospital or ASC may also charge a fee of up to $1 per year of records requested. Records copied for the purpose of continuing medical care are not subject to a charge and a hospital or ASC must allow any person who is authorized to receive copies of records to examine the original records, or suitable reproductions, with reasonable terms to ensure that such records are not damaged, destroyed, or altered.[25]

Patient records from hospitals and ASCs are confidential, exempt from disclosure under public records laws, and may not be disclosed without the consent of the patient or his or her legal representative. A patient's records may be accessed without the consent of the patient by specific entities for purposes related to the treatment of the patient, licensure actions, investigations, audits, and quality assurance.[26]

Substance Abuse Records

A person's right to the confidentiality of their individual substance abuse records requires a substance abuse service provider to protect an individual's identity, diagnosis, prognosis, and service provided. Such records are confidential, in accordance with state and federal law, and are exempt from disclosure under state public records laws. Substance abuse records may not be disclosed without the written consent of the individual to whom they pertain, except under limited circumstances, such as a medical emergency.[27]

[20] Section 394.4615(9), F.S.
[21] Section 394.4615(10), F.S.
[22] *Id.*
[23] Specified as the patients guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such person in writing.
[24] Section 395.3025, F.S. This section does apply to records maintained at a psychiatric hospital or at licensed facilities whereby such records are governed pursuant to ss. 394.4615 and 397.501(7), F.S.
[25] Section 395.3025(1), F.S.
[26] Section 395.3025(4)(a)-(l) and (5), F.S.
[27] Section 397.501(7)(a) and (e), F.S.

The Marchman Act[28] establishes various processes, notice requirements, and legal procedures whereby confidential information from an individual's records may be legally disclosed by court order, such as for the purpose of conducting a criminal investigation.[29] The restrictions on the disclosure and use of confidential records held by substance abuse program service providers do not apply to communications from personnel of the substance abuse provider to law enforcement officers relating to the commission of a crime or a threat to commit such a crime, or when reporting incidents of suspected child abuse and neglect to the appropriate state or local authorities as required by law.[30]

Substance abuse service providers are not required under state law to release requested clinical records within a certain timeframe. There is no standardized fee structure established in statute to limit the amount a substance abuse service provider may charge to produce requested records.

Nursing Home Records

Nursing homes are required to provide copies of certain medical records to a resident, or their authorized representative, within 14 days for a current resident and 30 days for a former resident when the nursing home receives a written request in compliance with the HIPAA.[31] A nursing home may refuse to furnish requested medical records directly to a resident under certain circumstances and limitations,[32] and is generally not required to provide such records more than once per month.[33]

A nursing home is authorized to charge a reasonable fee for copying resident records not to exceed $1 per page for the first 25 pages and 25 cents per page for each additional page. A facility must allow an authorized person to examine the original records, or suitable reproductions, and may impose reasonable terms to ensure the records are not damaged, destroyed, or altered;[34] however, a nursing facility is not required by law to provide such access within a specified timeframe.

Ownership and Control of Patients' Medical Records

Under Florida law, a patient's medical records are not the property of the patient. A patient's medical records belong to the records owner, which includes certain health care practitioners and their employer, but does not include certain health care facilities.[35]

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[28] Chapter 93-39, Laws of Fla.; the Hal S. Marchman Alcohol and Other Drug Services Act (Marchman Act) is contained in ch. 397, F.S.

[29] Section 397.501(7)(f)-(i), F.S.

[30] Section 397.501(7)(b) and (c), F.S. However, the confidentiality restrictions continue to apply to the original substance abuse records maintained by the provider, including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

[31] Section 400.145(1), F.S. A nursing home is required to provide medical records and records concerning the care and treatment of a resident, but is not required to provide progress notes and consultation report sections of a psychiatric nature.

[32] Section 400.145(5), F.S. Disclosure of records is not required if deemed by the facility to be detrimental to the physical or mental health of the resident; however, such records must be provided to any other medical provider designated by, and at the written request of, the resident.

[33] Section 400.145(7), F.S. Copies of physician reports in the resident's records must be provided as often as necessary to allow the effective monitoring of the resident's condition.

[34] Section 400.145(4), F.S.

[35] Section 456.057, F.S. The term "records owner" means any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health

Certain health care practitioners and entities not considered to be records owners, or any person or entity that obtains medical records from a record owner, are considered records custodians and must maintain records or documents under the same confidentiality and disclosure requirements as any health care practitioner, or their employer, who is a records owner.[36]

Health Care Practitioners' Records

Any health care practitioner licensed by the Department of Health (DOH), or a board within the DOH,[37] who makes an examination of a patient, administers treatment or dispenses legend drugs, must, in a timely manner, furnish to the patient, or his or her legal representative, without delays for legal review or conditioned upon payment of a fee for services rendered, copies of all reports and records relating to the examination, treatment, X-rays, and insurance information.[38]

A health care practitioner or records owner who furnishes copies of reports or records, or makes the reports or records available for digital scanning, is authorized to charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the DOH when there is no board.[39] The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) have adopted rules related to the fees its licensees may charge for copying patient medical records.

Florida Board of Medicine Rule

The BOM encourages allopathic physicians to provide patients with a copy of their medical records free of charge, especially if the patient is disadvantaged.[40] However, an allopathic physician is authorized to charge a patient or governmental entity a fee of $1 per page for the

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care practitioner who receives records transferred by a previous records owner; or any health care practitioner's employer, but does not include health care practitioners or entities regulated under part II of ch. 464, F.S., (certified nursing assistants) or part V of ch. 468, F.S., (respiratory therapists); licensed under ch. 465, F.S., (pharmacists and pharmacies), s. 466.023, F.S., (dental hygienists), part II (nursing home administrators) and part XIII (athletic trainers) of ch. 468, F.S., ch. 478, F.S., (electrologists), and part II (clinical laboratory personnel) and part III (medical physicists) of ch. 483, F.S.; licensed or permitted under part I of chapter 484, F.S., (opticians and optical establishments); or persons or entities performing personal injury protection (PIP) examinations for insurance carriers under s. 627.736(7), F.S. The aforementioned excluded health care practitioners and entities are not authorized to acquire or own medical records, but are authorized to maintain documents required by their respective practice acts under the same confidentiality and disclosure requirements of records owners. Additionally, the term "records owner," and the requirements of s. 456.057, F.S., does not apply to hospitals and ambulatory surgical centers licensed pursuant to ch. 395, F.S.

[36] Section 456.057(3) and (4), F.S.

[37] A health care practitioner is any person licensed under ch. 457, F.S., (acupuncture); ch. 458, F.S., (medical practice); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathy); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry, dental hygiene, and dental laboratories); ch. 467, F.S., (midwifery); part I, part II, part III, part V, part X, part XIII, or part XIV of ch. 468, F.S., (speech language pathology and audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, or orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrolysis); ch. 480, F.S., (massage practice); part III or part IV of ch. 483, F.S., (clinical laboratory personnel or medical physicists); ch. 484, F.S., (dispensers of optical devices and hearing aids); ch. 486, F.S., (physical therapy practice); ch. 490, F.S., (psychological services); or ch. 491, F.S., (clinical, counseling, and psychotherapy services).

[38] Section 456.057(6), F.S. In lieu of copies of certain medical records related to psychiatric or psychological treatment, a practitioner may release a report of examination and treatment.

[39] Section 456.057(17), F.S.

[40] Fla. Admin Code R. 64B8-10.003 (2019).

first 25 pages, and no more than 25 cents for each subsequent page.[41] For all other entities, an allopathic physician may charge up to $1 per page. An allopathic physician may charge the actual cost for reproducing certain documents, such as X-rays and other special kinds of records.[42] Actual costs include the materials, supplies, labor, and overhead costs associated with such duplication.[43] No timeline is specified for the provision of these records.

Florida Board of Osteopathic Medicine Rule

An osteopathic physician may charge up to $1 per page for the first 25 pages, and no more than 25 cents for each subsequent page, regardless of the requestor.[44] An osteopathic physician must comply with a patient's written request for records within 30 days of such request unless there are circumstances beyond the osteopathic physician's control that prevents such compliance.[45] An osteopathic physician may charge the actual cost for reproducing certain documents, such as X-rays and other special kinds of records.[46] Actual costs include the materials, supplies, labor, and overhead costs associated with such duplication.[47]

Transparency of Health Care Quality Information

Patient Safety Plan

Hospitals and ASCs are required to adopt a patient safety plan in accordance with state and federal laws and regulations.[48] Hospitals and ASCs designate an employee to serve as a patient safety officer, and establish a patient safety committee, to promote the health and safety of patients, evaluate the quality of patient safety measures utilized by the facility, and ensure the accountability of, and fidelity to, the facility's patient safety plan.[49]

Hospital Compare

The federal Centers for Medicare & Medicaid Services (CMS) maintains the Hospital Compare website,[50] which provides consumers with data about the quality of care at over 4,000 Medicare-certified hospitals.[51] Hospital Compare allows consumers to select multiple hospitals and directly compare performance measure information related to heart attack, heart failure, pneumonia, surgery and other conditions.[52] Performance measures are derived from consumers' responses to

[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] Fla. Admin. Code R. 64B15-15.003, (2019).
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] Section 395.1012, F.S., and 42 C.F.R. § 482.21.
[49] Section 395.1012(2), F.S. At least one member of the patient safety committee must be a person who is neither employed by nor practicing in the hospital or ASC.
[50] Centers for Medicare & Medicaid Services, Hospital Compare, available at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalcompare.html (last visited on March 12, 2019)
[51] Medicare.gov, What is Hospital Compare? available at https://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html (last visited March 12, 2019).
[52] *Id.*

the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey[53] which collects data on patient satisfaction and readmission, hospital-acquired infection, and mortality rates.[54] Overall hospital performance is presented to consumers through a star rating of one to five stars.[55]

Florida Center for Health Information and Transparency

The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system that includes the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data. The Florida Center is housed within the Agency for Health Care Administration (AHCA).[56] The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ASC, emergency department, and comprehensive rehabilitation hospital on a quarterly basis.[57]

The Florida Center maintains www.FloridaHealthFinder.gov, which assists consumers in making informed health care decisions and leads to improvements in quality of care in Florida. The website provides a wide array of search and comparative tools to the public that allows easy access to information on hospitals, ASCs, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator; hospital and ASCs performance data; data on mortality, complication, readmission, and acquired infection rates for hospitals; and a facility/provider locator.

Access to Primary and Specialist Care in a Hospital Setting

Continuity of Care

'Continuity of care' generally refers to a patient's care over time by a single individual or team of health professionals but can also include effective and timely communication of health information at different levels of care between the patient, the primary care provider, and other treating specialists.[58] This long-term patient-physician relationship in which the physician knows the patient's history from experience allows the physician to integrate new information and decisions from a holistic perspective efficiently without extensive investigation or record review.[59]

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[53] The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a national survey that asks patients about their experiences during a recent hospital stay. The HCAHPS is endorsed by the National Quality Forum as a measure of hospital quality. Available at: http://www.hcahpsonline.org/ (last visited March 29, 2019).
[54] Medicare.gov, Measures and current data collection periods, available at: https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html# (last visited March 12, 2019).
[55] Medicare.gov, Hospital Compare overall hospital rating, available athttps://www.medicare.gov/hospitalcompare/About/Hospital-overall-ratings.html (last viewed March 12, 2019).
[56] Section 408.05, F.S.
[57] Section 408.061, F.S., and chs. 59B-9 and 59E-7, F.A.C.
[58] Institute of Medicine Committee on the Future of Primary Care; M.S. Donaldson et. al., *Primary Care: America's Health in a New Era*, 27-51 (National Academies Press, 1996), available at: https://www.ncbi.nlm.nih.gov/books/NBK232643/pdf/Bookshelf_NBK232643.pdf (last visited Mar. 29, 2019).
[59] *Id.* at 52-75; *See also*, American Academy of Family Physicians, Continuity of Care, https://www.aafp.org/about/policies/all/definition-care.html (last visited Mar. 29, 2019).

When a patient's various healthcare providers do not communicate with one another, the lack of coordination results in fragmented care. Fragmented care can have an adverse impact on the quality of care, and is associated with increased healthcare costs, medical errors,[60] and risk of re-hospitalization.[61]

Patient handoff – when the patient care responsibility is transferred from one health care professional to another – is a critical moment in the continuum of care. This is especially significant during transition from an inpatient to an outpatient setting. Based on reports and studies, it is not common practice for a treating physician at a hospital to communicate with the patient's primary care provider during a patient's admission or even at discharge.[62] Primary care providers are often wholly unaware of the hospitalization or do not receive a discharge summary or information from the hospital.

A growing body of research and articles recommend that a primary care provider be informed of the patient's admission to, or discharge from, a hospital, with the most effective care being provided when information is shared between the primary care provider and treating physician throughout the course of the admission.[63] In an effort to better coordinate care, some hospitals

[60] "Medical error" generally refers to failure of a planned action to be completed as intended or a preventable adverse effect of care, and can range from documentation errors to improper diagnosis or failure to test or treat as required.

[61] Study of 86 patients seen by their primary care physicians two months after hospital discharge found 49% experienced medical errors and patients with a work-up error were 6.2 times more likely to be re-hospitalized within three months after the first outpatient visit. Carlton Moore et. al., *Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting*, 18:8 J. Gen. Internal Med. 646-51 (Aug. 2013), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494907/ (last visited Mar. 29, 2019).

[62] Sunil Kripalani, M.D., M.Sc., et. al., *Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care*, 297:8 JAMA 831-41 (Feb. 2007), available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.522.2320&rep=rep1&type=pdf (last visited Mar. 29, 2019); extracted and synthesized data from existing body of research and found that direct communication between the hospital and primary care physician occurred less than 20 percent of the time, the availability of the discharge summary at the first post-discharge visit was less than 34 percent and remained poor even four weeks after discharge and affected the quality of care in 25 percent of follow-up visits.

[63] Diane Shannon, M.D., M.P.H, Effective Physician-to-Physician Communication: An Essential Ingredient for Care Coordination, 38(1) Physician Exec. J. 16-21 (Jan.-Feb. 2012), available at: http://www.mdwriter.com/uploads/1/8/0/3/18033585/md_to_md_communication_pej.pdf (last visited Mar. 29, 2019); *See also*, Stacey S. Brener, M.Sc., *Association Between In-Hospital Supportive Visits by Primary Care Physicians and Patient Outcomes: A Population-Based Cohort Study*, 11:6 J. Hosp. Med. 418-24 (June 2016), a retrospective cohort study of 164,059 patients, the 12 percent of patients who received visits from their primary care physicians had lower risks of adverse patient outcomes, fewer emergency room visits, and increased utilization of community health services; Carl van Walraven, M.D., M.Sc., *Effect of Discharge Summary Availability During Post-Discharge Visits on Hospital Readmission*, 17:3 J. Gen. Intern. Med. 186-92 (Mar. 2002), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495026/ (last visited Mar. 29, 2019), studied 888 patients discharged from a single hospital after treatment for an acute illness and found that the discharge summary was only given to the primary physician in 25 percent of cases and in those cases, the patients had a decreased risk of re-hospitalization compared to their counterparts; *See generally*, Gregory A. Harlan, et. al., *Improving Transitions of Care at Hospital Discharge—Implications for Pediatric Hospitalists and Primary Care Providers*, 32:5 J. Healthcare Quality 51-60 (Sept.-Oct. 2010); Vicenza Snow, M.D., et. al., *Transitions of Care Consensus Policy Statement: American College of Physicians, Society of General Internal Medicine, Society of Hospital Medicine, American Geriatrics Society, American College of Emergency Physicians, and Society for Academic Emergency Medicine*, 4:6 J. Hosp. Med. 364-370 (July 2009), available at: https://pdfs.semanticscholar.org/4d62/22d8eadfdb0e3dc7edad34cc86b1290afbd5.pdf (last visited Mar. 29, 2019).

have implemented continuity visits or increased communication procedures so the primary care provider can be consulted in the patient's care.[64]

Regulation of Hospitals

Hospitals are regulated by the AHCA.[65] Hospitals are not required to coordinate care with patients' primary care providers or to comply with patients' request for such coordination. There is no statutory requirement that a treating physician at a hospital consult with a patient's primary care provider during the admission, or notify such provider after a patient is discharged.

Patient Notification of Hospital Observation Status

When a patient enters a hospital, the physician or other practitioner responsible for a patient's care must decide whether the patient should be admitted for inpatient care. The factors considered include:

- The severity of signs and symptoms exhibited by the patient;
- The medical probability of something adverse happening to the patient;
- The need for diagnostic studies to assist in the admitting decision; and
- The availability of diagnostic procedures at the time when, and the location where, the patient presents.[66]

Observation status is commonly ordered for a person who presents to the emergency department and requires treatment or monitoring to determine if he or she should be admitted or discharged.[67] A patient receives observation services when on observation status and can spend one or more nights in the hospital. These services can occur in the hospital's emergency department or in another area of the hospital.[68]

Observation services are covered under Medicare Part B, rather than Part A, so some patients with Medicare will experience an increase in out-of-pocket costs for observation services versus being admitted to the hospital.[69] For example, hospital inpatient services are covered under Medicare Part A and require the patient to pay a one-time deductible ($1,364) for the first 60 days of his or her stay. Alternately, hospital outpatient services, including observation services, are covered under Medicare Part B and require the patient to pay a deductible ($185) as

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[64] Allan H. Goroll, M.D. and Daniel P. Hunt, M.D., *Bridging the Hospitalist-Primary Care Divide Through Collaborative Care*, 372:4 N. Engl. J. Med. 308-309 (Jan. 2015), available at: https://www.researchgate.net/publication/271222735_Bridging_the_HospitalistPrimary_Care_Divide_through_Collaborative_Care (last visited Mar. 29, 2019); *See also*, Larry Beresford, *Continuity Visits by Primary Care Physicians Could Benefit Inpatients*, The Hospitalist (Apr. 2015), https://www.the-hospitalist.org/hospitalist/article/122479/continuity-visits-primary-care-physicians-could-benefit-inpatients (last visited Mar. 29, 2019).

[65] Ch. 395, F.S.

[66] Medicare Benefit Policy Manual, ch. 1 § 10, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html (last visited Mar. 13, 2019).

[67] *Id* at ch. 6 § 20.6.

[68] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Product No. 11435, *Are You a Hospital Inpatient or Outpatient? If You Have Medicare – Ask!* (May 2014) available at https://www.medicare.gov/Pubs/pdf/11435-Are-You-an-Inpatient-or-Outpatient.pdf (last visited Mar. 12, 2019).

[69] AARP Public Policy Institute, *Rapid Growth in Medicare Hospital Observation Services: What's Going On?*, p. 1 (September 2013), available at http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2013/rapid-growth-in-medicare-hospital-observation-services-AARP-ppi-health.pdf (last visited Mar. 12, 2019).

well as 20 percent of the Medicare-approved amount for doctor services.[70] A person who is treated for an extended period of time as a hospital outpatient receiving services may incur greater financial liability. However, it can be difficult for a person to determine his or her status based purely on the type of care provided at the hospital.[71]

Once a person is discharged from a hospital, additional rehabilitation in a nursing home is often necessary. Hospital admission can affect a person's eligibility for other services.[72] When a person is admitted and has a three-night inpatient stay in a hospital[73] and needs rehabilitative care, Medicare Part A will pay for up to 60 days in a skilled nursing facility. However, if a person is not admitted to the hospital – such as when a patient is under observation status for the duration of the hospital stay – and subsequently goes into a nursing home, the patient will have not met the requirements of a qualifying inpatient hospital stay, and Medicare will not pay for the skilled nursing facility care.[74]

The federal Notice of Observation Treatment and Implication for Care Eligibility Act requires hospitals to provide the Medicare Outpatient Observation Notice (MOON) to patients when observation status services last more than 24 hours.[75] The MOON must be provided to the patient if the patient is discharged, transferred, or admitted within 36 hours. The notice informs patients that observation status may affect their health care costs.

Florida law requires hospitals to notify patients or a patient's proxy of their observation status through documentation in the patient's discharge papers provided when leaving the hospital.[76] The documentation is not required to inform patients that observation status may affect their health care costs.

Pediatric Cardiac Standards of Care

Current Standards for Pediatric Cardiac Services

Hospital facilities are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of ch. 408, F.S. Hospitals are also subject to the Certificate of Need (CON) provisions in Part I of ch. 408, F.S.

A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Certain specialty programs offered within a hospital may also be subject to a CON process as prescribed by statute. All health-care-related projects are subject to review and must file a CON

[70] Medicare.gov., *Medicare 2015 costs at a glance*, available at http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html (last visited Mar. 12, 2019) and 42 CFR s. 419.40.
[71] *See* Amanda Cassidy, *The Two-Midnight Rule*, Health Affairs, Health Policy Briefs (Jan. 22, 2015) available at http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=133 (last visited Mar. 12, 2019).
[72] *Id.*
[73] *See* 42 C.F.R. § 409.30. A patient must have a qualifying inpatient hospital stay, defined as three consecutive days of inpatient care, to be covered by Medicare Part A.
[74] *Id.*
[75] Centers for Medicare and Medicaid Services, Medicare Outpatient Observation Status, available at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/MOON.html (last viewed Mar. 29, 2019).
[76] Section 395.301, F.S.

application with the AHCA, unless specifically exempt from the process.[77] Examples of covered health-care-related projects include hospice services, skilled nursing facilities, intermediate care facilities for the developmentally disabled, organ transplantation, and level II and level III neonatal intensive care units. Additionally, programs for pediatric cardiac catheterization and pediatric open heart surgery are considered health-care-related projects.[78]

Pediatric Surgery Programs

Pediatric Open Heart Surgery Programs

Pediatric open heart surgery programs are regulated through the CON process and governed by Rule 59C-1.033, F.A.C. The administrative rule establishes five service areas, defines the pediatric patient as those patients under 15 years of age, and specific services included in a pediatric open heart surgery program. To be considered for an open heart surgery program, a facility must meet certain minimum requirements and provide additional services in the event complications arise during the performance of pediatric open heart surgery.[79]

The pediatric open heart surgery team must be available for elective open heart surgery eight hours per day, five days per week and available for rapid mobilization of the surgical and medical support teams for emergency cases 24 hours a day, seven days per week.[80]

For pediatric open heart surgery, any CON applicant must document an adequate number of the following properly trained personnel that can perform during surgery:

- A cardiovascular surgeon, board certified by the American Board of Thoracic Surgery, or board eligible.
- A physician to assist the operating surgeon.
- A board certified or board eligible anesthesiologist trained in open heart surgery.
- A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties.
- A perfusionist to perform extracorporeal perfusion, or a physician or specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.[81]

Follow-up care after open heart surgery must be provided in an intensive care unit that provides 24 hour nursing coverage with a nurse-to-patient ratio of no less than one nurse for every two patients for the first hours of post-operative care. The facility must have at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of the hospital seeking the CON

[77] Section 408.036, F.S.
[78] *See* s. 408.036(1)(f), F.S. (2018) and Rule 59C-1.004, F.A.C.
[79] Rule 59C-1.033, F.A.C., requires a facility be able to repair or replace heart valves; repair congenital heart defects; perform cardiac revascularization; repair or reconstruct intrathoracic vessels; and treat cardiac trauma, and provide the following additional services: cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases; pathology, including anatomical, clinical blood bank and coagulation laboratory services; anesthesiology, including respiratory therapy; radiology, including diagnostic nuclear medicine and magnetic resonance imaging studies; neurology; inpatient cardiac catheterization; non-invasive cardiographics, including electrocardiography, exercise stress testing, transthoracic and transesophageal echocardiography; intensive care; emergency care available 24 hours per day for cardiac emergencies; and extracorporeal life support (ECLS).
[80] Rule 59C-1.033(4)(b), F.A.C.
[81] Rule 59C-1.033(5)(a), F.A.C.

for a pediatric open heart surgery.[82] Back-up personnel must be available for consultation to the surgical team, including a clinical cardiologist, cardiologist, anesthesiologist, pathologist, thoracic surgeon, and radiologist.

Pediatric Cardiac Catheterization and Angioplasty Institutional Health Services

As with the requirements for the pediatric open heart surgery program, the pediatric cardiac catheterization program requires a hospital to have a CON before it may operate its program. A cardiac catheterization is a medical procedure requiring the passage of a catheter into one or more cardiac chambers with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.[83]

A facility must demonstrate as part of the CON approval process that it is capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording to evaluate valvular disease or heart failure.[84] The facility must also ensure a range of additional services and equipment are available within the facility.[85]

The cardiac catheterization team must be capable of rapidly mobilizing within 30 minutes, 24 hours a day, seven days a week for emergency procedures.[86] The team must be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease or heart failure.[87] The team must be able to document these standards.

In addition to documentation of the required staff[88] that is available to perform the pediatric cardiac catheterization and angiographic processes, the CON applicant facility is required to have a department, service, or other similar unit organized, directed, staffed, and integrated with the other units and departments of the hospital to assure the provision of quality of care.[89] A pediatric catheterization program must also be co-located at a facility where pediatric open heart surgeries are performed.[90]

[82] Rule 59C-1.033(5)(b), F.A.C.
[83] Rule 59C-1.032(2), F.A.C.
[84] Rule 59C-1.032(3)(a), F.A.C.
[85] Rules 59C-1.032(3)(b) and 59C-1.032(3)(b), F.A.C. Additional services and equipment include: hematology studies or coagulation studies; electrocardiography; chest x-ray; blood gas studies; clinical pathology studies and blood chemistry analysis; a special procedure x-ray room; a film storage and darkroom for proper processing of films; x-ray equipment with the capability in cineangiocardiography, or equipment with similar capabilities; an image intensifier; an automatic injector; a diagnostic x-ray examination table for special procedures; an electrocardiograph; a blood gas analyzer; a multi-channel polygraph; emergency equipment, including but not limited to, a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator; biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40mL/s; and one or more crash carts containing the necessary medication and equipment for ventilatory support, which must be located in each pediatric cardiac catheterization procedure room.
[86] Rule 59C-1.032(4)(a), F.A.C.
[87] Rule 59C-1.032(3)(a), F.A.C.
[88] The staff required for these programs are listed in Rule 59C-1.032(b), F.A.C.
[89] Rule 59C-1.032(5)(a), F.A.C.
[90] Rule 59C-1.032(6), F.A.C.

Pediatric cardiac facilities granted CONs under either program are required to provide the AHCA with quarterly utilization reports within 45 days of the end of each quarter showing the number of pediatric procedures under both programs.

Technical Advisory Panel for Pediatric Cardiac Programs

During the 2017 Legislative Session, a Technical Advisory Panel (panel) for Pediatric Cardiac Programs was established to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric cardiac cardiovascular programs, and make recommendations about regulatory guidelines for pediatric open heart surgery programs. The panel is housed administratively at the AHCA, and appointments to the panel are made by the AHCA Secretary in accordance with the statutory guidelines.

To be eligible as a voting member on the panel, a hospital must maintain its pediatric CON and the individual member must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.[91]

The AHCA Secretary appoints three at-large members, one of whom is a cardiologist who is board certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists. None of the three at-large members may be employed by any of the named facilities who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officer of their respective hospitals, plus an alternate member. The named member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

The panel membership comprises the following:

Cardiac Program Technical Advisory Panel Membership[92]			
Members\Type of Members:	**Voting**	**Alternate**	**Non-Voting**
Johns Hopkins All Children's Hospital in St. Petersburg	■	■	
Arnold Palmer Hospital for Children in Orlando	■	■	
Joe DiMaggio Children's Hospital in Hollywood			
Nicklaus Children's Hospital in Miami	■	■	
St. Joseph's Children's Hospital in Tampa	■	■	
University of Florida Health Shands Hospital in Gainesville	■	■	
University of Miami Holtz Children's Hospital in Miami	■	■	
Wolfson Children's Hospital in Jacksonville	■	■	
Florida Hospital for Children in Orlando	■	■	
Nemours Children's Hospital in Orlando	■	■	
AHCA Secretary may appoint following nonvoting members:			
Secretary, AHCA			■
Surgeon General, DOH			■
Deputy Secretary of Children's Medical Services, DOH			■
Any current or past Director of Children's Medical Services, DOH			■
A parent of a child with congenital heart disease			■
An adult with congenital heart disease			■
3- At Large Members			

[91] Section 395.1055(9)(a) and (b), F.S.
[92] Section 395.1055(9)(b) and (c), F.S.

Cardiac Program Technical Advisory Panel Membership[92]			
Members\Type of Members:	**Voting**	**Alternate**	**Non-Voting**
1 Cardiologist - Board Certified in caring for adults with congenital health disease	■		
2 Pediatric Cardiologists – Board Certified	■		
A representative from each of the following organizations:			
Florida Chapter of the American Academy of Pediatrics			■
Florida Chapter of the American College of Cardiology			■
Greater Southeast Affiliate of the American Heart Association			■
Adult Congenital Heart Association			■
March of Dimes			■
Florida Association of Children's Hospitals			■
Florida Society of Thoracic and Cardiovascular Surgeons			■

The panel is required to meet at least biannually, or more frequently, upon the call of the AHCA Secretary. Meetings may be held telephonically or by other electronic means. The panel has held at least 26 meetings since its inception in 2017, and has been working toward proposed rules and policies on cardiology, surgery, public reporting and transparency, and facility standards.

At a minimum, the statute requires the panel to make recommendations for additional rules and standards for pediatric cardiac programs[93] which must include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery services, including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.
- Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

By January 1, 2020, the panel is required to submit an annual report to the Governor, President of the Senate, the Speaker of the House of Representatives, the AHCA Secretary, and the Surgeon General which summarizes the panel's activities during the preceding fiscal year. The report must include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.[94]

Once the panel has developed recommendations for pediatric cardiac care, the panel will forward such recommendations to the AHCA for adoption through the formal administrative rulemaking process.[95]

[93] Chapter 395, Florida Statutes, provides standards for cardiac programs. For example, a pediatric cardiac program must be affiliated with a hospital licensed under chapter 395; have a pediatric cardiac catheterization laboratory and pediatric cardiovascular surgical program located in the hospital; and have a risk-adjusted surgical procedure protocol which follows the guidelines established by the Society of Thoracic Surgeons. *Also see* The Society of Thoracic Surgeons, https://www.sts.org/about-sts (last visited March 13, 2019).
[94] Section 395.1055(9)(f), F.S.
[95] *See* s. 395.1055(10)(a-c) and (12), F.S.

Liability for Good Faith Actions

Currently, the volunteer physicians and other members of the panel are not covered by any liability or immunity clauses in the panel's implementing statute. During panel meetings, the members have held discussions relating to sovereign immunity for panel members when they are engaged in activities related to the panel.[96] Members on other panels, boards of directors, or volunteers in programs have been granted similar provisions of immunity for their official actions by the Legislature, such as individuals in the Division of Rehabilitation and Liquidation of the Department of Financial Services,[97] guardians ad litem,[98] and employees and board of directors of the Health Maintenance Organization Consumer Assistance Plan.[99]

Children's Medical Services

Children's Medical Services (CMS) is a group of programs administered by the Department of Health (DOH) that serve children with special health care needs.[100] One such program is the newborn screening program, which screens all newborns in Florida for 32 core disorders and 22 secondary disorders, unless a parent objects in writing.[101] The most recently added disorders to the newborn screening panel include critical congenital heart disease (CCHD), X-linked adrenoleukodystrophy (X-ALD), Pompe, Muccupolysachariidosis Type I (MPS I), and spinal muscular atrophy (SMA). The newborn screening program currently tests for CCHD and X-ALD,[102] and the program is expected to begin testing for Pompe, MPS I, and SMA in the 2019-2010 fiscal year.[103]

Direct Primary Care

Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the provider-patient relationship. A DPC contractual agreement is not considered insurance and is not subject to regulation under the Florida Insurance Code (Code).[104] The agreement, however, must meet certain requirements, such as being in writing and including the scope of services, duration of the agreement, amount of the fees, and specifying what the fees cover under the agreement. A primary care provider, which includes a primary care group practice, or his or her agent, is exempted from any certification or licensure requirements in the

[96] Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel Meeting Minutes (October 2, 2018), pg. 3, http://ahca.myflorida.com/SCHS/PCTAP/docs/102518/PCTAPDraftMinutes100218.pdf (last visited March 13, 2019).
[97] *See* s. 631.391, F.S.
[98] *See* s. 61.405, F.S.
[99] *See* s. 631.825, F.S.
[100] *See* ss. 383.14 and 383.145, F.S., (newborn screening program); s. 391.301, F.S., (Early Steps Program); and ss. 391.055 and 409.974(4), F.S., (Children's Medical Services Managed Care Plan).
[101] Department of Health, *Newborn Screening* http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html (last visited April 5, 2019).
[102] *Id.*
[103] The sum of $3.8 million is provided in SB 2500, First Engrossed, the Senate's proposed 2019-2020 General Appropriations Bill, for the program to begin testing for Pompe, MPS I, and SMA in the 2019-2020 fiscal year, *see* Section, 3, Specific Appropriations 467 and 469, at page 97; 474, at page 98; 480, at page 100; and 525, at page 106.
[104] Section 624.27, F.S.

Code for marketing, selling, or offering to sell an agreement, and establishes criteria for DPC agreements.[105]

A patient generally pays a monthly retainer fee– on average $77 per individual[106] – to the primary care provider for defined primary care services, such as office visits, preventative care, annual physical examination, and routine laboratory tests. An estimated 1,000 DPC practices exist in 48 states and the District of Columbia, covering over 330,000 patients, including Florida.[107]

After paying the monthly fee, a patient can access all services under the agreement at no extra charge contingent upon the agreement's provisions. Typically, DPC practices provide routine preventative services, screenings, or testing services, such as lab tests, mammograms, Pap screenings, and vaccinations. A primary care provider DPC model can be designed to address most health care issues, including women's health services, pediatric care, urgent care, wellness education, and chronic disease management.

DPC agreements in Florida are currently limited to primary care services offered by primary care providers licensed under chapters 458 (allopathic medicine), 459 (osteopathic medicine), 460 (chiropractic medicine), or 464 (nursing), or a primary care group practice.

Not all states call such arrangements DPC agreements or limit the agreements to primary care physicians. In Missouri, the agreement is a *medical retainer agreement* between a physician and an individual patient or a patient's representative. The Missouri statute requires that the fees for the agreement be paid from a health savings account in compliance with federal law.[108] In Alabama, the agreement is specific to both primary care physicians and dentists and is known as the *Alabama Physicians and Dentists Direct Pay Act.*[109]

Cost-Containment in Health Insurance

Step-Therapy Protocols

Insurers and health maintenance organizations (HMOs) use many cost containment and utilization review strategies to manage medical and drug spending and patient safety. For example, plans may impose clinical management or utilization management requirements on the use of certain medical treatments or drugs on their formulary. In some cases, insurers or HMOs require an insured to use a step-therapy protocol for drugs or a medical treatment, which requires

[105] *Id.*
[106] A study of 141 DPC practices found the average monthly retainer fee to be $77.38. Of the 141 practices identified, 116 (82 percent) have cost information available online. When these 116 practices were analyzed, the average monthly cost to the patient was $93.26 (median monthly cost, $75.00; range, $26.67 to $562.50 per month). Of the 116 DPCs noted, 36 charged a one-time enrollment fee and the average enrollment fee was $78. Twenty-eight of 116 DPCs charged a fee for office visits in addition to the retainer fee, and the average visit fee was $16. *See* Phillip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation,* Journal of the Amer. Bd. of Family Med. (Nov.-Dec. 2015) Vol. 28, No. 6, p. 797, *available at:* http://www.jabfm.org/content/28/6/793.full.pdf (last viewed Mar. 12, 2019).
[107] Direct Primary Care Coalition, *About the Direct Primary Care Coalition https://www.dpcare.org/about* (last viewed Mar. 12, 2019).
[108] Mo. Rev. Stat. §376.1800 (2015).
[109] 2017 Ala. Laws 460.

the insured to try one drug or medical procedure first to treat the medical condition before the insurer or HMO will authorize coverage for another drug or procedure for that condition.

Regulation of Health Insurance

Federal Law

The federal Patient Protection and Affordable Care Act (PPACA)[110] requires health insurers to make coverage available to all individuals and employers without exclusions for preexisting conditions, and mandates specified essential health benefits, including prescription drugs.[111] Insurers are required to publish a current and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the way a drug can be obtained, in a manner that is easily accessible to insureds, prospective insureds, and the public.[112]

Florida Regulatory Entities

The Office of Insurance Regulation (OIR) regulates the activities of insurers, HMOs, and other risk-bearing entities.[113] The AHCA regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.[114]

Florida State Employee Group Insurance Program

The Department of Management Services, through the Division of State Group Insurance, administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with s. 125, Internal Revenue Code.[115] To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a Pharmacy Benefits Manager for the state employees' prescription drug program.[116]

The Florida Medicaid Program

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, the AHCA oversees the Medicaid program.[117] The Statewide Medicaid Managed Care (SMMC) program comprises a Managed Medical Assistance (MMA) component and a Long-term Care (LTC) managed care component. The AHCA contracts with managed care plans to provide services to eligible enrollees.[118]

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[110] The Patient Protection and Affordable Care Act (Pub. L. 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.
[111] 42 U.S.C. s.18022.
[112] 45 C.F.R. s. 156.122(d).
[113] Section 20.121(3)(a), F.S.
[114] Section 641.21(1), F.S.
[115] Section 110.123, F.S.
[116] Section 110,12315, F.S.
[117] Parts II and III of ch. 409, F.S., govern the Medicaid managed care program.
[118] A managed care plan that is eligible to provide services under the SMMC program must have a contract with the agency to provide services under the Medicaid program and must also be a health insurer; an exclusive provider organization or a HMO authorized under ch. 624, 627, or 641, F.S., respectively; a provider service network authorized under s. 409.912(2), F.S., or an accountable care organization authorized under federal law. Section 409.962, F.S.

The benefit package offered by the MMA plans is comprehensive and covers all Medicaid state plan benefits (with very limited exceptions). This includes all medically necessary services for children. Most Florida Medicaid enrollees who are eligible for the full array of Florida Medicaid benefits are enrolled in an MMA plan. Florida Medicaid managed care plans cannot be more restrictive than these policies or the Florida Medicaid state plan (which is approved by the federal CMS) in providing services to their enrollees.

Health Care Price Transparency in Florida

Florida Patient's Bill of Rights and Responsibilities

Health care providers and health care facilities are required to make available to patients a summary of their rights under Florida law. Medical providers are expected to observe standards of care when providing medical treatment and communicating with their patients.[119] A patient has the right to request certain financial information from health care providers and facilities, such as a reasonable estimate of the cost of medical treatment prior to the provision of treatment.[120]

Price Transparency Required of Urgent Care Centers

Urgent care centers[121] are required to publish a schedule of charges for the medical services offered to patients.[122] The schedule requirements for urgent care centers are the same as those established for primary care providers, including the requirement the schedule include the prices charged to an uninsured person paying for such services by cash, check, or credit or debit card.[123] The schedule must describe each medical service in language comprehensible to a layperson. An urgent care center that fails to publish and post the schedule of charges is subject to a fine of not more than $1,000 per day.[124]

Price Transparency Required of Hospitals and Ambulatory Surgical Centers (ASCs)

Hospitals and ASCs are required, within 7 days of a written request, to provide a good faith estimate of reasonably anticipated charges for the facility to treat a patient's condition.[125] The estimate may represent the average charges for that diagnosis related group or the average charges for that procedure.[126] When providing the estimate, the facility is required to inform the

[119] Section 381.026(4), F.S. The standards of care are defined in terms of individual dignity; provision of information; financial information and the disclosure of financial information; access to health care; experimental research; and the patient's knowledge of rights and responsibilities.
[120] Section 381.026(4)(c), F.S.
[121] Section 395.002(29), F.S. An "urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care to patients. The term includes an offsite emergency department of a hospital that is presented to the general public in any manner as a department where immediate and not only emergent medical care is provided. The term also includes hospital-physician joint ventures (licensed under chapters 395 and 458, or 459, F.S., respectively); and health care clinics licensed under part X of ch. 400, F.S., that operate in three or more locations.
[122] Section 395.107(2), F.S. *See also:* s. 381.026(4)(c)3., F.S.
[123] Section 395.107(2), F.S.
[124] Section 395.107(6), F.S.
[125] Section 395.301, F.S.
[126] *Id.*

patient to contact their health insurer or health maintenance organization for additional information concerning cost-sharing responsibilities.[127]

Hospitals and ASCs must notify a patient during admission and at discharge of his or her right to receive an itemized statement or bill. If requested, within 7 days of discharge or release, the licensed facility must provide an itemized statement or bill detailing the specific nature of charges or expenses incurred by the patient. The initial statement or bill must contain a statement of specific services received and expenses incurred for the items of service, enumerating in detail the constituent components of the services received within each department of the licensed facility and including unit price data on rates charged by the licensed facility.[128]

Each Hospital and ASC is required to provide on its website information on payments made to that facility for defined bundles of services and procedures. The same information for each licensed facility is required to be made publicly available on pricing.floridahealthfinder.gov,[129] Florida Health Price Finder,[130] and provides consumers with the ability to research and compare health care costs in Florida at the national, state, and local levels. Supported by a database of more than 15 million lines of insurance claim data sourced directly from Florida insurers, the website displays costs as Care Bundles representing the typical set of services a patient receives as part of treatment for a specific medical conditions. Care Bundles are broken down into logical steps, which may include one or more procedures and tests and the 295 care bundles currently available on Florida Health Price Finder account for 90 percent of consumer searches on national pricing websites.

Portability of Health Care Occupational Licensure in America

Occupational Licensure Compacts

Interstate compacts are authorized under the U.S. Constitution, art. I, section 10, cl. 3.[131] Compacts that affect a power delegated to the federal government or that affect or alter the political balance within the federal system require the consent of Congress.[132] There are currently more than 200 compacts between the states, including 50 national compacts of which six are for health professions.[133,134]

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[127] *Id.*
[128] *Id.*
[129] Section 408.05, F.S.
[130] see https://pricing.floridahealthfinder.gov/#! (last visited Mar. 12, 2019).
[131] "No state shall, without the Consent of Congress…enter into any Agreement or Compact with another State, or with a foreign Power[.]" *see* U.S. Constitution, art. I, sect. 10, cl. 3. While the language of the provision says congressional approval is required, not all compacts require congressional approval.
[132] This issue was settled in *Virginia v. Tennessee*, 148 U.S. 503 (1893). *See also Interstate Compacts & Agencies (1998),* William Kevin Voit, Sr. Editor and Gary Nitting, Council of State Governments, pg. 7, http://www.csg.org/knowledgecenter/docs/ncic/CompactsAgencies98.pdf (last visited Mar. 8, 2019)
[133] Ann O'M. Bowman and Neal D. Woods, *Why States Join Interstate Compacts,* The Council of State Governments (March 2017) p. 19 and 20, http://knowledgecenter.csg.org/kc/system/files/Bowman%202017.pdf, (last visited Mar. 8, 2019).
[134] Federal Trade Commission, *Policy Perspectives: Options to Enhance Occupational License Portability* (September 2018), p. 9, https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Mar. 8, 2019). The six health professions are nurses, medical, emergency medical services, physical therapy, psychology, and advanced registered nurse practitioners. The only two compacts currently operational are the Enhanced Nurse Compact and the physicians compacts as the others are awaiting the completion of an administrative structure.

The licensing of professions is predominantly a state responsibility as each state has developed its own regulations, oversight boards, and requirements for dozens of professions and occupations. More than 25 percent of the American workforce are currently in a profession that requires a professional license.[135]

In September 2018, the Federal Trade Commission (FTC) looked at the issue of state-by-state occupational licensure and its unintended consequences. In particular, the FTC noted that state-by-state licensing can have a particularly hard effect on those in the military and their spouses who are required to move frequently, those who provide services across state lines, or deliver services through telehealth.[136] The FTC also suggested that improved licensed portability would enhance competition, choice, and access for consumers, especially where services may be in short supply.[137]

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (IMLC) provides an expedited pathway for medical and osteopathic physicians to qualify to practice medicine across state lines within a Licensure Compact. Currently, 24 states and one territory, which cover 31 medical and osteopathic boards participate in the IMLC, and, as of February 2019, six other states have active legislation to join the IMLC.[138, 139]

The Interstate Commission is created in Section 11 of the Compact and serves as the administrative arm of the Compact and member states. Each member state of the Compact has two voting representatives on the Commission. If a state has separate regulatory boards for allopathic and osteopathic, then the representation is split between the two boards.[140]

Approximately 80 percent of physicians meet the eligibility guidelines for licensure through the Compact.[141] The providers' applications are expedited by using the information previously submitted in their State of Principal Licensure (SPL), then the physician can select which states to practice in after a fresh background check is completed.

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[135] Albert Downs and Iris Hentze, *License Overload? Lawmakers are questioning whether we've gone too far with occupational and professional licensing (April 1, 2018),* STATE LEGISLATURES MAGAZINE, *ncsl.org*, http://www.ncsl.org/bookstore/state-legislatures-magazine/occupational-licensing-can-balance-safety-and-employment-opportunities.aspx (last visited Mar. 8, 2019).

[136] Federal Trade Commission, *Policy Perspectives: Options to Enhance Occupational License Portability (September 2018), Executive Summary,* https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Mar. 8, 2019).

[137] *Id*.

[138] Interstate Medical Licensure Compact, *The IMLC,* https://imlcc.org/ (last visited Mar. 8, 2019).

[139] Interstate Medical Licensure Compact, Draft Executive Committee Meeting Minutes (February 5, 2019), https://imlcc.org/wp-content/uploads/2019/02/2019-IMLC-Executive-Committee-Minutes-February-5-2019-DRAFT.pdf (last visited Mar. 8, 2019).

[140] Interstate Medical Licensure Compact, Section 11, (d), pg. 11, https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Mar. 8, 2019).

[141] Interstate Medical Licensure Compact, *The IMLC, https://imlcc.org/* (last visited Mar. 7, 2019).

To qualify for consideration, the physician must:

- Hold a full, unrestricted medical license from a Compact member state and meet one of the following additional qualifications:
  - The physician's primary resident is the State of Principal licensure (SPL).
  - The physician's practice of medicine occurs in the SPL for at least 25 percent of the time.
  - The physician's employer is located in the SPL.
  - The physician uses the SPL as his or her state of residence for U.S. federal income tax purposes.

Additionally, the physician must maintain his or her licensure from the SPL at all times. The SPL may be changed after the original qualification. Other requirements for eligibility for an IMLC Compact license include:

- Graduation from an accredited medical school, or a school listed in the International Medical Education Directory.
- Successful completion of graduate medical education from a school which has received accreditation from Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA).
- Passage – in no more than three attempts – of each component of the United States Medical Licensing Exam (USMLE) or the Comprehensive Osteopathic Medical Licensing Exam (COMLEX-USA) or equivalent.
- Holding a current specialty certification or time-unlimited certification by an American Board of Medical Specialties (ABMS) or American Osteopathic Association/Bureau of Osteopathic Specialists (AOABOS) board.
- Not having any history of disciplinary actions as to their medical license.
- Not having a criminal history.
- Not having any history of controlled substance actions as to their medical license.
- Not currently under investigation.[142]

The application cost is $700 plus the cost of the license for the state in which the applicant wishes to practice. The individual state fees currently vary from a low of $75.00 in Alabama to a high of $700 in Maine.[143]

Regulation of Physicians in Florida

Licensing of Florida Physicians

The regulation of the practices of medicine and osteopathic medicine fall under chapters 458 and 459, F.S., respectively. The practice acts for both professions establish the regulatory boards, a variety of licenses, the application process with eligibility requirements, and financial responsibilities for the practicing physicians. The boards have the authority to establish, by rule, standards of practice and standards of care for particular settings.[144] Such standards may include education and training, medication including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed

[142] Interstate Medical Licensure Compact, *Do I Qualify*, *https://imlcc.org/do-i-qualify/* (last visited Mar. 7, 2019).
[143] Interstate Medical Licensure Compact, *What Does It Cost?* https://imlcc.org/what-does-it-cost/ (last visited Mar. 8, 2019).
[144] Sections 458.331(1)(v) and 459.015(1)(z), F.S.

consent, and policy and procedures manuals.[145] The current licensure application fee for a medical doctor is $350 and is non-refundable.[146] Applications must be completed within one year. If a license is approved, the initial license fee is $355.[147] The entire process may take from t to 6 months from the time the application is received.[148]

For osteopathic physicians, the current application fee is non-refundable $200, and if approved, the initial licensure fee is $305.[149] The same application validity provision of one year applies and the processing time of two to six months is the range of time that applicants should anticipate for a decision.[150] If an applicant is licensed in another state, the applicant may request that Florida "endorse" those exam scores and demonstrate that the license was issued based on those exam scores. The applicant must also show that the exam was substantially similar to any exam that Florida allows for licensure.[151]

The general requirements for licensure under both practice acts are very similar with the obvious differences found in the educational backgrounds of the applicants. However, the practice acts are not identical in their licensure offerings as shown in the table below which compares some of the contents of the two practice acts. Where the practice acts share the most similarities are the qualifications for licensure. Both the Board of Medicine and the Board of Osteopathic Medicine require their respective applicants to meet these minimum qualifications:

- Complete an application form as designated by the appropriate regulatory board.
- Be at least 21 years of age.
- Be of good moral character.
- Have completed at least two years (medical) or three years (osteopathic) of pre-professional post-secondary education.
- Have not previously committed any act that would constitute a violation of this chapter or lead to regulatory discipline.
- Have not had an application for a license to practice medicine or osteopathic medicine denied or a license revoked, suspended or otherwise acted upon in another jurisdiction by another licensing authority.
- Must submit a set of fingerprints to the DOH for a criminal background check.
- Demonstrate that he or she is a graduate of a medical college recognized and approved by the applicant's respective professional association.

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[145] *Id.*
[146] Florida Board of Medicine, *Medical Doctor - Fees, https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted /*(Last visited Mar. 8, 2019).
[147] A change to Rule 64B-3.002, F.A.C., is effective March 11, 2019 which modifies the fee schedule for licensure applications. The fee for licensure by examination will increase to $500 and the fee for licensure by endorsement will increase also to $500. The time to complete an initial applications is also reduced from one year to six months.
[148] Florida Board of Medicine, *Medical Doctor Unrestricted – Process, https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/* (last visited Mar. 8, 2019).
[149] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Fees, https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/* (last visited: Mar. 8, 2019).
[150] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Process, https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/* (last visited Mar. 8, 2019).
[151] Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure – Requirements, https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/* (last visited Mar. 8, 2019).

- Demonstrate that she or he has successfully completed a resident internship (osteopathic medicine) or supervised clinical training (medical) of not less than 12 months in a hospital approved for this purpose by the applicant's respective professional association.
- Demonstrate that he or she has obtained a passing score, as established by the applicant's appropriate regulatory board, on all parts of the designated professional examination conducted by the regulatory board's approved medical examiners no more than five years before making application to this state; or, if holding a valid active license in another state, that the initial licensure in the other state occurred no more than five years after the applicant obtained a passing score on the required examination.[152]

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	**Medical Physicians**	**Osteopathic Physicians**
Regulatory Board	Board of Medicine s. 458.307, F.S.	Board of Osteopathic Medicine s. 459.004, F.S.
Rulemaking Authority	s. 458.309., F.S.	s. 459.005, F.S.
General Requirements for Licensure	s. 458.311, F.S.	s. 459.0055, F.S.
Licensure Types		
Restricted License	s. 458.310, F.S.	No provision
Restricted License Certain foreign physicians	s. 458.3115, F.S.	No provision
Licensure by Endorsement	s. 458.313, F.S.	No provision
Temporary Certificate (Approved Cancer Centers)	s. 458.3135, F.S.	No provision
Temporary Certificate (Training Programs)	s. 458.3137, F.S.	No provision
Medical Faculty Certificate	s. 458.3145, F.S.	s. 459.0077, F.S.
Temporary Certificate Areas of Critical Need	s. 458.315, F.S.	s. 459.0076, F.S.
Temporary Certificate Areas of Critical Need – Active Duty Military & Veterans	s. 458.3151, F.S.	s. 459.00761, F.S.
Public Health Certificate	s. 458.316, F.S.	No provision
Public Psychiatry Certificate	s. 458.3165, F.S.	No provision
Limited Licenses	s. 458.317, F.S.	s. 459.0075, F.S.
Expert Witness	s. 458.3175, F.S.	s. 459.0066, F.S.
License Renewal	s. 458.319, F.S. $500/max/biennal renewal	s. 459.008, F.S.
Financial Responsibility *Condition of Licensure*	s. 458.320, F.S.	s. 459.0085, F.S.

[152] *See* ss. 458.311, F.S. and 459.0055, F.S.

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	**Medical Physicians**	**Osteopathic Physicians**
Penalty for Violations	s. 458.327, F.S.	s. 459.013, F.S.

In Florida, to practice medicine an individual must become a licensed medical doctor through licensure by examination[153] or licensure by endorsement.[154] Florida does not recognize automatically another state's medical license or provide licensure reciprocity. Licensure by endorsement requires the medical physician to meet the following requirements:

- Be a graduate of an allopathic United States Medical School recognized and approved by the United States Office of Education (AMG) and completed at least one year of residency training;
- Be a graduate of an allopathic international medical school (IMG) and have a valid Educational Commission for Foreign Medical Graduates (ECFMG) certificate and completed an approved residency of at least two years in one specialty area; or
- Be a graduate who has completed the formal requirements of an international medical school except the internship or social service requirements, passed parts I and II of the National Board of Medical Examiners (NBME) or ECFMG equivalent examination, and completed an academic year of supervised clinical training (5th pathway) and completed an approved residency of at least two years in one specialty area.
- And both of the following:
  - Passed all parts of a national examination (the NBME; the Federation Licensing Examination offered by the Federation of State Medical Boards of the United States, Inc.; or the United States Medical Licensing Exam); and
  - Be licensed in another jurisdiction and actively practiced medicine in another jurisdiction for at least two of the immediately preceding four years; or passed a board-approved clinical competency examination within the year preceding filing of the application or; successfully completed a board approved postgraduate training program within 2 years preceding filing of the application.[155]

Financial Responsibility

Florida-licensed allopathic physicians are required to maintain professional liability insurance or other financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions.[156] Physicians who perform surgeries in a certain setting or have hospital privileges must maintain professional liability insurance or other financial responsibility to cover an amount not less than $250,000 per claim.[157] Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than $100,000 per claim.[158] Certain physicians who are exempted from the

[153] Section 458.311, F.S.
[154] Section 458.313, F.S.
[155] Florida Board of Medicine, *Medical Doctor-Unrestricted; Licensure by Endorsement,* https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/ (last visited Apr. 1, 2019).
[156] Section 458.320, F.S.
[157] Section 458.320(2), F.S.
[158] Section 458.320(1), F.S.

requirement to carry professional liability insurance or other financial responsibility must provide notice to their patients.[159]

Florida-licensed osteopathic physicians have similar financial responsibility requirements as allopathic physicians[160]. With specified exceptions, the DOH must suspend, on an emergency basis, any licensed allopathic or osteopathic physician who fails to satisfy a medical malpractice claim against him or her within specified time frames.[161]

Disciplinary Process: Fines and Sanctions

Chapter 456, F.S., contains the general regulatory provisions for health care professions and occupations under the Division of Medical Quality Assurance (MQA) in the DOH. Section 456.072, F.S., specifies 40 acts that constitute grounds for which disciplinary actions may be taken against a health care practitioner. Section 458.331, F.S., identifies 43 acts that constitute grounds for which disciplinary actions may be taken against a medical physician and s. 459.015, F.S., identifies those acts which are specific to an osteopathic physician. Some parts of the review process are public and some are confidential.[162]

Complaints and allegations are received by the MQA unit for determination of legal sufficiency and investigation. A determination of legal sufficiency is made if the ultimate facts show that a violation has occurred.[163] The complainant is notified by letter as to the whether the complaint will be investigated and if any additional information is needed. Complaints which involve an immediate threat to public safety are given the highest priority.

The DOH is responsible for reviewing each report to determine if discipline against the provider is warranted.[164] Authorization for the discipline of allopathic and osteopathic physicians can be found in state law and administrative rule.[165] If held liable for one of the offenses, the fines and sanctions by category and by offense are based on whether it is the physician's first, second, or third offense.[166] The boards may issue a written notice of noncompliance for the first occurrence of a single minor violation.[167] The amount of fines assessed can vary depending on the severity of the situation, such as improper use of a substance to concealment of a material fact. A penalty may come in the form of a reprimand, a licensure suspension, or revocation followed by some designated period of probation if there is an opportunity for licensure reinstatement. Other

[159] Section 458.320(5)(f) and (g), F.S.
[160] Section 459.0085, F.S
[161] Sections 458.320(8) and 459.0085(9), F.S.
[162] Fla. Department of Health, Division of Medical Quality Assurance, *Enforcement Process,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/_documents/enforcement-process-chart.pdf (last updated Mar. 11, 2019).
[163] Fla. Department of Health, *Consumer Services – Administrative Complaint Process,* http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/consumer-services.html (last visited Mar. 11, 2019).
[164] *See* ss. 458.351(5) and 459.026(5), F.S.
[165] *See* ss. 458.307 and 459.004, F.S., for the regulatory boards, and ss. 64B8-8 and 64B15-19, F.A.C., for administrative rules relating to disciplinary procedures.
[166] *Id.*
[167] Sections 64B8-8.011 and 64B15-19.0065, F.A.C. A minor violation is deemed to not endanger the public health, safety, and welfare and does not demonstrate a serious inability to practice.

sanctions may include supplemental continuing education requirements which require proof of completion before the license can be reinstated.

III. Effect of Proposed Changes:

Patient Records

Sections 1 through 5 direct that specified service providers required to release clinical or medical records must furnish applicable records in their possession within certain timeframes after receiving a request. These provider types and applicable authority are as follows:

- s. 394.4615, F.S., relating to mental health providers (Section 1),
- s. 395.3025, F.S., relating to hospitals and ambulatory surgical centers (Section 2),
- s. 397.501, F.S., relating to substance abuse treatment providers (Section 3),
- s. 400.145, F.S., relating to nursing facility providers (Section 4), and
- s. 456.057, F.S., relating to health care practitioners (Section 5).

Mental health and substance abuse treatment providers, hospitals, ambulatory surgical centers, and health care practitioners are required to furnish such records within 14 working days. Nursing facility providers are required to follow federal regulations which stipulate a resident must be provided such records upon request and with two working days advance notice to the facility.[168]

If a service provider or facility maintains a system of electronic health records,[169] the bill requires the service provider or facility to provide the records in the manner chosen by the requester, which may include:

- Paper document;
- Electronic format;
- Access through a web-based patient portal; or
- Submission through a patient's electronic personal health record.

The bill authorizes a service provider or facility to charge a requester no more than the reasonable costs of reproducing the clinical records, including reasonable staff time, and defines the reasonable costs of reproducing various forms of clinical records as follows:

- Written or typed documents or reports, in any format or medium, may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter; and
- X-rays and other forms of images must be the actual costs; and actual costs includes the cost of the material, supplies used to duplicate the record, and the labor and overhead costs associated with the duplication.

In addition to the charges above, a special service charge is authorized if the nature and volume of records requested requires extensive use of technology resources or extensive clerical or supervisory assistance by personnel of the service provider or facility. That special service charge must be reasonable and must be based on costs incurred.

[168] *See* 42 C.F.R. s. 483.10(g)(2)(ii).
[169] Section 408.051(2)(a), F.S., defines "Electronic health record" as a record of a person's medical treatment which is created by a licensed health care provider and stored in an interoperable and accessible digital format.

The bill directs that the reproduction charges apply to all records furnished, whether directly from a service provider or facility or from a copy service acting on behalf of a service provider or facility.

The bill directs that a patient whose records are being copied or searched for the purpose of continuing to receive care, may not be required to pay a charge for the copying or searching of their records.

In addition to the above provisions, the bill contains additional provisions applicable to specific provider types and facilities, including:

- Hospitals, ambulatory surgical centers, substance abuse treatment providers, nursing facility providers, and health care practitioners must provide that, within 10 working days of a request to view the provider's or facility's original records pertaining to a particular patient, from a requester who is authorized to have access, such requester must be provided access to examine such original records or other suitable reproductions. Service providers and facilities may impose reasonable terms to ensure that records are not damaged, destroyed, or altered in this process.
- The DOH, rather than the AHCA, is authorized to access records pursuant to a subpoena issued under s. 456.071, F.S.
- For purposes of access to substance abuse treatment records and health care practitioner records, the term "legal representative" is defined to mean an individual's guardian or, if the individual is younger than 18 years of age, his or her parent or legal guardian.

Hospital Quality Information

Section 6 amends s. 395.1012, F.S., to require each hospital to provide to any patient upon admission, upon scheduling of non-emergency care, or prior to treatment, written information on a form created by the AHCA that contains data reported for the most recent year available for the hospital and the statewide average for:

- The rate of hospital-acquired infections;
- The overall rating of the Hospital Consumer Assessment of Healthcare Providers Systems Survey; and
- The 15-day readmission rate.

The hospital must also provide the required data to any party upon request. The hospital must present the data in a manner that is easily understandable and accessible to the patient and include an explanation of the relationship between the data and patient safety.

Patient Access to Primary Care and Specialty Providers

Section 7 creates s. 395.1052, F.S., to require that a hospital notify a patient's primary care provider (PCP) within 24 hours of the patient's admission and discharge from the hospital. A hospital must also notify a patient of his or her right to request that the hospital's treating physician consult with the patient's PCP or specialist, and, if the patient so requests, the treating physician must make reasonable efforts to consult with the PCP or specialist when developing

the patient's plan of care. Additionally, a hospital is required to provide the discharge summary and any related information and records to the PCP within 14 days of the patient's discharge.

Notification of Hospital Observation Status

Section 8 amends s. 395.301, F.S., to require a hospital to provide a patient written notice of their observation status immediately when he or she is placed upon observation status. The bill requires Medicare patients receive the notice through the Medicare Outpatient Observation Notice form adopted under 42 C.F.R. s. 489.20, and non-Medicare patients through a form adopted by rule of the AHCA. The bill also makes conforming changes.

Pediatric Cardiac Technical Advisory Panel

Section 9 amends s. 395.1055, F.S., to modify the composition and duties of the Pediatric Cardiac Technical Advisory Panel (panel) as established in the AHCA by:

- Authorizing the AHCA to reimburse members of the panel for travel and per diem expenses.
- Authorizing the appointment of three alternate, at-large members from affiliations different than those of the voting at-large members.
- Adding a two-year term limit to voting panel members; however, members may be re-appointed to the panel after a two-year retirement period.
- Providing panel members immunity from criminal and civil liability for the good faith performance of duties assigned to them by the Secretary of the AHCA.
- Requiring the Secretary of the AHCA to consult with the panel for an advisory recommendation on all Certificate of Need (CON) applications to establish pediatric cardiac surgical centers.
- Authorizing the Secretary of the AHCA to request announced or unannounced site visits to any existing pediatric cardiac surgical center or a facility seeking licensure as a pediatric cardiac surgical center through the CON process to ensure compliance with the process.
- Authorizing the Secretary of the AHCA to request recommendations from the panel for in-state physician experts to conduct on-site visits and permitting the Secretary to appoint up to two out-of-state physician experts for such visits.
- Establishing procedures for site visit team on-site inspections of a hospital's pediatric medical and surgical programs and requiring each team member to submit a written report of their findings to the panel.
- Authorizing the panel to discuss the written reports from review team members and present an advisory opinion and suggested actions for correction to the Secretary of the AHCA.
- Requiring each on-site inspection to include:
  - An inspection of the program's physical facilities, clinics, and laboratories.
  - Interviews with support staff and hospital administration.
  - A review of randomly selected medical records and reports, clinical outcome data from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), mortality reports, and program volume data from the preceding year.
- Requiring the Surgeon General of the Department of Health to provide quarterly reports to the Secretary of the AHCA consisting of data from the Children's Medical Services' (CMS) critical congenital heart disease screening program for review by the panel.

Direct Health Care Agreements

Section 10 amends s. 624.27, F.S., to authorize direct care agreements with health care providers licensed under chapters 458 (medicine), 459 (osteopathic medicine), 460 (chiropractic medicine), or 464 (nursing), F.S., or a primary care group practice, for any health care service within their competency and training and adds health care providers licensed under ch. 466, F.S., (dentistry) to the list of providers who can provide direct health care services. Additionally, all references to "primary care" are replaced with "health care" throughout the section.

Step-Therapy Protocols

Sections 11-13 create s. 627.42393 and amend s. 641.31(45), and s. 409.973(6), F.S., respectively, relating to step-therapy protocols of health insurers and HMOs issuing major medical coverage, both individual and group, and Medicaid managed care plans. **Sections 11** and **12** are effective January 1, 2020, and will therefore apply to all such health insurance policies and HMO contracts issued or renewed on or after that date.

The sections prohibit an insurer, HMO, or Medicaid managed care plan from requiring a covered individual to undergo a step-therapy protocol under the policy, contract, or plan, respectively, for a covered prescription drug if the insured, subscriber, or recipient has been approved previously to receive the drug through the completion of a step-therapy protocol required by a separate health coverage plan[170] or Medicaid managed care plan, respectively; however, an insurer or HMO is not required to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer or HMO does not otherwise cover. To trigger this provision, a covered individual must provide documentation originating from the prior health coverage plan that the prescription drug was paid by the health coverage plan on behalf of the covered individual during the 180 days immediately prior to the request. The documentation requirement does not apply to a recipient enrolled in a Medicaid managed care plan. For Medicaid managed care, the AHCA must implement this requirement by amending the managed care plan contracts concurrent with the start of a new capitation cycle.

The term, "health coverage plan" means any of the following plans which previously provided coverage or is currently providing major medical or similar comprehensive coverage or benefits to the insured or subscriber: a health insurer or health maintenance organization, a plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, a multiple-employer welfare arrangement as defined in s. 624.437, F.S., or a governmental entity providing a plan of self-insurance.

[170] The bill defines the term "health coverage plan" to mean any of the following plans which previously provided coverage or is currently providing major medical or similar comprehensive coverage or benefits to the insured or subscriber: a health insurer or health maintenance organization, a plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, a multiple-employer welfare arrangement as defined in s. 624.437, F.S., or a governmental entity providing a plan of self-insurance.

Price Transparency for Services Covered by Health Insurance

Section 14 creates s. 627.4303, F.S., to prohibit a health insurer[171] from limiting a health care provider's ability to disclose whether a patient's cost-sharing obligation under his or her health coverage exceeds the cash price for a covered service in the absence of health insurance coverage or the availability of a more affordable service. The bill specifies that a health insurer may not require a covered individual to make payment for a covered service in an amount that exceeds the cash price of that service in the absence of health insurance coverage.

Interstate Medical Licensure Compact

Section 15 creates the Interstate Medical Licensure Compact (compact) as s. 456.4501, F.S., which enters Florida into the compact. The compact has 24 sections which establish the compact's administration and components and prescribe how the Interstate Medical Licensure Compact Commission will oversee the compact and conduct its business. The table below describes new statutory language, by compact section, which creates the components of the compact.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
1	Provides the purpose of the Compact Establishes prevailing standard of care	The purpose of the Interstate Medical Licensure Compact (compact) is to provide a streamlined, comprehensive process that allows physicians to become licensed in multiple states. It allows physicians to become licensed without changing a state's Medical Practice Act(s). The compact also adopts the prevailing standard of care based on where the patient is located at the time of the patient-provider encounter. Jurisdiction for disciplinary action or any other adverse actions against a physician's license is retained in the jurisdiction where the license is issued to the physician.
2	Definitions Establishes standard definitions for operation of the compact and the Commission.	Definitions are provided for: - Bylaws: means those Bylaws established by the Commission pursuant to Section 11 for governance, direction, and control of its action and conduct. - Commissioner: means the voting representative appointed by each member board pursuant to Section 11 whereby each member state appoints two members to the Commission. If the member state has two medical boards, the two representatives should be split between the two boards. - Conviction: means a finding by a court that an individual is guilty of a criminal offense through adjudication, or entry of a plea of guilt or no contest to the charge by the offender. A conviction also means evidence of an entry of a conviction of a criminal offense by the court

[171] The bill defines the term "health insurer" to mean a health insurer issuing major medical coverage through an individual or group policy or an HMO issuing major medical coverage through an individual or group contract.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		shall be considered final for the purposes of disciplinary action by a member board. - Expedited license: means a full and unrestricted medical license granted by a member state to an eligible physician through the process set forth in the compact. - Interstate Commission: means the interstate commission created pursuant to Section 11. - License: means authorization by a state for a physician to engage in the practice of medicine, which would be unlawful without the authorization. - Medical Practice Act: means laws and regulations governing the practice of allopathic and osteopathic medicine within a member state. (In Florida, the Medical Practice Act for allopathic medicine is under ch. 458, F.S., and for osteopathic medicine, under ch. 459, F.S.) - Member Board: means a state agency in a member state that acts in the sovereign interests of the state by protecting the public through licensure, regulation, and education of physicians as directed by the state government. (The Florida Board of Medicine and the Florida Board of Osteopathic Medicine are responsible for the licensure, regulation, and education of physicians in Florida.) - Member State: means a state that has enacted the compact. - Practice of medicine: means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical, or mental condition, by attendance, advise, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts. - Physician means: any persons who is a graduate of medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent; passed each component of the USMLE or the COMPLEX-USA within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes; successfully completed graduate medical education approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; holds specialty certification or time-unlimited specialty certificate recognized by the American Board of Medical Specialties or the American Osteopathic Association's Board of Osteopathic Specialties; however, the times unlimited specialty certificate does not have to be maintained once the physician is initially determined through the expedited compact process; possess a full and unrestricted license to engage in the practice of medicine issued by a member board; has never been convicted received adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction; has never held a license authorizing the practice of medicine subjected to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license; has never had a controlled substance license or permit suspended or revoked by a

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		state or the United States Drug Enforcement Administration; and is not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction. - Offense means: A felony, high court misdemeanor, or crime of moral turpitude. - Rule means: A written statement by the Commission promulgated pursuant to Section 12 of the compact that is of general applicability, implements, interprets, or prescribes a policy or provision of the compact, or an organizational, procedural, or practice requirement of the Commission, and has the force and effect of statutory law in a member state, if the rule is not inconsistent with the laws of the member state. The term includes the amendment, repeal, or suspension of an existing rule. - State means: Any state, commonwealth, district, or territory of the United States. - State of Principal License means: A member state where a physician holds a license to practice medicine and which has been designated as such by the physician for purposes of registration and participation in the compact.
3	Eligibility Provides minimum requirements to receive an expedited license	To be eligible to participate and receive an expedited license, a physician must meet the requirements of Section 2 (definition of physician). A physician who does not meet the requirements of Section 2 may obtain a license to practice medicine in a member state outside of the compact if the individual complies with all of the laws and requirements to practice medicine in that state.
4	State of Principal License (SPL) Defines a SPL	The compact requires participating physicians to designate a State of Principal License (SPL) for purposes of registration for expedited licensure if the physician possesses a full and unrestricted license to practice medicine in that state. The SPL must be a state where: - The physician has his/her primary residence, or - The physician has at least 25 percent of his/her practice, or - The state where the physician's employer is located. If no state qualifies for one of the above options, then the state of residence as designated on physician's federal income taxes. A SPL may be re-designated at any time as long as the physician possesses a full and unrestricted license to practice medicine in that state. The Commission is authorized to develop rules to facilitate the re-designation process.
5	Application and Issuance of Expedited Licensure	Section 5 of the compact establishes the process for the issuance of the expedited license. A physician must file an application with the member of the state selected as the SPL. The SPL will evaluate the application to determine whether the physician is eligible for the expedited

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	Qualifications *Commission rulemaking provisions*	licensure process and issue a letter of qualification, either verifying or denying eligibility, to the Commission. - Static Qualifications: Include verification of medical education, graduate medical education, results of any medical or licensing examinations and any other qualifications set by the Commission through rule. - Performance of Criminal Background Checks by the member board through FBI, with the exception of federal employees who have suitability determined in accordance with U.S. 5 CFR section 731.202. - Appeals on eligibility determinations are handled through the member state. - Upon completion of eligibility verification process with member state, applicant's suitable for an expedited license are directed to complete the registration process with the Commission, including the payment of any fees. - After receipt of registration and payment of fees, the physician receives his/her expedited license. The license authorizes the physician to practice medicine in the issuing state consistent with the Medical Practice Act and all applicable laws and regulations of the issuing member board and member state. - An expedited license shall be valid for a period consistent with the member state licensure period and in the same manner as required for other physicians holding a full and unrestricted license. - An expedited license obtained through the compact shall be terminated if a physician fails to monitor a license in the SPL for a non-disciplinary reason, without re-designation of a new SPL. - The Commission is authorized to develop rules relating to the application process, including fees and issuing the expedited license.
6	Fees for Expedited Licensure *Rulemaking authority*	A member state is authorized to charge a fee for an expedited license that is issued or renewed through the compact. The Commission is authorized is develop rules relating to fees for expedited licenses. The rules are not permitted to limit the authority of the member states, the regulating authority of the member states, or to impose and determine the amount of the fee charged by the member states.
7	Renewal and Continued Participation *Renewal license process created*	A physician with an expedited license in a member state must complete a renewal process with the Commission if the physician: - Maintains a full and unrestricted license in a SPL. - Has not been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction. - Has not had a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action relating to non-payment of fees related to a license.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	Continuing education required for renewal with member state *Fees collected, if any, by member state.* *Rulemaking authority.*	- Has not had a controlled substance license or permit suspended or revoked by a state or the United State Drug Enforcement Administration. Physicians are required to comply with all continuing education and professional development requirements for renewal of a license issued by a member state. The Commission shall collect any renewal fees charged for the renewal of a license and distribute the fees to the appropriate member board. Upon payment of fees, a physician's license shall be renewed. Any information collected during the renewal process shall also be shared with all member boards. The Commission is authorized to develop rules to address the renewal of licenses.
8	Coordinated Information Systems *Authorized to create database of all applicants* *By request, may share data* *Rulemaking authority*	The Commission is required to establish a database of all licensed physicians who have applied for licensure. Member boards are required to report disciplinary or investigatory actions as required by Commission rule. Member boards may also report any non-public complaint, disciplinary, or investigatory information not required to be reported to the Commission. Upon request, member boards shall share complaint or disciplinary information about physicians to another member board. All information provided to the Commission or distributed by the member boards shall be confidential, filed under seal, and used only for investigatory or disciplinary matters. The Commission is authorized to develop rules for mandated or discretionary sharing of information by member boards.
9	Joint Investigations *Permits joint investigations between the state and the member boards*	Licensure and disciplinary records of physicians are deemed investigative. A member board may participate with other member boards in joint investigations of physicians licensed by the member boards in addition to the authority granted by the member board and its respective Medical Practice Act or other respective state law. Member boards may share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the compact. Any member state may investigate actual or alleged violations of the statutes authorizing the practice of medicine in any other member state in which a physician holds a license to practice medicine.

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
10	Disciplinary Actions *Discipline by a member state has reciprocal actions* *Licensure actions specific actions to reinstate*	Any disciplinary action taken by any member board against a physician licensed through the compact shall be deemed unprofessional conduct which may be subject to discipline by other member boards, in addition to any violation of the Medical Practice Act or regulations in that State. If the physician's license is revoked, surrendered, or relinquished in lieu of discipline in the SPL, or suspended, then all licenses issued to that physician by member boards shall be automatically placed, without any further action necessary by any member board, on the same status. If the SPL subsequently reinstates the physician's license, a license issued to the physician by any other member board shall remain encumbered until that respective board takes action to specifically reinstate the license in a manner consistent with the Medical Practice Act in that state. If a disciplinary action is taken against the physician in a member state that is the physician's SPL, any other member state may deem the action conclusive as to matter of law and fact decided, and: - Impose the same or lesser sanction or sanctions against the physician so long as such sanctions are consistent with the Medical Practice Act of that state; or - Pursue separate disciplinary action against the physician under the Medical Practice Act, regardless of the action taken in other member states. If a license granted to a physician by a member board is revoked, surrendered, or relinquished in lieu of discipline, or suspended, then any license issued to the physician by any other member board or boards shall be suspended, automatically, and without further action necessary by the other board(s), for ninety (90) days upon entry of the order by the disciplining board, to permit the member board(s) to investigate the basis for the action under the Medical Practice Act of that state. A member board may terminate the automatic suspension of the license it issued prior to the completion of the ninety (90) day suspension period in a manner consistent with the Medical Practice Act of that state.
11	Interstate Medical Licensure Compact Commission *Recognizes creation of Commission*	The member states create the Interstate Medical Licensure Compact Commission as a joint agency of the member states and administration of the compact. The Commission has all the duties, powers, and responsibilities set forth in the compact, plus any other powers conferred upon it by the member states through the compact. Each member state has two (2) two voting representatives appointed by each member state to serve as Commissioners. For states with separate regulatory boards for allopathic and osteopathic regulatory

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	and state's representative with 2 Commissioners, one from each regulatory board *Availability of Commission meetings, except for certain topics* *Availability of public data from the Commission* *Public notice required* *Creates an executive committee to act on behalf of the Commission*	boards, the member state shall appoint one representative from each member board. A Commissioner shall be: - An allopathic or osteopathic physician appointed to a member board. - Executive director, executive secretary, or similar executive or a member board, or - Member of the public appointed to a member board. The Commission shall meet at least once per calendar year and at least a portion of the meeting shall be a business meeting which shall include the election of officers. The Chair may call additional meeting and shall call for all meeting upon the request of a majority of the member states. Meetings are permitted via telecommunication according to the Bylaws. Each Commissioner is entitled to one vote. A majority of Commissioners shall constitute a quorum, unless a larger quorum is required by the Bylaws of the Commission. A Commissioner shall not delegate a vote to another Commissioner. In the absence of its Commissioner, a member state may delegate voting authority for a specified meeting to another person from that state who meets the requirements of being a Commissioner. The Commission shall provide public notice of all meetings and all meetings shall be open to the public. A meeting may be closed to the public, in full or in portion, when it determines by a 2/3 vote of the Commissioners present, that an issue or matter would likely to: - Relate solely to the internal personnel practices and procedures of the Interstate Commission. - Discuss matters specifically exempted from disclosure by federal statute; - Discuss trade secrets, commercial, or financial information that is privileged or confidential; - Involve accusing a person of a crime, or formally censuring a person; - Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy; - Discuss investigative records compiled for law enforcement purposes; or - Specifically relate to the participation in a civil action or other legal proceeding. The Commission shall make its information and official records, to the extent, not otherwise designated in the Compact or by its rules, available to the public for inspection.

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Section	**Title**	**Description**
		An executive committee is established which has the authority to act on behalf of the Commission, with the exception of rulemaking, when the Commission is not in session. The executive committee shall oversee the administration of the compact, including enforcement and compliance with the compact, its bylaws and rules, and other such duties as necessary. The Commission may establish other committees for governance and administration of the compact.
12	Powers and Duties of the Interstate Commission *Recognizes creation of the Commission*	The Commission shall have the duties and the powers to: - Oversee and administer the compact. - Promulgate rules which are binding. - Issue advisory opinions upon the request of member states concerning the meaning or interpretation of the compact or its bylaws, rules, and actions. - Enforce compliance with the compact, provisions, the rules, and the bylaws. - Establish and appoint committees, including the executive committee, which has the power to act on behalf of the Interstate Commission. - Pay, or provide for the payment of Commission expenses. - Establish and maintain one or more offices. - Borrow, accept, hire, or contract for services of personnel. - Purchase and maintain insurance and bonds. - Employ an executive director with power to employ, select, or appoint employees, agents, or consultants, determine their duties, and fix their compensation. - Establish personnel policies and programs. - Accept donations and grants of money, equipment, supplies, materials, and services, and to receive, utilize and dispose of it consistent with conflict of interest policies as established by the Commission. - Lease, purchase, accept contributions, or donation of, or otherwise own, hold, improve or use, any property, real, personal, or mixed. - Establish a budget and make expenditures. - Adopt a seal and bylaws governing the management and operation of the Commission. - Report annually to the legislatures and governors of the members concerning the activities of the Commission during the preceding year, including reports of financial audits and any recommendations that may have been adopted by the Commission. - Coordinate education, training, and public awareness regarding the compact, its implementation and operation. - Maintain records in accordance with bylaws. - Seek and obtain trademarks, copyrights, and patents. - Perform such functions as may be necessary or appropriate to achieve the purpose of the compact.
13	Finance Powers	The compact authorizes an annual assessment levied on each member state to cover the costs of operations and activities of the

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
	Provides for annual assessment *Requires rule for any assessment* *No pledging credit without authorization* *Yearly audits*	Commission and its staff. The assessment must be sufficient to cover the amount not provided by other sources and needed to cover the annual budget approved each year by the Commission. The compact requires that the assessment be memorialized by rule binding all the member states. The Commission is not authorized to pledge the credit of any of the member states, except by, and with the authority of, the member states. The compact requires yearly financial audits conducted by a certified or licensed public accountant and the report is to be included in the Commission's annual report.
14	Organization and Operation of the Interstate Commission *Annual officer election* *No officer remuneration* *Liability protection for actions within scope of duties and responsibilities only for officers, employees, and agents*	The compact creates a requirement for the Commission to adopt bylaws by a two-thirds (2/3) vote within twelve months of the first meeting which has already occurred. The first Bylaws were adopted in October 2015.[172] A Chair, Vice Chair, and Treasurer shall be elected or appointed each year by the Commission. Officers serve without remuneration. Officers and employees are immune from suit and liability, either personally or in their professional capacity, for a claim for damage to or loss of property or personal injury or other civil liability cause or arising out of, or relating to, an actual or alleged act, error or omission that occurred with the scope of Commission employment, duties, or responsibilities, provided such person should not be protected from suit or liability for damage or loss, injury or liability caused by the intentional or willful and wanton conduct of such a person. The liability of the executive director and Commission employees or representatives of the Commission, acting within the scope of their employment, may not exceed the limits set forth under the state's Constitution and laws for state officials, employees, and agents. The compact provides that the Commission is considered an instrumentality of the state for this purpose. The compact provides that the Commission shall defend the executive director, its employees, and subject to the approval of the state's attorney general or other appropriate legal counsel, shall

[172] Interstate Medical Licensure Compact, *Annual Report 2017*, https://imlcc.org/wp-content/uploads/2018/03/IMLCC-Annual-Report-2017-1.pdf (last visited Mar. 11, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		defend in any civil action seeking to impose liability within scope of duties. The compact provides that employees and representatives of the Commission shall be held harmless in the amount of any settlement or fees, including attorney fees and costs, that occurred within the scope of employment or responsibilities and not a result of willful or wanton misconduct.
15	Rulemaking Functions of the Interstate Commission *Promulgate reasonable rules* *Judicial review at U.S. Federal District Court*	The Commission is required to promulgate reasonable rules in order to implement and operate the compact and the commission. The compact adds that any attempt to exercise rulemaking beyond the scope of the compact renders the action invalid. The rules should substantially conform to the "Model State Administrative Procedures Act" of 2010 and subsequent amendments thereto. The compact allows for judicial review of any promulgated rule. A petition may be filed thirty (30) days after a rule has been promulgated in the U.S. District Court in Washington, D.C., or the federal court where the Commission is located.[173] The compact requests deference to the Commission's action consistent with state law.
16	Oversight of Interstate Contract *Enforcement* *Service of process*	The compact is the responsibility of each state's own executive, legislative, and judicial branch to oversee and enforce. All courts are to take judicial notice of the compact and any adopted administrative rules in a proceeding involving compact subject matter. The compact provides that the Commission is entitled to receive service of process in any proceeding and shall have standing in any proceeding. Failure to serve the Commission shall render a judgment null and void as to the Commission, the compact, or promulgated rule.
17	Enforcement of Interstate Contract	The compact provides the Commission reasonable discretion to enforce the provisions and rules of the compact, including when and where to initiate legal action. The Commission is permitted to seek a range of remedies.
18	Default Procedures	The compact provides a number of reasons a member state may default on the compact, including failure to perform required duties and responsibilities and the options available to the Commission. The compact requires the Commission to promulgate rules to address how physician licenses are affected by the termination of a

[173] The Interstate Medical Licensure Compact Commission is currently headquartered in Littleton, Colorado. *See* Interstate Medical License Commission, Frequently Asked Questions (FAQS), https://imlcc.org/faqs/

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
		member state from the compact. The rules must also ensure that a member state does not bear any costs when a state has been found to be in default. The compact provides an appeal process for the terminating state and procedures for attorney's fees and costs.
19	Dispute Resolution	The compact authorizes the Commission to use dispute resolution tools to resolve disputes between states, such as mediation and binding dispute resolution. The Commission shall promulgate rules for the dispute resolution process.
20	Member States, Effective Date and Amendment	The compact allows any state to become a member state and that the compact is binding upon the legislative enactment of the compact by no less than seven (7) states.[174]
21	Withdrawal	A member state may withdraw from the compact through repeal of this section of law which inserted the compact into state statute. Any repeal of the compact through repeal of the state law cannot take effect until one (1) year after the effective date of such an action and written notice has been given by the withdrawing state to the governor of each other member state. The compact provision also requires that upon introduction of any repeal legislation, that the withdrawing state immediately notify the Chairperson of the Commission of the legislation. The compact provides that it is the Commission's responsibility to notify the other member states within 60 (sixty) days of its receipt of information about legislation that would repeal that state's participation in the compact. The withdrawing state would be responsible for any dues, obligations, or liabilities incurred through the date of withdrawal. Reinstatement is an option under the compact. The compact authorizes the Commission to develop rules to address the impact of the withdrawal of a member state on licenses.
22	Dissolution	When the membership of the compact is reduced to one, the compact shall be dissolved. Once dissolved, the compact shall be null and void. Once concluded, any surplus funds of the Commission shall be distributed in accordance with the bylaws.

[174] The Compact is in force now. The Commission was seated for the first time in October 2015 and issued its first letters of qualification to physicians in April 2017. *See* Interstate Medical Licensure Compact, *https://imlcc.org/faqs/* (last Mar. 11, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	**Title**	**Description**
23	Severability and Construction	If any part of this compact is not enforceable, the remaining provisions are still enforceable. The provisions of the compact are to be liberally construed. and nothing is to be construed so as to prohibit the applicability of other interstate compacts to which states might be members.
24	Binding Effect of Compact and Other Laws	This compact does not prohibit the enforcement of other laws which are not in conflict with this compact. All laws which are in a member state which are inconsistent with this compact are superseded to the point of the contact. The actions of the Commission are binding on the member states, including all promulgated rules and the adopted bylaws of the Commission. All agreements between the Commission and the member state are binding in accordance with their terms. In the event that any provision of this Compact exceeds Florida's constitutional limits imposed on the legislature of any member state, such provision shall be ineffective to the extent that the conflict of the constitutional provision in question in that member state.

Section 16 provides an effective date of July 1, 2019, except as otherwise provided in the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

Section 15. The Interstate Commission requires most of its meetings to be open to the public. The notice requirements vary depending on the purpose of the meeting, however. Rulemaking hearings, where rules are proposed in a manner substantially similar to the model state administrative procedure act of 2010, are submitted to the Bylaws and Rules Committee for review and action. Prior to final consideration by the Commission, the final proposed rule must be publicly noticed on the Commission's website or other agreed upon distribution site at least 30 days prior to the meeting at which the vote is scheduled.[175] A reason for the proposed rule action will also be posted.[176] The public must also be provided a reasonable opportunity to provide public comment, orally or in

[175] Interstate Medical Licensure Commission, *Rule on Rulemaking (Adopted June 24, 2016), Rule 1.4(c),* https://imlcc.org/wp-content/uploads/2018/02/IMLCC-Rule-Chapter-1-Rule-on-Rulemaking-Adopted-June-24-2016.pdf (last visited Mar. 11, 2019).
[176] *Supra,* Note 42, Interstate Medical Licensure Commission, *Rule on Rulemaking (Adopted June 24, 2016), Rule 1.4(b).*

writing, for proposed rules. A committee of the Commission may propose a rule at any time by a majority vote of that committee.

The written procedure states for every proposed rule action that there will also be instruction on how interested parties may attend the scheduled public hearing, may submit their intent to attend the public hearing and submit any written comments.[177] A transcript of these meetings are not made unless one is specifically requested and then the requestor is responsible for the cost the transcription.[178]

Not later than 30 (thirty) days after its adoption, any interested party may petition for judicial review of the rule in the United States District Court for the District of Columbia or in the federal court where the Commission's headquarters are currently located. The Commission's mailing address currently is in Littleton, Colorado.[179]

The compact also permits the commission, with a two-thirds vote of the Commissioners present, to meet in closed, nonpublic meetings if the commission must address any matters that:

- Relate solely to the internal personnel practices and procedures of the Interstate Commission.
- Specifically exempted from disclosure by federal statute;
- Discuss trade secrets, commercial, or financial information that is privileged or confidential;
- Involve accusing a person of a crime, or formally censuring a person;
- Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;
- Discuss investigative records compiled for law enforcement purposes; or
- Specifically relate to the participation in a civil action or other legal proceeding.[180]

The rulemaking process, its timelines and public involvement process, plus the closure of public meetings for some of these detailed reasons, may be inconsistent with Florida law on public meetings.

While the provisions of the compact and its administrative rules and corporate bylaws require minutes to be kept of some of these closed sessions, it is not clear that it is applicable to all closed sessions and it does require an interested party to request a transcriber in some cases to be present and to expend personal funds to ensure the availability of minutes. A third party may or may not be as likely either to fully describe all matters discussed and provide an accurate summary of actions taken, including a record of any roll call votes.[181]

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[177] *Supra,* Note, 42, Interstate Medical Licensure Commission, *Rule on Rulemaking (Adopted June 24, 2016), Rule 1.4(d).*
[178] *Supra* Note 42, Interstate Medical Licensure Commission, *Rule on Rulemaking (Adopted June 24, 2016), Rule 1.4(e).*
[179] Interstate Medical Licensure Compact, FAQs, *https://imlcc.org/faqs/* (last visited Mar. 10, 2019).
[180] Interstate Medical License Compact Bylaws, *Section 11 – Interstate Medical License Compact Commission, Section (h)-(l), https://imlcc.org/wp-content/uploads/2018/04/IMLC-Compact-Law.pdf (last visited Mar. 11, 2019).*
[181] *Id.*

According to the Commission's Bylaws, the public notice for a regular meeting of the Commission is at least ten (10) days prior to the meeting according to the compact and the notice will be posted on the Commission's website or distributed through another website designated by the Commission for interested parties to receive notice who have requested to receive such notices.[182]

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

Article VII, section 19 of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, section 19(d)(1) of the State Constitution defines "fee" to mean "any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service."

Section 15 of the bill authorizes the Interstate Medical Licensure Compact to assess and collect fees from allopathic and osteopathic physicians who elect to participate in the expedited licensure process.

For physicians who elect this license, a non-refundable service fee of $700 for the letter of qualification is charged to the applicant when the initial application is submitted to the Interstate Commission on Medical Licensure (ICML). Of that $700, $300 is remitted to the applicant's home state or state of principal licensure and the remaining $400 is sent to the Interstate Commission's general fund.

Every time the applicant requests that a letter of qualification be disseminated to one or more of the member states that participate in the ICML after the initial dissemination of the letter for the expedited license, the cost to the registrant is $100. Of this amount, one hundred percent is sent to the ICML General Fund.

For each expedited licensed that is renewed through the compact, a non-refundable fee of $25 shall be assessed to the physician and paid to the ICML General Fund. The ICML receives 100 percent of these funds.

E. Other Constitutional Issues:

The Interstate Compact authorizes compact administrators to develop rules that member states must adopt, which is potentially an unlawful delegation of legislative authority. If enacted into law, the state will bind itself to rules not yet promulgated and adopted by the commission. The Florida Supreme Court has held that while it is within the province of the Legislature to adopt federal statutes enacted by Congress and rules promulgated by federal administrative bodies that are in existence at the time the Legislature acts, it is an

[182] *Id.*

unconstitutional delegation of legislative authority to prospectively adopt federal statutes not yet enacted by Congress and rules not yet promulgated by federal administrative bodies.[183,184] Under this holding, the constitutionality of the bill's adoption of prospective rules might be questioned, and there does not appear to be Florida case law that squarely addresses this issue in the context of interstate compacts.

The most recent case Florida courts have had to address this issue was in *Department of Children and Family Services v. L.G.*, involving the Interstate Compact for the Placement of Children (ICPC).[185] The First District Court of Appeal considered an argument that the regulations adopted by the Association of Administrators of the Interstate Compact were binding and that the lower court's order permitting a mother and child to relocate to another state was in violation of the ICPC. The court denied the appeal and held that the Association's regulations did not apply as they conflicted with the ICPC and the regulations did not apply to the facts of the case.

The court also references language in the ICPC that confers to its compact administrators the "power to promulgate rules and regulations to carry out more effectively the terms and provisions of this compact."[186] The court states that "the precise legal effect of the ICPC compact administrators' regulations in Florida is unclear," but noted that it did not need to address the question to decide the case.[187] However, in a footnote, the court said:

> Any regulations promulgated before Florida adopted the ICPC did not, of course, reflect the vote of a Florida compact administrator, and no such regulations were ever themselves enacted into law in Florida. When the Legislature did adopt the ICPC, it did not (and could not) enact as the law of Florida or adopt prospectively regulations then yet to be promulgated by an entity not even covered by the Florida Administrative Procedure Act. *See Freimuth v. State*, 272 So.2d 473, 476 (Fla.1972); *Fla. Indus. Comm'n v. State ex rel. Orange State Oil Co.,* 155 Fla. 772, 21 So.2d 599, 603 (1945) ("[I]t is within the province of the legislature to approve and adopt the provisions of federal statutes, and all of the administrative rules made by a federal administrative body, that are in existence and in effect at the time the legislature acts, but it would be an unconstitutional delegation of legislative power for the legislature to adopt in advance any federal act or the ruling of any federal administrative body that Congress or such administrative body might see fit to adopt in the future."); *Brazil v. Div. of Admin.,* 347 So.2d 755, 757–58 (Fla. 1st DCA 1977), *disapproved on other grounds by LaPointe Outdoor Adver. v. Fla. Dep't of Transp.,*

[183] *Freimuth v. State*, 272 So.2d 473, 476 (Fla. 1972) (quoting *Fla. Ind. Comm'n v. State ex rel Orange State Oil Co.,* 155 Fla. 772 (1945).
[184] This prohibition is based on the separation of powers doctrine, set forth in Article II, Section 3 of the Florida Constitution, which has been construed in Florida to require the Legislature, when delegating the administration of legislative programs, to establish the minimum standards and guidelines ascertainable by reference to the enactment creating the program. *See Avatar Development Corp. v. State*, 723 So.2d 199 (Fla. 1998).
[185] 801 So.2d 1047 (Fla. 1st DCA 2001).
[186] Id at 1052.
[187] Id.

398 So.2d 1370, 1370 (Fla.1981). The ICPC compact administrators stand on the same footing as federal government administrators in this regard.[188]

In accordance with that footnote, the bill's delegation of rule-making authority to the commission is similar to the delegation to the ICPC compact administrators, and thus, could constitute an unlawful delegation of legislative authority. The referenced case, however, does not appear to be binding as precedent as the court's footnote discussion is dicta.[189]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Sections 1 through 5, in **s**pecifying a specific cost for various forms of copies of clinical and medical records, could reduce the costs of a patient obtaining copies of his or her records.

Section 10, by modifying the availability of direct patient contracting for health care services, access to expanded health care services may be extended to patients who may not otherwise have access to certain types of health care services or in underserved or rural areas of the state. Statistics also show that more than one third of current direct primary care patients nationally are Medicare patients.

Current Florida law allows physicians to contract only for primary care agreements. This bill removes that restriction and expands the scope of those agreements so patients may have additional options. This model is seen as a mechanism for providers to reduce their administrative burdens with payers. By adding reimbursement options for more provider types and health care services, provider access may be improved for Floridians.

C. Government Sector Impact:

Section 6. The bill will create an insignificant negative fiscal impact to the Agency for Health Care Administration (AHCA) to create the form hospitals must provide to patients, and any other person upon request, pertaining to required hospital quality measures, and the additional workload for the AHCA to monitor compliance by hospitals of such requirements. The fiscal impact can be absorbed within existing resources of the AHCA.[190]

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[188] *Id.*

[189] Dicta are statements of a court that are not essential to the determination of the case before it and are not a part of the law of the case. Dicta has no biding legal effect and is without force as judicial precedent. 12A FLA JUR. 2D *Courts and Judges* s. 191 (2015).

[190] Email from James Kotas, Agency for Health Care Administration (April 2, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

Section 8. The bill requires the AHCA to create a form for hospitals and ambulatory surgical centers to immediately notify non-Medicare patients of their placement on observation status. Such form must be adopted by the AHCA through rule which will create an insignificant negative fiscal impact that can be absorbed within existing resources of the AHCA.[191]

Section 9. The bill authorizes, but does not require, the AHCA to reimburse members of the Pediatric Cardiac Technical Advisory Council Panel (panel) for per diem and travel expenses; therefore, there is no impact on state expenditures. The AHCA estimates an annual cost of approximately $21,000 if it were to reimburse panel members.[192]

The bill authorizes, but does not require, the Secretary of the AHCA to request announced or unannounced site visits of existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process. At the Secretary's request, the panel must recommend in-state physician experts to conduct such on-site visit, and the Secretary may appoint up to two out-of-state physician experts. The bill does not establish a deadline nor a frequency for the site visits required of existing pediatric cardiac centers; however, the panel has recommended that experts conduct three annual site visits.[193] The increase in state expenditures as a result of the onsite visits for the existing pediatric cardiac centers is addressed through an appropriation of $150,000 in SB 2500, First Engrossed, the Senate's proposed General Appropriations Bill for the 2019-2020 fiscal year.[194] The number of facilities seeking licensure as a pediatric cardiac surgical center is unknown; therefore, the fiscal impact of conducting onsite visits prior to the completion of the certificate of need process is indeterminate.

The Surgeon General of the Department of Health (DOH) is required to provide a quarterly report to the Secretary of the AHCA that summarizes data from the Children's Medical Services critical congenital heart disease (CCHD) newborn screening program. This data will be reviewed by the panel. The bill does not specify the data to be included in such quarterly report. According to the DOH, the current aggregate data collected and provided to the Genetic and Newborn Screening Advisory Council (GNSAC) for CCHD is minimal. To the extent that the information required in the quarterly report is the same data that is provided to the GNSAC, there would be no increase in state expenditures; however, if the requested data exceeds that which is provided to the GNSAC, then there would be an indeterminate increase in state expenditures.[195]

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[191] *Id.*
[192] *Id.*
[193] Pediatric Technical Advisory Panel, Agency for Health Care Administration, *Draft Meeting Minutes*, pg. 2 (Dec. 13, 2018), *available at:* http://ahca.myflorida.com/SCHS/PCTAP/docs/020719/PCTAPDraftMinutes121318.pdf (last visited Apr. 5, 2019).
[194] *See* SB 2500, First Engrossed, the Senate's proposed Fiscal Year 2019-2020 General Appropriations Bill, Section 3, Specific Appropriation 226, at page 61. An appropriation of $150,000 of nonrecurring funds from the Health Care Trust Fund is provided to the Agency for Health Care Administration for the Pediatric Cardiac Technical Advisory Panel.
[195] Email correspondence from Gary Landry, Department of Health (April 5, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

Section 13. The bill prohibits Medicaid managed care plans from requiring an enrolled Medicaid recipient to use a step-therapy protocol before the plan approves a requested covered prescription drug if the recipient has already been approved to receive the drug through the completion of a step-therapy protocol employed by another Medicaid managed care plan which paid for the drug on the recipient's behalf during the 180 days immediately prior to the request. This provision could have a negative fiscal impact on the Medicaid program to the extent that it causes Medicaid managed care plans to spend more on prescription drugs than they currently spend under current law. Whether such a result will materialize is indeterminate.[196]

Section 15. As a member state to the compact, the state will see an increased volume in the number of licensure applications at the Division of Medical Quality Assurance, Board of Medicine, and Board of Osteopathic Medicine. Applicants for the expedited licensure process must have a designated state of principal license (SPL) where the physician has acquired his full and unrestricted license to practice medicine, is in good standing, practices medicine at least 25 percent of the time, is the physician's primary state of residence, or is the location of the physician's employer. Applications for an expedited license with a member board through the Interstate Commission would first go through a Florida eligibility vetting process to issue a letter of qualification or to deny a letter of qualification.

The DOH could experience an indeterminate increase in administrative costs from:

- Processing applications from out-of-state physicians for expedited licensure under the compact;
- Conducting a fresh background screening for Florida physicians wishing to apply for licensure in other member compact states:
- Participation in joint investigations and disciplinary actions related to physicians located within member states of the Interstate Commission; and
- Information technology costs related to information sharing between the DOH and the Interstate Commission.

The Interstate Commission is authorized to levy an annual assessment on member states to offset the Commission's administrative and information technology costs. The cost of the annual assessment is indeterminate because the amount of the assessment is contingent on the formula developed by the Commission and is proportional to the number of participating member states.

The state could experience a need for additional resources at DOH to handle an increase in physician applications for expedited licensure under the compact, as well as additional revenue from application fees. The resulting overall impact of **Section 15** is indeterminate.

Overall, the bill has an indeterminate fiscal impact on state revenues and state expenditures.

[196] *Supra* note 208.

VI. Technical Deficiencies:

Line 553 of the bill authorizes panel members to be reimbursed for travel and per diem; however, the provision does not include the statutory cross reference to s. 112.061, F.S., which limits travel reimbursement for individuals who travel on public business. Without the cross reference to the state guidelines, a different travel reimbursement schedule could be implemented for the panel members.

Line 621 of the bill grants immunity to panel members from any civil or criminal liability for events resulting from their good faith performance of duties assigned to them by the Secretary of the AHCA; however, the use of the term "immunity" is likely broader than intended, and could have unintended consequences. An amendment should be considered to clarify that the panel members are instead granted sovereign immunity in the performance of their duties rather than civil liability.

Lines 671 through 697 of the bill authorizes the Pediatric Cardiac Technical Advisory Council Panel (panel) to review and discuss the results of the onsite visits and inspections for existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process. The bill prescribes the activities of the onsite review team members during the inspection of existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process.

SB 7080, the linked public records bill, may need to be amended to exempt from public meetings requirements the portions of meetings of the panel where results of the onsite visits and inspections are discussed for existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center, and to exempt from public records disclosure requirements the activities of the onsite review team members during the inspection of existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process.

VII. Related Issues:

Section 10. The Office of Insurance Regulation suggests that several additional terms or conditions be added to the Direct Access Agreements:

- Define the term "health care group practice." Under currently law, the term "primary care group practice" is used and is also not defined.
- Include guaranteed renewal terms or continuity of care provisions for patients who are undergoing treatment or receiving services for a condition to limit risk of a contract being canceled with 30 days' notice and no recourse.
- Add an enforcement mechanism for violations of the statute or failure to include the mandatory provisions in the agreement.[197]

Section 15. The Interstate Medical Licensure Compact is inserted into statute as written by the Interstate Medical Licensing Commission (IMLC). Unlike other compacts entered by the state,

[197] Office of Insurance Regulation, *2019 Agency Legislative Bill Analysis – HB 7* (February 20, 2019) (on file with the Senate Committee on Health Policy).

existing statutes relating to physician licensure have not been modified to recognize the existence of this new process.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 394.4615, 395.1012, 395.1055, 395.301, 395.3025, 397.501, 400.145, 409.973, 456.057, 624.27, and 641.31.

This bill creates the following sections of the Florida Statutes: 395.1052, 456.4501, 627.42393, and 627.4303.

IX. Additional Information:

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

Recommended CS by Appropriations Subcommittee on Health and Human Services on April 4, 2019:
The committee substitute:

- Requires that any medium or format of medical records requested is subject to the maximum amount permitted to be charged by health care facilities and health care practitioners rather than just those records in paper format;
- Reduces the timeframe that a nursing facility provider is required to respond to a request for a residents' records from 14 days to 2 days in compliance with federal regulations;
- Extends the timeframe that a hospital is required to provide the discharge summary and any related information and records to a patient's primary care provider from seven to 14 days of the patient's discharge;
- Modifies the composition and duties of the Pediatric Cardiac Technical Advisory Panel;
- Provides members of the Pediatric Cardiac Technical Advisory Panel immunity from civil or criminal liability for the good faith performance of duties assigned to them by the Secretary of the AHCA; and
- Clarifies step-therapy protocols such that an insurer or HMO is not required to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer or HMO does not otherwise cover.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment

Delete lines 119 - 407

and insert:

(a) The reasonable costs of reproducing copies of written or typed documents or reports, in any format or medium, may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

(b) The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be

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the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(c) If the nature or volume of the clinical records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the service provider, or both, the service provider may charge, in addition to the charges imposed under paragraphs (a) and (b), a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the service provider or attributable to the service provider for the clerical and supervisory assistance required, or both.

(d) The charges established in this subsection apply to all records furnished, whether directly from a service provider or from a copy service acting on behalf of the service provider. However, a patient whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search.

Section 2. Subsection (1) and paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, are amended to read:

395.3025 Patient and personnel records; copies; examination.—

(1)(a) Any licensed facility shall, upon written request, and only after discharge of the patient, furnish, in a timely manner as provided in paragraph (b), without delays for legal review, to any person admitted therein for care and treatment or

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treated thereat, or to any such person's guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such person in writing, a true and correct copy of all patient records, including X rays, and insurance information concerning such person, which records are in the possession of the licensed facility, provided the person requesting such records agrees to pay a charge as provided in paragraph (d).

(b) Within 14 working days after receiving a request made in accordance with paragraph (a), a licensed facility must furnish applicable patient records in its possession.

(c) If a licensed facility maintains a system of electronic health records as defined in s. 408.051, the licensed facility shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through a patient's electronic personal health record.

(d) The licensed facility may charge a requester no more than the reasonable costs of reproducing the patient records, including reasonable staff time.

1. The reasonable costs of reproducing copies of written or typed documents or reports, in any format or medium, may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated

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with the duplication.

3. If the nature or volume of the patient records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the licensed facility, or both, the licensed facility may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the licensed facility or attributable to the licensed facility for the clerical and supervisory assistance required, or both.

4. The charges established in this paragraph ~~The exclusive charge for copies of patient records may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed $2, may not exceed $1 per page. A fee of up to $1 may be charged for each year of records requested. These charges shall~~ apply to all records furnished, whether directly from the facility or from a copy service acting ~~providing these services~~ on behalf of the facility. However, a patient whose records are copied or searched for the purpose of continuing to receive ~~medical~~ care is not required to pay a charge for copying or for the search.

(e) If a person authorized to receive copies of patient records under paragraph (a) requests to examine the licensed facility's original records pertaining to the patient, the licensed facility shall, within 10 working days after receiving such a request, provide such person with access to examine such

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original records, microforms, or other suitable reproductions of such records in its possession. A licensed facility may impose any reasonable terms necessary to ensure ~~further allow any such person to examine the original records in its possession, or microforms or other suitable reproductions of the records, upon such reasonable terms as shall be imposed to assure~~ that the records will not be damaged, destroyed, or altered.

(4) Patient records are confidential and may ~~must~~ not be disclosed without the consent of the patient or his or her legal representative; however~~, but~~ appropriate disclosure may be made without such consent to:

(e) The department ~~agency~~ upon subpoena issued pursuant to s. 456.071, but the records obtained thereby must be used solely for the purpose of the department ~~agency~~ and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the department ~~agency~~ requests copies of the records, the facility shall charge no more than its actual copying costs, including reasonable staff time. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department ~~agency~~ or the appropriate regulatory board. However, the department ~~agency~~ must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

Section 3. Present paragraphs (a) through (j) of subsection

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(7) of section 397.501, Florida Statutes, are redesignated as paragraphs (d) through (m), respectively, and new paragraphs (a), (b), and (c) are added to that subsection, to read:

397.501 Rights of individuals.—Individuals receiving substance abuse services from any service provider are guaranteed protection of the rights specified in this section, unless otherwise expressly provided, and service providers must ensure the protection of such rights.

(7) RIGHT TO ACCESS TO AND CONFIDENTIALITY OF INDIVIDUAL RECORDS.—

(a)1. Within 14 working days after receiving a written request from an individual or an individual's legal representative, a service provider shall furnish a true and correct copy of all records pertaining to that individual in the possession of the service provider.

2. For the purpose of this subsection, the term "legal representative" means an individual's legal guardian or, if the individual is younger than 18 years old, the individual's parent or legal guardian.

3. If a service provider maintains a system of electronic health records as defined in s. 408.051, the service provider shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through an individual's electronic personal health record.

(b) A service provider may charge the requester no more than the reasonable costs of reproducing the records, including reasonable staff time.

1. The reasonable costs of reproducing copies of written or

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typed documents or reports, in any format or medium, may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and such other kinds of records shall be the actual costs. Actual costs are the sum of the cost of the material and supplies used to duplicate the records and the labor and overhead costs associated with the duplication.

3. If the nature or volume of the records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the service provider, or both, the service provider may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the service provider or attributable to the service provider for the clerical and supervisory assistance required, or both.

4. The charges established in this paragraph apply to all records furnished, whether directly from a service provider or from a copy service acting on behalf of the service provider. However, an individual whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search.

(c) Within 10 working days after receiving a request from an individual or an individual’s legal representative to examine the service provider’s original records pertaining to that

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individual, a service provider shall provide access to examine such original records, microforms, or other suitable reproductions of such records in its possession. A service provider may impose any reasonable terms necessary to ensure that the records will not be damaged, destroyed, or altered.

Section 4. Subsections (1) and (4) of section 400.145, Florida Statutes, are amended to read:

400.145 Copies of records of care and treatment of resident.—

(1) Upon receipt of a written request that complies with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and this section, a nursing home facility shall furnish to a competent resident, or to a representative of that resident who is authorized to make requests for the resident's records under HIPAA or subsection (2), copies of the resident's paper and electronic records that are in possession of the facility. Such records must include any medical records and records concerning the care and treatment of the resident performed by the facility, except for progress notes and consultation report sections of a psychiatric nature. The facility shall provide copies of the requested records according to the timeframe requirements of 42 C.F.R. s. 483.10(g)(2)(ii) for ~~within 14 working days after receipt of~~ a request relating to a current resident or within 30 working days after receipt of a request relating to a former resident.

(4)(a) After receiving a request made in accordance with subsections (1)-(3), a nursing home facility must furnish applicable records in its possession in accordance with the timeframe requirements of subsection (1) and the provisions of

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this subsection.

(b) If a nursing home facility maintains a system of electronic health records as defined in s. 408.051, the facility shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, or access through a web-based portal.

(c) The nursing home facility may charge a requester no more than the reasonable costs of reproducing the records, including reasonable staff time.

1. The reasonable costs of reproducing copies of written or typed documents or reports, in any format or medium, may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

3. If the nature or volume of the records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the nursing home facility, or both, the facility may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the facility or attributable to the facility for the clerical and supervisory assistance required, or both.

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4. The charges established in this paragraph apply to all records furnished, whether directly from a nursing home facility or from a copy service acting on behalf of the facility. However, a resident whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search

(d) Within 10 working days after receiving a request from a person who is authorized to act on behalf of a resident to examine the nursing home facility's original records pertaining to the resident, the facility shall provide access to examine such original records, microforms, or other suitable reproductions of such records in its possession. A facility may impose any reasonable terms necessary ~~A nursing home facility may charge a reasonable fee for the copying of resident records. Such fee may not exceed $1 per page for the first 25 pages and 25 cents per page for each additional page. The facility shall allow a person who is authorized to act on behalf of the resident to examine the original records, microfilms, or other suitable reproductions of the records in its possession upon any reasonable terms imposed by the facility~~ to ensure that the records are not damaged, destroyed, or altered.

Section 5. Subsections (6) and (17) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(6)(a) Any health care practitioner licensed by the department or a board within the department who makes a physical or mental examination of, or administers treatment or dispenses legend drugs to, any person shall, upon written request of such

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person or the person's legal representative, furnish, within 14 working days after such request ~~in a timely manner, without delays for legal review~~, copies of all reports and records relating to such examination or treatment, including X-rays ~~X rays~~ and insurance information. If the health care practitioner maintains a system of electronic health records as defined in s. 408.051, the health care practitioner shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through a patient's electronic personal health record.

(b) Within 10 working days after receiving a written request by a patient or the patient's legal representative to examine the health care practitioner's original reports and records pertaining to the patient, a health care practitioner must provide access to examine such original reports and records, or microforms or other suitable reproductions of the reports and records in the health care practitioner's possession. The health care practitioner may impose any reasonable terms necessary to ensure that the reports and records will not be damaged, destroyed, or altered.

(c) For the purposes of this subsection, the term "legal representative" means a patient's legal guardian or, if the patient is younger than 18 years old, the patient's parent or legal guardian.

(d) ~~However,~~ When a patient's psychiatric, chapter 490 psychological, or chapter 491 psychotherapeutic records are requested by the patient or the patient's legal representative, the health care practitioner may provide a report of examination

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and treatment in lieu of copies of records. Upon a patient's written request, complete copies of the patient's psychiatric records shall be provided directly to a subsequent treating psychiatrist. The furnishing of such report or copies may ~~shall~~ not be conditioned upon payment of a fee for services rendered.

(17) A licensed health care practitioner may charge the requester no more than the reasonable costs of reproducing the reports and records, including reasonable staff time.

(a) The reasonable costs of reproducing copies of written or typed documents or reports, in any format or medium, may not exceed $1 per page

169096

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment

Delete lines 308 - 316

and insert:

(4)(a) After receiving a request made in accordance with subsections (1)-(3), a nursing home facility must furnish applicable records in its possession in accordance with the timeframe requirements of subsection (1) and the provisions of this subsection.

(b) If a nursing home facility maintains a system of

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electronic health records as defined in s. 408.051, the facility shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through a patient's electronic personal health record.

310648

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment

Delete line 479

and insert:

if any, within 14 days after the patient's discharge from the

224512

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment (with title amendment)

Between lines 495 and 496

insert:

Section 9. Present subsections (9) through (12) of section 395.1055, Florida Statutes, are amended, and new subsections (10), (13), and (14) are added to that section, to read:

395.1055 Rules and enforcement.—

(9) The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. 20.052, to develop

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procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs.

(a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may ~~not~~ be reimbursed for per diem and travel expenses.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following hospitals:

1. Johns Hopkins All Children’s Hospital in St. Petersburg.
2. Arnold Palmer Hospital for Children in Orlando.
3. Joe DiMaggio Children’s Hospital in Hollywood.
4. Nicklaus Children’s Hospital in Miami.
5. St. Joseph’s Children’s Hospital in Tampa.
6. University of Florida Health Shands Hospital in Gainesville.
7. University of Miami Holtz Children’s Hospital in Miami.
8. Wolfson Children’s Hospital in Jacksonville.
9. Florida Hospital for Children in Orlando.
10. Nemours Children’s Hospital in Orlando.

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Appointments made under subparagraphs 1.-10. are contingent upon the hospital's maintenance of pediatric certificates of need and the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to maintain such certificates or comply with standards may serve only as a nonvoting member until the hospital restores such certificates or complies with such standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term.

(c) The Secretary of Health Care Administration may appoint nonvoting members to the panel. Nonvoting members may include:

1. The Secretary of Health Care Administration.

2. The Surgeon General.

3. The Deputy Secretary of Children's Medical Services.

4. Any current or past Division Director of Children's Medical Services.

5. A parent of a child with congenital heart disease.

6. An adult with congenital heart disease.

7. A representative from each of the following organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Cardiology, the Greater Southeast Affiliate of the American Heart Association, the Adult Congenital Heart Association, the March of Dimes, the Florida Association of Children's Hospitals, and the Florida Society of Thoracic and Cardiovascular Surgeons.

(d) The panel shall meet biannually, or more frequently

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upon the call of the Secretary of Health Care Administration. Such meetings may be conducted telephonically, or by other electronic means.

(e) The duties of the panel include recommending to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.

(f) Beginning on January 1, 2020, and annually thereafter, the panel shall submit a report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

(g) Members of the panel are immune from any civil or criminal liability for events resulting from their good faith performance of duties assigned to them by the Secretary of Health Care Administration.

(10) The Secretary of Health Care Administration shall consult the pediatric cardiac technical advisory panel for an advisory recommendation on all certificate of need applications to establish pediatric cardiac surgical centers.

(11) ~~(10)~~ Based on the recommendations of the pediatric cardiac technical advisory panel ~~in subsection (9)~~, the agency shall adopt rules for pediatric cardiac programs which, at a minimum, include:

(a) Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality

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of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.

(b) Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.

(c) Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

(12) ~~(11)~~ A pediatric cardiac program shall:

(a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter.

(b) Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgical program located in the hospital.

(c) Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons.

(d) Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.

(e) Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

(13)(a) The Secretary of Health Care Administration may request announced or unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate

224512

of need process, to ensure compliance with this section and rules adopted hereunder.

(b) At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an on-site visit. The Secretary may also appoint up to two out-of-state physician experts.

(c) A site visit team shall conduct an on-site inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of his or her findings to the panel. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and any suggested actions for correction.

(d) Each on-site inspection must include all of the following:

1. An inspection of the program's physical facilities, clinics, and laboratories.

2. Interviews with support staff and hospital administrators.

3. A review of:

a. Randomly selected medical records and reports, including, but not limited to, advanced cardiac imaging, computed tomography, magnetic resonance imaging, cardiac ultrasound, cardiac catheterization, and surgical operative notes.

b. The program's clinical outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(k).

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c. Mortality reports from cardiac-related deaths that occurred in the previous year.

d. Program volume data from the preceding year for interventional and electrophysiology catheterizations and surgical procedures.

(14) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory panel.

(15) ~~(12)~~ The agency may adopt rules to administer the requirements of part II of chapter 408.

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

And the title is amended as follows:

Between lines 73 and 74

insert:

395.1055, F.S.; authorizing the reimbursement of per diem and travel expenses to members of the pediatric cardiac technical advisory panel, established within the Agency for Health Care Administration; revising panel membership to include certain alternate at-large members; providing term limits for voting members; providing immunity from civil and criminal liabilities to members of the panel; requiring the Secretary of Health Care Administration to consult the panel for advisory recommendations on certain certificate of need applications; authorizing the secretary to request announced or unannounced site visits to any existing pediatric cardiac surgical centers or

facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process; providing a process for the appointment of physician experts to a site visit team; requiring each member of a site visit team to submit a report to the panel; requiring the panel to discuss such reports and present an advisory opinion to the secretary; providing requirements for an on-site inspection; requiring the Surgeon General of the Department of Health to provide specified reports to the secretary; amending s.

870336

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/10/2019	.	
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Appropriations Subcommittee on Health and Human Services (Harrell) recommended the following:

Senate Amendment (with title amendment)

Delete lines 583 - 609

and insert:

(3) This section does not require a health insurer to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer does not otherwise cover.

Section 11. Effective January 1, 2020, subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

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(45)(a) A health maintenance organization issuing major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a covered prescription drug requested by a subscriber if:

1. The subscriber has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

2. The subscriber provides documentation originating from the health coverage plan that approved the prescription drug as described in subparagraph 1. indicating that the health coverage plan paid for the drug on the subscriber's behalf during the 180 days immediately prior to the request.

(b) As used in this subsection, the term "health coverage plan" means any of the following which previously provided or is currently providing major medical or similar comprehensive coverage or benefits to the subscriber:

1. A health insurer or health maintenance organization;

2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406;

3. A multiple-employer welfare arrangement as defined in s. 624.437; or

4. A governmental entity providing a plan of self-insurance.

(c) This subsection does not require a health maintenance organization to add a drug to its prescription drug formulary or to cover a prescription drug that the health maintenance organization does not otherwise cover.

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========== T I T L E A M E N D M E N T ==========
And the title is amended as follows:
Delete lines 80 - 84
and insert:
term "health coverage plan"; clarifying that a health insurer is not required to take specific actions regarding prescription drugs; amending s. 641.31, F.S.; prohibiting certain health maintenance organizations from employing step-therapy protocols under certain circumstances; defining the term "health coverage plan"; clarifying that a health maintenance organization is not required to take specific actions regarding prescription drugs; amending s. 409.973, F.S.; prohibiting Medicaid

By the Committee on Health Policy

588-03183-19 20197078__

A bill to be entitled

An act relating to health care; amending s. 394.4615, F.S.; requiring a service provider to furnish and provide access to clinical records within a specified timeframe after receiving a request for such records; providing a conditional requirement that such records be furnished in the manner chosen by the requester; authorizing the service provider to charge a reasonable cost associated with reproducing such records; providing for a special service charge under specified conditions; amending s. 395.3025, F.S.; requiring a licensed facility to furnish and provide access to patient records within a specified timeframe after receiving a request for such records; providing a conditional requirement that such records be furnished in the manner chosen by the requester; authorizing the licensed facility to charge a reasonable cost associated with reproducing such records; providing for a special service charge under specified conditions; revising provisions relating to the appropriate disclosure of patient records without consent; amending s. 397.501, F.S.; requiring a service provider to furnish and provide access to records within a specified timeframe after receiving a request from an individual or an individual's legal representative; defining the term "legal representative"; providing a conditional requirement that such records be furnished in the manner chosen by the requester; authorizing the service provider to

588-03183-19 20197078__

charge a reasonable cost associated with reproducing such records; providing for a special service charge under specified conditions; amending s. 400.145, F.S.; requiring a nursing home facility to furnish and provide access to records within a specified timeframe after receiving a request; providing a conditional requirement that such records be furnished in the manner chosen by the requester; authorizing the nursing home facility to charge a reasonable cost associated with reproducing such records; providing for a special service charge under specified conditions; amending s. 456.057, F.S.; requiring certain licensed health care practitioners to furnish and provide access to copies of reports and records within a specified timeframe after receiving a request from a patient or a patient's legal representative; authorizing such licensed health care practitioners to impose reasonable terms necessary to preserve such reports and records; defining the term "legal representative"; authorizing such licensed health care practitioners to charge a reasonable cost associated with reproducing such reports and records; providing for a special service charge under specified conditions; amending s. 395.1012, F.S.; requiring a licensed hospital to provide specified information and data relating to patient safety and quality measures to a patient under certain circumstances or to any person upon request; creating s. 395.1052, F.S.; requiring a hospital to notify a patient's primary

care provider within a specified timeframe after the patient's admission; requiring a hospital to inform a patient, upon admission, of the option to request consultation between the hospital's treating physician and the patient's primary care provider or specialist provider; requiring a hospital to notify a patient's primary care provider of the patient's discharge and provide specified information and records to the primary care provider within a specified timeframe after discharge; amending s. 395.301, F.S.; requiring a licensed facility, upon placing a patient on observation status, to immediately notify the patient of such status using a specified form; requiring that such notification be documented in the patient's medical records and discharge papers; amending s. 624.27, F.S.; expanding the scope of direct primary care agreements, which are renamed "direct health care agreements"; conforming provisions to changes made by the act; creating s. 627.42393, F.S.; prohibiting certain health insurers from employing step-therapy protocols under certain circumstances; defining the term "health coverage plan"; amending s. 641.31, F.S.; prohibiting certain health maintenance organizations from employing step-therapy protocols under certain circumstances; defining the term "health coverage plan"; amending s. 409.973, F.S.; prohibiting Medicaid managed care plans from employing step-therapy protocols under certain circumstances; creating s. 627.4303, F.S.; defining the term "health insurer";

prohibiting limitations on price transparency with patients in contracts between health insurers and health care providers; prohibiting a health insurer from requiring an insured to make a certain payment for a covered service under certain circumstances; creating s. 456.4501, F.S.; implementing the Interstate Medical Licensure Compact in this state; providing for an interstate medical licensure process; providing requirements for multistate practice and telemedicine practice; providing effective dates.

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

Section 1. Present subsections (3) through (11) of section 394.4615, Florida Statutes, are redesignated as subsections (5) through (13), respectively, and new subsections (3) and (4) are added to that section, to read:

394.4615 Clinical records; confidentiality.—

(3)(a) Within 14 working days after receiving a request made in accordance with paragraphs (2)(a), (b), or (c), a service provider must furnish applicable clinical records in its possession.

(b) If a service provider maintains a system of electronic health records as defined in s. 408.051, the service provider shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through a patient's electronic personal health record.

(4) The service provider may charge a requester no more

than the reasonable costs of reproducing the clinical records, including reasonable staff time.

(a) The reasonable costs of reproducing paper copies of written or typed documents or reports may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

(b) The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(c) If the nature or volume of the clinical records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the service provider, or both, the service provider may charge, in addition to the charges imposed under paragraphs (a) and (b), a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the service provider or attributable to the service provider for the clerical and supervisory assistance required, or both.

(d) The charges established in this subsection apply to all records furnished, whether directly from a service provider or from a copy service acting on behalf of the service provider. However, a patient whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search.

Section 2. Subsection (1) and paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, are amended to read:

395.3025 Patient and personnel records; copies; examination.—

(1)(a) Any licensed facility shall, upon written request, and only after discharge of the patient, furnish, in a timely manner as provided in paragraph (b), without delays for legal review, to any person admitted therein for care and treatment or treated thereat, or to any such person's guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such person in writing, a true and correct copy of all patient records, including X rays, and insurance information concerning such person, which records are in the possession of the licensed facility, provided the person requesting such records agrees to pay a charge as provided in paragraph (d).

(b) Within 14 working days after receiving a request made in accordance with paragraph (a), a licensed facility must furnish applicable patient records in its possession.

(c) If a licensed facility maintains a system of electronic health records as defined in s. 408.051, the licensed facility shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through a patient's electronic personal health record.

(d) The licensed facility may charge a requester no more than the reasonable costs of reproducing the patient records, including reasonable staff time.

1. The reasonable costs of reproducing paper copies of written or typed documents or reports may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

3. If the nature or volume of the patient records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the licensed facility, or both, the licensed facility may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the licensed facility or attributable to the licensed facility for the clerical and supervisory assistance required, or both.

4. The charges established in this paragraph ~~The exclusive charge for copies of patient records may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed $2, may not exceed $1 per page. A fee of up to $1 may be charged for each year of records requested. These charges shall~~ apply to all records furnished, whether directly from the facility or from a copy service acting ~~providing these services~~ on behalf of the facility. However, a

patient whose records are copied or searched for the purpose of continuing to receive ~~medical~~ care is not required to pay a charge for copying or for the search.

(e) If a person authorized to receive copies of patient records under paragraph (a) requests to examine the licensed facility's original records pertaining to the patient, the licensed facility shall, within 10 working days after receiving such a request, provide such person with access to examine such original records, microforms, or other suitable reproductions of such records in its possession. A licensed facility may impose any reasonable terms necessary to ensure ~~further allow any such person to examine the original records in its possession, or microforms or other suitable reproductions of the records, upon such reasonable terms as shall be imposed to assure~~ that the records will not be damaged, destroyed, or altered.

(4) Patient records are confidential and may ~~must~~ not be disclosed without the consent of the patient or his or her legal representative; however~~, but~~ appropriate disclosure may be made without such consent to:

(e) The department ~~agency~~ upon subpoena issued pursuant to s. 456.071, but the records obtained thereby must be used solely for the purpose of the department ~~agency~~ and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the department ~~agency~~ requests copies of the records, the facility shall charge no more than its actual copying costs, including reasonable staff time. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of

the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department ~~agency~~ or the appropriate regulatory board. However, the department ~~agency~~ must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

Section 3. Present paragraphs (a) through (j) of subsection (7) of section 397.501, Florida Statutes, are redesignated as paragraphs (d) through (m), respectively, and new paragraphs (a), (b), and (c) are added to that subsection, to read:

397.501 Rights of individuals.—Individuals receiving substance abuse services from any service provider are guaranteed protection of the rights specified in this section, unless otherwise expressly provided, and service providers must ensure the protection of such rights.

(7) RIGHT TO ACCESS TO AND CONFIDENTIALITY OF INDIVIDUAL RECORDS.—

(a)1. Within 14 working days after receiving a written request from an individual or an individual's legal representative, a service provider shall furnish a true and correct copy of all records pertaining to that individual in the possession of the service provider.

2. For the purpose of this subsection, the term "legal representative" means an individual's legal guardian or, if the individual is younger than 18 years old, the individual's parent or legal guardian.

3. If a service provider maintains a system of electronic health records as defined in s. 408.051, the service provider

shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a web-based patient portal, or submission through an individual's electronic personal health record.

(b) A service provider may charge the requester no more than the reasonable costs of reproducing the records, including reasonable staff time.

1. The reasonable costs of reproducing paper copies of written or typed documents or reports may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and such other kinds of records shall be the actual costs. Actual costs are the sum of the cost of the material and supplies used to duplicate the records and the labor and overhead costs associated with the duplication.

3. If the nature or volume of the records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the service provider, or both, the service provider may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the service provider or attributable to the service provider for the clerical and supervisory assistance required, or both.

4. The charges established in this paragraph apply to all

records furnished, whether directly from a service provider or from a copy service acting on behalf of the service provider. However, an individual whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search.

(c) Within 10 working days after receiving a request from an individual or an individual's legal representative to examine the service provider's original records pertaining to that individual, a service provider shall provide access to examine such original records, microforms, or other suitable reproductions of such records in its possession. A service provider may impose any reasonable terms necessary to ensure that the records will not be damaged, destroyed, or altered.

Section 4. Subsection (4) of section 400.145, Florida Statutes, is amended to read:

400.145 Copies of records of care and treatment of resident.—

(4)(a) Within 14 working days after receiving a request made in accordance with subsections (1)-(3), a nursing home facility must furnish applicable resident records in its possession in accordance with this subsection.

(b) If a nursing home facility maintains a system of electronic health records as defined in s. 408.051, the facility shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, or access through a web-based portal.

(c) The nursing home facility may charge a requester no more than the reasonable costs of reproducing the records, including reasonable staff time.

1. The reasonable costs of reproducing paper copies of written or typed documents or reports may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

2. The reasonable costs of reproducing X-rays and other forms of images shall be the actual costs. Actual costs shall be the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

3. If the nature or volume of the records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the nursing home facility, or both, the facility may charge, in addition to the charges imposed under subparagraphs 1. and 2., a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the facility or attributable to the facility for the clerical and supervisory assistance required, or both.

4. The charges established in this paragraph apply to all records furnished, whether directly from a nursing home facility or from a copy service acting on behalf of the facility. However, a resident whose records are copied or searched for the purpose of continuing to receive care is not required to pay a charge for copying or for the search

(d) Within 10 working days after receiving a request from a person who is authorized to act on behalf of a resident to examine the nursing home facility's original records pertaining

to the resident, the facility shall provide access to examine such original records, microforms, or other suitable reproductions of such records in its possession. A facility may impose any reasonable terms necessary ~~A nursing home facility may charge a reasonable fee for the copying of resident records. Such fee may not exceed $1 per page for the first 25 pages and 25 cents per page for each additional page. The facility shall allow a person who is authorized to act on behalf of the resident to examine the original records, microfilms, or other suitable reproductions of the records in its possession upon any reasonable terms imposed by the facility~~ to ensure that the records are not damaged, destroyed, or altered.

Section 5. Subsections (6) and (17) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(6)(a) Any health care practitioner licensed by the department or a board within the department who makes a physical or mental examination of, or administers treatment or dispenses legend drugs to, any person shall, upon written request of such person or the person's legal representative, furnish, within 14 working days after such request ~~in a timely manner, without delays for legal review~~, copies of all reports and records relating to such examination or treatment, including X-rays ~~x rays~~ and insurance information. If the health care practitioner maintains a system of electronic health records as defined in s. 408.051, the health care practitioner shall furnish the requested records in the manner chosen by the requester, which may include paper documents, electronic format, access through a

web-based patient portal, or submission through a patient's electronic personal health record.

(b) Within 10 working days after receiving a written request by a patient or the patient's legal representative to examine the health care practitioner's original reports and records pertaining to the patient, a health care practitioner must provide access to examine such original reports and records, or microforms or other suitable reproductions of the reports and records in the health care practitioner's possession. The health care practitioner may impose any reasonable terms necessary to ensure that the reports and records will not be damaged, destroyed, or altered.

(c) For the purposes of this subsection, the term "legal representative" means a patient's legal guardian or, if the patient is younger than 18 years old, the patient's parent or legal guardian.

(d) ~~However,~~ When a patient's psychiatric, chapter 490 psychological, or chapter 491 psychotherapeutic records are requested by the patient or the patient's legal representative, the health care practitioner may provide a report of examination and treatment in lieu of copies of records. Upon a patient's written request, complete copies of the patient's psychiatric records shall be provided directly to a subsequent treating psychiatrist. The furnishing of such report or copies may ~~shall~~ not be conditioned upon payment of a fee for services rendered.

(17) A licensed health care practitioner may charge the requester no more than the reasonable costs of reproducing the reports and records, including reasonable staff time.

(a) The reasonable costs of reproducing paper copies of

written or typed documents or reports may not exceed $1 per page for the first 25 pages and 25 cents per page for all pages thereafter.

(b) The reasonable costs of reproducing X-rays and such other kinds of records shall be the actual costs. Actual costs are the sum of the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(c) If the nature or volume of the records requested to be copied requires extensive use of information technology resources or extensive clerical or supervisory assistance by personnel of the health care practitioner, or both, the health care practitioner may charge, in addition to the charges imposed under paragraphs (a) and (b), a special service charge, which shall be reasonable and shall be based on the cost incurred for such extensive use of information technology resources or the labor cost of the personnel providing the service which is actually incurred by the health care practitioner or attributable to the health care practitioner for the clerical and supervisory assistance required, or both.

(d) The charges established in this subsection apply to all reports and records furnished, whether directly from a health care practitioner or from a copy service providing such services on behalf of the health care practitioner. However, a patient whose reports and records are copied or searched for the purpose of continuing to receive medical care is not required to pay a charge for copying or for the search ~~A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning~~

~~pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the department when there is no board~~.

Section 6. Subsection (3) is added to section 395.1012, Florida Statutes, to read:

395.1012 Patient safety.—

(3)(a) Each hospital shall provide to any patient upon admission, upon scheduling of nonemergency care, or prior to treatment, written information on a form created by the agency that contains the following information available for the hospital for the most recent year and the statewide average for all hospitals related to the following quality measures:

1. The rate of hospital-acquired infections;

2. The overall rating of the Hospital Consumer Assessment of Healthcare Providers and Systems survey; and

3. The 15-day readmission rate.

(b) A hospital must also provide the written information specified in paragraph (a) to any person upon request.

(c) The information required by this subsection must be presented in a manner that is easily understandable and accessible to the patient and must also include an explanation of the quality measures and the relationship between patient safety and the hospital's data for the quality measures.

Section 7. Section 395.1052, Florida Statutes, is created to read:

395.1052 Patient access to primary care and specialty providers; notification.—A hospital shall:

(1) Notify each patient's primary care provider, if any,

within 24 hours after the patient's admission to the hospital.

(2) Inform a patient immediately upon admission that he or she may request to have the hospital's treating physician consult with the patient's primary care provider or specialist provider, if any, when developing the patient's plan of care. Upon the patient's request, the hospital's treating physician shall make reasonable efforts to consult with the patient's primary care provider or specialist provider when developing the patient's plan of care.

(3) Notify the patient's primary care provider, if any, of the patient's discharge from the hospital within 24 hours after discharge.

(4) Provide the discharge summary and any related information or records to the patient's primary care provider, if any, within 7 days after the patient's discharge from the hospital.

Section 8. Subsection (3) of section 395.301, Florida Statutes, is amended to read:

395.301 Price transparency; itemized patient statement or bill; patient admission status notification.—

(3) If a licensed facility places a patient on observation status rather than inpatient status, the licensed facility must immediately notify the patient of such status using the form adopted under 42 C.F.R. s. 489.20 for Medicare patients or a form adopted by agency rule for non-Medicare patients. Such notification must ~~observation services shall~~ be documented in the patient's medical records and discharge papers. The ~~patient or the~~ patient's survivor or legal guardian must ~~shall~~ be notified of observation services through discharge papers, which

may also include brochures, signage, or other forms of communication for this purpose.

Section 9. Section 624.27, Florida Statutes, is amended to read:

624.27 Direct health ~~primary~~ care agreements; exemption from code.—

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

(a) "Direct health ~~primary~~ care agreement" means a contract between a health ~~primary~~ care provider and a patient, a patient's legal representative, or a patient's employer, which meets the requirements of subsection (4) and does not indemnify for services provided by a third party.

(b) "Health ~~Primary~~ care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 464, or chapter 466, or a health ~~primary~~ care group practice, who provides health ~~primary~~ care services to patients.

(c) "Health ~~Primary~~ care services" means the screening, assessment, diagnosis, and treatment of a patient conducted within the competency and training of the health ~~primary~~ care provider for the purpose of promoting health or detecting and managing disease or injury.

(2) A direct health ~~primary~~ care agreement does not constitute insurance and is not subject to the Florida Insurance Code. The act of entering into a direct health ~~primary~~ care agreement does not constitute the business of insurance and is not subject to the Florida Insurance Code.

(3) A health ~~primary~~ care provider or an agent of a health ~~primary~~ care provider is not required to obtain a certificate of authority or license under the Florida Insurance Code to market,

sell, or offer to sell a direct health ~~primary~~ care agreement.

(4) For purposes of this section, a direct health ~~primary~~ care agreement must:

(a) Be in writing.

(b) Be signed by the health ~~primary~~ care provider or an agent of the health ~~primary~~ care provider and the patient, the patient's legal representative, or the patient's employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of health ~~primary~~ care services that are covered by the monthly fee.

(e) Specify the monthly fee and any fees for health ~~primary~~ care services not covered by the monthly fee.

(f) Specify the duration of the agreement and any automatic renewal provisions.

(g) Offer a refund to the patient, the patient's legal representative, or the patient's employer of monthly fees paid in advance if the health ~~primary~~ care provider ceases to offer health ~~primary~~ care services for any reason.

(h) Contain, in contrasting color and in at least 12-point type, the following statement on the signature page: "This agreement is not health insurance and the health ~~primary~~ care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any health ~~primary~~ care services covered by the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual

shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not workers' compensation insurance and does not replace an employer's obligations under chapter 440."

Section 10. Effective January 1, 2020, section 627.42393, Florida Statutes, is created to read:

627.42393 Step-therapy protocol.—

(1) A health insurer issuing a major medical individual or group policy may not require a step-therapy protocol under the policy for a covered prescription drug requested by an insured if:

(a) The insured has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

(b) The insured provides documentation originating from the health coverage plan that approved the prescription drug as described in paragraph (a) indicating that the health coverage plan paid for the drug on the insured's behalf during the 180 days immediately prior to the request.

(2) As used in this section, the term "health coverage plan" means any of the following which previously provided or is currently providing major medical or similar comprehensive coverage or benefits to the insured:

(a) A health insurer or health maintenance organization.

(b) A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.

(c) A multiple-employer welfare arrangement as defined in s. 624.437.

(d) A governmental entity providing a plan of self-insurance.

Section 11. Effective January 1, 2020, subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45)(a) A health maintenance organization issuing major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a covered prescription drug requested by a subscriber if:

1. The subscriber has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

2. The subscriber provides documentation originating from the health coverage plan that approved the prescription drug as described in subparagraph 1. indicating that the health coverage plan paid for the drug on the subscriber's behalf during the 180 days immediately prior to the request.

(b) As used in this subsection, the term "health coverage plan" means any of the following which previously provided or is currently providing major medical or similar comprehensive coverage or benefits to the subscriber:

1. A health insurer or health maintenance organization;

2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406;

3. A multiple-employer welfare arrangement as defined in s. 624.437; or

4. A governmental entity providing a plan of self-insurance.

Section 12. Present subsection (6) of section 409.973, Florida Statutes, is redesignated as subsection (7), and a new subsection (6) is added to that section, to read:

409.973 Benefits.—

(6) PROVISION OF PRESCRIPTION DRUG SERVICES.—

(a) A managed care plan may not require a step-therapy approval process for a covered prescription drug requested by an enrolled recipient if:

1. The recipient has been approved to receive the prescription drug through the completion of a step-therapy approval process required by a managed care plan in which the recipient was previously enrolled under this part; and

2. The managed care plan in which the recipient was previously enrolled has paid for the drug on the recipient's behalf during the 180 days immediately before the request.

(b) The agency shall implement paragraph (a) by amending managed care plan contracts concurrent with the start of a new capitation cycle.

Section 13. Section 627.4303, Florida Statutes, is created to read:

627.4303 Price transparency in contracts between health insurers and health care providers.—

(1) As used in this section, the term "health insurer" means a health insurer issuing major medical coverage through an individual or group policy or a health maintenance organization issuing major medical coverage through an individual or group contract.

(2) A health insurer may not limit a provider's ability to disclose whether a patient's cost-sharing obligation exceeds the

cash price for a covered service in the absence of health insurance coverage or the availability of a more affordable service.

(3) A health insurer may not require an insured to make a payment for a covered service in an amount that exceeds the cash price of the service in the absence of health insurance coverage.

Section 14. Section 456.4501, Florida Statutes, is created to read:

456.4501 Interstate Medical Licensure Compact.—The Interstate Medical Licensure Compact is hereby enacted into law and entered into by this state with all other jurisdictions legally joining therein in the form substantially as follows:

SECTION 1
PURPOSE

In order to strengthen access to health care, and in recognition of the advances in the delivery of health care, the member states of the Interstate Medical Licensure Compact have allied in common purpose to develop a comprehensive process that complements the existing licensing and regulatory authority of state medical boards, provides a streamlined process that allows physicians to become licensed in multiple states, thereby enhancing the portability of a medical license and ensuring the safety of patients. The Compact creates another pathway for licensure and does not otherwise change a state's existing Medical Practice Act. The Compact also adopts the prevailing standard for licensure and affirms that the practice of medicine

occurs where the patient is located at the time of the physician-patient encounter, and therefore, requires the physician to be under the jurisdiction of the state medical board where the patient is located. State medical boards that participate in the Compact retain the jurisdiction to impose an adverse action against a license to practice medicine in that state issued to a physician through the procedures in the Compact.

SECTION 2
DEFINITIONS

In this compact:

(a) "Bylaws" means those bylaws established by the Interstate Commission pursuant to Section 11 for its governance, or for directing and controlling its actions and conduct.

(b) "Commissioner" means the voting representative appointed by each member board pursuant to Section 11.

(c) "Conviction" means a finding by a court that an individual is guilty of a criminal offense through adjudication, or entry of a plea of guilt or no contest to the charge by the offender. Evidence of an entry of a conviction of a criminal offense by the court shall be considered final for purposes of disciplinary action by a member board.

(d) "Expedited License" means a full and unrestricted medical license granted by a member state to an eligible physician through the process set forth in the Compact.

(e) "Interstate Commission" means the interstate commission created pursuant to Section 11.

(f) "License" means authorization by a state for a physician to engage in the practice of medicine, which would be unlawful without the authorization.

(g) "Medical Practice Act" means laws and regulations governing the practice of allopathic and osteopathic medicine within a member state.

(h) "Member Board" means a state agency in a member state that acts in the sovereign interests of the state by protecting the public through licensure, regulation, and education of physicians as directed by the state government.

(i) "Member State" means a state that has enacted the Compact.

(j) "Practice of medicine" means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition, by attendance, advice, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts.

(k) "Physician" means any person who:

(1) Is a graduate of a medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent;

(2) Passed each component of the United States Medical Licensing Examination (USMLE) or the Comprehensive Osteopathic Medical Licensing Examination (COMLEX-USA) within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes;

(3) Successfully completed graduate medical education approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association;

(4) Holds specialty certification or a time-unlimited specialty certificate recognized by the American Board of Medical Specialties or the American Osteopathic Association's Bureau of Osteopathic Specialists; however, the specialty certification or a time-unlimited specialty certificate does not have to be maintained once a physician is initially determined to be eligible for expedited licensure through the Compact;

(5) Possesses a full and unrestricted license to engage in the practice of medicine issued by a member board;

(6) Has never been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction;

(7) Has never held a license authorizing the practice of medicine subjected to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license;

(8) Has never had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration; and

(9) Is not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction.

(l) "Offense" means a felony, high court misdemeanor, or crime of moral turpitude.

(m) "Rule" means a written statement by the Interstate

Commission promulgated pursuant to Section 12 of the Compact that is of general applicability, implements, interprets, or prescribes a policy or provision of the Compact, or an organizational, procedural, or practice requirement of the Interstate Commission, and has the force and effect of statutory law in a member state, if the rule is not inconsistent with the laws of the member state. The term includes the amendment, repeal, or suspension of an existing rule.

(n) "State" means any state, commonwealth, district, or territory of the United States.

(o) "State of Principal License" means a member state where a physician holds a license to practice medicine and which has been designated as such by the physician for purposes of registration and participation in the Compact.

SECTION 3
ELIGIBILITY

(a) A physician must meet the eligibility requirements as defined in Section 2(k) to receive an expedited license under the terms and provisions of the Compact.

(b) A physician who does not meet the requirements of Section 2(k) may obtain a license to practice medicine in a member state if the individual complies with all laws and requirements, other than the Compact, relating to the issuance of a license to practice medicine in that state.

SECTION 4
DESIGNATION OF STATE OF PRINCIPAL LICENSE

(a) A physician shall designate a member state as the state of principal license for purposes of registration for expedited licensure through the Compact if the physician possesses a full and unrestricted license to practice medicine in that state, and the state is:

(1) the state of primary residence for the physician, or

(2) the state where at least 25% of the practice of medicine occurs, or

(3) the location of the physician's employer, or

(4) if no state qualifies under subsection (1), subsection (2), or subsection (3), the state designated as state of residence for purpose of federal income tax.

(b) A physician may redesignate a member state as state of principal license at any time, as long as the state meets the requirements in subsection (a).

(c) The Interstate Commission is authorized to develop rules to facilitate redesignation of another member state as the state of principal license.

SECTION 5
APPLICATION AND ISSUANCE OF EXPEDITED LICENSURE

(a) A physician seeking licensure through the Compact shall file an application for an expedited license with the member board of the state selected by the physician as the state of principal license.

(b) Upon receipt of an application for an expedited license, the member board within the state selected as the state

of principal license shall evaluate whether the physician is eligible for expedited licensure and issue a letter of qualification, verifying or denying the physician's eligibility, to the Interstate Commission.

(i) Static qualifications, which include verification of medical education, graduate medical education, results of any medical or licensing examination, and other qualifications as determined by the Interstate Commission through rule, shall not be subject to additional primary source verification where already primary source verified by the state of principal license.

(ii) The member board within the state selected as the state of principal license shall, in the course of verifying eligibility, perform a criminal background check of an applicant, including the use of the results of fingerprint or other biometric data checks compliant with the requirements of the Federal Bureau of Investigation, with the exception of federal employees who have suitability determination in accordance with U.S. 5 CFR §731.202.

(iii) Appeal on the determination of eligibility shall be made to the member state where the application was filed and shall be subject to the law of that state.

(c) Upon verification in subsection (b), physicians eligible for an expedited license shall complete the registration process established by the Interstate Commission to receive a license in a member state selected pursuant to subsection (a), including the payment of any applicable fees.

(d) After receiving verification of eligibility under subsection (b) and any fees under subsection (c), a member board

shall issue an expedited license to the physician. This license shall authorize the physician to practice medicine in the issuing state consistent with the Medical Practice Act and all applicable laws and regulations of the issuing member board and member state.

(e) An expedited license shall be valid for a period consistent with the licensure period in the member state and in the same manner as required for other physicians holding a full and unrestricted license within the member state.

(f) An expedited license obtained through the Compact shall be terminated if a physician fails to maintain a license in the state of principal licensure for a non-disciplinary reason, without redesignation of a new state of principal licensure.

(g) The Interstate Commission is authorized to develop rules regarding the application process, including payment of any applicable fees, and the issuance of an expedited license.

SECTION 6

FEES FOR EXPEDITED LICENSURE

(a) A member state issuing an expedited license authorizing the practice of medicine in that state, or the regulating authority of the member state, may impose a fee for a license issued or renewed through the Compact.

(b) The Interstate Commission is authorized to develop rules regarding fees for expedited licenses. However, those rules shall not limit the authority of a member state, or the regulating authority of the member state, to impose and determine the amount of a fee under subsection (a).

SECTION 7

RENEWAL AND CONTINUED PARTICIPATION

(a) A physician seeking to renew an expedited license granted in a member state shall complete a renewal process with the Interstate Commission if the physician:

(1) Maintains a full and unrestricted license in a state of principal license;

(2) Has not been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction;

(3) Has not had a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license; and

(4) Has not had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration.

(b) Physicians shall comply with all continuing professional development or continuing medical education requirements for renewal of a license issued by a member state.

(c) The Interstate Commission shall collect any renewal fees charged for the renewal of a license and distribute the fees to the applicable member board.

(d) Upon receipt of any renewal fees collected in subsection (c), a member board shall renew the physician's license.

(e) Physician information collected by the Interstate

Commission during the renewal process will be distributed to all member boards.

(f) The Interstate Commission is authorized to develop rules to address renewal of licenses obtained through the Compact.

SECTION 8

COORDINATED INFORMATION SYSTEM

(a) The Interstate Commission shall establish a database of all physicians licensed, or who have applied for licensure, under Section 5.

(b) Notwithstanding any other provision of law, member boards shall report to the Interstate Commission any public action or complaints against a licensed physician who has applied or received an expedited license through the Compact.

(c) Member boards shall report disciplinary or investigatory information determined as necessary and proper by rule of the Interstate Commission.

(d) Member boards may report any non-public complaint, disciplinary, or investigatory information not required by subsection (c) to the Interstate Commission.

(e) Member boards shall share complaint or disciplinary information about a physician upon request of another member board.

(f) All information provided to the Interstate Commission or distributed by member boards shall be confidential, filed under seal, and used only for investigatory or disciplinary matters.

(g) The Interstate Commission is authorized to develop rules for mandated or discretionary sharing of information by member boards.

SECTION 9
JOINT INVESTIGATIONS

(a) Licensure and disciplinary records of physicians are deemed investigative.

(b) In addition to the authority granted to a member board by its respective Medical Practice Act or other applicable state law, a member board may participate with other member boards in joint investigations of physicians licensed by the member boards.

(c) A subpoena issued by a member state shall be enforceable in other member states.

(d) Member boards may share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the Compact.

(e) Any member state may investigate actual or alleged violations of the statutes authorizing the practice of medicine in any other member state in which a physician holds a license to practice medicine.

SECTION 10
DISCIPLINARY ACTIONS

(a) Any disciplinary action taken by any member board against a physician licensed through the Compact shall be deemed

unprofessional conduct which may be subject to discipline by other member boards, in addition to any violation of the Medical Practice Act or regulations in that state.

(b) If a license granted to a physician by the member board in the state of principal license is revoked, surrendered or relinquished in lieu of discipline, or suspended, then all licenses issued to the physician by member boards shall automatically be placed, without further action necessary by any member board, on the same status. If the member board in the state of principal license subsequently reinstates the physician's license, a license issued to the physician by any other member board shall remain encumbered until that respective member board takes action to reinstate the license in a manner consistent with the Medical Practice Act of that state.

(c) If disciplinary action is taken against a physician by a member board not in the state of principal license, any other member board may deem the action conclusive as to matter of law and fact decided, and:

(i) impose the same or lesser sanction(s) against the physician so long as such sanctions are consistent with the Medical Practice Act of that state;

(ii) or pursue separate disciplinary action against the physician under its respective Medical Practice Act, regardless of the action taken in other member states.

(d) If a license granted to a physician by a member board is revoked, surrendered or relinquished in lieu of discipline, or suspended, then any license(s) issued to the physician by any other member board(s) shall be suspended, automatically and immediately without further action necessary by the other member

board(s), for ninety (90) days upon entry of the order by the disciplining board, to permit the member board(s) to investigate the basis for the action under the Medical Practice Act of that state. A member board may terminate the automatic suspension of the license it issued prior to the completion of the ninety (90) day suspension period in a manner consistent with the Medical Practice Act of that state.

SECTION 11

INTERSTATE MEDICAL LICENSURE COMPACT COMMISSION

(a) The member states hereby create the "Interstate Medical Licensure Compact Commission".

(b) The purpose of the Interstate Commission is the administration of the Interstate Medical Licensure Compact, which is a discretionary state function.

(c) The Interstate Commission shall be a body corporate and joint agency of the member states and shall have all the responsibilities, powers, and duties set forth in the Compact, and such additional powers as may be conferred upon it by a subsequent concurrent action of the respective legislatures of the member states in accordance with the terms of the Compact.

(d) The Interstate Commission shall consist of two voting representatives appointed by each member state who shall serve as Commissioners. In states where allopathic and osteopathic physicians are regulated by separate member boards, or if the licensing and disciplinary authority is split between multiple member boards within a member state, the member state shall appoint one representative from each member board. A

Commissioner shall be a(n):

(1) Allopathic or osteopathic physician appointed to a member board;

(2) Executive director, executive secretary, or similar executive of a member board; or

(3) Member of the public appointed to a member board.

(e) The Interstate Commission shall meet at least once each calendar year. A portion of this meeting shall be a business meeting to address such matters as may properly come before the Commission, including the election of officers. The chairperson may call additional meetings and shall call for a meeting upon the request of a majority of the member states.

(f) The bylaws may provide for meetings of the Interstate Commission to be conducted by telecommunication or electronic communication.

(g) Each Commissioner participating at a meeting of the Interstate Commission is entitled to one vote. A majority of Commissioners shall constitute a quorum for the transaction of business, unless a larger quorum is required by the bylaws of the Interstate Commission. A Commissioner shall not delegate a vote to another Commissioner. In the absence of its Commissioner, a member state may delegate voting authority for a specified meeting to another person from that state who shall meet the requirements of subsection (d).

(h) The Interstate Commission shall provide public notice of all meetings and all meetings shall be open to the public. The Interstate Commission may close a meeting, in full or in portion, where it determines by a two-thirds vote of the Commissioners present that an open meeting would be likely to:

(1) Relate solely to the internal personnel practices and procedures of the Interstate Commission;

(2) Discuss matters specifically exempted from disclosure by federal statute;

(3) Discuss trade secrets, commercial, or financial information that is privileged or confidential;

(4) Involve accusing a person of a crime, or formally censuring a person;

(5) Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

(6) Discuss investigative records compiled for law enforcement purposes; or

(7) Specifically relate to the participation in a civil action or other legal proceeding.

(i) The Interstate Commission shall keep minutes which shall fully describe all matters discussed in a meeting and shall provide a full and accurate summary of actions taken, including record of any roll call votes.

(j) The Interstate Commission shall make its information and official records, to the extent not otherwise designated in the Compact or by its rules, available to the public for inspection.

(k) The Interstate Commission shall establish an executive committee, which shall include officers, members, and others as determined by the bylaws. The executive committee shall have the power to act on behalf of the Interstate Commission, with the exception of rulemaking, during periods when the Interstate Commission is not in session. When acting on behalf of the

Interstate Commission, the executive committee shall oversee the administration of the Compact including enforcement and compliance with the provisions of the Compact, its bylaws and rules, and other such duties as necessary.

(l) The Interstate Commission may establish other committees for governance and administration of the Compact.

SECTION 12

POWERS AND DUTIES OF THE INTERSTATE COMMISSION

The Interstate Commission shall have the duty and power to:

(a) Oversee and maintain the administration of the Compact;

(b) Promulgate rules which shall be binding to the extent and in the manner provided for in the Compact;

(c) Issue, upon the request of a member state or member board, advisory opinions concerning the meaning or interpretation of the Compact, its bylaws, rules, and actions;

(d) Enforce compliance with Compact provisions, the rules promulgated by the Interstate Commission, and the bylaws, using all necessary and proper means, including but not limited to the use of judicial process;

(e) Establish and appoint committees including, but not limited to, an executive committee as required by Section 11, which shall have the power to act on behalf of the Interstate Commission in carrying out its powers and duties;

(f) Pay, or provide for the payment of the expenses related to the establishment, organization, and ongoing activities of the Interstate Commission;

(g) Establish and maintain one or more offices;

(h) Borrow, accept, hire, or contract for services of personnel;

(i) Purchase and maintain insurance and bonds;

(j) Employ an executive director who shall have such powers to employ, select or appoint employees, agents, or consultants, and to determine their qualifications, define their duties, and fix their compensation;

(k) Establish personnel policies and programs relating to conflicts of interest, rates of compensation, and qualifications of personnel;

(l) Accept donations and grants of money, equipment, supplies, materials and services, and to receive, utilize, and dispose of it in a manner consistent with the conflict of interest policies established by the Interstate Commission;

(m) Lease, purchase, accept contributions or donations of, or otherwise to own, hold, improve or use, any property, real, personal, or mixed;

(n) Sell, convey, mortgage, pledge, lease, exchange, abandon, or otherwise dispose of any property, real, personal, or mixed;

(o) Establish a budget and make expenditures;

(p) Adopt a seal and bylaws governing the management and operation of the Interstate Commission;

(q) Report annually to the legislatures and governors of the member states concerning the activities of the Interstate Commission during the preceding year. Such reports shall also include reports of financial audits and any recommendations that may have been adopted by the Interstate Commission;

(r) Coordinate education, training, and public awareness

regarding the Compact, its implementation, and its operation;

(s) Maintain records in accordance with the bylaws;

(t) Seek and obtain trademarks, copyrights, and patents; and

(u) Perform such functions as may be necessary or appropriate to achieve the purposes of the Compact.

SECTION 13

FINANCE POWERS

(a) The Interstate Commission may levy on and collect an annual assessment from each member state to cover the cost of the operations and activities of the Interstate Commission and its staff. The total assessment, subject to appropriation, must be sufficient to cover the annual budget approved each year for which revenue is not provided by other sources. The aggregate annual assessment amount shall be allocated upon a formula to be determined by the Interstate Commission, which shall promulgate a rule binding upon all member states.

(b) The Interstate Commission shall not incur obligations of any kind prior to securing the funds adequate to meet the same.

(c) The Interstate Commission shall not pledge the credit of any of the member states, except by, and with the authority of, the member state.

(d) The Interstate Commission shall be subject to a yearly financial audit conducted by a certified or licensed public accountant and the report of the audit shall be included in the annual report of the Interstate Commission.

SECTION 14

ORGANIZATION AND OPERATION OF THE INTERSTATE COMMISSION

(a) The Interstate Commission shall, by a majority of Commissioners present and voting, adopt bylaws to govern its conduct as may be necessary or appropriate to carry out the purposes of the Compact within twelve (12) months of the first Interstate Commission meeting.

(b) The Interstate Commission shall elect or appoint annually from among its Commissioners a chairperson, a vice-chairperson, and a treasurer, each of whom shall have such authority and duties as may be specified in the bylaws. The chairperson, or in the chairperson's absence or disability, the vice-chairperson, shall preside at all meetings of the Interstate Commission.

(c) Officers selected in subsection (b) shall serve without remuneration from the Interstate Commission.

(d) The officers and employees of the Interstate Commission shall be immune from suit and liability, either personally or in their official capacity, for a claim for damage to or loss of property or personal injury or other civil liability caused or arising out of, or relating to, an actual or alleged act, error, or omission that occurred, or that such person had a reasonable basis for believing occurred, within the scope of Interstate Commission employment, duties, or responsibilities; provided that such person shall not be protected from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

(1) The liability of the executive director and employees of the Interstate Commission or representatives of the Interstate Commission, acting within the scope of such person's employment or duties for acts, errors, or omissions occurring within such person's state, may not exceed the limits of liability set forth under the constitution and laws of that state for state officials, employees, and agents. The Interstate Commission is considered to be an instrumentality of the states for the purposes of any such action. Nothing in this subsection shall be construed to protect such person from suit or liability for damage, loss, injury, or liability caused by the intentional or willful and wanton misconduct of such person.

(2) The Interstate Commission shall defend the executive director, its employees, and subject to the approval of the attorney general or other appropriate legal counsel of the member state represented by an Interstate Commission representative, shall defend such Interstate Commission representative in any civil action seeking to impose liability arising out of an actual or alleged act, error or omission that occurred within the scope of Interstate Commission employment, duties or responsibilities, or that the defendant had a reasonable basis for believing occurred within the scope of Interstate Commission employment, duties, or responsibilities, provided that the actual or alleged act, error, or omission did not result from intentional or willful and wanton misconduct on the part of such person.

(3) To the extent not covered by the state involved, member state, or the Interstate Commission, the representatives or employees of the Interstate Commission shall be held harmless in

the amount of a settlement or judgment, including attorney's fees and costs, obtained against such persons arising out of an actual or alleged act, error, or omission that occurred within the scope of Interstate Commission employment, duties, or responsibilities, or that such persons had a reasonable basis for believing occurred within the scope of Interstate Commission employment, duties, or responsibilities, provided that the actual or alleged act, error, or omission did not result from intentional or willful and wanton misconduct on the part of such persons.

SECTION 15

RULEMAKING FUNCTIONS OF THE INTERSTATE COMMISSION

(a) The Interstate Commission shall promulgate reasonable rules in order to effectively and efficiently achieve the purposes of the Compact. Notwithstanding the foregoing, in the event the Interstate Commission exercises its rulemaking authority in a manner that is beyond the scope of the purposes of the Compact, or the powers granted hereunder, then such an action by the Interstate Commission shall be invalid and have no force or effect.

(b) Rules deemed appropriate for the operations of the Interstate Commission shall be made pursuant to a rulemaking process that substantially conforms to the "Model State Administrative Procedure Act" of 2010, and subsequent amendments thereto.

(c) Not later than thirty (30) days after a rule is promulgated, any person may file a petition for judicial review

of the rule in the United States District Court for the District of Columbia or the federal district where the Interstate Commission has its principal offices, provided that the filing of such a petition shall not stay or otherwise prevent the rule from becoming effective unless the court finds that the petitioner has a substantial likelihood of success. The court shall give deference to the actions of the Interstate Commission consistent with applicable law and shall not find the rule to be unlawful if the rule represents a reasonable exercise of the authority granted to the Interstate Commission.

SECTION 16

OVERSIGHT OF INTERSTATE COMPACT

(a) The executive, legislative, and judicial branches of state government in each member state shall enforce the Compact and shall take all actions necessary and appropriate to effectuate the Compact's purposes and intent. The provisions of the Compact and the rules promulgated hereunder shall have standing as statutory law but shall not override existing state authority to regulate the practice of medicine.

(b) All courts shall take judicial notice of the Compact and the rules in any judicial or administrative proceeding in a member state pertaining to the subject matter of the Compact which may affect the powers, responsibilities or actions of the Interstate Commission.

(c) The Interstate Commission shall be entitled to receive all service of process in any such proceeding, and shall have standing to intervene in the proceeding for all purposes.

Failure to provide service of process to the Interstate Commission shall render a judgment or order void as to the Interstate Commission, the Compact, or promulgated rules.

SECTION 17
ENFORCEMENT OF INTERSTATE COMPACT

(a) The Interstate Commission, in the reasonable exercise of its discretion, shall enforce the provisions and rules of the Compact.

(b) The Interstate Commission may, by majority vote of the Commissioners, initiate legal action in the United States District Court for the District of Columbia, or, at the discretion of the Interstate Commission, in the federal district where the Interstate Commission has its principal offices, to enforce compliance with the provisions of the Compact, and its promulgated rules and bylaws, against a member state in default. The relief sought may include both injunctive relief and damages. In the event judicial enforcement is necessary, the prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

(c) The remedies herein shall not be the exclusive remedies of the Interstate Commission. The Interstate Commission may avail itself of any other remedies available under state law or the regulation of a profession.

SECTION 18
DEFAULT PROCEDURES

(a) The grounds for default include, but are not limited to, failure of a member state to perform such obligations or responsibilities imposed upon it by the Compact, or the rules and bylaws of the Interstate Commission promulgated under the Compact.

(b) If the Interstate Commission determines that a member state has defaulted in the performance of its obligations or responsibilities under the Compact, or the bylaws or promulgated rules, the Interstate Commission shall:

(1) Provide written notice to the defaulting state and other member states, of the nature of the default, the means of curing the default, and any action taken by the Interstate Commission. The Interstate Commission shall specify the conditions by which the defaulting state must cure its default; and

(2) Provide remedial training and specific technical assistance regarding the default.

(c) If the defaulting state fails to cure the default, the defaulting state shall be terminated from the Compact upon an affirmative vote of a majority of the Commissioners and all rights, privileges, and benefits conferred by the Compact shall terminate on the effective date of termination. A cure of the default does not relieve the offending state of obligations or liabilities incurred during the period of the default.

(d) Termination of membership in the Compact shall be imposed only after all other means of securing compliance have been exhausted. Notice of intent to terminate shall be given by the Interstate Commission to the governor, the majority and minority leaders of the defaulting state's legislature, and each

of the member states.

(e) The Interstate Commission shall establish rules and procedures to address licenses and physicians that are materially impacted by the termination of a member state, or the withdrawal of a member state.

(f) The member state which has been terminated is responsible for all dues, obligations, and liabilities incurred through the effective date of termination including obligations, the performance of which extends beyond the effective date of termination.

(g) The Interstate Commission shall not bear any costs relating to any state that has been found to be in default or which has been terminated from the Compact, unless otherwise mutually agreed upon in writing between the Interstate Commission and the defaulting state.

(h) The defaulting state may appeal the action of the Interstate Commission by petitioning the United States District Court for the District of Columbia or the federal district where the Interstate Commission has its principal offices. The prevailing party shall be awarded all costs of such litigation including reasonable attorney's fees.

SECTION 19
DISPUTE RESOLUTION

(a) The Interstate Commission shall attempt, upon the request of a member state, to resolve disputes which are subject to the Compact and which may arise among member states or member boards.

(b) The Interstate Commission shall promulgate rules providing for both mediation and binding dispute resolution as appropriate.

SECTION 20
MEMBER STATES, EFFECTIVE DATE AND AMENDMENT

(a) Any state is eligible to become a member state of the Compact.

(b) The Compact shall become effective and binding upon legislative enactment of the Compact into law by no less than seven (7) states. Thereafter, it shall become effective and binding on a state upon enactment of the Compact into law by that state.

(c) The governors of non-member states, or their designees, shall be invited to participate in the activities of the Interstate Commission on a non-voting basis prior to adoption of the Compact by all states.

(d) The Interstate Commission may propose amendments to the Compact for enactment by the member states. No amendment shall become effective and binding upon the Interstate Commission and the member states unless and until it is enacted into law by unanimous consent of the member states.

SECTION 21
WITHDRAWAL

(a) Once effective, the Compact shall continue in force and remain binding upon each and every member state; provided that a

member state may withdraw from the Compact by specifically repealing the statute which enacted the Compact into law.

(b) Withdrawal from the Compact shall be by the enactment of a statute repealing the same, but shall not take effect until one (1) year after the effective date of such statute and until written notice of the withdrawal has been given by the withdrawing state to the governor of each other member state.

(c) The withdrawing state shall immediately notify the chairperson of the Interstate Commission in writing upon the introduction of legislation repealing the Compact in the withdrawing state.

(d) The Interstate Commission shall notify the other member states of the withdrawing state's intent to withdraw within sixty (60) days of its receipt of notice provided under subsection (c).

(e) The withdrawing state is responsible for all dues, obligations and liabilities incurred through the effective date of withdrawal, including obligations, the performance of which extend beyond the effective date of withdrawal.

(f) Reinstatement following withdrawal of a member state shall occur upon the withdrawing state reenacting the Compact or upon such later date as determined by the Interstate Commission.

(g) The Interstate Commission is authorized to develop rules to address the impact of the withdrawal of a member state on licenses granted in other member states to physicians who designated the withdrawing member state as the state of principal license.

SECTION 22

DISSOLUTION

(a) The Compact shall dissolve effective upon the date of the withdrawal or default of the member state which reduces the membership in the Compact to one (1) member state.

(b) Upon the dissolution of the Compact, the Compact becomes null and void and shall be of no further force or effect, and the business and affairs of the Interstate Commission shall be concluded and surplus funds shall be distributed in accordance with the bylaws.

SECTION 23

SEVERABILITY AND CONSTRUCTION

(a) The provisions of the Compact shall be severable, and if any phrase, clause, sentence, or provision is deemed unenforceable, the remaining provisions of the Compact shall be enforceable.

(b) The provisions of the Compact shall be liberally construed to effectuate its purposes.

(c) Nothing in the Compact shall be construed to prohibit the applicability of other interstate compacts to which the states are members.

SECTION 24

BINDING EFFECT OF COMPACT AND OTHER LAWS

(a) Nothing herein prevents the enforcement of any other law of a member state that is not inconsistent with the Compact.

(b) All laws in a member state in conflict with the Compact are superseded to the extent of the conflict.

(c) All lawful actions of the Interstate Commission, including all rules and bylaws promulgated by the Commission, are binding upon the member states.

(d) All agreements between the Interstate Commission and the member states are binding in accordance with their terms.

(e) In the event any provision of the Compact exceeds the constitutional limits imposed on the legislature of any member state, such provision shall be ineffective to the extent of the conflict with the constitutional provision in question in that member state.

Section 15. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2019.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Health Policy, *Chair*
Appropriations Subcommittee on Health and Human Services, *Vice Chair*
Appropriations Subcommittee on Criminal and Civil Justice
Children, Families, and Elder Affairs
Military and Veterans Affairs and Space

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR GAYLE HARRELL
25th District

March 27, 2019

Senator Aaron Bean
405 Senate Building
404 South Monroe Street
Tallahassee, FL 32399

Chair Bean,

I respectfully request that **SB 7078 – Healthcare** be placed on the next available agenda for the Appropriations Subcommittee on Health and Human Services Meeting.

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

Thank you,

Gayle

Senator Gayle Harrell
Senate District 25

Cc: Tonya Kidd, Staff Director
Robin Jackson, Committee Administrative Assistant

REPLY TO:
❒ 215 SW Federal Highway, Suite 203, Stuart, Florida 34994 (772) 221-4019
❒ 310 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5025

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

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

4/4/19
Meeting Date

7078
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Cynthia Henderson

Job Title _____

Address 108 E. Jefferson St. Suite A
Street

Tall. FL 32301
City *State* *Zip*

Phone 850 559 0855

Email cynenderson@me.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

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)

4/4/2019
Meeting Date

7078
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Health Care

Name Zayne Smith

Job Title Associate State Director

Address 200 W. College Ave.
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Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

April 4, 2019
Meeting Date

SB 7078
Bill Number (if applicable)

224512
Amendment Barcode (if applicable)

Topic Pediatric Cardiac Advisory Panel

Name Philip Gold

Job Title Attorney

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Street

Phone 305 567 2525

Miami FL 33156
City *State* *Zip*

Email pgold@goldlawpa.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing FJA

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 4, 2019
Meeting Date

SB 7078
Bill Number (if applicable)

195108
Amendment Barcode (if applicable)

Topic Medical Records Copy Charges

Name Philip Gold

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Miami FL 33156
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Email pgold@goldlawpa.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing FJA

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 1528
INTRODUCER:	Health Policy Committee and Senator Bean and others
SUBJECT:	Canadian Prescription Drug Importation Program
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Fav/CS**
2.	McKnight	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1528 creates the Canadian Prescription Drug Importation Program (Program). The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential for cost savings to the state.

The bill requires the AHCA to competitively procure and contract with a vendor to administer the Program by December 1, 2019, develop a plan for federal approval of the Program, and submit the plan to the U.S. Department of Health and Human Services (HHS) by July 1, 2020, Once federal approval is granted, the AHCA is required to return to the Legislature and receive final approval before implementation. As part of that final approval process, the bill requires the Legislature to consider the estimated cost savings to the state and whether the Program has met the required safety standards.

The bill contains numerous requirements for the vendor and for Program participants, designed to ensure the Program is safe and effective and results in cost-savings. The vendor, any participating supplier, and any participating importer must post two surety bonds of at least $1 million each; one bond is for administrative and performance-related actions and the other is to ensure participation in and payment of any civil and criminal causes of action.

The bill also provides that the administrative fees borne by the state and the profit margins for any participating wholesaler, pharmacy, or pharmacist relating to drugs imported through the program will be limited to a maximum amount as specified each year in the General Appropriations Act.

The AHCA is annually required to submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives providing required information by December 1. The AHCA is authorized to adopt rules to implement the Program.

The bill has an overall indeterminate fiscal impact at this time with an expectation that there will be start-up costs associated with the implementation prior to any achievement of potential savings under the Program, including costs associated with competitively soliciting a qualified vendor and hiring additional personnel to manage the contract and conduct appropriate oversight and monitoring activities. The AHCA anticipates requiring six additional full-time equivalent positions for Fiscal Year 2019-2020, estimating a total cost of $572,495, and an estimated total recurring cost of $545,837 for Fiscal Year 2020-2021 and beyond. The AHCA will need to determine the level of federal financial participation in the Program. See Section V. Fiscal Impact Statement.

The bill takes effect on July 1, 2019.

II. Present Situation:

U.S. Healthcare Marketplace

Health care spending represents over 17 percent of the nation's Gross Domestic Product.[1] In comparison to other countries, the United States' per capita health care costs nearly double other counties of comparable size and wealth.[2] In 2017, health care spending in the United States increased 3.9 percent over the prior year to $3.5 trillion, or average health care spending of $10,739 per person.[3]

Spending on prescription drugs in 2017 was $333.4 billion.[4] Of that amount, the vast majority, $285 billion, was paid through health insurance coverage which includes private health insurance, Medicare, Medicaid, and other health insurance coverage.[5]

In a study sponsored by the federal Centers for Disease Control and Prevention (CDC), a majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the

[1] Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, p. 1, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited March 28, 2019).
[2] Peter J. Peterson Foundation, *Per Capita Healthcare Costs-International Comparison* (August 10, 2018), https://www.pgpf.org/chart-archive/0006_health-care-oecd (last visited March 28, 2019).
[3] *Supra* note 1.
[4] *Id.*
[5] Centers for Medicare and Medicaid Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017,* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited March 21, 2019).

past 12 months.[6] Further, approximately 70 percent of prescription medications carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or a deductible, with generics costing an average of $6 per prescription and brand names an average cost of $30 per prescription.[7]

Many adults who are prescribed drugs with higher out-of-pocket costs will forego their prescriptions or will take other measures, including considering other non-medication therapies, to avoid the out-of-pocket costs. The CDC study found that while the number of adults who asked their health care provider for an alternative medical treatment option with a lower out-of-pocket cost had dropped from a prior study, the percentage remained relatively constant from 2015 through 2017 at 19.5 percent.[8] Other strategies that adults used included not taking the medication as prescribed, which could mean skipping doses, taking less than the prescribed dose, delaying a refill, or using alternative therapies instead of the prescribed medication.[9]

As with the comparison of general health care costs, the United States' prescription drug spending on its own also stands in stark contrast to other industrialized nations. By 2015, the United States' spending on prescription drugs had exceeded $1,000 per person per year and was 30 to 190 percent higher than nine other western countries.[10]

Role of Price Controls

Reasons given for the price differentials among the countries primarily are related to the fact that most of these nations have some type of price control over drug pricing. In the United States, only two federal entities, the U.S. Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA), negotiate directly with drug manufacturers for drug prices, and they pay approximately 50 percent of what is paid at a retail pharmacy.[11] The discount is equal to 24 percent off of a drug's average price or the lowest price paid by other non-federal buyers, as well as other discounts if a drug's price outstrips inflation.[12]

The United States typically uses drug price controls in one of two ways. First, in the manner described above with the DoD and the VA in the form of a required discount of the average price paid by other purchasers of the same product. The other manner is through negotiated pricing when the government wields its market power as a large purchaser of health care services to bargain for more favorable rates from pharmaceutical suppliers.[13]

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[6] Robin A. Cohen, et al, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017, NCHS Data Brief* (March 2019), p. 1, https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf (last visited March 28, 2019).
[7] *Id*.
[8] *Id*.
[9] Robin A. Cohen, *supra* note 6, at 2 - 4.
[10] Dana O. Sarnak, et al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier (last visited March 28, 2019). The nine western countries used in comparison are Switzerland, Germany, Canada, France, United Kingdom, Australia, Netherlands, Norway, and Sweden.
[11] Dana O. Sarnak, et al, *supra* note 10.
[12] David Blumenthal, M.D. and David Squires, *Drug Price Control: How Some Government Programs Do It*, The Commonwealth Fund, (May 10, 2016) www.commonwealthfund.org, https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it?redirect_source=/~/media/2aca550e3b1446fd91b0f5d0b16eb87c.ashx (last visited March 28, 2019).
[13] David Blumenthal, M.D. and David Squires, *supra* note 12.

Medicaid is also the recipient of manufacturer discounts and rebates, receiving whichever is lower: typically 23.1 percent less than the average price paid for the drug by other buyers, or the lowest price at which the drug is sold to other buyers.[14] Medicaid can also negotiate additional rebates and will receive additional discounts if the price of the drug rises faster than inflation.[15]

Medicare Part D, the prescription drug benefit for Medicare, differs from Medicaid in the prices paid for prescription drugs and in the measures used to control prescription drug spending. These differences are often a function of the varying options statutorily available relating to copayment restrictions, rebate levels, and the fact that the two programs do not serve the same constituencies, and therefore, the drug usage between the programs do not match up.[16]

Programmatic Differences – Prescription Drugs[17]		
	Medicare Part D	**Medicaid Fee for Service**
Average Rebate	17 percent	56 percent
Use of Generic Drugs	75 percent	70 percent
Average Price of Drugs in 53 Therapeutic Classes	$49	$36

Out of Pocket Costs

From a cost perspective, 58 percent of respondents to a recent Kaiser Family Foundation survey reported spending $100 or more a month on prescriptions, 49 percent reported being in fair or poor health, 35 percent said they were taking four or more prescriptions a month, and 35 percent reported an annual income of less than $40,000. Further, three in ten of all adults (29 percent) reported not taking their medicines as prescribed at some point in the past year because of the cost and one in ten (8 percent) said their condition got worse as a result of not taking their prescription as recommended.[18]

The survey also demonstrated that the public views profits made by pharmaceutical companies as the largest contributor to prescription drug prices (80 percent), followed by the cost of research and development (69 percent), profits made by pharmacy benefit managers or PBMs (63 percent), and the cost of marketing and advertising (52 percent).[19]

When the survey asked the public how prescription drug costs could be kept down, the top five answers were:

- Requiring drug companies to include list prices in ads (88 percent).
- Making it easier for generic drugs to come to market (88 percent).

[14] David Blumenthal, M.D. and David Squires, *supra* note 12.
[15] *Id.*
[16] Congressional Budget Office, Competition and the Cost of Medicare's Prescription Drug Program (July 2014), p. 30, https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf (last visited March 28, 2019).
[17] Congressional Budget Office, *supra* note 16, at 31-32.
[18] KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/ (last visited March 28, 2019).
[19] *Id.*

- Allowing the government to negotiate with drug companies to get a lower price for people with Medicare (86 percent).
- Allowing Americans to buy drugs imported from Canada. (80 percent)
- Planning an annual limit on out-of-pocket drug costs for people with Medicare (76 percent).[20]

Blame for prescription costs in the U.S. can likely be attributed to a number of different causes if the number of newspaper articles, blog posts, and magazine stories about the issue are anything to go by in the past several years. Representatives from the PBMs will argue that the country cannot be responsible for subsidizing the research and development costs for the world.[21] Drug makers often insist that comparing prices country to country or even payor to payor is not a true comparison of prices since comparisons do not include all of the discounts drug makers may provide.[22] In remarks to stakeholders and the news media, the current Secretary of the U.S. Department of Health and Human Services (HHS), Alex Azar, remarked that "the problem has multiple parts: high list prices, overpaying in government programs, high out-of-pocket costs, foreign government free-loading. They are connected in a way that attempting to squeeze one end of the balloon won't lead to lasting change."[23]

Federal Regulation of Prescription Drugs

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for ensuring that food, drugs, biological products, and medical devices are effective and safe for public consumption. The FDA regulates these areas under the authority of the Food, Drug, and Cosmetic Act (FDCA).[24] Generally, the state boards of pharmacy have primary responsibility for oversight and regulation of pharmacy; however, the FDA regulates, and in some cases preempts state action, through the FDCA and the Drug Quality and Security Act (DQSA). The DQSA created a national uniform standard and an electronic system for the tracing of drugs at the package level, preempting pedigree laws that previously existed in Florida and 28 other states. During the 2016 Legislative Session, Florida conformed its statutes to the revised federal standards.[25]

The FDCA prohibits any drug from being introduced or delivered for introduction or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further

[20] KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/ (last visited March 28, 2019).
[21] Robert Langreth, et al, *The U.S. Pays a Lot More for Top Drugs Than Other Countries,* Bloomberg News (December 18, 2015), https://www.bloomberg.com/graphics/2015-drug-prices/ (last visited March 28, 2019). "We can no longer sustain a system where 300 million Americans subsidize drug development for the entire world," said Steve Miller, chief medical officer for Express Scripts Holding Co.
[22] Robert Langreth, et al, Bloomberg News. "The difference in prices here in the U.S. compared to other countries is often vastly overstated," said Robert Zirkelbach, spokesman for the Pharmaceutical Research Manufacturers of America trade group.
[23] Alex M. Azar, II, *Remarks on Drug Pricing Blueprint (May 14, 2018) as prepared for delivery,* delivered in Washington, D.C., https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (last visited March 28, 2019).
[24] Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq. 52 Stat. 1040 et. seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.
[25] *See* ch. 2016-212 Laws of Florida (CS/CS/HB 1211)

prohibits adulterated[26] or misbranded drugs[27] and devices from being introduced, delivered for introduction, or received in interstate commerce.[28] In a warning letter dated February 26, 2019, to CanaRx, the FDA cited this statutory reference and at least five others it believed had been violated by a foreign pharmacy and its business associates in the delivery of prescription drugs from Canada to recipients in the United States.[29] CanaRx serves as a broker between foreign pharmacies and public and private employer sponsored health plans to provide employees with prescription drugs, according to the FDA. The letter identified issues with dispensing unapproved new drugs, substitution of FDA approved drugs with recalled or unapproved drugs, misbranded drugs, and drugs subject to the Risk Evaluation and Mitigation Strategy program.[30] More than 150 websites were included in the letter as affiliated with CanaRx. The FDA gave CanaRx 10 days to respond to the warning letter.

Drug Approval Process

The FDA process for new and innovative drugs is rigorous and requires an exhaustive and extensive series of clinical trials, first on animals and then on humans, before a new drug application (NDA) can even be formally filed with the FDA.[31] The NDA process has three goals:

- Whether the drug is safe and effective in its proposed uses(s), and whether the benefits of the drug outweigh the risks.
- Whether the drugs proposed labeling (package insert) is appropriate and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[32]

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[26] An "adulterated drug or device" is defined, in part, under 21 U.S.C. 351, as a drug or device that consists "in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…"

[27] A "misbranded drug or device" is defined, in part, under 21 U.S.C. 352, as a drug or device whose "labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to false or misleading under this paragraph if the health care economic information related to an indication approved under section 505 or under section 351 of the Public Health Service Act for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act…

[28] *See* 21 U.S.C. 331 (as amendment through P.L. 115-271, enacted October 24, 2018).

[29] Letter to Gregory Anthony Howard, CanaRx Services, Inc. (Feb. 26, 2019), U.S. Food and Drug Administration Warning Letter, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm (last visited March 28, 2019).

[30] The FDA's Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program for drugs that have a narrow therapeutic index, and/or is the drug is indicated to treat a serious condition such as HIV, cancer, or hepatitis. A strategy is designed specific to a particular drug to address the safety and risk concerns unique to that drug, such as requiring that a drug only be administered in a health care facility or by a provider. Another strategy may be a special patient information pamphlet insert included with the prescription. All of the strategies are aimed at reducing the frequency or severity of an adverse event.

[31] U.S. Food and Drug Administration, *New Drug Application,* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited March 28, 2019).

[32] U.S. Food and Drug Administration, *supra* note 31.

Drug Manufacturer Compliance

The FDA ensures the quality of the United States' drug products by carefully monitoring drug manufacturer's compliance with its Current Good Manufacturer's Practice Regulations. (CGMP), which are the main regulatory standard for ensuring pharmaceutical quality for human pharmaceuticals.[33] The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, packaging, and labeling pharmaceuticals. The regulations are found in 21 Code of Federal Regulations (CFR) Part 211 and specify the responsibilities of the quality control unit, personnel qualifications and responsibilities, the design and construction of facilities, the equipment requirements, production and process controls, packaging and labelling control, including tamper-evident package requirements, laboratory controls, requirements for records and reports, and returned and salvaged drug products.

Drug Distribution

The Drug Supply Chain Security Act[34] (DSCSA) establishes procedures to ensure the integrity of prescription drugs as they are distributed along the supply chain. Effective July 1, 2015, the DSCSA requires manufacturers, re-packagers, wholesale distributers, and dispensers to exchange product tracing information when transferring a product along the distribution chain. As noted earlier, this national product tracing process replaces Florida's previous pedigree paper system.

This product tracing information includes the following:

- Name of the drug.
- Strength and dosage form of the drug.
- National Drug Code number of the drug.
- Container size and number of containers.
- Lot number of the drug.
- Date of the transaction.
- Date of the shipment, if more than 24 hours after the date of transaction.
- Business name and address of the person from whom ownership is being transferred.
- Business name and address of the person to whom ownership is being transferred.

These entities must maintain these records for 6 years and provide them to the FDA upon request.

Drug Supply Chain Security

The path a drug takes from unfinished product to when it is handed to a patient, either at a hospital bedside or to a customer at a community pharmacy, is called the supply or distribution chain. Along that path, there are several opportunities for the product to become mishandled or adulterated, whether it is in the United States or abroad.

The first legislation that dealt with such issues was the 1906 Food and Drugs Act, which addressed the labeling of drugs; then the 1938 Food, Drug, and Cosmetics Act (FDCA), which

[33] U.S. Food and Drug Administration, *Questions and Answers on Current Good Manufacturing Practices (CGMPs),* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm124740.htm (last visited March 28, 2019).
[34] *See* Title II of DQSA, the Drug Supply Chain Security Act, Pub. Law 113-54 (2015).

introduced the concepts of adulteration, misbranding, registration, and inspection of manufacturing establishments; and the Prescription Drug Marketing Act (PDMA, P.L. 100-293), which required that wholesale distributors be licensed by the states and that a wholesale distributor, except in certain circumstances, must issue a pedigree, which has since been superseded by the tracing requirements in the DQSA in 2015.[35]

Supply security issues can include contamination of products, diversion, counterfeiting, and other adulteration, according to statements made by the Director of the Center for Drug Evaluation and Research (CDER) at the FDA, Dr. Janet Woodcock, in testimony to Congress in 2013.[36] In her testimony, she referenced cases involving counterfeit and fraudulent versions of Botox sold in the United States, Lipitor sold in the United Kingdom, and Avastin in the United States.[37]

Interaction with the Foreign Market

As globalization has increased, the FDA has established foreign offices to work closely with foreign governments, industry, and other stakeholders to enable the FDA to more effectively protect American consumers, including inspections and investigations in those countries. The FDA indicates that about 35 percent of the medical devices used in the United States are imported.[38]

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import in the United States must register with the FDA.[39] Today, there are 136,400 foreign facilities in more than 150 countries that export FDA-regulated products to the United States.[40] The FDA estimates that 80 percent of the active pharmaceutical ingredients and 40 percent of the finished drugs in the U.S. market are actually manufactured in FDA-registered facilities in other countries, primarily India and China.[41]

The FDA does not regularly inspect every foreign facility and instead relies on a risk-based assessment to determine which facilities to inspect and how often.[42] In federal fiscal year 2017-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and

[35] Susan Thaul, Congressional Research Service, *Pharmaceutical Supply Chain Security* (October 31, 2013), Summary, http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf (last visited March 28, 2019).
[36] Susan Thaul, Congressional Research Service, *supra* note 35, at 1.
[37] Susan Thaul, Congressional Research Service, *supra* note 35, at 2.
[38] U.S. Food and Drug Administration, *FDA Globalization*, https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm (last visited March 28, 2019).
[39] Section 510 of the federal Food, Drug, and Cosmetic Act.
[40] U.S. Food and Drug Administration, *FDA Globalization*, *supra* note at 38.
[41] FDA Commissioner Margaret Hamburg, *The Safety of Prescription Drugs Made Outside the U.S.*, The Diane Rehm Show (February 20, 2014), *transcript available at* https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us (last visited March 28, 2019).
[42] Section 705 of the FDA Safety and Innovation Act, 2012. Factors considered include the establishment's compliance history or history and nature of recalls, the inherent risk of the drug being manufactured, whether the establishment has been inspected in the last 4 years, whether a foreign government has inspected the establishment, and anything else the FDA determines is important in determining where inspection resources should be spent.

historically, 381 since 2014-2015.[43] This means that less than 1 percent of foreign FDA-registered drug manufacturing facilities are inspected by the FDA each year.

Since the FDA does not have the resources to effectively enforce drug manufacturing regulations in every facility overseas, it must instead rely on cooperation with the governments of each country to ensure the safety of drugs or pharmaceutical products imported into the United States. The FDA may memorialize these partnerships in an international arrangement, which is a written understanding between two or more countries recognizing one another's conformity with certain processes or procedural standards and describing the willingness and good-faith intentions of the countries to engage in cooperative activities.[44] International arrangements can have a variety of titles, including "cooperation agreement," "memorandum of understanding," or "mutual recognition agreement." The FDA currently has at least 60 such international arrangements with foreign governments.[45]

In instances where the U.S. determines that another country adheres to current good manufacturing practices for pharmaceutical products, it may enter into an international arrangement and authorize the foreign government to conduct facility inspections on the FDA's behalf. The FDA has such international arrangements with Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Malta, Romania, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Drug Importation

The FDCA generally prohibits the importation of foreign drugs into the U.S. unless the drug was manufactured by a foreign facility registered with the FDA and the foreign drug is specifically FDA-approved, or the drug was manufactured in the U.S., is FDA-approved, and is being reintroduced into the U.S. by the original manufacturer.

The FDA approval requires the manufacturer to submit documentation establishing the drug's safety and efficacy, which includes information as to the method, facilities, and manner of manufacture.[46] Without this FDA-approval, these drugs are considered misbranded and illegal for importation. The FDCA prohibits interstate shipment, including importation, of 'unapproved new drugs,'[47] which includes any drugs, including foreign-made versions of U.S.-approved drugs, which have not been manufactured in accordance with and pursuant to FDA approval (i.e.

[43] U.S. Food and Drug Administration, *Total Number of Inspections Completed in the Month,* https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-commodity (last visited March 28, 2019).
[44] U.S. Food and Drug Administration, *International Agreements,* https://www.fda.gov/InternationalPrograms/Agreements/default.htm (last visited March 28, 2019); *See also, FAQs: The Mutual Recognition Agreement,* https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf (last visited March 28, 2019)
[45] U.S. Food and Drug Administration, *Cooperative Arrangements* https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm (last visited March 28, 2019).
[46] 21 U.S.C. s. 355(b)(1).
[47] 21 U.S.C. s. 355(a).

not in an FDA-registered facility or by an FDA-approved manufacturer).[48] The FDCA further prohibits importation of an FDA-approved drug by anyone other than the original manufacturer of the drug.[49]

Additionally, the DSCSA requires all health care entities that distribute, dispense, and administer prescription drugs to patients to purchase their prescription drug products only from authorized "trading partners" (wholesale distributors, manufacturers, re-packagers, and dispensers) that are licensed or registered with the state or federal government.[50]

Therefore, any importation, by any person or entity other than the original manufacturer, of drugs not FDA-approved in the manner described above, would be a violation of federal law.

However, federal law does authorize the HHS to grant individual persons waivers to import drugs, exercise discretion in enforcing the law against individuals importing for personal use, and focus enforcement efforts on cases that pose a significant threat to public health.[51] The FDA has stated in guidance documents that enforcing such prohibitions against individual persons was not considered a priority.[52]

The Medicare Modernization Act of 2003 [53]

The federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a provision on the importation of pharmaceutical drugs. It authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with the approval of the HHS. Specifically, after consulting with relevant federal agencies and determining that such importation would produce costs savings and would not pose an additional risk to public health and safety, the HHS is required to adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs[54] from Canada into the United States. These regulations must:

- Require compliance with safeguard requirements of 21 U.S. sections 355 (regarding new drugs) and 351 (regarding adulteration) and 352 (regarding misbranding);
- Require an importer of a prescription drug to comply with the documentation and sample-testing requirements of the MMA; and
- Contain any additional provisions the HHS Secretary deems appropriate to safeguard public health or to facilitate the importation of prescription drugs.

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[48] Marvin Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy, FDA*, U.S. Food & Drug Admin., (September 25, 2015), https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm (last visited March 28, 2019).
[49] 21 U.S.C. s. 381(d)(1). This prohibition also applies to wholesalers, 21 U.S.C. sec. 384(a)(5)(B). The FDA justifies this by saying that the safety and integrity of the drugs cannot be ensured by any other entity but the manufacturer, *Imported Drugs Raise Safety Concerns*, U.S. Food & Drug Admin. (May 4, 2016), https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm (last visited March 28, 2019).
[50] Pub.L. 113–54
[51] 21 U.S.C. s. 384(j).
[52] U.S. Food and Drug Administration, *Importations of Drugs*, Information on the Importation of Drugs, https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm (last visited March 28, 2019).
[53] Pub. L. No. 108-173 s. 1121.
[54] Excluding controlled substances, biological products, infused drugs, IV-injected drugs, drugs inhaled during surgery, or a parenteral drug the HHS Secretary deems to pose a threat to public health.

This would allow licensed or permitted entities to import FDA-approved drugs from Canada, whereas currently only the original manufacturer may do so.

However, this section of the MMA provides that it becomes effective only if the HHS Secretary certifies to the U.S. Congress that the implementation will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. To date, no HHS Secretary has done so or has otherwise authorized an importation program under this provision.[55] Shortly after the MMA passed, states and local governments requested waivers from the FDA in an attempt to import prescription drugs within their jurisdictions, but states that sought prior approval have all been denied on the basis that they did not ensure the safety of drugs that would be imported.[56]

In 2004, Illinois announced a plan to allow residents to order medications through a pharmacy-benefits manager network based in Canada that would access pharmacies located in Canada, Ireland, or the United Kingdom.[57] Only prescriptions that were refills, did not require refrigeration, were not controlled substances, and were for chronic conditions, would be allowed under the program.[58] Pharmacies that participated would also have to agree to allow state inspectors on-site.[59] News reports indicated that the program incurred $1 million in start-up costs and enrolled fewer than 4,000 before it was terminated at the end of 2008.[60]

Maine passed legislation in 2013 to facilitate personal importation of prescription drugs through the mail from Canada, the United Kingdom, Australia, and New Zealand via retail pharmacies shortly after the passage of the MMA.[61] The law was introduced after the City of Portland, Maine, was banned in August 2012 by the state's then-Attorney General from purchasing pharmaceuticals from Canada.[62] Before implementation could begin, a lawsuit was filed by the Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and the Retail Association of Maine alleging that the federal FDCA preempted the new state importation law and the changes to the Maine Pharmacy Act; jeopardized the safety of the nation's prescription

[55] Additionally, in March 2017, the four most recent FDA commissioners sent a letter to Congress attesting that drug importation would "harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." *letter available at* http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf (last visited March 28, 2019).
[56] Peral, Eloy A. *FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation*. HEALTH LAW & POLICY Brief 3, no. 1 (2009), 48 - 55, *available at* https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1094&context=hlp (last visited March 28, 2019).
[57] Donna Young, *Illinois Initiates Importation Plan,* https://www.ashp.org/news/2004/08/17/illinois_initiates_importation_plan (last visited March 28, 2019).
[58] Donna Young, *supra* note at 57.
[59] *Id.*
[60] Sally C. Pipes, *Blagojevich's failed drug importation plan a cautionary tale,* https://www.pacificresearch.org/blagojevichs-failed-drug-importation-plan-a-cautionary-tale/ (last visited March 28, 2019).
[61] 2013 Me. Laws 373. *See* http://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=20663 (last visited March 28, 2019).
[62] Thomas Hemphill, *Prescription Drug Imports: Maine Leads, the Nation Follows?* https://www.americanactionforum.org/insight/prescription-drug-imports-maine-leads-the-nation-follows/ (last visited March 28, 2019).

drug supply; and opened the door to counterfeit and tainted medications.[63] The Seventh District Court in Maine agreed, citing the basics of federalism in its opinion:

> *Federalism, central to the constitutional design, adopts the principal that both the National and State Government have elements of sovereignty the other is bound to respect. From the existence of two sovereigns follows the possibility that laws can be in conflict or at cross-purposes. The Supremacy Clause provides a clear rule that federal law shall be the supreme Law of the Land and the Judges in every State shall be bound thereby, any Thing in the Constitution or Law of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under this principle, Congress has the power to preempt state law.*

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012) (citations omitted).

Since 2015, there has been renewed interest in drug importation. Over a dozen states each year have considered drug importation legislation in different formats, and in 2018, Vermont was the first state to pass wholesale prescription drug importation program legislation.[64] Vermont's program is not a waiver of existing law, but is an importation program that seeks to satisfy both the safety and security assurances. Drugs may be imported only from Canada under provision, 21 U.S.C. section 384, with the inclusion of the required laboratory testing. Controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery are excluded.[65] The initial program design focused on providing savings to the Vermont Medicaid program; however, the benefit to Medicaid was minimal because Vermont's Medicaid program was already yielding substantial savings through existing rebates, and implementation of the drug importation program for that population would not result in any net savings.[66]

Vermont found that a small number of drugs imported through Canada may be more cost-effective for a limited period of time; however, the state's stakeholders decided to see if greater savings could be found for the state's commercial health insurers.[67] Using conservative estimates, participating plans estimated savings in the range of $2.61- $2.82 per member per month, or $1-$5 million per year, without taking into account the state's operating costs.[68]

As part of the proposed regulatory process, Vermont plans to create two new licenses: Rx Drug Importer Wholesaler and Canadian Rx Drug Supplier. Vermont will extend the DCSA requirements to the licensees and has also established other participation requirements for both

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[63] *Ouellette et al v. Mills et al*, 13-347 - *Order on Parties Competing Motions on Facial Preemption (Docket No: 1:13-cv-00347-NT)(U.S. D.Ct. Maine)(February 23, 2015).*
[64] NATIONAL ACADEMY FOR STATE HEALTH POLICY, *State Legislative Action to Lower Pharmaceutical Costs* (updated March 1, 2019), https://nashp.org/rx-legislative-tracker-2019/ (last visited March 28, 2019).
[65] Vermont Agency of Human Services, *Wholesale Importation Program for Prescription Drugs Legislative Report* (December 31, 2018), https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf (last visited March 28, 2019).
[66] Vermont Agency of Human Services, *supra* note 65, at 3.
[67] Vermont Agency of Human Services, *supra* note 65, at 3.
[68] Vermont Agency of Human Services, *supra* note 65, at 4.

licenses.[69] Licensure will provide a potential revenue sources for the program through application, registration, and audit fees.[70]

Vermont has not yet sent a plan to the federal government for approval. The state still has a list of tasks and options that need to be worked through before a plan is submitted.

The Trump Administration has also shown interest in lowering the costs of prescription drugs for American consumers, including the possibility of drug importation.

In May 2018, American Patients First, the Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs was released.[71] The Blueprint includes four challenges in the American drug market:

- High list prices for drugs.
- Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools.
- High and rising out-of-pocket costs for consumers.
- Foreign governments taking advantage of American investments in innovation.

Some of the opportunities listed in the *Blueprint* for lower costs include restricting the use of rebates, calling for Medicaid demonstration projects to test coverage and financing reforms that build on private sector best practices with drug formularies, creating incentives to lower list prices, addressing transparency in pricing in Medicare and Medicaid, and seeking public comment on further ideas and opportunities.

In July 2018, the HHS directed the FDA to establish a work group on drug importation.[72] The work group is examining the potential for importation to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. The work group has not yet issued any recommendations or reports.

Personal Importation

The MMA also authorized the HHS to allow individuals to import drugs from Canadian-licensed pharmacies for personal use without penalty in certain circumstances, either on a case-by-case waiver basis or by regulation.[73] The HHS has not yet implemented this provision, however, the FDA uses its enforcement discretion and does not generally enforce violations of drug importation for personal use.

The FDA generally does not object to a person importing a drug from any country so long as it is for personal use, even though such importation would violate the FDCA.[74] The FDA recognizes

[69] Vermont Agency of Human Services, *supra* note 65, at 5-6.
[70] Vermont Agency of Human Services, *supra* note 65, at 10.
[71] U.S. Department of Health and Human Services, *American Patients First*, https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html (last visited March 28, 2019).
[72] U.S. Department of Health and Human Services, *Press Release* (July 19, 2018) https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html (last visited March 28, 2019).
[73] 21 U.S.C. s. 384(j).
[74] U.S. Food and Drug Administration, *Personal Importation*, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm (last visited March 28, 2019).

there are situations where foreign medications may be appropriate for a particular individual consumer and that the FDA's resources are better served enforcing regulations against commercial shipments of foreign medication into the United States.[75]

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CBP). The CBP is instructed to only notify the FDA when it appears that there is an FDA-regulated drug intended for commercial distribution, the FDA has specifically requested that drug be detained, or the drug appears to represent a health fraud or an unknown risk to health.[76]

This FDA policy is not intended to cover importation of foreign-made chemical versions of drugs available in the U.S. (i.e., cheaper, foreign versions of U.S. drugs). However, since there is a permissive attitude towards drugs for personal use shipped or brought into the U.S., it is likely that people are importing such drugs undetected. A 2016 poll showed that eight percent of U.S. households have bought prescription drugs from Canada or other countries in order to pay a lower price.[77]

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.[78] They must have exhausted all other treatment options in the United States and be unable to participate in a clinical trial for an investigational drug. The particular drug imported must be actively pursuing FDA-approval and have completed the first phase of clinical trials.

State Regulation of Prescription Drugs

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy together regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of the DBPR or the DOH, as applicable. Due to the overlap in these two industries, the law requires entities permitted or licensed under either the DBPR or the DOH to comply with the laws and rules of both.[79]

The DBPR's Division of Drugs Devices and Cosmetics

The DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and

[75] U.S. Food and Drug Administration, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, (December 2017) at 9-2, *available at* https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf (last visited March, 28, 2019).
[76] U.S. Food and Drug Admin., *supra* note 72.
[77] KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll: November 2016*, http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline (last visited March 28, 2019).
[78] Right to Try Act of 2017, Pub. Law No 115-176.
[79] Sections 499.067 and 465.023, F.S.

cosmetics by enforcing Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.[80] The Florida Drug and Cosmetic Act conforms to the FDA drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[81]

Florida has 18 distinct permits based on the type of entity and intended activity and includes permits for entities within the state, out of state, or even outside of the United States.[82] The DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[83]

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[84] A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[85] Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[86] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[87]

Prescription Drug Wholesale Distributor Permit

Wholesale distribution is the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, with various exceptions for activities related to healthcare entities, governmentally-contracted public health services, and charitable organizations.[88] A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state.[89]

Out-of-State Prescription Drug Wholesale Distributor Permit

An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories,

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[80] Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/ (last visited March 28, 2019).
[81] Section 499.01, F.S.
[82] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. Section 499.01(1), F.S.
[83] Section 499.051, 499.062, 499.065. 499.066, 499.0661, and 499.067, F.S.
[84] Section 499.003(28), F.S.
[85] Section 499.01(2), F.S.
[86] Section 499.01(2), F.S.
[87] Section 499.003(16), F.S.
[88] Section 499.003(48), F.S.
[89] Section 499.01(2), F.S.

which engages in the wholesale distribution of prescription drugs into this state.[90] The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor by the FDA.[91]

Board of Pharmacy

The Board of Pharmacy (Board) within the DOH regulates the practice of pharmacy by enforcing the Florida Pharmacy Act (Act), adopting rules that set the standards of practice in the state, and licensing and monitoring pharmacists and pharmacies to ensure safe practice.[92] To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.[93] Any person or entity licensed, permitted, or registered pursuant to ch. 465, F.S., must practice pharmacy in accordance with the provisions of the Act and the Board rules.

The practice of pharmacy is also subject to the requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act, ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, the FDCA, and the Federal Comprehensive Drug Abuse Prevention and Control Act. The DOH has broad authority to inspect pharmacies for violations and the Board can discipline a person or entity's license, permit, or registration for violation of any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.[94]

III. Effect of Proposed Changes:

Section 1 creates the Canadian Prescription Drug Importation Program (Program) under newly created s. 381.02035, F.S. The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

Definitions for the Program are specifically created:

- *Agency* means the Agency for Health Care Administration (AHCA).
- *Canadian supplier* means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.
- *Drug or Prescription drug* has the same meaning as "prescription drug" in s. 499.003, F.S.
- *Federal Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.
- *Importer* means a wholesale distributer, pharmacy, or pharmacist importing prescription drugs into this state under this Program.
- *Pharmacist* means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

[90] Section 499.01(2), F.S.
[91] Section 499.01(2), F.S.
[92] Chapter 465, F.S.; Florida Board of Pharmacy, https://floridaspharmacy.gov/ (last visited March 28, 2019).
[93] Section 465.022, F.S
[94] Section 465.0465(1), F.S.

- *Program* means the Canadian Prescription Drug Importation Program.
- *Track and Trace* means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.
- *Vendor* means the entity contracted by the Agency to manage specified functions of the Program.

An importation process for the Program is established which includes the selection of a vendor by the AHCA, the identification of importers and suppliers, and establishment of eligibility for these entities. Criteria is also established for eligible prescription drugs as well as requirements for distribution and prescription drug supply chain documentation.

Steps in the implementation process delegated to the vendor or other entities to perform are reflected in the chart below.

The AHCA is also:
- Provided the authority to immediately suspend importation of a specific drug by an importer upon learning that any drug activity is in violation of the Program or any federal or state law or regulation.
- Required to request approval of the Program from the HHS Secretary by July 1, 2020, and upon federal approval, notify the President of the Senate, the Speaker of the House of Representatives, and the relevant legislative committees. Prior to implementation, the Legislature must approve the Program as authorized by the HHS.
- Submit an annual report to the Governor, President of the Senate, and Speaker of the House of Representatives by December 1, entailing specific information about the operation of the Program during the previous year.
- Authorized to adopt rules necessary to implement the Program.

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
AHCA Responsibilities		
Contract	Contract with a vendor to provide services.	
Safety concerns	Authorized to immediately suspend the importation of a specific drug or the importation of specific drugs by a specific importer if there are safety concerns or there is any activity in violation of Canadian, federal, or state law. The suspension may be revoked if, after conducting an investigation, the AHCA determines that no threat to public safety exists from unsafe drugs.	
Program Plan	The plan that is submitted for federal approval must include, at a minimum, the following elements: • The AHCA's plan for operating the Program.	Required to submit to the HHS by January 1, 2020

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
	• A demonstration of how the prescription drugs will be imported into the state and meet the applicable federal and state standards for safety and cost effectiveness. • A demonstration of how the drugs imported into the state under the Program will comply with federal tracing procedures. • A list of prescription drugs that have the highest potential for cost savings to the state through importation at the time the request is submitted. • Inclusion of an estimate of the total cost savings attributable to the Program. • Inclusion of an estimate of the total costs of Program implementation to the state. • Inclusion of a list of potential Canadian suppliers from which the state would import drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.	
Federal Approval	Once approved by the HHS, the AHCA will notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House. The Program may not be implemented until reviewed and approved by the Legislature. The bill requires that the estimated cost savings to the state and whether the proposed Program meets the safety standards must be considered as part of the final review process.	
Annual Report	Submit an annual report to the Governor, President of the Senate, and Speaker of the House of Representatives containing required information about the operation of the Program during the previous year, including documentation demonstrating how the Program ensures that: • Canadian suppliers participating in the Program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations; • Prescription drugs imported under the Program are not shipped, sold, or dispensed outside of the state once in the possession of the importer; • Prescription drugs imported under the Program are pure, unadulterated, potent, and safe; • The Program does not put consumers at a higher health and safety risk than if the Program did not exist; and • The Program provides cost savings to the state on imported prescription drugs.	Due annually by December 1

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
Rules	Adopt rules necessary to implement the Program.	
Vendor Responsibilities		
Drug List	Develop a list of prescription drugs every 3 months that have the highest potential for cost savings to the state. Vendor is required to consider which drugs have shortages, specialty prescriptions, and high volume prescription drugs. The AHCA may direct the vendor to revise the list, as necessary.	Review list every 3 months and revise as necessary
Relationship with Suppliers	Identify Canadian suppliers that are in full compliance with Canadian federal and provincial laws and regulations and the Federal Act who have agreed to export drugs on the list. Suppliers must also agree to meet all, or exceed, federal track and trace requirements and applicable federal and state laws and regulations. Verify that all Canadian suppliers on the list meet all of the requirements and will export drugs at prices that will provide the state with cost savings. Contract with or facilitate contracts between eligible Canadian suppliers and eligible importers to import drugs under the Program. Ensure compliance with Title II of the DQSA by all suppliers, importers, and other distributors and participants in the Program. Assist the AHCA with the annual report and provide any requested information on a timely basis.	
	For an imported shipment, the vendor is required to statistically sample and test for authenticity and degradation in a manner consistent with the Federal Act: • For the initial shipment: **Each batch** of the drug in the shipment. • For each subsequent shipment: A statistically valid sample of the **shipment**.	Each batch or each shipment has requirements, depending on whether it is an initial or subsequent shipment of the drug
Drug Importation Safety *Lab Testing Requirements*	Maintain qualified laboratory records, including data derived from all tests necessary to ensure drug comply with these requirements. Maintain information and documentation which demonstrates required testing was done in compliance with	

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
	the Federal Act and any required federal and state testing guidelines. Require all testing to be performed in a qualified lab which meets federal standards under the Federal Act, applicable federal laws and regulations, and state laws and regulations.	
Certification Requirements	Certify that any imported drug is approved for marketing in the U.S., is not adulterated or misbranded, and meets all of the required U.S. labeling standards.	Certification for every drug
Drug Importation Safety Certification Requirements	Maintain records, information, and documentation under this section for at least seven years.	Seven-year requirement
Records Retention	Maintain a list of all registered importers participating in the Program.	The vendor must maintain a current list of importers
Importers and Eligible Drugs for Importation		
Eligibility	The following entities or persons may be eligible to import drugs from a Canadian supplier under the Program after registering with the vendor and being deemed in compliance with all other requirements: 1. A wholesale distributor 2. A pharmacy 3. A pharmacist	
Eligible Drugs	Eligible importers may import a drug from an eligible Canadian supplier, if the importer: • Meets the FDA's standards relating to safety, effectiveness, misbranding, and adulteration; • Importation would not violate patent law; • Importation is expected to generate cost savings; and • The drug is not: o A controlled substance as defined in 21 U.S.C. section 802; o A biological product as defined in 42 U.S.C. section 262; o An infused drug; o An intravenously injected drug; o A drug that is inhaled during surgery; or o A drug that is a parenteral drug, a drug which is determined by the HHS Secretary to pose a threat.	
	Participating importers must provide the following information to the vendor:	

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
Drug Eligibility – Information Requirements	1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage form of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received. 5. The point of origin and destination of the drug. 6. The price paid by the importer of the drug.	
	An importer must submit all of the following to the vendor: 1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received. 5. The point of origin and destination of the drug. 6. The price paid by the importer for the drug.	
Suppliers		
Supplier Eligibility Requirements	A supplier may export prescription drugs into this state under the Program if the supplier is: • In full compliance with relevant Canadian federal and provincial laws and regulations; • Complies with track and trace at the package level. • Identified by the vendor as eligible to participate in the Program.	
Information and Documentation requirements	A participating Canadian supplier must submit the following information and documentation specifying all of the following, in addition to any other information deemed necessary by the AHCA to ensure the protection of the public health: 1. The original source of the drug, including: a. The name of the manufacturer of the drug. b. The date the drug was manufactured. c. The location (country, state/province, and city) where the drug was manufactured. 2. The date the drug was shipped. 3. The quantity of each lot of the drug originally received and from which source. 4. The quantity of each lot of the drug originally received and from which source. 5. The lot or control number and the batch number assigned to the drug by the manufacturer. The AHCA may require that the vendor collect any other information necessary to ensure the protection of the public health.	Information must be submitted for each drug imported

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**
Required information submission	Eligible Canadian suppliers and importers participating under the Program must: 1. Comply with the tracking and tracing requirements under federal law. 2. May not distribute, dispense, or sell prescription drugs under the Program outside of the state.	
Responsibilities – Applicable to Multiple Parties		
Surety Bond – Administrative Penalties for non-performance *Vendor, Suppliers, and Wholesalers*	Requires the vendor and all suppliers and wholesalers to secure a $1 million minimum surety bond or comparable security arrangement which escalates in value as volume escalates for contractual performance issues to ensure: 1. Payment of administrative penalties imposed by the AHCA or any other state agencies. 2. Performance of contractual and statutory obligations while acting on behalf of the AHCA, the state, or other state agencies. 3. Assessment of unpaid administrative which are unpaid 30 days after assessment. 4. Assessment of claims up to one year after the end of the contract, the vendor, supplier, or wholesaler's licensure is no longer valid, or the Program has ended, whichever occurs later.	Must secure surety bond or comparable arrangement at contract award and maintain throughout contract term.
Surety Bond Requirements for Claims related to civil and criminal litigation. *Vendor, Suppliers, and Wholesalers*	Requires the vendor and all suppliers and wholesalers to secure a $1 million minimum surety bond or comparable security arrangement which escalates in value as volume escalates for negligence related claims issues and other torts, for example, to ensure: 1. Payment of legal claims awarded in a court of law; 2. Performance of contractual and statutory obligations while acting on behalf of the AHCA, the state, or other state agencies. 3. Assessment of judgements or claims which are unpaid 60 days after final judgement. 4. Assessment of claims up to one year after the end of the contract, the vendor, supplier, or wholesaler's licensure is no longer valid, or the Program has ended, whichever occurs later.	Must secure surety bond or comparable arrangement at contract award and maintain throughout contract term.
Track and Trace Requirements *Suppliers and Importers*	Eligible Canadian suppliers and importers participating under the Program must comply with tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq. Suppliers and importers may not distribute, dispense, or sell drugs imported under the Program outside of the Program or the state.	

Canadian Prescription Drug Importation Program Responsibilities of the Parties		
Responsibility		**Deadline/Timeframe**

Section 2 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Supremacy Clause

As noted earlier in the analysis, in Maine, several pharmacy groups sued the state under a variety of theories, including the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, arguing that federal law preempted state law and that federal law had, for now, created a "closed regulatory scheme which strictly limited the introduction of prescription drugs into interstate commerce. The plaintiffs also pointed out that Congress contemplated the potential importation of prescription drugs from Canada in the MMA, but that this section had not taken effect because the HHS Secretary has not granted the necessary certification."[95]

The opinion further discusses those situations where state law can still rebut the presumption regarding preemption. The Court must begin with the "presumption that the state statute is valid,[96] particularly if the state law is a matter involving issues regulating public health.[97] There is also a presumption for the state if the area and subject matter is "in any field in which there is a history of state law regulation, even if there is also a history of federal law regulation."[98] To preempt state law, Congress must clearly preempt

[95] *Ouellette et al v. Mills et al, supra* note 63, at 9.
[96] *Pharm. Research & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 661 (2003); quoted in *Ouellette v. Mills, at 10.*
[97] *See Hillsborough County., Fla. v. Automated Med. Lab., Inc.,* 471 U.S. 707, 718 (1985); quoted in *Ouellette et al v. Mills et al, at 10.*
[98] *In re Pharm. Indus. Average Wholesale Price Litig.,* 582 F.3d 156., 176 (1st Cir. 2009) (citing *Wyeth,* 555 U.S. at 565, n. 3).

state law when it is regulating in an area where the state traditionally regulates.[99] In *Ouellette,* the Plaintiffs' argument was that preemption should apply because the amendments passed by the state of Maine to allow for the drug importation program touch on foreign affairs and that subject matter is reserved traditionally for the federal government.[100]

The Court noted in *Ouellette* that Congress had legislated explicitly with respect to the importation of drugs from Canada and the MMA has provided a specific path to legally permissible importation.[101] The Eighth Circuit had also weighed in on this issue and the *Ouellette* court repeated those findings:

> That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. section 384.[102]

Foreign Dormant Commerce Clause

A state's drug importation program must also be carefully reviewed to ensure that it can meet the constitutionality tests of the foreign dormant commerce clause and does not place an undue burden on foreign commerce and the role that the federal government plays in the implementation of foreign policy. The possibility of potential conflicts, therefore, are less likely since a federal statute sets forward a path for federal approval of a program. Concerns regarding intersections with other pharmaceutical programs and arguments, such as those about multiple regulatory schemes, may be issues to be aware of, but they should not have an impact on international relations.[103]

Recently in a case from Maryland, the U.S. Supreme Court declined to review a decision from the U.S. Circuit Court of Appeals for the Fourth Circuit finding that Maryland's state-based price-gouging statute was a violation of the dormant commerce clause because it interfered with

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[99] *Nat'l Foreign Trade Council v. Natsios,* 181 F.3d 38, 73 (1st Cir. 1999)(citing *Rice,* 331 U.S. at 230). The *Natsios* case dealt with a claim by Massachusetts' that its law restricting trade with Burma was an exercise of its procurement authority, a traditional area of state power.
[100] *Supra* note 63, at 11.
[101] *Ouellette v. Mills, supra* note 63, at 15.
[102] *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006) (cited in *Ouellette v. Mills*).
[103] Anna Zaret and Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*(November 2017) National Academy for State Health Policy, https://nashp.org/wp-content/uploads/2017/11/DCC-White-Paper.pdf (last visited March 28, 2019).

interstate commerce as it regulated transactions outside of the state.[104] "The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that 'a state may not regulate commerce occurring wholly outside of its borders."[105]

The Fourth Circuit held that Maryland illegally regulated wholesale pricing by drug companies through a provision enacted in 2017, which prohibited what the state termed as "unconscionable" price increases for essential drugs no longer covered by patents or generics that were sold in the state.[106] The conduct targeted by the law was the upstream pricing and sale of prescription drugs, all of which occurred outside of Maryland which as the court noted then requires the manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.[107]

From its "cases concerning extraterritorial effects of state economic regulation," the Supreme Court outlined the principle against extraterritoriality in a Connecticut case where residents were prohibited from crossing state lines to purchase cheaper beer:

1) A state statute may not regulate "commerce that takes place wholly outside of the State's borders, whether or not the comer has effects within the State.[108] Specifically, a state law may not have the practical effect of establishing a scale of prices for use in other states."[109]
2) A statute that directly controls commerce occurring wholly outside the [legislating state's] boundaries… is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature."[110] The statute's "practical effect" is the focus of the inquiry.[111]
3) In evaluating a statute's "practical effect," the Court considers "not only… the consequences of the statute itself, but also …how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.[112] This is because "the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State."[113]

[104] *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (U.S. App. 4th Cir. 2018).
[105] *Id*. (citing *Star Sci., Inc. v. Beales*, 278 F. 3d 339, 355 (4th Cir. 2002) (citing *Healy v. Beer Inst.*, 324, 335-36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582-83 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982)(plurality opinion)).
[106] *Id*.
[107] *Id.*
[108] *Healy at 336.*
[109] *Healy* (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935)).
[110] *Id.*
[111] *Id.*
[112] *Healy* at 336.
[113] *Healy* at 336-37.

Because the Act targets wholesale rather than retail pricing, the court notes that it has the potential to subject the manufacturers to conflicting state requirements.[114]

"The manufacturer's compliance would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state's price restrictions…The potential for 'the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude'[115] is therefore both real and significant. We are thus pressed to invalidate the Act."[116]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Wholesalers, pharmacies, and pharmacists who are licensed entities would potentially be eligible under the bill to participate as importers under the Program which they are not currently able to do. To the extent that such entities participate in the Program to import less expensive FDA-approved drugs, they may experience cost savings which may be passed along to entities that purchase those drugs in Florida.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the AHCA. The AHCA anticipates needing additional resources to implement the bill before any cost savings from the importation Program are implemented.[117]

While the bill has the potential to bring savings to the Florida Medicaid program and to other state government programs through lowering the cost of prescription drugs to individuals served by those programs, the amount of those savings currently cannot be quantified. However, since the federal law requires the program to generate significant savings in order to be approved, this impact should be offset by drug price savings.

The bill also provides that the administrative fees borne by the state and the profit margins for any participating wholesaler, pharmacy, or pharmacist relating to drugs imported through the program will be limited to a maximum amount as specified each year in the General Appropriations Act.

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[114] *Supra* note 104, at 19-21.
[115] *Healy* at 337.
[116] *Supra* note 104, at 21.
[117] Agency for Health Care Administration, *House Bill 19 Analysis* (March 1, 2019) (on file with the Senate Committee on Health Policy).

The AHCA is required to contract with a vendor to provide services under the Canadian Prescription Drug Importation Program. The AHCA did not provide an estimate of the cost to procure a contract with a qualified third-party vendor to administer the Program.

The AHCA indicated the need for six additional personnel dedicated to the project who will be developing, procuring, and managing and conducting oversight and monitoring activities. The AHCA would begin recruitment activities immediately upon adoption of the bill as staff are needed to start Program design activities, development of the competitive solicitation, request for federal authority, etc. The AHCA will need to determine the level of federal financial participation in the Program.

AHCA Fiscal Impact		
(Contingent Upon Federal Approval)	**First Year Implementation**	**2nd Year and Beyond: Recurring Expenditures**
FTE:		
1.00 – AHCA Administrator – SES	$98,345	$98,345
5.00 – Government Analyst II	$409,770	$409,770
Operational Expenses:	$64,380	$37,722
Grand Total	**$575,495**	**$545,837**

The Board of Pharmacy, within the DOH, would be responsible for the licensing and permitting of business entities acting as importers, wholesalers, or suppliers.

VI. Technical Deficiencies:

The DBPR indicates that the bill applies to "prescription drugs" which, pursuant to s. 499.003(40), F.S., applies not only to finished dosage forms, but also to active pharmaceutical ingredients (API) that are routinely imported for further manufacturing and/or distribution by Florida companies.[118]

VII. Related Issues:

Canadian Drug Supply

In 2015, Canada's population (35 million) was one-ninth the population of the United States (318 million).[119] The number of prescriptions dispensed in the United States was almost seven times larger than in Canada and, taking into account the number of individuals and the number of prescriptions, one researcher in 2010, and again in 2015, calculated how long Canada's drug supply would last if 20 percent of Americans sought to have their prescriptions filled in Canada. In 2015, the number of days' supply without any additional manufacturing or imports was

[118] Department of Business and Professional Regulation, *Senate Bill 1528 Analysis*, at 11 (March 5, 2019) (on file with the Senate Committee on Health Policy).
[119] Marv Shepherd, *U.S. Drug Importation: Impact on Canada's Prescription Drug Supply,* Health Economics & Outcome Research: Open Access, Vol. 4, Iss.1 (February 5, 2018) http://www.safemedicines.org/wp-content/uploads/2017/08/us-drug-importation-impact-on-canadas-prescription-drug-supply-2471-268X-1000146.pdf (last visited March 28, 2019).

150.83 days.[120] In 2010, the number of days' supply was 201 days before the then-existing Canadian drug supply was depleted.[121]

That researcher pointed out that Canada has options to meet a growing demand, such as increasing its drug manufacturing output, increasing pharmaceutical imports, continuing the practice of allowing internet pharmacies to fill medications from foreign sources while looking the other way from a regulatory standpoint, or calling a halt to foreign sales of prescriptions.[122] That researcher also noted that Canada imported $13.180 billion in pharmaceuticals with $5.16 billion coming from the United States in 2015. In other words, the United States was Canada's largest supplier of pharmaceuticals in 2015, representing33.1 percent of all drugs imported by Canada.[123]

Another concern maybe that Canada has been experiencing its own access to drug issues and rising drug prices. Health Canada, Canada's national health ministry, recently released its own *Interim Report of the Advisory Council on the Implementation of National Pharmacare* on how to implement a national drug care program.[124] How Canada moves forward with this plan may impact how pharmacies and vendors in Canada operate in the future.

Canadian Law

The import and export of health products in Canada is regulated under Canada's *Food and Drugs Act* and its associated regulations. No drugs may be sold that are mislabeled, or adulterated.[125] Depending on how a product is labeled as it leaves Canada, for the Canadian market or the U.S. market, it may be considered "mislabeled" in one of the markets.

Additionally, under Canadian Federal Regulation A.01.045, all exports of food and drugs from Canada must have a certificate attached which is signed by the exporter attesting to the legality of the items and that the items being shipped are done so accordance with the laws of its destination.[126] An inspector is also authorized by law to take samples of an article at any reasonable time if the inspector believes that a package contains an item which is covered by the *Food and Drugs Act* and those items may also be subject to seizure.[127]

Federal Approval

The bill directs the AHCA, by July 1, 2020, to submit a request to the HHS Secretary for approval of the Florida Program under 21 USC s. 384(l). That subsection of federal law provides that the federal drug importation program under 21 USC s. 384 becomes effective only if the

[120] Marv Shepherd, *supra* note 132, at 3.
[121] Marv Shepherd, *supra* note 132, at 3.
[122] Marv Shepherd, *supra* note 132, at 4.
[123] Marv Shepherd, *supra* note 132, at 4.
[124] Health Canada, *Advisory Council on the Implementation of National Pharmacare*, https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare.html#a1 (last visited March 22, 2019).
[125] R.S., c. F-27, s. 8. (Can.)
[126] C.R.C., SOR/80-318, s-1(Can.)
[127] R.S.C., 1985, C. F-27, Part II(23)

Secretary certifies to the U.S. Congress that the implementation of the federal program will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer. No HHS Secretary has yet sent such a certification to the U.S. Congress. The cited subsection also provides for termination of the federal program. However, the subsection contains no authority for the HHS Secretary to approve any state-based drug importation program under any circumstances, nor to waive any aspects of the federal program regarding public health and safety or cost reduction, which other states have requested through the FDA for their own state-based program proposals.

VIII. Statutes Affected:

This bill creates section 381.02035 of the Florida Statutes.

IX. Additional Information:

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

CS by Health Policy on March 25, 2019:
The CS removes several provisions from the underlying bill, adds several safety and transparency components, clarifies existing components, and aligns the Program with updated tracing procedures under federal law. The CS:

- Removes from the underlying bill the provision that pharmacists or wholesalers may import Canadian prescription drugs under the Program only if they are employed by or under contract with:
  - The DOH's central pharmacy, for distribution to a county health department or free clinic for clients served in those settings;
  - A Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients;
  - The Department of Corrections (DOC), for dispensing to inmates in DOC custody;
  - A developmental disabilities center, for dispensing to clients treated in those settings; or
  - A state-owned, state-operated, or state-supported treatment facility for persons with mental illness, or a private facility designated by the Department of Children and Families for that purpose, for dispensing to persons treated in those settings.
- Removes from the underlying bill the requirement for the AHCA to begin operating the Program within six months of receiving federal approval.
- Requires that any Canadian supplier must comply fully with U.S. law and any other federal and state laws and regulation relating to track and trace procedures. The definitions were updated to define what is meant by track and trace procedures.
- Requires the vendor, suppliers, and importers under the Program to post two surety bonds of at least $1 million each at the time of contract execution to ensure contractual performance and non-payment of any administrative penalties over the contract term and to ensure participation in any civil or criminal litigation and payment of any claims or judgment that may arise from those actions. For suppliers and importers, the minimum amount of the bonds may escalate over time depending on Program volume.

- Requires the vendor under contract with the AHCA to maintain a list of all registered importers participating in the Program.
- Requires the vendor to ensure that all suppliers, importers, distributers, and other Program participants remain in compliance with all laws and regulations, U.S. and Canadian.
- Requires that a maximum administrative fee and profit margin amount or rate will be set by the state in the General Appropriations Act for any participating wholesaler, pharmacy, or pharmacist in the Program.
- Adds a limitation for participating suppliers and importers that drugs imported under this Program may not be sold outside of the Program.
- Sets a record retention requirement for laboratory testing records of seven years.
- Adds components to what should be included in the state's plan submission to the HHS to include information about the state's track and trace procedures, the state's estimated costs to implement the Program, and a list of Canadian suppliers willing to do business in Florida.
- Requires that the Program approved at the federal level to receive final approval from the Legislature before being implemented. Additional information about safety and cost effectiveness of the plan must accompany the approval request to the Legislature.
- Requires that the AHCA describe how it has complied with federal track and trace requirements in its Annual Report.

B. Amendments:

None.

872890

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
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Appropriations Subcommittee on Health and Human Services (Bean) recommended the following:

Senate Amendment

Delete lines 116 - 281

and insert:

required regardless of the type of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(d) Is identified by the vendor as eligible to participate in the program.

(e) Submits evidence at the time of contract award and

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throughout the contract term of a surety bond or a comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangement for the program are to:

1. Indemnify the supplier in the event that any civil or criminal legal action is brought by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to, causes of action for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier of legal judgments and claims that have been awarded to the state, the agency, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgment or other monetary penalty in a court of law for a civil or criminal action related to participation in the program. The bond or comparable security arrangement may be accessed if the supplier fails to pay any judgment or claim within 60 days after final judgment; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangement

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for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(4) ELIGIBLE IMPORTERS.—

(a) The following entities or persons may import prescription drugs from a Canadian supplier under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must meet all of the following requirements at the time of contract award and throughout the contract term:

1. Register with the vendor before importing drugs into this state under the program and be deemed in compliance with all requirements, including any relevant provisions of the Federal Act.

2. Submit evidence at the time of contract award and throughout the contract term of a surety bond or other comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the importer may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangement for the program are to:

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a. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the importer fails to pay within 30 days after assessment;

b. Ensure that the importer meets contractual and statutory obligations through use of a bond or other comparable security arrangements to pay any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the importer fails to meet its contractual and statutory obligations. If the importer is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

c. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the importer's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required, regardless of the type of bid or negotiation process the agency used or the type of final contract or agreement executed for services.

(c) An eligible importer must submit evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of

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Florida as a beneficiary. In lieu of the surety bond, the importer may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangement for the program are to:

1. Ensure the importer's participation in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the importer because of the importer's failure to perform under the contract, including, but not limited to causes of action for personal injury, negligence, and wrongful death;

2. Ensure payment by the importer through the use of a bond or other comparable security arrangements of legal judgments and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the importer is assessed a final judgment or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement may be accessed if the importer fails to pay any judgment or claim within 60 days after final judgment; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the importer's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

(5) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide

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services under the program. The vendor shall submit evidence of a surety bond with any bid or initial contract negotiation documents and shall maintain documentation of evidence of such a bond with the agency throughout the contract term. The surety bond may be from this state or any other state in the United States in the minimum amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the vendor may provide a comparable security agreement, such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangement for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the vendor fails to pay within 30 days after assessment;

2. Ensure that the vendor meets contractual and statutory obligations through use of a surety bond or other comparable security arrangements to pay any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the vendor fails to meet its contractual and statutory obligations. If the vendor is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor’s contract under the program has ended with the agency or

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the state or the program has ended, whichever occurs last.

A surety bond or comparable document is required, regardless of the type of bid or negotiation process the agency used or the type of final contract or agreement executed for services.

(b) The eligible vendor must submit evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the vendor may provide a

104102

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
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Appropriations Subcommittee on Health and Human Services (Bean) recommended the following:

Senate Amendment

Delete lines 321 - 339

and insert:

Canadian suppliers meet all of the requirements of the program, while meeting or exceeding the federal and state track-and-trace laws and regulations.

3. Contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

104102

4. Maintain a list of all registered importers that participate in the program.

5. Ensure compliance with Title II of the federal Drug Quality and Security Act, Pub. L. No. 113-54, by all suppliers, importers and other distributors, and participants in the program.

6. Assist the agency in the preparation of the annual report required by subsection (12) and timely provide any information requested by the agency for the report.

By the Committee on Health Policy; and Senators Bean and Gruters

588-03459-19 20191528c1

A bill to be entitled

An act relating to the Canadian Prescription Drug Importation Program; creating s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside the state; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating

588-03459-19 20191528c1

the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and the Legislature by a specified date; providing requirements for such report; authorizing the agency to adopt rules; providing an effective date.

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

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The Agency for Health Care Administration shall establish a program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

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

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

(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

(c) "Drug" or "prescription drug" has the same meaning as "prescription drug" in s. 499.003.

(d) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351

et seq.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(g) "Program" means the Canadian Prescription Drug Importation Program.

(h) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

(i) "Vendor" means the entity contracted by the agency to manage specified functions of the program.

(3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export drugs into this state under the program if the supplier meets all of the following requirements:

(a) Complies fully with relevant Canadian federal and provincial laws and regulations.

(b) Complies fully with the Federal Act, including all other state and federal law and regulations relating to the track-and-trace requirements at the package level.

(c) Submits evidence at time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security

arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the supplier fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the supplier through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the supplier is non-compliant with its contractual and statutory obligations. If the supplier is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or other comparable security arrangement is required regardless of the time of bid or negotiation process

used by the agency or the type of final contract or agreement executed for services.

(d) Is identified by the vendor as eligible to participate in the program.

(e) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Indemnify the supplier in the event that any civil or criminal legal action is brought by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to, causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier of legal judgements and claims that have been awarded to the state, the agency, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action related to participation in the program. The bond or

comparable security arrangement may be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(4) ELIGIBLE IMPORTERS.—

(a) The following entities or persons may import prescription drugs from a Canadian supplier under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must meet all of the following requirements at time of contract award and throughout the contract term:

1. Register with the vendor before importing drugs into the state under the program and be deemed in compliance with all requirements, including any relevant provisions of the Federal Act.

2. Submit evidence at time of contract award and throughout the contract term of a surety bond or other comparable security arrangement from this state or any other state in the United States in the amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an

irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

a. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the importer fails to pay within 30 days after assessment;

b. Ensure performance of contractual and statutory obligations by the importer through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the importer is non-compliant with its contractual and statutory obligations. If the importer is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

c. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the importer's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(c) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable

security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the supplier in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program

has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(5) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program. The vendor must submit evidence of a surety bond with any bid or initial contract negotiation documents and maintain documentation of evidence of such a bond with the agency throughout the contract term of a surety bond from this state or any other state in the United States in the same amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the vendor fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the vendor through use of a surety bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the vendor is non-compliant with its contractual and statutory obligations. If the vendor is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or

an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(b) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which names the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the vendor in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the vendor because of the vendor's failure to perform under the contract,

including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the vendor through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the vendor is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the vendor fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the vendor's license is no longer valid, or the program has ended, whichever occurs last.

(c) The vendor shall provide all of the following services at a minimum:

1. Develop a list every 3 month of drugs that have the highest potential for cost savings to the state if imported from Canada. In developing the list, the vendor shall consider, at a minimum, which drugs will provide the greatest cost savings to the state, including drugs for which there are shortages, specialty drugs, and high-volume drugs. The agency may direct the vendor to revise the list, as necessary.

2. Identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the Federal Act and who have agreed to export

drugs identified on the list. The vendor must verify that such Canadian suppliers meet all of the requirements of the program and will export drugs at prices that will provide cost savings to the state while meeting or exceeding the track-and-trace federal and state laws and regulations.

3. Contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

4. Maintain a listing of all registered importers that participate in the program.

5. Ensure compliance with Title II of the federal Drug Quality and Security Act P.L. 113-54 by all suppliers, importers and other distributors and participants in the program.

6. Assist the agency with the annual report as required in subsection (12) and provide any information requested by the agency for such report on a timely basis.

(d) The profit margin and administrative fees of any participating wholesaler, pharmacy, or pharmacist on imported drug products is limited to a maximum amount as specified annually in the General Appropriations Act.

(6) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may import a drug from an eligible Canadian supplier if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and importers participating under the program:

(a) Must comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.

(b) May not distribute, dispense, or sell drugs imported under the program outside of the program or outside of this state.

(8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

1. For an initial imported shipment, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the Federal Act.

2. For any subsequent imported shipment, ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the Federal Act.

3. Certify that the drug:

a. Is approved for marketing in the United States and is

not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

4. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

5. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the vendor:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying

all of the following:

1. The original source of the drug, including:

a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug which is shipped.

4. The quantity of each lot of the drug originally received and from which source.

5. The lot or control number and the batch number assigned to the drug by the manufacturer.

(f) The agency may require that the vendor collect any other information necessary to ensure the protection of the public health.

(9) IMMEDIATE SUSPENSION.—The agency shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The agency may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the state.

(10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(l). At a minimum, the request must do all of the following:

(a) Describe the agency's plan for operating the program.

(b) Demonstrate how the drugs imported into the state under

the program will meet the applicable federal and state standards for safety and effectiveness.

(c) Demonstrate how the drugs imported into the state under the program will comply with federal tracing procedures.

(d) Include a list of proposed drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(e) Estimate the total cost savings attributable to the program.

(f) Provide the costs of program implementation to the state.

(g) Include a list of potential Canadian suppliers from which the state would import drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

(11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of federal approval of the program, the agency shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. The program may not be implemented until the Legislature approves the program as authorized by the federal government. As part of its review process for implementation approval, the Legislature shall consider the estimated cost savings to the state and whether the program has met the required safety standards.

(12) ANNUAL REPORT.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the

operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the drugs that were imported under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date in the program;

(e) A description of the methodology used to determine which drugs should be included; and

(f) Documentation of how the program ensures the following criteria:

1. Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all United States and Florida laws and regulations;

2. Drugs imported under the program are not shipped, sold, or dispensed outside of the state or the program once in the possession of the importer;

3. Drugs imported under the program are unadulterated, potent, and safe;

4. The program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

5. The program provides cost savings to the state.

(13) RULEMAKING.—The agency may adopt rules necessary to implement this section.

Section 2. This act shall take effect July 1, 2019.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 646
INTRODUCER:	Children, Families, and Elder Affairs Committee and Senators Book and Rader
SUBJECT:	Child Welfare
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Preston	Hendon	CF	**Fav/CS**
2.	Sneed	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 646 makes a number of changes related to the care of children and young adults in out-of-home care and by foster parents. The bill summarizes current requirements into a Foster Children's Bill of Rights. The bill provides roles and responsibilities for the Department of Children and Families (department), the community-based care lead agencies and other agency staff, and those of caregivers, to ensure that children and young adults in out-of-home care are informed of these rights. The bill also codifies the role and responsibilities of the Foster Children's Ombudsman to serve as an autonomous entity within the department, to receive and resolve complaints from children in out-of-home care. The bill requires the department to establish a statewide toll-free telephone number for the Foster Children's Ombudsman and post the number on the homepage of the department's website.

The bill clarifies roles and responsibilities of foster parents and other caregivers of children in out-of-home care. The bill requires caseworkers to inform foster parents of the costs and requirements for child care and requires each community-based care lead agency to develop a plan to recruit and retain foster homes.

The bill has an indeterminate, though expected minimal, impact on state expenditures.

The bill takes effect October 1, 2019.

II. Present Situation:

Florida Law

Currently, the provisions of Florida law pertaining to dependent children are contained in chapter 39, F.S. Statements of legislative intent with regard to child safety and protection found in ch. 39, F.S., include the provisions that:

- Judicial procedures, as well as other procedures to assure due process to children and other parties, are conducted fairly in order to protect constitutional and other legal rights;
- The health and well-being of all children under the care of the state are promoted; and
- The child's family ties are preserved and strengthened whenever possible by only removing the child from parental custody when his or her welfare or public safety cannot be otherwise assured.[1]

Current law also stipulates that all children of this state are afforded general protections to include:

- Protection from abuse, neglect, and exploitation;
- A permanent and stable home;
- A safe and nurturing environment which will preserve a sense of personal dignity and integrity;
- Adequate nutrition, shelter, and clothing;
- Effective treatment for physical, social, and emotional needs;
- Equal opportunity and access to education, recreation and other community resources;
- Access to preventive services; and
- An independent, trained advocate, when intervention is necessary, and a skilled guardian or caregiver in a safe environment when alternative placement is necessary.[2]

Pursuant to s. 39.013(2), F.S., the circuit court has exclusive original jurisdiction of all proceedings under chapter 39, for children voluntarily placed with a licensed child-caring agency, a licensed child-placing agency, or the department, and for the adoption of children whose parental rights have been terminated. Jurisdiction attaches when the initial shelter petition, dependency petition, or termination of parental rights petition is filed, or when a child is taken into the custody of the department.

Currently, decisions on how to properly care for dependent children and how to assess need for such services as counseling, education, and vocational training are discretionary judgmental decisions made pursuant to broad authority vested in the department by the Legislature and have been found by the courts to be immune from tort liability.

In Department of Health and Rehabilitative Services[3] v. B.J.M., 656 So. 2d 906 (Fla. 1995), the Florida Supreme Court (court) held that the decisions of HRS regarding placement of juveniles

[1] Section 39.001(1), F.S.
[2] Section 39.001(3), F.S.
[3] The Department of Health and Rehabilitative Services (HRS) became the Department of Children and Family Services (DCFS) in 1996. See Chapter 1996-403, L.O.F. The Department was subsequently renamed the Department of Children and Families (DCF) in 2012. See Chapter 2012-84, L.O.F.

and rehabilitative services provided to juveniles constituted performance of discretionary governmental functions for which the state was immune. The court found that:

> Decisions on how to properly care for a dependent child or rehabilitate a delinquent juvenile, and to assess the need for counseling, education, and vocational training are discretionary judgmental decisions to be made pursuant to the broad discretion vested in HRS by the Legislature. These decisions represent the cutting edge of HRS policy. Additionally, it is apparent that both the nature of and the amount of services that may be provided is limited by HRS resources, and by the legislative-executive policy decisions as to what resources to provide and how those resources may be utilized….
>
> HRS, along with other governmental agencies in this state, must constantly take into account practical considerations, such as budgetary constraints, when deciding how to allocate its limited funds among a virtually unlimited number of needs. (citation omitted) As a result, in setting up its programs and providing services, HRS is to a great extent financially "strait-jacketed." When there are thousands of children in need and resources provide for only a fraction, decisions as to allocation may be difficult and sometimes arbitrary. For the courts to impose liability for tort damages on HRS for decisions as to the provision of services would not only "saddle [it] with a potentially crushing burden of financial liability, but would also [cause] the judicial branch of government to trespass into the domain of the legislative branch."[4]

To further support its decision that HRS's failure to provided certain services was shielded immunity, the court looked to express provisions of s. 39.455 (1)(2), F.S.[5] The subsection reads:

- In no case shall employees or agents of the department or a social service agency acting in good faith be liable for damages as a result of failing to provide services agreed to under the case plan unless the failure to provide such services occurs as a result of bad faith or malicious purpose, or occurs in a manner exhibiting wanton and willful disregard of human rights, safety, or property.
- The inability or failure of the department or of a social service agency or the employees or agents of the social service agency to provide the services agreed to under the case plan shall not render the state or the social service agency liable for damages unless such failure to provide services occurs in a manner exhibiting wanton or willful disregard of human rights, safety, or property.

Statutorily Created Bill of Rights in Florida

Currently there are several "Bills of Rights" delineated in Florida Statutes. Typically these provisions enunciate certain rights, and in some cases responsibilities, of particular classes of individuals. Some specifically permit a cause of action for violation of the rights, some

[4] See *Department of Health and Rehabilitative Services v. B.J.M.*, 656 So. 2d 906 (Fla. 1995), *available at* https://law.justia.com/cases/florida/supreme-court/1995/83067-0.html (last visited Feb. 26, 2019).
[5] Now renumbered as s. 39.011(1)(2), F.S.

specifically disallow a remedy, and others are silent. Rights in statute include, but are not limited to:

- Florida Patients' Bill of Rights and Responsibilities[6]
- Bill of Rights of Persons Who are Developmentally Disabled[7]
- Rights of Mental Health Patients[8]
- Nursing Home Resident Rights[9]
- Residents' Bill of Rights for Assisted Living Facilities[10]
- Residents' Bill of Rights for Adult Family-Care Homes[11]
- Residents' Rights in Continuing Care Facilities[12]

Foster Children's Bill of Rights in Other States

Foster Children Bills of Rights that have been enacted in states are typically designed to inform foster children of their rights within the child welfare system. Many children's bill of rights provide that they must be posted in a place where children will see them and include provisions requiring foster children to be informed about why they are in foster care and how the process will proceed. In addition, participation in extracurricular or community activities, efforts to maintain educational stability, access to guardians ad litem, access to mental, behavioral and physical health care, access to or communication with siblings and family members are major features of the foster children's bill of rights.

According to the National Conference of State Legislatures (NCSL), as of August 2016, a Foster Children's Bill of Rights has been enacted in 15 states and Puerto Rico. Also, during the 2014 legislative session, ten states introduced fifteen bills (six enacted) either seeking to enact a bill of rights or otherwise extending or defining the rights of foster children and parents including independent living services for older youth, educational consistency and enrollment, foster child input into evaluations of out-of-home care placements, and extracurricular activities.[13]

Foster Children's Ombudsman

The department created an ombudsman position in the 2016-2017 fiscal year with the intent to listen and be a voice for children and youth involved in the child welfare system. The ombudsman receives complaints about placement, care, and services, assisting in mediating concerns. The ombudsman is a resource to identify and explain relevant polices or procedures to children, young adults, and their caregivers.

[6] Section 381.026, F.S.
[7] Section 393.13, F.S.
[8] Section 394.459, F.S.
[9] Section 400.022, F.S.
[10] Section 429.28, F.S.
[11] Section 429.85, F.S.
[12] Section 651.083, F.S.
[13] National Conference of State Legislatures (NCSL), *Foster Care Bill of Rights* (August 25, 2016), *available at* http://www.ncsl.org/research/human-services/foster-care-bill-of-rights.aspx#Children (last visited Feb. 27, 2019).

The Rilya Wilson Act

Rilya Wilson disappeared from state custody in January 2001. The child's caregiver maintained that someone from the department removed Rilya from her home sometime in January 2001. The department was unaware that the child was missing until April 2002 due to casework failures. While her caregiver was sentenced to 55 years in prison in 2013 for her disappearance, Rilya remains missing.[14]

With the disappearance of Rilya Wilson, the responsibility of the state to ensure the safety of the children while in the state's care received heightened attention. Frequent and continuous face-to-face contact with children who are in the custody or under the supervision of the state has been identified as a mechanism for ensuring the children's safety and well-being. The current requirement that each child in the custody or supervision of the state receive a monthly home visit offers child protection staff a regular opportunity to check on the well-being of the child.

For a number of children, the increased visibility that participation in early education and childcare programs provides can minimize further abuse, neglect, or abandonment. Participation in these programs can also be an important ingredient in reversing the developmental effects that abuse, neglect, and abandonment can have on children. Early education and child care programs are provided in Florida through the school readiness program under ss. 1001.213 and 1002.82, F.S. With the establishment of the school readiness program, the different early education and child care programs and their funding sources were merged for the delivery of a comprehensive program of school readiness services to be designed and administered through local early learning coalitions.[15] The school readiness program is housed with the Office of Early Learning.

Historically, children who have been abused, neglected, or abandoned and are being served through the dependency system have received one of the highest priorities for child care service. This is due, at least in part, to the interpretation of earlier statutory language that these children were to be provided the highest priority. Current law requires each early learning coalition to give priority for participation in the school readiness program according to specified criteria with an at-risk child being second on the priority list.[16]

The cost of participating in the school readiness program is subsidized in part or fully by the funding of the coalition for eligible children. Criteria have been established for the children who are to receive priority for participating in the program at no cost or at a subsidized rate. The cost of child care shall be assumed by the licensed out-of-home caregiver to the extent that subsidized child care is unavailable.[17]

III. Effect of Proposed Changes:

Section 1 amends s. 39.4085, F.S., relating to goals for children in out-of-home care, to create a Foster Children's Bill of Rights for children who are in, and for young adults who are leaving,

[14] David Ovalle, *Geralyn Graham get 55 years in Rilya Wilson foster child abuse case*, MIAMI HERALD, Feb. 12, 2013), *available at* http://www.miamiherald.com/latest-news/article1947207.html. (last visited Feb. 28, 2019).
[15] Section 1002.83, F.S.
[16] Section 1002.87, F.S.
[17] Rule 65C-13.030, F.A.C.

out-of-home care. The section does not create any new rights, but codifies and places current rights into one section of the law. The bill also provides roles and responsibilities for the department, the community-based care lead agencies and other agency staff, as well as caregivers, related to ensuring that children and young adults in out-of-home care are informed of these rights. The bill authorizes the department to adopt rules to implement the section.

Section 2 creates s. 39.4088, F.S., relating to the Florida Children's Ombudsman, to codify and provide duties for an already existing entity within the department which is currently staffed with one position. The ombudsman is required to collect certain specified data related to complaints received and must compile and post that information on the department's website. The ombudsman, in consultation with other entities, is required to develop information explaining the rights to children and young adults in out-of-home care. The department is required to establish a statewide toll-free telephone number for the ombudsman and make the number available on the department's website homepage. The department is given rulemaking authority to implement the section.

Section 3 amends s. 39.6011, F. S., relating to case plan development, to require that information related to their rights be provided to a child who has attained 14 years of age or is otherwise of an appropriate age and capacity to understand be included in the case plan. Documentation that consumer credit report checks were requested for the child as required by federal law and that information related to that report was provided to the child.

The bill also requires that if the child is 14 years of age, or is otherwise of an appropriate age and capacity to understand, he or she must be involved in the case planning process. The child may express a placement preference, choose individuals to be on the case planning team and must sign the case plan unless there is reason to waive the signature. A copy of the case plan must be provided to the child. A copy of the case plan must also be provided to the caregiver if the child is placed in a licensed foster home.

Section 4 amends s. 39.604, F.S., relating to the Rilya Wilson Act, to require that when children are placed in a licensed foster home and are required to be enrolled in an early education or child care program under this section, the caseworker shall inform the caregiver of the amount of the subsidy provided by an early learning coalition, that this amount may not be sufficient to pay the full cost of the services, and that the caregiver will be responsible for paying the difference between the subsidy and the full cost charged by the early education or child care program.

Section 5 amends 39.701, F.S., relating to judicial reviews, to require that the social study report required for each judicial review must include documentation that the child has been provided with a copy of the bill of rights, that the rights have been reviewed with the child, and signed acknowledgement by the child or caregiver that the child has been provided with an explanation of the rights.

Section 6 amends s. 409.145, F.S., relating to the care of children, quality parenting, and the reasonable and prudent parent standard, to require that caregivers:

- Pay the difference between the subsidy from an early learning coalition and the full cost charged by an early education or child care program;

- Ensure that the child in the caregiver's care is aware of and understands his or her rights under s. 309.4085, F.S.; and
- Assist a child in contacting the Florida Children's Ombudsman, if necessary.

The department and other providers are responsible for providing a caregiver with information on treatment plans and how the caregiver can support a treatment plan as well as information on how the caregiver can manage behavioral issues.

Section 7 amends s. 409.145, F.S., relating to the licensure of family foster homes, residential child-caring agencies, and child placing agencies, to provide that the requirements for licensure and operation shall include provisions to safeguard the rights of children established under the bill of rights.

Section 8 amends s. 409.1753, F.S., relating to foster care, to clarify that each community-based care lead agency must provide each foster home with a telephone number for the foster parent to call during normal working hours whenever immediate assistance is needed and the child's caseworker is unavailable. Current law is unclear as to whether this is a duty for the department or the lead agency.

Section 9 amends s. 409.988, F.S., relating to community-based care lead agency duties, to require each lead agency to recruit and retain foster homes. Each lead agency must:
- Develop a plan to recruit and retain foster homes using best practices identified by the department and specify how the lead agency complies with s. 409.1753, F.S.;
- Annually submit such plan to the department for approval;
- Provide to the department a quarterly report detailing the number of licensed foster homes and beds and occupancy rate; and
- Conduct exit interviews with foster parents who voluntarily give up their license to determine the reasons for giving up their license and identify suggestions for how to better recruit and retain foster homes, and provide a quarterly summary of such interviews to the department.

Section 10 amends s. 39.6013, F.S., relating to case plan amendments, to conform a reference to changes made by the act.

Section 11 provides an effective date of October 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

According to the department, the bill is expected to have an indeterminate, yet minimal impact on state expenditures to establish and manage a toll-free number for the Florida Children's Ombudsman.[18]

The department currently has a Children's Ombudsman position that will be responsible for the additional duties included in the bill regarding maintaining the toll-free number, collecting and reporting data annually, and developing a brochure. The additional workload can be performed within existing department resources.[19]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 39.4085, 39.6011, 39.604, 39.701, 409.145, 409.175, 409.1753, 409.988, and 39.6013.

[18] Department of Children and Families, *Senate Bill 646 Agency Analysis* (February 8, 2019) (on file with the Senate Committee on Children, Families, and Elder Affairs).
[19] *Id*.

The bill creates section 39.4088 of the Florida Statutes.

IX. Additional Information:

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

CS by Children, Families, and Elder Affairs Committee on March 4, 2019:
The CS:

- Makes several technical changes to the bill to conform to current state and federal law and adds the right of a child to be informed about any funds being held in the master trust on his or her behalf.
- Changes a credit reporting provision relating to credit report checks for children in care to reflect the federal requirement that reports be requested from all three credit reporting agencies.

B. Amendments:

None.

By the Committee on Children, Families, and Elder Affairs; and Senator Book

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A bill to be entitled

An act relating to child welfare; amending s. 39.4085, F.S.; providing legislative findings and intent; specifying the rights of children and young adults in out-of-home care; providing roles and responsibilities for the Department of Children and Families, community-based care lead agencies, and other agency staff; providing roles and responsibilities for caregivers; requiring the department to adopt certain rules; creating s. 39.4088, F.S.; requiring the Florida Children's Ombudsman to serve as an autonomous entity within the department for certain purposes; providing general roles and responsibilities for the ombudsman; requiring the ombudsman to collect certain data; requiring the ombudsman, in consultation with the department and other specified entities and by a specified date, to develop standardized information explaining the rights of children and young adults placed in out-of-home care; requiring the department, community-based care lead agencies, and agency staff to use the information provided by the ombudsman in carrying out specified responsibilities; requiring the department to establish a statewide toll-free telephone number for the ombudsman; requiring the department to adopt certain rules; amending s. 39.6011, F.S.; requiring that a case plan be developed in a face-to-face conference with a caregiver of a child under certain circumstances; providing additional requirements for the content of a case

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plan; providing additional requirements for a case plan when a child is 14 years of age or older or is of an appropriate age and capacity; requiring the department to provide a copy of the case plan to the caregiver of a child placed in a licensed foster home; amending s. 39.604, F.S.; requiring a caseworker to provide information about subsidies provided by early learning coalitions to caregivers of certain children; amending s. 39.701, F.S.; providing additional requirements for social study reports for judicial review; amending s. 409.145, F.S.; providing additional requirements for caregivers; providing additional requirements for records and information the department and any additional providers are required to make available to caregivers; amending s. 409.175, F.S.; providing additional requirements for the licensure and operation of family foster homes, residential child-caring agencies, and child-placing agencies; amending s. 409.1753, F.S.; requiring a lead agency, rather than the department, to provide caregivers with a contact when the caseworker is unavailable; amending s. 409.988, F.S.; requiring lead agencies to recruit and retain foster homes; amending s. 39.6013, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Section 39.4085, Florida Statutes, is amended to

read:

(Substantial rewording of section. See s. 39.4085, F.S., for present text.)

39.4085 Foster Children's Bill of Rights.—

(1) LEGISLATIVE FINDINGS AND INTENT.—

(a) The Legislature finds that children in, and young adults leaving, out-of-home care face more developmental, psychosocial, and economic challenges than their peers outside of the child welfare system and are more likely to be unemployed, undereducated, homeless, and dependent on public assistance; and to experience early parenthood and to suffer from substance abuse and mental health disorders.

(b) The Legislature also finds that emotional trauma, separation from family, frequent changes in placement, and frequent changes in school enrollment, as well as being dependent on the state to make decisions regarding current and future life options, may contribute to feelings of limited control over life circumstances for children and young adults in out-of-home care.

(c) The Legislature also recognizes that there are basic human rights guaranteed to everyone, but children and young adults in out-of-home care have additional rights that they should be aware of in order to better advocate for themselves.

(d) Therefore, it is the intent of the Legislature to empower these children and young adults by helping them become better informed of their rights so they can become stronger self-advocates.

(2) BILL OF RIGHTS.—The department's child welfare system shall operate with the understanding that the rights of children

and young adults in out-of-home care are critical to their safety, permanence, and well-being and shall work with all stakeholders to help such children and young adults become knowledgeable about their rights and the resources available to them. A child should be able to remain in the custody of his or her parents or legal custodians unless a qualified person exercising competent professional judgment determines that removal is necessary to protect the child's physical, mental, or emotional health or safety. Except as otherwise provided in this chapter, the rights of a child placed in out-of-home care are:

(a) To live in a safe, healthy, and comfortable home where he or she is treated with respect and where the caregiver is aware of and understands the child's history, needs, and risk factors.

(b) To be free from physical, sexual, emotional, or other abuse, or corporal punishment. This includes the right to be placed away from other children or young adults who are known to pose a threat of harm to him or her because of his or her own risk factors or those of the other child or young adult.

(c) To receive adequate and healthful food, adequate clothing, and an allowance.

(d) To receive medical, dental, vision, and mental health services, as needed.

(e) To be free of the administration of psychotropic medication or chemical substances, unless authorized by this chapter.

(f) To be able to contact and visit his or her family members and fictive kin, unless prohibited by court order.

(g) To be placed together with his or her siblings who are

under the court's jurisdiction, or to maintain contact with and visit his or her siblings at least once per week, unless prohibited by court order.

(h) To be able to contact the Florida Children's Ombudsman, as described in s. 39.4086, regarding violations of rights; to speak to the ombudsman confidentially; and to be free from threats or punishment for making complaints.

(i) To make and receive uncensored telephone calls and to send and receive unopened mail, unless prohibited by court order.

(j) To attend the religious services and activities of his or her choice, and to not be compelled to unwillingly attend religious services or activities.

(k) To maintain a bank account and manage personal income, consistent with his or her age and developmental level, unless prohibited by the case plan and to be informed about any funds being held in the master trust on behalf of the child.

(l) To not be locked in any room, building, or facility premises, unless placed in a residential treatment center pursuant to this chapter.

(m) To attend school and participate in extracurricular, cultural, and personal enrichment activities consistent with his or her age and developmental level.

(n) To work and develop job skills at an age-appropriate level that is consistent with state law.

(o) To have social contact with people outside of the foster care system such as teachers, church members, mentors, and friends.

(p) To attend independent living program classes and

activities if he or she meets the age requirements.

(q) To attend all court hearings and address the court.

(r) To have storage space for private use.

(s) To participate in creating and reviewing his or her case plan if he or she is 14 years of age or older or, if younger, is of an appropriate age and capacity to receive information about his or her out-of-home placement and case plan, including being told of changes to the plan, and to have the ability to object to provisions of the case plan.

(t) To be free from unreasonable searches of his or her personal belongings.

(u) To the confidentiality of all juvenile court records consistent with state law.

(v) To have fair and equal access to all available services, placement, care, treatment, and benefits, and to not be subjected to discrimination or harassment on the basis of actual or perceived race, ethnic group identification, ancestry, national origin, color, religion, sex, sexual orientation, gender identity, mental or physical disability, or HIV status.

(w) If he or she is 16 years of age or older, to have access to existing information regarding the educational and financial assistance options available to him or her, including, but not limited to, the coursework necessary for vocational and postsecondary educational programs, postsecondary educational services and support, the Keys to Independence program, and the tuition waiver available under s. 1009.25.

(x) To not be moved by the department or a community-based care lead agency to another out-of-home placement unless the current home is unsafe or the change is court-ordered and, if

moved, the right to a transition that respects his or her relationships and property pursuant to s. 409.145.

(y) To have a guardian ad litem appointed to represent his or her best interests and, if appropriate, an attorney ad litem appointed to represent his or her legal interests. The guardian ad litem and attorney ad litem shall have immediate and unlimited access to the children they represent.

(3) ROLES AND RESPONSIBILITIES OF THE DEPARTMENT, COMMUNITY-BASED CARE LEAD AGENCIES, AND OTHER AGENCY STAFF.—

(a) The department shall develop training related to the rights of children and young adults in out-of-home care under this section. All child protective investigators, case managers, and other appropriate staff must complete annual training relating to these rights.

(b) The department shall provide a copy of this bill of rights to all children and young adults entering out-of-home care, and the department shall explain the bill of rights to the child or young adult in a manner the child or young adult can understand. Such explanation must occur in a manner that is the most effective for each individual and must use words and terminology that make sense to the child or young adult. If a child or young adult has cognitive, physical, or behavioral challenges that would prevent him or her from fully comprehending the bill of rights as presented, such information must be documented in the case record.

(c) The caseworker or other appropriate agency staff shall document in court reports and case notes the date he or she reviewed the bill of rights in age-appropriate language with the foster child or young adult.

(d) The bill of rights must be reviewed with the child or young adult by appropriate staff upon entry into out-of-home care and must be subsequently reviewed with the child or young adult every 6 months until the child leaves care and upon every change in placement. Each child or young adult must be given the opportunity to ask questions about any of the rights that he or she does not clearly understand.

(e) Facilities licensed to care for six or more children and young adults in out-of-home care must post information about the rights of these individuals in a prominent place in the facility.

(4) ROLES AND RESPONSIBILITIES OF CAREGIVERS.—All caregivers must ensure that a child or young adult in their care is aware of and understands his or her rights under this section and must assist the child or young adult in contacting the Florida Children's Ombudsman, if necessary.

(5) RULEMAKING.—The department shall adopt rules to implement this section.

Section 2. Section 39.4088, Florida Statutes, is created to read:

39.4088 Florida Children's Ombudsman.—The Florida Children's Ombudsman shall serve as an autonomous entity within the department for the purpose of providing children and young adults who are placed in out-of-home care with a means to resolve issues related to their care, placement, or services without fear of retribution. The ombudsman shall have access to any record of a state or local agency which is necessary to carry out his or her responsibilities and may meet or communicate with any child or young adult in the child or young

adult's placement or elsewhere.

(1) GENERAL ROLES AND RESPONSIBILITIES OF THE OMBUDSMAN.—The ombudsman shall:

(a) Disseminate information on the rights of children and young adults in out-of-home care under s. 39.4085 and the services provided by the ombudsman.

(b) Attempt to resolve a complaint informally.

(c) Conduct whatever investigation he or she determines is necessary to resolve a complaint.

(d) Update the complainant on the progress of the investigation and notify the complainant of the final outcome.

The ombudsman may not investigate, challenge, or overturn court-ordered decisions.

(2) DATA COLLECTION.—The ombudsman shall:

(a) Document the number, source, origin, location, and nature of all complaints.

(b) Compile all data collected over the course of the year including, but not limited to, the number of contacts to the toll-free telephone number; the number of complaints made, including the type and source of those complaints; the number of investigations performed by the ombudsman; the trends and issues that arose in the course of investigating complaints; the number of referrals made; and the number of pending complaints.

(c) Post the compiled data on the department's website.

(3) DEVELOPMENT AND DISSEMINATION OF INFORMATION.—

(a) By January 1, 2020, the ombudsman, in consultation with the department, children's advocacy and support groups, and current or former children and young adults in out-of-home care,

shall develop standardized information explaining the rights granted under s. 39.4085. The information must be age-appropriate, reviewed and updated by the ombudsman annually, and made available through a variety of formats.

(b) The department, community-based care lead agencies, and other agency staff must use the information provided by the ombudsman to carry out their responsibilities to inform children and young adults in out-of-home care of their rights pursuant to the duties established under s. 409.145.

(c) The department shall establish a statewide toll-free telephone number for the ombudsman and post the number on the homepage of the department's website.

(4) RULEMAKING.—The department shall adopt rules to implement this section.

Section 3. Subsections (4) through (8) of section 39.6011, Florida Statutes, are redesignated as subsections (5) through (9), respectively, paragraph (a) of subsection (1) and paragraph (b) of present subsection (6) of that section are amended, paragraph (f) is added to subsection (2) of that section, and a new subsection (4) is added to that section, to read:

39.6011 Case plan development.—

(1) The department shall prepare a draft of the case plan for each child receiving services under this chapter. A parent of a child may not be threatened or coerced with the loss of custody or parental rights for failing to admit in the case plan of abusing, neglecting, or abandoning a child. Participating in the development of a case plan is not an admission to any allegation of abuse, abandonment, or neglect, and it is not a consent to a finding of dependency or termination of parental

rights. The case plan shall be developed subject to the following requirements:

(a) The case plan must be developed in a face-to-face conference with the parent of the child, any court-appointed guardian ad litem, and, if appropriate, the child and the temporary custodian or caregiver of the child.

(2) The case plan must be written simply and clearly in English and, if English is not the principal language of the child's parent, to the extent possible in the parent's principal language. Each case plan must contain:

(f) If the child has attained 14 years of age or is otherwise of an appropriate age and capacity:

1. A document that describes the rights of the child under s. 39.4085 and the right to be provided with the documents pursuant to s. 39.701.

2. A signed acknowledgement by the child or young adult, or the caregiver if the child is too young or otherwise unable to sign, that the child has been provided with a copy of the document and that the rights contained in the document have been explained to the child in a way that the child understands.

3. Documentation that a consumer credit report for the child was requested from all three credit reporting agencies pursuant to federal law at no charge to the child and that any results were provided to the child. The case plan must include documentation of any barriers to obtaining the credit reports. If the consumer credit report reveals any accounts, the case plan must detail how the department ensured the child received assistance with interpreting the credit report and resolving any inaccuracies, including any referrals made for such assistance.

(4) If the child has attained 14 years of age or, if younger, is of an appropriate age and capacity, the child must:

(a) Be consulted on the development of the case plan; have the opportunity to attend a face-to-face conference, if appropriate; have the opportunity to express a placement preference; and have the option to choose two members for the case planning team who are not a foster parent or caseworker for the child.

1. An individual selected by a child to be a member of the case planning team may be rejected at any time if there is good cause to believe that the individual would not act in the best interest of the child. One individual selected by a child to be a member of the child's case planning team may be designated to act as the child's advisor and, as necessary, advocate with respect to the application of the reasonable and prudent parent standard to the child.

2. The child may not be included in any aspect of case plan development if information could be revealed or discussed which is of a nature that would best be presented to the child in a therapeutic setting.

(b) Sign the case plan, unless there is reason to waive the child's signature.

(c) Receive an explanation of the provisions of the case plan from the department.

(d) After the case plan is agreed on and signed by all parties, and after jurisdiction attaches and the case plan is filed with the court, be provided a copy of the case plan within 72 hours before the disposition hearing.

(7) ~~(6)~~ After the case plan has been developed, the

department shall adhere to the following procedural requirements:

(b) After the case plan has been agreed upon and signed by the parties, a copy of the plan must be given immediately to the parties, including the child if appropriate, the caregiver if the child is placed in a licensed foster home, and to other persons as directed by the court.

1. A case plan must be prepared, but need not be submitted to the court, for a child who will be in care no longer than 30 days unless that child is placed in out-of-home care a second time within a 12-month period.

2. In each case in which a child has been placed in out-of-home care, a case plan must be prepared within 60 days after the department removes the child from the home and shall be submitted to the court before the disposition hearing for the court to review and approve.

3. After jurisdiction attaches, all case plans must be filed with the court, and a copy provided to all the parties whose whereabouts are known, not less than 3 business days before the disposition hearing. The department shall file with the court, and provide copies to the parties, all case plans prepared before jurisdiction of the court attached.

Section 4. Paragraph (c) is added to subsection (3) of section 39.604, Florida Statutes, to read:

39.604 Rilya Wilson Act; short title; legislative intent; child care; early education; preschool.—

(3) REQUIREMENTS.—

(c) For children placed in a licensed foster home and who are required to be enrolled in an early education or child care

program under this section, the caseworker shall inform the caregiver of the amount of the subsidy provided by an early learning coalition, that this amount may not be sufficient to pay the full cost of the services, and that the caregiver will be responsible for paying the difference between the subsidy and the full cost charged by the early education or child care program.

Section 5. Paragraph (a) of subsection (2) and paragraph (a) of subsection (3) of section 39.701, Florida Statutes, are amended to read:

39.701 Judicial review.—

(2) REVIEW HEARINGS FOR CHILDREN YOUNGER THAN 18 YEARS OF AGE.—

(a) *Social study report for judicial review.*—Before every judicial review hearing or citizen review panel hearing, the social service agency shall make an investigation and social study concerning all pertinent details relating to the child and shall furnish to the court or citizen review panel a written report that includes, but is not limited to:

1. A description of the type of placement the child is in at the time of the hearing, including the safety of the child and the continuing necessity for and appropriateness of the placement.

2. Documentation of the diligent efforts made by all parties to the case plan to comply with each applicable provision of the plan.

3. The amount of fees assessed and collected during the period of time being reported.

4. The services provided to the foster family or legal

custodian in an effort to address the needs of the child as indicated in the case plan.

5. A statement that either:

a. The parent, though able to do so, did not comply substantially with the case plan, and the agency recommendations;

b. The parent did substantially comply with the case plan; or

c. The parent has partially complied with the case plan, with a summary of additional progress needed and the agency recommendations.

6. A statement from the foster parent or legal custodian providing any material evidence concerning the return of the child to the parent or parents.

7. A statement concerning the frequency, duration, and results of the parent-child visitation, if any, and the agency recommendations for an expansion or restriction of future visitation.

8. The number of times a child has been removed from his or her home and placed elsewhere, the number and types of placements that have occurred, and the reason for the changes in placement.

9. The number of times a child's educational placement has been changed, the number and types of educational placements which have occurred, and the reason for any change in placement.

10. If the child has reached 13 years of age but is not yet 18 years of age, a statement from the caregiver on the progress the child has made in acquiring independent living skills.

11. Copies of all medical, psychological, and educational

records that support the terms of the case plan and that have been produced concerning the parents or any caregiver since the last judicial review hearing.

12. Copies of the child's current health, mental health, and education records as identified in s. 39.6012.

13. Documentation that the Foster Children's Bill of Rights, as described in s. 39.4085, has been provided to and reviewed with the child.

14. A signed acknowledgement by the child, or the caregiver if the child is too young or otherwise unable to sign, stating that the child has been provided an explanation of the rights under s. 39.4085.

(3) REVIEW HEARINGS FOR CHILDREN 17 YEARS OF AGE.—

(a) In addition to the review and report required under paragraphs (1)(a) and (2)(a), respectively, the court shall hold a judicial review hearing within 90 days after a child's 17th birthday. The court shall also issue an order, separate from the order on judicial review, that the disability of nonage of the child has been removed pursuant to ss. 743.044, 743.045, 743.046, and 743.047, and for any of these disabilities that the court finds is in the child's best interest to remove. The court shall continue to hold timely judicial review hearings. If necessary, the court may review the status of the child more frequently during the year before the child's 18th birthday. At each review hearing held under this subsection, in addition to any information or report provided to the court by the foster parent, legal custodian, or guardian ad litem, the child shall be given the opportunity to address the court with any information relevant to the child's best interest, particularly

in relation to independent living transition services. The department shall include in the social study report for judicial review written verification that the child has:

1. A current Medicaid card and all necessary information concerning the Medicaid program sufficient to prepare the child to apply for coverage upon reaching the age of 18, if such application is appropriate.

2. A certified copy of the child's birth certificate and, if the child does not have a valid driver license, a Florida identification card issued under s. 322.051.

3. A social security card and information relating to social security insurance benefits if the child is eligible for those benefits. If the child has received such benefits and they are being held in trust for the child, a full accounting of these funds must be provided and the child must be informed as to how to access those funds.

4. All relevant information related to the Road-to-Independence Program, including, but not limited to, eligibility requirements, information on participation, and assistance in gaining admission to the program. If the child is eligible for the Road-to-Independence Program, he or she must be advised that he or she may continue to reside with the licensed family home or group care provider with whom the child was residing at the time the child attained his or her 18th birthday, in another licensed family home, or with a group care provider arranged by the department.

5. An open bank account or the identification necessary to open a bank account and to acquire essential banking and budgeting skills.

6. Information on public assistance and how to apply for public assistance.

7. A clear understanding of where he or she will be living on his or her 18th birthday, how living expenses will be paid, and the educational program or school in which he or she will be enrolled.

8. Information related to the ability of the child to remain in care until he or she reaches 21 years of age under s. 39.013.

9. A letter providing the dates that the child is under the jurisdiction of the court.

10. A letter stating that the child is in compliance with financial aid documentation requirements.

11. The child's educational records.

12. The child's entire health and mental health records.

13. The process for accessing his or her case file.

14. A statement encouraging the child to attend all judicial review hearings occurring after the child's 17th birthday.

15. Information on how to obtain a driver license or learner's driver license.

16. Been provided with the Foster Children's Bill of Rights, as described in s. 39.0485, and that the rights have been reviewed with the child.

17. Signed an acknowledgement stating that he or she has been provided an explanation of the rights or, if the child is too young or otherwise unable to sign, that such acknowledgment has been signed by the child's caregiver.

Section 6. Paragraphs (a) and (d) of subsection (2) of

section 409.145, Florida Statutes, are amended to read:

409.145 Care of children; quality parenting; "reasonable and prudent parent" standard.—The child welfare system of the department shall operate as a coordinated community-based system of care which empowers all caregivers for children in foster care to provide quality parenting, including approving or disapproving a child's participation in activities based on the caregiver's assessment using the "reasonable and prudent parent" standard.

(2) QUALITY PARENTING.—A child in foster care shall be placed only with a caregiver who has the ability to care for the child, is willing to accept responsibility for providing care, and is willing and able to learn about and be respectful of the child's culture, religion and ethnicity, special physical or psychological needs, any circumstances unique to the child, and family relationships. The department, the community-based care lead agency, and other agencies shall provide such caregiver with all available information necessary to assist the caregiver in determining whether he or she is able to appropriately care for a particular child.

(a) *Roles and responsibilities of caregivers.*—A caregiver shall:

1. Participate in developing the case plan for the child and his or her family and work with others involved in his or her care to implement this plan. This participation includes the caregiver's involvement in all team meetings or court hearings related to the child's care.

2. Complete all training needed to improve skills in parenting a child who has experienced trauma due to neglect,

abuse, or separation from home, to meet the child's special needs, and to work effectively with child welfare agencies, the court, the schools, and other community and governmental agencies.

3. Respect and support the child's ties to members of his or her biological family and assist the child in maintaining allowable visitation and other forms of communication.

4. Effectively advocate for the child in the caregiver's care with the child welfare system, the court, and community agencies, including the school, child care, health and mental health providers, and employers.

5. Participate fully in the child's medical, psychological, and dental care as the caregiver would for his or her biological child.

6. Support the child's educational success by participating in activities and meetings associated with the child's school or other educational setting, including Individual Education Plan meetings and meetings with an educational surrogate if one has been appointed, assisting with assignments, supporting tutoring programs, and encouraging the child's participation in extracurricular activities.

a. Maintaining educational stability for a child while in out-of-home care by allowing the child to remain in the school or educational setting that he or she attended before entry into out-of-home care is the first priority, unless not in the best interest of the child.

b. If it is not in the best interest of the child to remain in his or her school or educational setting upon entry into out-of-home care, the caregiver must work with the case manager,

guardian ad litem, teachers and guidance counselors, and educational surrogate if one has been appointed to determine the best educational setting for the child. Such setting may include a public school that is not the school of origin, a private school pursuant to s. 1002.42, a virtual instruction program pursuant to s. 1002.45, or a home education program pursuant to s. 1002.41.

7. Work in partnership with other stakeholders to obtain and maintain records that are important to the child's well-being, including child resource records, medical records, school records, photographs, and records of special events and achievements.

8. Ensure that the child in the caregiver's care who is between 13 and 17 years of age learns and masters independent living skills.

9. Ensure that the child in the caregiver's care is aware of the requirements and benefits of the Road-to-Independence Program.

10. Work to enable the child in the caregiver's care to establish and maintain naturally occurring mentoring relationships.

11. Pay the difference between the subsidy from an early learning coalition and the full cost charged by an early education or child care program.

12. Ensure that the child in the caregiver's care is aware of and understands his or her rights under s. 309.4085.

13. Assist the child in contacting the Florida Children's Ombudsman, if necessary.

(d) *Information sharing.*—Whenever a foster home or

residential group home assumes responsibility for the care of a child, the department and any additional providers shall make available to the caregiver as soon as is practicable all relevant information concerning the child. Records and information that are required to be shared with caregivers include, but are not limited to:

1. Medical, dental, psychological, psychiatric, and behavioral history, as well as ongoing evaluation or treatment needs or treatment plans and information on how the caregiver can support any treatment plan within the foster home;

2. School records;

3. Copies of his or her birth certificate and, if appropriate, immigration status documents;

4. Consents signed by parents;

5. Comprehensive behavioral assessments and other social assessments and information on how the caregiver can manage any behavioral issues;

6. Court orders;

7. Visitation and case plans;

8. Guardian ad litem reports;

9. Staffing forms; and

10. Judicial or citizen review panel reports and attachments filed with the court, except confidential medical, psychiatric, and psychological information regarding any party or participant other than the child.

Section 7. Paragraph (b) of subsection (5) of section 409.175, Florida Statutes, is amended to read:

409.175 Licensure of family foster homes, residential child-caring agencies, and child-placing agencies; public

records exemption.—

(5) The department shall adopt and amend rules for the levels of licensed care associated with the licensure of family foster homes, residential child-caring agencies, and child-placing agencies. The rules may include criteria to approve waivers to licensing requirements when applying for a child-specific license.

(b) The requirements for licensure and operation of family foster homes, residential child-caring agencies, and child-placing agencies shall include:

1. The operation, conduct, and maintenance of these homes and agencies and the responsibility which they assume for children served and the evidence of need for that service.

2. The provision of food, clothing, educational opportunities, services, equipment, and individual supplies to assure the healthy physical, emotional, and mental development of the children served.

3. The appropriateness, safety, cleanliness, and general adequacy of the premises, including fire prevention and health standards, to provide for the physical comfort, care, and well-being of the children served.

4. The ratio of staff to children required to provide adequate care and supervision of the children served and, in the case of foster homes, the maximum number of children in the home.

5. The good moral character based upon screening, education, training, and experience requirements for personnel.

6. The department may grant exemptions from disqualification from working with children or the

developmentally disabled as provided in s. 435.07.

7. The provision of preservice and inservice training for all foster parents and agency staff.

8. Satisfactory evidence of financial ability to provide care for the children in compliance with licensing requirements.

9. The maintenance by the agency of records pertaining to admission, progress, health, and discharge of children served, including written case plans and reports to the department.

10. The provision for parental involvement to encourage preservation and strengthening of a child's relationship with the family.

11. The transportation safety of children served.

12. The provisions for safeguarding the cultural, religious, and ethnic values of a child.

13. Provisions to safeguard the legal rights of children served, as well as rights of children established under s. 39.4085.

Section 8. Section 409.1753, Florida Statutes, is amended to read:

409.1753 Foster care; duties.—The department shall ensure that each lead agency provides~~, within each district,~~ each foster home with ~~is given~~ a telephone number for the foster parent to call during normal working hours whenever immediate assistance is needed and the child's caseworker is unavailable. This number must be staffed and answered by individuals possessing the knowledge and authority necessary to assist foster parents.

Section 9. Paragraph (l) is added to subsection (1) of section 409.988, Florida Statutes, to read:

409.988 Lead agency duties; general provisions.—

(1) DUTIES.—A lead agency:

(l) Shall recruit and retain foster homes. In performing such duty, a lead agency shall:

1. Develop a plan to recruit and retain foster homes using best practices identified by the department and specify how the lead agency complies with s. 409.1753.

2. Annually submit such plan to the department for approval.

3. Provide to the department a quarterly report detailing the number of licensed foster homes and beds and occupancy rate.

4. Conduct exit interviews with foster parents who voluntarily give up their license to determine the reasons for giving up their license and identify suggestions for how to better recruit and retain foster homes, and provide a quarterly summary of such interviews to the department.

Section 10. Subsection (8) of section 39.6013, Florida Statutes, is amended to read:

39.6013 Case plan amendments.—

(8) Amendments must include service interventions that are the least intrusive into the life of the parent and child, must focus on clearly defined objectives, and must provide the most efficient path to quick reunification or permanent placement given the circumstances of the case and the child's need for safe and proper care. A copy of the amended plan must be immediately given to the persons identified in s. 39.6011(7)(b) ~~s. 39.6011(6)(b)~~ .

Section 11. This act shall take effect October 1, 2019.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Children, Families, and Elder Affairs, *Chair*
Appropriations
Appropriations Subcommittee on Education
Appropriations Subcommittee on Health and Human Services
Health Policy
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR LAUREN BOOK
32nd District

March 7, 2019

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

Chair Bean:

I respectfully request that **CS/SB 646—Child Welfare**, also known as the Foster Children's Bill of Rights, be placed on the agenda for the next Appropriations Subcommittee on Health and Human Services meeting.

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

Thank you,

Senator Lauren Book
Senate District 32

Cc: Tonya Kidd, Staff Director
Robin Jackson, Administrative Assistant

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

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

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 732
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Clinics and Office Surgery
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Gerbrandt	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 732 authorizes the Department of Health (DOH) to register and regulate office surgery centers.

The bill amends the Health Care Clinic Act to:

- Specify that the definition of "clinic" means an entity that provides health care services to individuals and that "receives compensation" for those services, as opposed to such an entity that "tenders charges for reimbursement" for such services;
- Require that an applicant for a clinic license provide proof that it maintains the financial responsibility to pay claims and related costs that could result from the provision of medical care and services, or the failure to provide such care and services, for physicians and osteopathic physicians who perform liposuction procedures under certain conditions in an office setting;
- Require a clinic director or medical director to ensure that the clinic complies with the standards of practice adopted by the Board of Medicine and the Board of Osteopathic Medicine for office surgery; and
- Require the Agency for Health Care Administration (AHCA) to impose an administrative fine on a clinic not registered with the Department of Health that performs certain office surgeries.

The bill requires the DOH to deny or revoke the registration of or impose certain penalties against any facility where certain office surgeries are performed under certain circumstances. The bill provides that a certified registered nurse anesthetist may provide services in an office registered to perform office surgery within the framework of an established protocol with a licensed anesthesiologist.

The bill will have an indeterminate fiscal impact upon the DOH. The AHCA expects a significant, negative fiscal impact as a result of the bill's expansion of the definition of the term "clinic," and estimates that the bill will require an additional 7 full-time equivalent positions (FTE) to assist in the application, licensure, renewal, and complaint processes, and follow-up visits when deficiencies at clinics are found and cited.

The bill is effective upon becoming a law.

II. Present Situation:

Health Care Clinic Act

The AHCA is the chief health policy and planning entity for the state and is responsible for, among other things, health care clinic licensure, inspection, and regulatory enforcement.[1] Part X of ch. 400, F.S., is known as the Health Care Clinic Act (the Act). The purpose of the Act is to provide for the licensure, establishment, and enforcement of basic standards for health care clinics and to provide administrative oversight to the AHCA.[2]

Current law defines "clinic" as an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and portable equipment provider.[3] Health care clinics in the state must be licensed by the AHCA;[4] however, there are numerous exclusions from the definition of "clinic" and from the requirement to obtain a license as a clinic.[5] The definition of "clinic" includes only entities that "tender charges for reimbursement." The AHCA interprets this phrase to include only entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that provide health care services and accept "cash only" for services are excluded from the definition of "clinic" and are not subject to licensure by the AHCA.[6]

Clinic License Application

In order to obtain a clinic license, an applicant must file an application with the AHCA and pay a fee not to exceed $2,000.[7] The Act defines "applicant" to mean an individual owner, corporation,

[1] *See* Agency for Health Care Administration, *Division of Health Quality Assurance*, available at http://ahca.myflorida.com/MCHQ/index.shtml (last visited Mar. 28, 2019).
[2] Section 400.990, F.S.
[3] Section 400.9905(4), F.S.
[4] Section 400.991, F.S.
[5] Section 400.9905(4)(a)-(n), F.S.
[6] *See* Agency for Health Care Administration, *Senate Bill 486 Analysis* (2015) (on file with the Senate Committee on Health Policy).
[7] *Supra* note 3 and s. 400.9925(3), F.S.

partnership, firm, business, association, or other entity that owns or controls, directly or indirectly, 5 percent or more of an interest in the clinic and that applies for a clinic license.[8]

The application requires a variety of information, including, but not limited to, the name, residence and business address, phone number, social security number, and license number of the medical or clinic director. The applicant must also provide proof of compliance with the Act, including a listing of services to be provided, the number and discipline of each professional staff member to be employed and proof of financial ability to operate.[9] The AHCA requires a Level 2 background screening for applicants and personnel as required in s. 408.809(1)(e), F.S., pursuant to ch. 435 and s. 408.809, F.S.[10]

Clinic Director Responsibilities

The Act requires that each clinic appoint a medical director or clinic director who must agree in writing to accept legal responsibility for the following activities on behalf of the clinic:[11]

- Have signs identifying the medical director or clinic director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active, appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner;
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure the billings are neither fraudulent nor unlawful;
- Refrain from referring a patient to the clinic if the referral would constitute a conflict of interest; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.

Unlicensed Clinics and Administrative Penalties

The Act provides that operating a clinic without a license is a third degree felony punishable as provided in ss. 775.082, 775.083, or 775.084, F.S., with each day of continued operation being a separate offense.[12] Any person found guilty of unlicensed activity a second or subsequent time commits a felony of the second degree, with each day of continued operation being a separate offense.[13] Additionally, any health care provider who is aware of the operation of an unlicensed clinic must report that facility to the AHCA. Failure to report a clinic that the provider knows or

[8] Section 400.9905(2), F.S.
[9] Section 400.991(3) and (4), F.S.
[10] Section 400.991(5)(b), F.S.
[11] Section 400.9935, F.S.
[12] Section 400.9935(1), F.S.
[13] Section 400.9935(4), F.S.

has reasonable cause to suspect is unlicensed must be reported to the provider's licensing board.[14]

The AHCA also has the authority to deny the application for a license renewal, revoke and suspend the license, and impose administrative fines of up to $5,000 per violation for violations of the requirements of the Act or rules of the AHCA.[15]
Each day of continuing violation after the date fixed for termination of the violation constitutes an additional, separate, and distinct violation. Any action taken to correct a violation shall be documented in writing by the owner, medical director, or clinic director of the clinic and verified through follow up visits by AHCA personnel.[16]

Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic shall be subject to an administrative fine of $5,000 per day. Any clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership is subject to a fine of $5,000. During an inspection, the AHCA must make a reasonable attempt to discuss each violation with the owner, medical director, or clinic director, prior to written notification.[17]

Regulation of Office Surgery

The practice of medicine in Florida is regulated under ch. 458, F.S., and the practice of osteopathic medicine is regulated under ch. 459, F.S. Both professions have broad authority to adopt rules to implement the provisions of their respective practice acts.[18] The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) were created within the Department of Health (DOH) to ensure that every physician practicing in the state meets minimum requirements for safe practice.[19]

In Florida, surgeries performed in a doctor's office, outside a facility licensed under ch. 390 or ch. 395, F.S., are regulated by ss. 458.309(3) and 459.005(2), F.S. Both sections are identical except for the references to the BOM or the BOOM. Both require that a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures lasting more than five minutes, and all Level III surgical procedures in an office setting, to register the doctor's office with the DOH, unless that office is licensed as a facility under ch. 395, F.S. Level II procedures and Level III procedures are not defined in the Florida statute, but the respective boards have defined three levels of office surgery by administrative rule,[20] which are subject to change by the boards through the administrative rule propagation process.

The DOH is required to inspect a registered doctor's office annually unless the office is accredited by a nationally-recognized accrediting agency or an accrediting organization approved

[14] *Id.*
[15] Section 400.995(1), F.S.
[16] Section 400.995(2) and (3), F.S.
[17] Section 400.995(4-6), F.S.
[18] Sections 458.309(1) and 459.005(1), F.S.
[19] Sections 458.307(1), 458.301, 459.004 and 459.001, F.S.
[20] *See* rules 64B8-9.009 and 64B15-14.007, F.A.C.

by the BOM or the BOOM. The actual costs of registration, inspection and/or accreditation are to be paid by the person seeking to register and operate the office in which office surgeries are performed.[21]

All other aspects of office surgeries are regulated by administrative rules promulgated by the BOM and the BOOM.

Specifically, the BOM and the BOOM have established the standards of practice and the standards of care for particular practice settings, including but not limited to:

- Education and training;
- Equipment and supplies;
- Medications, including anesthetics;
- Assistance of and delegation to other personnel;
- Transfer agreements;
- Sterilization;
- Records;
- Performance of complex or multiple procedures;
- Informed consent; and
- Policy and procedure manuals.[22]

The current BOM and BOOM rules are very similar, with only three substantive differences. The BOOM's rule requires the following, and the BOM's rule does not require, that:

- If a surgeon is unavailable to provide post-operative care, the surgeon must notify the patient, prior to the procedure, of his or her unavailability after the procedure;[23]
- When Level II, IIA, or III procedures are performed, the surgeon is responsible for providing the patient, in writing, prior to the procedure, the name and location of the hospital where the surgeon has privileges to perform the same procedure as that being performed in the outpatient setting, or the name and location of the hospital where the surgeon or facility has a transfer agreement;[24] and
- The surgeon performing Level I procedures in an office setting must hold a current certification in an Advanced Cardiac Life Support course with didactic and skills components, approved by Pacific Medical Training, the American Heart Association , or the American Safety and Health Institute .[25]

The BOM and BOOM rules regarding levels of office surgeries (I, II, IIA and III) differentiate each level primarily by the level of sedation and anesthesia required for the procedure and patient risk.

[21] *See* ss. 358.309(3) and 459.005(2), F.S.
[22] *Id.*
[23] Rule 64B15-14.007(2)(h), F.A.C.
[24] Rule 64B15-14.007, F.A.C.
[25] Rule 64B15-14.003(3)(b)1., F.A.C. The BOM recommends the surgeon have Basic Life Support Certification, but it is not required. *See* 64B8-9.009(3)(b)1., F.A.C.

The BOM and the BOOM general requirements for all office surgery,[26] as well as specific standards for the levels of office surgery, are virtually identical, other than the three substantive differences noted above, further reference to the rules in this analysis will pertain to BOM Rule 64B8-9.009, F.A.C.

General Office Surgery Practice Standards

Current rule requires a surgeon[27] to examine the patient immediately before the surgery to evaluate the patient's risk of anesthesia and the surgical procedure to be performed. The surgeon may delegate the preoperative heart and lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. The surgeon must maintain complete records[28] of each surgical procedure, including:

- Anesthesia records;
- A written informed consent from the patient reflecting the patient's knowledge of:
  - Identified risks;
  - Consent to the procedure;[29]
  - Type of anesthesia;
  - Anesthesia provider; and
  - The availability of a choice of anesthesia provider, including an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.[30]

The rule further requires the surgeon to maintain a log of all Level II and Level III surgical procedures performed, which must include:

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;
- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;

[26] "Office surgery" is defined by the BOM and the BOOM, as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). *See* Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C.

[27] Rules 64B8-9.009(1)(b) and 64B15-14.007(1)(b), F.A.C., define a "surgeon" as a licensed physician performing any procedure included within the definition of surgery.

[28] *See* Rules 64B8-9.003(2)(a) and 64B15-14.007(2)(a), F.A.C.

[29] A written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa. See Rule 64B8-9.009(2)(b), F.A.C.

[30] Rule 64B8-9.009(2)(a), F.A.C.

- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

The log and all surgical records must be provided to the DOH investigators upon request.[31]

Current rules define the three levels of office surgery as follows:[32]

Level I Office Surgery[33] includes:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4000cc supernatant fat;
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints);
- The patient's level of sedation is that of minimal sedation and anxiolysis[34] and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a defined as a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilation and cardiovascular functions are unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, F.S., are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain; and
- Chances of complication requiring hospitalization are remote.

Level II Office Surgery[35] includes, but is not limited to:

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat;
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. Moderate sedation and analgesia or conscious sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- The physician, or the facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within reasonable proximity if the physician performing the procedure does not have staff privileges to perform the same procedure as that being

[31] Rule 64B8-9.009(2)(c), F.A.C.
[32] *See* rules 64B8-9.009 and 64B15-14.007, F.A.C.
[33] Rule 64B8-9.009(3), F.A.C.
[34] "Anxiolysis" is defined as a state of mild sedation obtained with minor tranquilizers or antianxiety medication. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1993866/
[35] Rule 64B8-9.009(4) and (5), F.A.C.

performed in the out-patient setting at a licensed hospital within reasonable proximity; and "Reasonable proximity" is defined as not to exceed 30 minutes transport time to the hospital.

Level III Office Surgery[36] includes:

- Surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. Deep sedation and analgesia is defined as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia shall be considered Level III;
- Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery, and require:
  - All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center; and
  - For all ASA II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.
- In addition to the standards for Level II Office Surgery, the surgeon must:
  - Have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia;
  - Have one assistant who is currently certified by an American Heart Association, American Safety and Health Institute, American Red Cross, Pacific Medical Training approved Basic Life Support course with didactic and skills components, or ACLS Certification Institute Basic Life Support course with didactic and skills components, and the surgeon must be currently certified by an American Heart Association, American

[36] Rule 64B8-9.009(6), F.A.C.

Safety and Health Institute, Pacific Medical Training approved Advanced Cardiac Life Support course with didactic and skills components, or ACLS Certification Institute Advanced Cardiac Life Support course with didactic and skills components;

- Have emergency policies and procedures related to serious anesthesia complications must be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location. Topics to be covered shall include the following:
  - Airway Blockage (foreign body obstruction),
  - Allergic Reactions,
  - Bradycardia,
  - Bronchospasm,
  - Cardiac Arrest,
  - Chest Pain,
  - Hypoglycemia,
  - Hypotension,
  - Hypoventilation,
  - Laryngospasm,
  - Local Anesthetic Toxicity Reaction; and,
  - Malignant Hyperthermia.

Liposuction Procedures in an Office Setting

Liposuction is the surgical removal of subcutaneous fat by means of an aspiration cannula introduced through small skin incisions, assisted by suction. Synonyms used in literature include liposuction surgery, suction-assisted lipectomy, suction lipoplasty, fat suction, blunt suction lipectomy, and liposculpture.[37]

The BOM sets the general practice requirements for all liposuction procedures in an office setting as follows:[38]

- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents, as identified in s. 458.351, F.S.
- In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.
- Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:
  - When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;

[37] Venkataram, Jayashree, Journal of Cutaneous and Aesthetic Surgery, *Tumescent Liposuction: A Review* July – December, 2008, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840906/ (last visited March 29, 2019).
[38] *See* rules 64B8-9.009(2)(b)-(e), F.A.C. and 64B15-14.007(2), F.A.C.

- When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat; and
- Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

III. Effect of Proposed Changes:

This bill defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services and "that receives compensation," expanding the definition to include more entities (entities that accept cash only or that provide free services) than those that bill third parties, such as Medicare, Medicaid, and insurance companies. **(Section 1)**

The bill amends s. 400.9935, F.S., to direct that if the clinic is registered with the DOH to perform office surgery, the medical director or the clinic director must ensure that the clinic complies with the rules related to the standards of practice for office surgery promulgated by the BOM and the BOOM. **(Section 3)**

The bill regulates office surgery procedures performed by physicians in an office setting and amends ss. 458.305 and 459.003, F.S., to define the following terms:

- "Surgeon" means a licensed physician performing any procedure included within the definition of surgery;
- "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic;
- "Office surgery" means surgery which is performed outside of any facility licensed under chapter 390 or 395, F.S., and includes:
  - "Level I Office Surgery" means surgery limited to minor procedures where anesthesia is limited to minimal sedation;
  - "Level II Office Surgery means any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation; and
  - Level III Office Surgery means surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The use of spinal or epidural anesthesia shall be considered Level III. (**Sections 7 and 10)**

The bill further amends ss. 458.305 and 459.003, F.S., to define six levels of anesthesia that are used to describe the three levels of office surgery as the following:

- "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected;
- "Moderate sedation and analgesia", or "conscious sedation", means a drug-induced depression of consciousness during which patients respond purposefully to verbal

commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;

- "Deep sedation and analgesia" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain respiratory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
- "General anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
- "Epidural anesthesia" means the injection of an anesthetic agent into the epidural space of the spinal cord to produce regional anesthesia resulting in loss of sensation in the lower abdominal, genital and/or pelvic areas.
- "Spinal Anesthesia" means the injection of an anesthetic agent beneath the arachnoid membrane that surrounds the spinal cord to produce a loss of sensation to the lower half of the body. **(See sections 7 and 10)**

The bill amends ss. 458.309 and 459.005, F.S., to authorize the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery; and directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery. The BOM and BOOM must impose a fine of $5,000 per day on a physician who performs certain office surgical procedures in an office that has not registered with the DOH. As a condition of registration, a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and level III office surgeries in an office setting, and the office itself is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. **(See sections 8 and 11)**

The bill amends ss. 458.331 and 459. 015(1), F.S., to establish specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH. **(See sections 9 and 12)**

The bill amends s. 464.012, F.S., to direct that any certified registered nurse anesthetist who provide services in an office registered under ss. 458.309(3) or 459.005(2), F.S., must do so within the framework of an established protocol with an anesthesiologist. **(Section 13)**

The bill amends s 456.004, F.S., to direct the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules; and authorizes the DOH to deny future office surgery registrations for five years to

any person named in office surgery registration documents, including owners and operators of an office surgery facility, that has had a registration revoked by the DOH. **(Section 5)**

The bill amends s. 456.074, F.S., to authorize the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a finding of:

- Probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery adopted by the BOM and the BOOM;
- Probable cause that the facility or its surgeons are in violation practicing or offering to practice beyond the scope permitted by law; and
- That such noncompliance constitutes an immediate danger to the public. **(Section 6)**

The bill amends s. 400.995, F.S., to direct the AHCA to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director also operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the DOH. **(Section 4)**

The bill amends s. 400.991, F.S., to direct that a clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or the failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic. **(Section 2)**

The bill is effective upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

As a condition of registration under ss. 458.308 and 459.003, F.S., a physician who performs office surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must now maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. This may produce an additional cost to the physician and the office if they are a separate legal entities.

C. Government Sector Impact:

The revised registration requirements created by the bill will have an indeterminate fiscal impact on the DOH.[39] However, current law allows the DOH to recover the cost of registration and inspection from the person seeking to register with the department.[40] The cost of rulemaking can be absorbed within existing resources.[41]

The AHCA expects a significant, negative fiscal impact as a result of the bill's expansion of the definition of the term "clinic." The AHCA expects the bill to require an additional 7 full-time equivalent positions (FTE) to assist in the application, licensure, renewal, and complaint processes, and follow-up visits when deficiencies at clinics are found and cited.[42]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 400.9905, 400.991, 400.9935, 400.995, 456.004, 456.074, 458.305, 458.309, 458.331, 459.003, 459.005, 459.015, 464.012, and 766.101.

[39] The Agency for Health Care Administration, *SB 732 (Strike All Amendment 859422) Bill Analysis* (March 3, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).
[40] *See* ss. 458.309(3), 459.005(2), F.S.
[41] Email from Ty Gentle, Budget Director, The Florida Department of Health (April 2, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).
[42] *Supra* note 40.

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 11, 2019:
The committee substitute:

- Defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services "that receives compensation," expanding the definition to include more than just those that bill third parties, such as Medicare, Medicaid, and insurance companies;
- Creates additional responsibilities for clinics to ensure that clinics complies with the standards of practice defined by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery;
- Directs the Agency for Health Care Administration (AHCA) to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility;
- Directs that the clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic;
- Regulates office surgery procedures performed by physicians; and defines surgeon, surgery, and office surgery, and six levels of anesthesia used to describe the three levels of office surgery as: Minimal sedation; Moderate sedation with analgesia or conscious sedation; Deep sedation with analgesia; General anesthesia; Epidural anesthesia; and Spinal anesthesia.
- Directs the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules;
- Authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and operators, of an office surgery facility that has had a registration revoked by the DOH;
- Authorizes the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a specific findings;
- Authorizes the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery;
- Directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery;

- Directs the BOM and the BOOM to impose a fine of $5,000 per day on a physician who performs office surgical procedures in an office that has not registered;
- Establishes specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH; and
- Directs that any certified registered nurse anesthetist who provide services in a registered office surgery facility work within the framework of an established protocol with an anesthesiologist;

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
04/09/2019	.	
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Appropriations Subcommittee on Health and Human Services (Flores) recommended the following:

Senate Amendment (with title amendment)

Delete lines 414 - 624

and insert:

must register the office with the department ~~unless that office is licensed as a facility under chapter 395~~. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Medicine. The actual costs for registration and inspection or

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accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 458.320.

(4)(a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.

(b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office.

(c) The department shall inspect the office at least annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection must be unannounced.

(d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a

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fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (3) in an office that is not registered with the department.

Section 9. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.309(3).

Section 10. Section 459.003, Florida Statutes, is amended to read:

459.003 Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Osteopathic Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

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(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(5) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(6) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(7) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected.

(8) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(9) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(11) ~~(3)~~ "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

(12) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.


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(13) "Surgeon" means a physician who performs surgery.

(14) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(10) ~~(4)~~ "Osteopathic physician" means a person who is licensed to practice osteopathic medicine in this state.

(4) ~~(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic Medicine," when referring to degrees, shall be construed to be equivalent and equal degrees.

Section 11. Subsection (2) of section 459.005, Florida Statutes, is amended and subsection (3) is added to that section, to read:

459.005 Rulemaking authority.—

(2) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department ~~unless that office~~

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~~is licensed as a facility under chapter 395~~. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 459.0085.

(3)(a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.

(b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office.

(c) The department shall inspect the office at least annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless

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the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection must be unannounced.

(d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (2) in an office that is not registered with the department.

Section 12. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 459.005(2).

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

And the title is amended as follows:

Delete lines 32 - 63

and insert:

Board of Medicine to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions;

authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 458.331, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.003, F.S.; defining terms; amending s. 459.005, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the Board of Osteopathic Medicine to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions; authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who


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perform certain office surgeries in an unregistered office; amending s. 459.015, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 766.101, F.S.;

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
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Appropriations Subcommittee on Health and Human Services (Flores) recommended the following:

Senate Substitute for Amendment (359744) (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (12) is added to section 456.004, Florida Statutes, to read:

456.004 Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(12) Deny or revoke the registration of, or impose any

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penalty set forth in s. 456.072(2) against, any facility where office surgery, as defined in ss. 458.305(8) and 459.003(9), is performed for failure of any of its physicians, owners, or operators to comply with rules adopted under ss. 458.309(3) and 459.005(2). Section 456.073 applies to enforcement actions brought against such facilities. If a facility's registration is revoked, the department may deny any person named in the registration documents of the facility, including the persons who own or operate the facility, individually or as part of a group, from registering a facility to perform surgical procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5 years after the revocation date.

Section 2. Subsection (6) is added to section 456.074, Florida Statutes, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(6) The department may issue an emergency order suspending or restricting the registration of a facility in which liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II office surgery, or Level III office surgery as those terms are defined in ss. 458.305(8) and 459.003(9), are performed upon a finding of probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.309(4) or s. 459.005(3), as applicable, or are in violation of s. 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance constitutes an immediate danger to the public.

Section 3. Section 458.305, Florida Statutes, is amended to

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read:

458.305 Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(4) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(5) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

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(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(6) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and respiratory and cardiovascular functions are unaffected.

(7) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(8) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in

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which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(10) ~~(3)~~ "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(11) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(12) "Surgeon" means a physician who performs surgery.

(13) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(9) ~~(4)~~ "Physician" means a person who is licensed to practice medicine in this state.

Section 4. Subsection (3) of section 458.309, Florida Statutes, is amended and subsection (4) is added to that section, to read:

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458.309 Rulemaking authority.—

(3) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 458.320.

(4)(a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.

(b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this

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chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office.

(c) The department shall inspect the office at least annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of a physician's office that meets the description of a clinic specified in s. 458.3265(1)(a)1.h., which must be announced.

(d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (3) in an office that is not registered with the department.

Section 5. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.309(3).

Section 6. Section 459.003, Florida Statutes, is amended to

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read:

459.003 Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Osteopathic Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(5) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(6) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

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(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(7) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected.

(8) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(9) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in

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which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(11) ~~(3)~~ "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

(12) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(13) "Surgeon" means a physician who performs surgery.

(14) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(10) ~~(4)~~ "Osteopathic physician" means a person who is

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licensed to practice osteopathic medicine in this state.

(4)~~(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic Medicine," when referring to degrees, shall be construed to be equivalent and equal degrees.

Section 7. Subsection (2) of section 459.005, Florida Statutes, is amended and subsection (3) is added to that section, to read:

459.005 Rulemaking authority.—

(2) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 459.0085.

(3)(a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.

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(b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office.

(c) The department shall inspect the office at least annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of a physician's office that meets the description of a clinic specified in s. 459.0137(1)(a)1.h., which must be announced.

(d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (2) in an office that is not registered with the department.

Section 8. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a

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license or disciplinary action, as specified in s. 456.072(2):

(xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 459.005(2).

Section 9. Paragraph (a) of subsection (1) of section 766.101, Florida Statutes, is amended to read:

766.101 Medical review committee, immunity from liability.—

(1) As used in this section:

(a) The term "medical review committee" or "committee" means:

1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641;

b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system;

c. A committee of a state or local professional society of health care providers;

d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home;

e. A committee of the Department of Corrections or the Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both;

f. A committee of a professional service corporation formed

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under chapter 621 or a corporation organized under part I of chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and which has at least 25 health care providers who routinely provide health care services directly to patients;

g. A committee of the Department of Children and Families which includes employees, agents, or consultants to the department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916;

h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

j. A peer review or utilization review committee organized under chapter 440;

k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records; or

l. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of

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health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 10. This act shall take effect upon becoming a law.

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

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to clinics and office surgery; amending s. 456.004, F.S.; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; specifying provisions that apply enforcement actions against such facilities; authorizing the department to deny certain persons associated with an office of which the registration was revoked from registering a new office to perform certain office surgery; amending s. 456.074, F.S.; authorizing the department to issue an emergency order suspending or restricting the registration of a

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certain office if it makes certain findings; amending s. 458.305, F.S.; defining terms; amending s. 458.309, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the Board of Medicine to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions; authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 458.331, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.003, F.S.; defining terms; amending s. 459.005, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the Board of Osteopathic Medicine to adopt rules to administer the registration, inspection, and

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safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions; authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 459.015, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 766.101, F.S.; conforming a cross-reference; providing an effective date.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
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Appropriations Subcommittee on Health and Human Services (Flores) recommended the following:

Senate Amendment to Amendment (978476)

Delete line 166
and insert:
description of a clinic specified in s. 458.3265(1)(a)3.g. and h.,

Delete line 318
and insert:
description of a clinic specified in s. 459.0137(1)(a)3.g. and h.,

By the Committee on Health Policy; and Senator Flores

588-02904-19 2019732c1

A bill to be entitled

An act relating to clinics and office surgery; amending s. 400.9905, F.S.; revising the definition of the term "clinic"; amending s. 400.991, F.S.; requiring a clinic to provide proof of its financial responsibility to pay certain claims and costs along with its application for licensure to the Agency for Health Care Administration; amending s. 400.9935, F.S.; requiring a medical director or a clinic director to ensure that the clinic complies with specified rules; amending s. 400.995, F.S.; requiring the agency to impose a specified administrative fine on an unregistered clinic that performs certain office surgeries; amending s. 456.004, F.S.; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; specifying provisions that apply enforcement actions against such facilities; authorizing the department to deny certain persons associated with an office of which the registration was revoked from registering a new office to perform certain office surgery; amending s. 456.074, F.S.; authorizing the department to issue an emergency order suspending or restricting the registration of a certain office if it makes certain findings; amending s. 458.305, F.S.; defining terms; amending s. 458.309, F.S.; requiring a physician who performs certain office surgery and the office in

588-02904-19 2019732c1

which the surgery is performed to maintain specified levels of financial responsibility; authorizing the department to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring the Board of Medicine to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 458.331, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.003, F.S.; defining terms; amending s. 459.005, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the department to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring the Board of Osteopathic Medicine to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 459.015, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 464.012, F.S.;

authorizing a certified registered nurse anesthetist to provide specified services in a an office registered to perform office surgery within the framework of an established protocol with a licensed anesthesiologist; amending s. 766.101, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Subsection (4) of section 400.9905, Florida Statutes, is amended to read:

400.9905 Definitions.—

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

(a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or

subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

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

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or

subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

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

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees at least two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians

covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, and that is wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner if one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) which provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or

chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic, prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners where one or more of the persons responsible for the operations of the entity is a health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the

entity and is responsible for the entity's compliance with state law for purposes of this part.

(n) Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 where the billing for medical services is under a single tax identification number. The application for exemption under this subsection shall contain information that includes: the name, residence, and business address and phone number of the entity that owns the practice; a complete list of the names and contact information of all the officers and directors of the corporation; the name, residence address, business address, and medical license number of each licensed Florida health care practitioner employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity and a certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under personal injury protection insurance coverage for the preceding year. If the agency determines that an entity which is exempt under this subsection has received payments for medical services under personal injury protection insurance coverage, the agency may deny or revoke the exemption from licensure under this subsection.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive

reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

Section 2. Subsection (4) of section 400.991, Florida Statutes, is amended to read:

400.991 License requirements; background screenings; prohibitions.—

(4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

(a) A listing of services to be provided either directly by the applicant or through contractual arrangements with existing providers;

(b) The number and discipline of each professional staff member to be employed; ~~and~~

(c) Proof of financial ability to operate as required under s. 408.810(8). As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least $500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond; and

(d) Proof that the clinic maintains the financial responsibility in the manner set forth in s. 458.320(2) or s. 459.0085(2), as applicable, to pay claims and costs ancillary thereto arising out of the rendering of or the failure to render medical care and services, for physicians and osteopathic physicians who perform liposuction procedures in which more than

1,000 cubic centimeters of supernatant fat is removed, Level II office surgery, or Level III office surgery as those terms are defined in ss. 458.305(8) and 459.003(9), in an office setting.

Section 3. Paragraph (j) is added to subsection (1) of section 400.9935, Florida Statutes, to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(j) If the clinic is registered with the department to perform office surgery, ensure that the clinic complies with the standards of practice for office surgery adopted by rule under ss. 458.309(4) and 459.005(3).

Section 4. Subsection (4) of section 400.995, Florida Statutes, is amended to read:

400.995 Agency administrative penalties.—

(4) Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic or a clinic that is not registered with the department where any liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed or where any Level II office surgery or Level III office surgery, as those terms are defined in ss. 458.305(8) and 459.003(9), is performed, is ~~shall be~~ subject to an administrative fine of $5,000 per day.

Section 5. Subsection (12) is added to section 456.004, Florida Statutes, to read:

456.004 Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(12) Deny or revoke the registration of, or impose any penalty set forth in s. 456.072(2) against, any facility where office surgery, as defined in ss. 458.305(8) and 459.003(9), is performed for failure of any of its physicians, owners, or operators to comply with rules adopted under ss. 458.309(3) and 459.005(2). Section 456.073 applies to enforcement actions brought against such facilities. If a facility's registration is revoked, the department may deny any person named in the registration documents of the facility, including the persons who own or operate the facility, individually or as part of a group, from registering a facility to perform surgical procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5 years after the revocation date.

Section 6. Subsection (6) is added to section 456.074, Florida Statutes, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(6) The department may issue an emergency order suspending or restricting the registration of a facility in which liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II office surgery, or Level III office surgery as those terms are defined in ss. 458.305(8) and 459.003(9), are performed upon a finding of probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.309(4) or s. 459.005(3), as applicable, or are in violation of s. 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance constitutes an immediate danger to the public.

Section 7. Section 458.305, Florida Statutes, is amended to read:

458.305 Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(4) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the dura mater of the spinal cord.

(5) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular

function.

(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(6) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and respiratory and cardiovascular functions are unaffected.

(7) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(8) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(10)~~(3)~~ "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(11) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(12) "Surgeon" means a physician who performs surgery.

(13) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(9)~~(4)~~ "Physician" means a person who is licensed to practice medicine in this state.

Section 8. Subsection (3) of section 458.309, Florida Statutes, is amended and subsection (4) is added to that

section, to read:

458.309 Rulemaking authority.—

(3) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 458.320.

(4) The department may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery. The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (3) in an office that is not registered with the department.

Section 9. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.309(3).

Section 10. Section 459.003, Florida Statutes, is amended to read:

459.003 Definitions.—As used in this chapter, the term:

(1) "Board" means the Board of Osteopathic Medicine.

(2) "Deep sedation and analgesia" means a drug-induced depression of consciousness during which all of the following apply:

(a) The patient cannot be easily aroused but responds by purposefully following repeated or painful stimulation.

(b) The patient's ability to independently maintain ventilatory function may be impaired.

(c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.

(d) The patient's cardiovascular function is usually maintained.

(e) The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.

(3) ~~(2)~~ "Department" means the Department of Health.

(5) "Epidural anesthesia" means anesthesia produced by the injection of an anesthetic agent into the space on or around the

dura mater of the spinal cord.

(6) "General anesthesia" means a drug-induced loss of consciousness administered by a qualified general anesthesia provider during which all of the following apply:

(a) The patient is not able to be aroused, even by painful stimulation.

(b) The patient's ability to independently maintain ventilatory function is often impaired.

(c) The patient has a level of depressed neuromuscular function.

(d) The patient may require assistance in maintaining a patent airway, and positive pressure ventilation may be required.

(e) The patient's cardiovascular function may be impaired.

(7) "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected.

(8) "Moderate sedation and analgesia" or "conscious sedation" means drug-induced depression of consciousness and a state of consciousness during which all of the following apply:

(a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

(b) Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate.

(c) Cardiovascular function is maintained.

(d) Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(9) "Office surgery" means a surgery that is performed in a physician's office or any facility that is not licensed under chapter 390 or chapter 395.

(a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is limited to minimal sedation.

(b) "Level II office surgery" includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

(11)~~(3)~~ "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

(12) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.

(13) "Surgeon" means a physician who performs surgery.

(14) "Surgery" means any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or

defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(10) ~~(4)~~ "Osteopathic physician" means a person who is licensed to practice osteopathic medicine in this state.

(4) ~~(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic Medicine," when referring to degrees, shall be construed to be equivalent and equal degrees.

Section 11. Subsection (2) of section 459.005, Florida Statutes, is amended and subsection (3) is added to that section, to read:

459.005 Rulemaking authority.—

(2) A physician who performs any liposuction procedure ~~procedures~~ in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery ~~level 2 procedures lasting more than 5 minutes~~, or any Level III office surgery ~~and all level 3 surgical procedures~~ in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization ~~subsequently~~ approved by the Board of Osteopathic Medicine. The actual costs for registration and

inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 459.0085.

(3) The department may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery. The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of $5,000 per day on a physician who performs a surgical procedure identified in subsection (2) in an office that is not registered with the department.

Section 12. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 459.005(2).

Section 13. Paragraph (b) of subsection (4) of section 464.012, Florida Statutes, is amended to read:

464.012 Licensure of advanced practice registered nurses; fees; controlled substance prescribing.—

(4) In addition to the general functions specified in subsection (3), an advanced practice registered nurse may perform the following acts within his or her specialty:

(b) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

11. Provide the services identified in subsections 1.-10. in an office registered to perform office surgery pursuant to s. 458.309(3) or s. 459.005(2) within the framework of an established protocol with an anesthesiologist licensed under chapter 458 or chapter 459.

Section 14. Paragraph (a) of subsection (1) of section 766.101, Florida Statutes, is amended to read:

766.101 Medical review committee, immunity from liability.—

(1) As used in this section:

(a) The term “medical review committee” or “committee” means:

1.a. A committee of a hospital or ambulatory surgical center licensed under chapter 395 or a health maintenance organization certificated under part I of chapter 641;

b. A committee of a physician-hospital organization, a provider-sponsored organization, or an integrated delivery system;

c. A committee of a state or local professional society of health care providers;

d. A committee of a medical staff of a licensed hospital or nursing home, provided the medical staff operates pursuant to written bylaws that have been approved by the governing board of the hospital or nursing home;

e. A committee of the Department of Corrections or the Correctional Medical Authority as created under s. 945.602, or employees, agents, or consultants of either the department or the authority or both;

f. A committee of a professional service corporation formed under chapter 621 or a corporation organized under part I of chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and which has at least 25 health care providers who routinely provide health care services directly to patients;

g. A committee of the Department of Children and Families which includes employees, agents, or consultants to the department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916;

h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;

j. A peer review or utilization review committee organized

under chapter 440;

k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records; or

l. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 15. This act shall take effect upon becoming a law.

The Florida Senate

Committee Agenda Request

To: Senator Aaron Bean, Chair
Appropriations Subcommittee on Health and Human Services

Subject: Committee Agenda Request

Date: March 12, 2019

I respectfully request that **Senate Bill #732**, relating to Office Surgery, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Anitere Flores

Senator Anitere Flores
Florida Senate, District 39

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	SB 1300
INTRODUCER:	Senator Benacquisto
SUBJECT:	Florida ABLE Program
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Hendon	Hendon	CF	**Favorable**
2.	Gerbrandt	Kidd	AHS	**Recommend: Favorable**
3.			AP	

I. Summary:

SB 1300 repeals section 11 of the 2018-2019 Implementing Bill. Section 10 of the Implementing Bill prohibits the Medicaid program, upon the death of a Medicaid recipient who has assets in an ABLE account, from filing a claim on the account to recover medical assistance. By repealing section 11, the changes in the implementing bill that prohibit a claim by Medicaid will remain in effect. Contributions to ABLE accounts are tax exempt and pay for a variety of expenses related to maintaining the health, independence and quality of life for people with disabilities.

The bill is expected to have an insignificant fiscal impact to the state and has an effective date of June 30, 2019.

II. Present Situation:

ABLE Act

Signed into law in December 2014, the Stephen Beck, Jr. Achieving a Better Life Experience (ABLE) Act authorized states to establish tax-advantaged savings programs for individuals with disabilities.[1] In 2015, Virginia became the first state to approve and pass ABLE legislation after passage of the federal ABLE Act. The act created Section 529A of the Internal Revenue Code. This is the federal legal framework that establishes the specific rules and requirements of an ABLE account. Such accounts are tax-advantaged savings accounts for eligible individuals with disabilities. Individuals with disabilities and their families depend on a wide variety of public benefits for income, health care, food and housing assistance. Many of these benefits require meeting a means or resource test that limits the eligibility of individuals who report more than $2,000 in cash savings, retirement funds and other items of significant value.

[1] ABLEnow website, see https://www.able-now.com/, last visited March 28, 2019.

For the first time in public policy, the ABLE Act recognized the extra and significant costs of living with a disability. ABLE accounts allow eligible individuals the opportunity to save and fund a variety of qualified disability expenses without endangering eligibility for certain benefits such as Medicaid and Supplemental Security Income (SSI).

Florida's ABLE Program

Section 1009.986, F.S., established the ABLE program to encourage and assist the saving of private funds in tax-exempt accounts in order to pay for the qualified disability expenses[2] of eligible individuals with disabilities. The Legislature intended that the ABLE program be implemented in a manner that is consistent with the federal law authorizing the program and that maximizes program efficiency and effectiveness.

Medicaid

The Florida Medicaid program is a partnership between the federal and state governments. Each state operates its own Medicaid program under a state plan approved by the federal Centers for Medicare and Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies. Florida Medicaid is administered by the Agency for Health Care Administration and financed with federal and state funds. Approximately 3.9 million Floridians are currently enrolled in Medicaid, and the program is expected to cost $28.2 billion in 2019-2020.[3]

Eligibility for Medicaid is based on a number of factors, including age, household, or individual income, and assets. State eligibility payment guidelines are provided in s. 409.903, F.S., for mandatory payments for eligible persons and s. 409.904, F.S., for optional payments for eligible persons. Minimum coverage thresholds are established in federal law for certain population groups, such as children. Many of the persons with developmental disabilities that are assisted by the ABLE program are also served by the Medicaid program. State and federal law require states to file a lien or claim on the estate of persons served by Medicaid after their death to recover the costs of their medical care.[4] In addition, s. 1009.986, F.S., allows the Medicaid program, upon the death of an ABLE account beneficiary, to make a claim on the account for the total amount of medical assistance provided under the Medicaid program.

2018-2019 General Appropriations Act and Implementing Bill

Specific Appropriation 70 of the Fiscal Year 2018-2019 General Appropriations Act[5] provided $2.2 million in general revenue to the ABLE program for student financial aid.

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[2] Qualified disability expenses include, but are not limited to, education, housing, transportation, employment training and support, assistive technology and personal support services, health, prevention and wellness, financial management and administrative services, legal fees, expenses for oversight and monitoring, funeral and burial expenses. (*See* s. 529A of the Internal Revenue).

[3] Social Services Estimating Conference, Medicaid Caseloads and Expenditures, November 18, 2018 and December 10, 2018—Executive Summary http://edr.state.fl.us/Content/conferences/medicaid/execsummary.pdf (last visited March 13, 2019).

[4] Section 409.9101, F.S.

[5] Chapter 2018-10, Laws of Florida

Each year, the Legislature passes an Implementing Bill to make temporary changes in the Florida Statutes to implement the provisions of the General Appropriations Act. The Fiscal Year 2018-2019 Implementing Bill[6] made needed changes in statute and provided for these changes to revert back to prior text on July 1, 2019.

Section 10 of the Implementing Bill amended s. 1009.986(7), F.S., prohibiting the Medicaid program, upon the death of a Medicaid recipient who has assets in an ABLE account, from filing a claim on the account to recover medical assistance provided by Medicaid. Section 11 restores the text so that this prohibition is in effect only during Fiscal Year 2018-2019.

III. Effect of Proposed Changes:

Section 1 of the bill repeals section 11 of the 2018-2019 Implementing Bill. Section 10 of the Implementing Bill prohibits the Medicaid program from filing a claim on a Medicaid client who receives assistance from the ABLE program. By repealing section 11, the changes in section 10 of the 2018-2019 Implementing Bill will remain in effect, which prohibits the Medicaid program from filing a claim on an ABLE account to recover medical assistance provided by Medicaid.

Section 2 provides an effective date of June 30, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[6] *Id.*

B. Private Sector Impact:

None.

C. Government Sector Impact:

The state's Medicaid program will not be able to make a claim on the ABLE account of any Medicaid recipient who also receives assistance from the ABLE program. The fiscal impact to the state is unknown, but is not expected to be significant.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill repeals section 11 of chapter 2018-10, Laws of Florida.

IX. Additional Information:

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

None.

B. Amendments:

None.

By Senator Benacquisto

27-01627-19 20191300__

A bill to be entitled

An act relating to the Florida ABLE program; repealing s. 11 of chapter 2018-10, Laws of Florida, relating to the scheduled reversion of provisions related to the distribution of funds in an ABLE account upon the death of a designated beneficiary; providing an effective date.

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

Section 1. Section 11 of chapter 2018-10, Laws of Florida, is repealed.

Section 2. This act shall take effect June 30, 2019.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	PCS/SB 1436 (612176)
INTRODUCER:	Appropriations Subcommittee on Health and Human Services and Senator Gibson
SUBJECT:	Closing the Gap Grant Proposals
DATE:	April 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Favorable**
2.	Gerbrandt	Kidd	AHS	**Recommend: Fav/CS**
3.			AP	

I. Summary:

PCS/SB 1436 adds a priority focus area eligible for funding under the "Closing the Gap" grant program to include Alzheimer's Disease and dementia. The bill removes the requirement that up to 20 percent of any grants awarded under the program be set-aside for projects related to Front Porch Florida Communities. The bill also prohibits the Department of Health (DOH) from establishing a minimum or maximum award amount, requires the DOH to determine grant award amounts based on the merit of the application, and requires the DOH to award grants in various regions of the state.

The bill has no fiscal impact on state government.

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

II. Present Situation:

The Closing the Gap Program

In 2000, the Florida Legislature created the Reducing the Racial and Ethnic Health Disparities: "Closing the Gap" (CTG) grant program.[1] The program is administered through the Department of Health's (DOH) Office of Minority Health and Health Equity. The purposes of the grant program is to improve health outcomes of racial and ethnic populations and promote disease prevention activities in the following priority areas:

- Maternal and infant mortality;
- Cancer;
- HIV/AIDS;
- Cardiovascular disease;

[1] Chapter 2000-256, ss. 31-32, Laws of Fla. (2000).

- Diabetes;
- Adult and child immunization;
- Oral health care;
- Sickle cell disease; and,
- Lupus.[2]

Closing the gap grants are intended to stimulate the development of community and neighborhood-based projects that impact health outcomes of racial and ethnic populations and stimulate partnerships between state and local governments, faith-based organizations, private sector organizations, and other non-traditional partners.[3] Priority is given to grant proposals that:

- Represent areas with the greatest documented ethnic and racial health status disparities;
- Exceeded the statutory local match requirement;[4]
- Demonstrate broad-based local community support from entities representing racial and ethnic populations;
- Demonstrate high levels of participation by the heath care community in clinical preventive services and health promotion activities;
- Have been submitted by counties with high levels of residents living in poverty and with poor health status indicators;
- Demonstrate a coordinated community approach to addressing racial and ethnic health disparities within existing publicly financed health care programs;
- Incorporate intervention mechanisms that have a high probability of improving the targeted populations health status;
- Demonstrate a commitment to quality management in all aspects of project administration and implementation; and
- Incorporate policy approaches that will lead to long-term sustainability and improvement.[5]

Grant Proposals

Grant proposals are awarded for one year through a proposal process and may be renewed annually subject to the availability of funds and the grantee's achievement of quality standards, objectives, and outcomes. Grants can be awarded to a county or a group of adjoining counties if those counties submit a multi-county application.[6] Grant funds may not be used to provide medical or clinical services.[7]

The DOH released the *Request for Applications* with an application deadline date of February 16, 2018, for grants beginning July 1, 2018 and ending June 30, 2019.[8] The next funding cycle

[2] Chapter 2018-157, Laws of Fla. Lupus was added to the list of priority areas during the 2018 Regular Legislative Session.
[3] Section 381.7352, F.S.
[4] Section 381.7356, F.S.
[5] Section 381.7355(3), F.S.
[6] Section 381.7356, F.S.
[7] *Infra* note 15 at page 13.
[8] Florida Department of Health, Office of Minority Health and Health Equity, *Reducing Racial and Ethnic Health Disparities Closing the Gap Grant Program (CTG) Request for Applications, RFA # 17-007, FY 2018-2019,* http://www.floridahealth.gov/programs-and-services/minority-health/closing-the-gap.html, (last visited March 28, 2019).

will be in 2021-2022.[9] Currently, the maximum award per applicant is $200,000 and the grant application states that approximately $3 million dollars would be available, subject to an appropriation.[10]

Matching Funds for Grants

Closing the Gap grants require the grantee to provide $1 in local matching funds for every $3 in state grant funds being requested. Counties that meet certain population demographics may provide the matching funds through in-kind contributions. The amount of a grant award is based on the county's or the neighborhood's population demographics.[11] Table 1 below illustrates how populations may meet the match requirement through different combinations of cash and in-kind contributions.

Table 1.
Closing the Gap Matching Funds Contribution Combinations[12]

Grantee Type	Matching Funds Requirements
County Populations greater than 50,000	One dollar for every $3 grant payment 50 percent must be in cash 50 percent may be in-kind
County Population of 50,000 or less	Local matching may be provided entirely through in-kind contributions
Grantee is a Front Porch Community[13]	No match requirement

On June 1, 2018, the DOH awarded grants under the Request for Applications process to the following vendors:

Vendors Awards Closing the Gap Contracts (2018-2019)			
BayCare Health System	Center for Change	Metropolitan Charities	Suwannee River AHEC
Big Bend Cares	Foundation for Sickle Cell Disease Research	Miami-Dade AHEC	Dept of Health – Duval County
Big Bend Rural Health	Gadsden County Healthy Start	Mother Care Network	Dept of Health – Franklin and Gulf
Brain Expansions	Healthy Mothers Healthy Babies	Prideline Youth Services	Dept of Health – Hardee County
Broward Urban League	Hebni Nutrition Consultants	Reclaiming the Land	Dept of Health – Seminole County
Caridad Center	Latino Salud	Sickle Cell Disease Foundation	Dept of Health – Highland County

Social Determinants of Health

Healthy People 2020 is an initiative of the United States Department of Health and Human Services that provides 10-year national objectives for improving the health of Americans. Its

[9] *Id.*
[10] *Id.*
[11] Section 381.7356, F.S.
[12] *Id.*
[13] *See Infra* note 31.

vision is a society in which all people live long, healthy lives.[14] One of the missions of *Healthy People 2020* is increase public awareness of determinants of health, disease, and disability and the opportunities for progress. The project seeks to achieve health equity, eliminate disparities, and improve the health of all groups while also attaining high-quality, longer lives, free of preventable disease, disability, injury, and premature death.[15] In Florida, the ethnic and racial disparity in some health categories is significant, as shown in Table 2 below.

Table 2.
Minority Health Profiles – Select Indicators for 2017 [16]

Indicator (per 100,000, unless noted)	White	Black	Hispanic	Non-Hispanic
Fetal Deaths[17] (per 1,000 deliveries)	5.2	10.4	5.5	7.2
Infant Deaths[18] (per 1,000 births)	4.4	11.3	5.1	6.4
Maternal Deaths[19]	13.3	24.9	10.5	19.3
Diabetes death rate	18.3	35.7	19.8	20.0
HIV Virus Disease	1.6	10.1	30.1	3.7
Coronary Heart Disease death rate	146.2	100	125.4	153.1
Stroke death rate	37.2	53.9	37.9	37.0
Alzheimer's	21.7	15.2	25.9	20.2

A statistical brief from the DOH in 2017 noted that the gap between the black mortality rate and the white mortality rate has decreased over time. In 1995, the age-adjusted mortality rate per 100,000 population was 1,224.9 for Black race and 811.6 for White race, and in 2015, these rates had come down to 851.9 for Black race and 735.0 for White race.[20]

Dementia

Dementia is not a specific disease but is a catch-all term that is used to describe a group of symptoms associated with a decline in memory or other cognitive abilities that reduce a person's ability to perform everyday activities.[21] Symptoms of dementia vary greatly, but at least two of these core mental functions must be significantly impaired for symptoms to be attributed to dementia:

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[14] United States Department of Health and Human Services, *Healthy People 2020 – Framework*, https://www.healthypeople.gov/sites/default/files/HP2020Framework.pdf, (last visited March 28, 2019).
[15] *Id.*
[16] Florida Department of Health, FLHealthCHARTS.com, *Resident Age Adjusted Death Rate (AADR) per 100,000 Population by Year by 50 Leading Rankable Causes of Death by Ethnicity* (chart generated on March 20, 2019).
[17] Florida Department of Health, *Supra* note 21, *Fetal Death Ratio per 100,000 Births per year* (chart generated on March 20, 2019).
[18] Florida Department of Health, *Supra* note 21, *Infant Death Ratio per 100,000 Births per year* (chart generated on March 20, 2019).
[19] Florida Department of Health, *Supra* note 21, *Maternal Death Rate per 100,000 Births per year* (chart generated on March 20, 2019).
[20] Florida Department of Health, FLHealthCHARTS.com Statistical Brief, *Gap Between Black and White Death Rate Narrows*, http://www.flhealthcharts.com/Charts/documents/StatisticalBriefs/GapNarrows.pdf, (last visited March 28, 2019).
[21] Alzheimer's Association, *What is Dementia*, https://www.alz.org/alzheimers-dementia/what-is-dementia (last visited March 28, 2019).

- Memory;
- Communication and language;
- Ability to focus and pay attention;
- Reasoning and judgment; and
- Visual perception.[22]

Alzheimer's disease also accounts for 60 to 80 percent of all dementia cases.[23]

Alzheimer's Disease

Alzheimer's disease is the most common cause of dementia. The disease likely develops from many factors such as genetics, lifestyle, and the environment, with age being the greatest known risk factor. Most individuals who develop the disease will do so after the age of 65.[24] The disease is a progressive disorder that causes brain cells to degenerate and die.[25]

Individuals with Alzheimer's may show symptoms such as:
- Repeating statements and questions numerous times over;
- Forgetting conversations, appointments, or events and not remembering them later;
- Misplacing possessions routinely, often putting them in illogical places;
- Getting lost in familiar places;
- Forgetting the names of family members; and
- Having trouble finding the right words to identify objects, express thoughts, or take part in conversations.[26]

Individuals may also have changes in behavior due to changes in their brains and they may experience depression, apathy, and social withdrawal along with mood swings and delusions.[27]

III. Effect of Proposed Changes:

The bill amends s. 381.7355, F.S., to expand the priority areas eligible for a Closing the Gap grant award to include Alzheimer's disease and dementia.

The bill amends s. 381.7354, F.S., to eliminate the requirement that up to 20 percent of any grants awarded under the program be set-side for projects related to Front Porch Florida Communities.[28] The bill also prohibits the Department of Health (DOH) from establishing a

[22] *Id.*
[23] *Id.*
[24] Alzheimer's Association, *Causes and Risk Factors,* https://www.alz.org/alzheimers-dementia/what-is-alzheimers/causes-and-risk-factors (last visited March 28, 2019).
[25] Mayo Clinic, *Alzheimer's Disease,* https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/symptoms-causes/syc-20350447 (last visited March 28, 2019).
[26] *Id.*
[27] *Id.*
[28] The Front Porch Florida Initiative began during Governor Jeb Bush's administration and was dedicated to revitalization efforts in some of the state's most distressed communities through the award of competitive grants to fund projects proposed by the community. Front Porch funding was used for economic development, beautification, revitalization, technical assistance, community training, and youth development. The initiative began in 1999 and received its last appropriation in the 2007 General Appropriations Act for the 2007-2008 fiscal year. During that span, the Legislature appropriated over

minimum or maximum award amount, requires the DOH to determine grant award amounts based on the merit of the application, and requires the DOH to award grants in various regions of the state.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Public and private community groups, foundations, and community partnerships that advocate for issues relating to reducing disparities in the prevalence of Alzheimer's disease and dementia among racial and ethnic populations will have a new potential opportunity to compete for grants

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$28 million in funding. *See:* Florida Senate Committee on Community Affairs, *Department Of Community Affairs - Review Of The Front Porch Florida Initiative*, Interim Project 2008-110 (October 2007) *available at* http://archive.flsenate.gov/data/Publications/2008/Senate/reports/interim_reports/pdf/2008-110ca.pdf (last visited March 28, 2019)

C. Government Sector Impact:

The annual appropriation of state funds to the Closing the Gap program is subject to an annual appropriation. Funding for the program is not mandated in PCS/SB 1436. The addition of a new priority does not impact the overall cost of the program.

County health departments and other local government entities will also have an opportunity to compete for funds under the program. During this current fiscal year, several local government entities received Closing the Gap grants.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.7354 and 381.7355.

IX. Additional Information:

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

Recommended CS by Appropriations Subcommittee on Health and Human Services on April 4, 2019:
The committee substitute:

- Prohibits the DOH from establishing a minimum or maximum award amount;
- Requires the DOH to determine grant award amounts based on the merit of the application; and
- Requires the DOH to award grants in various regions of the state.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/04/2019	.	
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	.	

Appropriations Subcommittee on Health and Human Services (Gibson) recommended the following:

Senate Amendment (with title amendment)

Delete lines 26 - 32

and insert:

(3) The department may not establish a minimum amount or a maximum amount for grants and shall determine the amount of each award based on the merits of the application. The department shall ensure that grants are awarded to applicants in various regions of the state. ~~In addition to the grants awarded under subsections (1) and (2), up to 20 percent of the funding for the~~

174138

~~Reducing Racial and Ethnic Health Disparities: Closing the Gap grant program shall be dedicated to projects that address improving racial and ethnic health status within specific Front Porch Florida Communities~~.

(4) Nothing in ss. 381.7351-381.7356 shall prevent a

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

And the title is amended as follows:

Delete line 3

and insert:

amending s. 381.7354, F.S.; prohibiting the Department of Health from establishing a minimum amount or a maximum amount for Closing the Gap grants; requiring that the amount of each award be based on the merit of each application and that grants be awarded to applicants in various regions of the state; removing provisions

By Senator Gibson

6-01246A-19 20191436__

A bill to be entitled

An act relating to Closing the Gap grant proposals; amending s. 381.7354, F.S.; removing provisions related to Front Porch Florida Communities; amending s. 381.7355, F.S.; adding a priority area that may be addressed in a Closing the Gap grant proposal; providing an effective date.

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

Section 1. Section 381.7354, Florida Statutes, is amended to read:

381.7354 Eligibility.—

(1) Any person, entity, or organization within a county may apply for a Closing the Gap grant and may serve as the lead agency to administer and coordinate project activities within the county and develop community partnerships necessary to implement the grant.

(2) Persons, entities, or organizations within adjoining counties with populations of less than 100,000, based on the annual estimates produced by the Population Program of the University of Florida Bureau of Economic and Business Research, may jointly submit a multicounty Closing the Gap grant proposal. However, the proposal must clearly identify a single lead agency with respect to program accountability and administration.

(3) ~~In addition to the grants awarded under subsections (1) and (2), up to 20 percent of the funding for the Reducing Racial and Ethnic Health Disparities: Closing the Gap grant program shall be dedicated to projects that address improving racial and~~

6-01246A-19 20191436__

~~ethnic health status within specific Front Porch Florida Communities.~~

~~(4)~~ Nothing in ss. 381.7351-381.7356 shall prevent a person, entity, or organization within a county or group of counties from separately contracting for the provision of racial and ethnic health promotion, health awareness, and disease prevention services.

Section 2. Subsection (2) of section 381.7355, Florida Statutes, is amended to read:

381.7355 Project requirements; review criteria.—

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

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

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

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

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

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

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

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

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

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

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

10. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to Alzheimer's disease and dementia.

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

(b) Identification and relevance of the target population.

(c) Methods for obtaining baseline health status data and assessment of community health needs.

(d) Mechanisms for mobilizing community resources and gaining local commitment.

(e) Development and implementation of health promotion and disease prevention interventions.

(f) Mechanisms and strategies for evaluating the project's objectives, procedures, and outcomes.

(g) A proposed work plan, including a timeline for implementing the project.

(h) Likelihood that project activities will occur and continue in the absence of funding.

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

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Rules, *Vice Chair*
Appropriations
Innovation, Industry, and Technology
Judiciary

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR AUDREY GIBSON
Minority Leader
6th District

March 25, 2019

Senator Aaron Bean, Chair
Committee on Appropriations Subcommittee on
Health and Human Services
201 The Capitol
404 S. Monroe Street
Tallahassee, FL 32399-1100

Thank you for your vote!

Chair Bean,

I respectfully request that SB 1436, relating to Closing the Gap grants addressing racial and ethnic disparities in morbidity and mortality rates to Alzheimer's disease and Dementia, be placed on the next committee agenda.

SB 1436, adds Alzheimer's disease and Dementia to Closing the Gap grant proposals. The Closing the Gap grant program provides funding to decrease ethnic disparities for a variety of diseases and illnesses, such as certain forms of Cancer, infant mortality, cardio vascular disease, high blood pressure and other ailments highly affecting people of color. The bill also removes Front Porch Florida Communities, a program which no longer exists and is not funded. The bill passed unanimously in the first committee.

Thank you for your kind consideration.

Sincerely,

Audrey Gibson
State Senator
District 6

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 1460
INTRODUCER:	Health Policy Committee and Senator Book and others
SUBJECT:	Stroke Centers
DATE:	April 3, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	Gerbrandt	Kidd	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1460 revises the criteria under which a hospital qualifies as a stroke center and adds a new class of stroke centers to the current-law list of stroke centers that the Agency for Health Care Administration (AHCA) is required to maintain and make available on its website and to the Department of Health (DOH).

The bill directs the AHCA to include thrombectomy-capable stroke centers (TSC) in its list of stroke centers, in addition to acute stroke-ready centers (ASRC), primary stroke centers (PSC), and comprehensive stroke centers (CSC) that current law requires the AHCA to include in the list.

The bill eliminates a hospital's ability to be included in the AHCA's list of stroke centers by attesting with an affidavit that it meets the criteria for qualifying as a stroke center or that it has been certified as a stroke center by a nationally recognized accrediting organization. Under the bill, in order to be included in the AHCA's list, a hospital must submit documentation verifying its certification as a stroke center, which may include offering and performing endovascular therapy consistent with standards identified by a nationally recognized, guidelines-based organization approved by the AHCA.

The bill also prohibits a hospital from advertising that it is a state-listed stroke center unless the hospital has submitted verifying documentation to the AHCA, as opposed to merely notifying the AHCA as under current law.

The bill directs the DOH to include data from TSCs in its annual list to the medical directors of licensed emergency medical service (EMS) providers and directs the medical directors to develop and implement transportation and rerouting protocols for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

The bill has an insignificant fiscal impact on the AHCA.

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

II. Present Situation:

What is a Stroke?

A stroke is a serious medical condition that occurs when the blood supply to the brain is interrupted or severely reduced, depriving brain tissue of oxygen and nutrients.[1] The brain needs a constant supply of oxygen and nutrients in order to function.[2] Even a brief interruption in blood supply from a stroke can cause significant problems.

There are two main types of strokes: an ischemic stroke and a hemorrhagic stroke. The former is the most common type and occurs when an artery in the brain becomes blocked. The latter occurs when a brain artery leaks blood or ruptures.[3]

There are two types of ischemic strokes: thrombotic and embolic.[4] In a thrombotic stroke, a blood clot (thrombus) forms in an artery that supplies blood to the brain.[5] In an embolic stroke, a blood clot or other substance, such as plaque or fatty material, travels through the bloodstream to an artery in the brain.[6] With both types of ischemic stroke, the blood clot or other substance blocks the flow of oxygenated blood to a portion of the brain.[7]

The two types of hemorrhagic stroke are intracerebral and subarachnoid.[8] In an intracerebral hemorrhage, a blood vessel inside the brain leaks blood or ruptures.[9] In a subarachnoid hemorrhage, a blood vessel on the surface of the brain leaks blood or ruptures, and bleeding occurs between the inner and middle layers of the membrane that covers the brain.[10] In both

[1] The Mayo Clinic, *Stroke*, available at: http://www.mayoclinic.org/diseases-conditions/stroke/home/ovc-20117264, (last visited Mar. 29, 2019).
[2] UCLA Health, *What is a Stroke?* available at: http://stroke.ucla.edu/what-is-a-stroke, (last visited Mar. 29, 2019).
[3] Id.
[4] Id.
[5] Id.
[6] Id. The blood clot or other substance traveling through the bloodstream is called an embolus.
[7] Id.
[8] Id.
[9] Id.
[10] Id.

types of hemorrhagic stroke, the leaked blood causes swelling of the brain and increased pressure in the skull. This swelling and pressure causes brain damage.[11]

Stroke Treatment

Time is of the essence in the treatment of a stroke. Medical personnel begin treatment in the ambulance on the way to the hospital.[12] Treatment for a stroke depends on how much time has elapsed since the symptoms began to appear and whether the stroke is ischemic or hemorrhagic.[13]

Treatment for an ischemic stroke may include medicines,[14] such as antiplatelet medicines and blood thinners, and medical procedures, but a hemorrhagic stroke may require surgery to find and stop the bleeding.[15] In addition to emergency care to treat a stroke, an individual may also receive treatment to prevent another stroke and rehabilitation to treat the side effects of the stroke.[16] According to the federal Centers for Disease Control and Prevention (CDC), research indicates that patients receiving care at a Primary Stroke Center (PSC) have a higher survival and recovery rate than those treated in hospitals without this type of specialized care.[17]

Stroke Centers in Florida

Florida first enacted legislation relating to PSCs and CSCs in 2004.[18] In 2017, the Legislature added ASRCs to the list of PSCs and CSCs, which is made available to licensed emergency medical services (EMS) providers.[19] The AHCA has adopted a rule establishing the criteria for ASRCs, PSCs, and CSCs.[20]

There are currently no Florida hospitals designated as ASRCs, 114 designated as PSCs in 40 counties, and 48 CSCs in 22 counties.[21]

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[11] Id.
[12] Center for Disease Control and Prevention, *Stroke Treatment* (updated May. 18, 2017) available at: https://www.cdc.gov/stroke/treatments.htm, (last visited Mar. 29, 2019).
[13] National Institutes of Health, National Heart, Lung and Blood Institute, *Treatment*, available at: https://www.nhlbi.nih.gov/health/health-topics/topics/stroke/treatment (last visited Mar. 29, 2019).
[14] Id. Such medication includes a tissue plasminogen activator (TPA), which dissolves, or breaks up the clot. TPA is an injection which must be given within 4 hours of stroke symptoms onset.
[15] Id.
[16] *Supra* note 122.
[17] Centers for Disease Control and Prevention, A *Summary Of Primary Stroke Center Policy In The United States* (2011), available at: https://www.cdc.gov/dhdsp/pubs/docs/primary_stroke_center_report.pdf, (last visited Mar. 29, 2019)
[18] Section 3, ch. 2004-325, Laws of Fla.
[19] Chapter 2017-172, Laws of Fla.
[20] *See* s. 395.3038(3), F.S. and rule 59A-3.246(4), F.A.C.
[21] Agency for Health Care Administration, Hospital & Outpatient Service Unit, Reports, *Stroke Centers* (updated Mar. 1, 2019), available at: http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Reports.shtml (last visited Mar. 29, 2019).

National Accrediting Organizations

The Joint Commission, the Healthcare Facilities Accreditation Program, and the DNV GL (formerly known as Det Norske Veritas) offer certifications to hospitals as an ASRC, PSC, CSC, and TSC.[22]

Licensure

A hospital may apply for designation as an ASRC, PSC, or CSC by submitting a hospital licensure application[23] and attaching a License Application Stroke Center Affidavit, both of which must be signed by the hospital's chief executive officer, attesting that the stroke program meets:

- The criteria for one of the designations as specified by rule, or
- Is certified as a stroke center by The Joint Commission, the Health Facilities Accreditation Program, or DNV GL.[24]

A hospital seeking stroke center certification must establish specific procedures for screening patients to recognize that numerous conditions, including cardiac disorders, often mimic stroke in children. Medical staff must ensure that transfer to an appropriate facility for specialized care is provided to children and young adults with known childhood diagnoses.[25]

Acute Stroke Ready Centers (ASRC)

An ASRC is a hospital that is designated by the AHCA as meeting Florida regulation requirements based on national guidelines to meet the initial needs of stroke patients and support better outcomes for stroke care as part of a stroke care system.[26] A hospital with an ASRC certification is required to notify the ACHA if it no longer meets the criteria.[27]

Many patients with an acute stroke live in areas without ready access to a PSC or CSC; more than half the U.S. population lives more than an hour away from a stroke center.[28] Hospitals in areas with low population densities and relatively small numbers of patients with strokes may be less likely to have the resources to become a stroke center and may lack the experience and

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[22]The Joint Commission, *Certification for Acute Stroke Ready Center*, available at: https://www.jointcommission.org/certification/acute_stroke_ready_hospitals.aspx; *Certification Comprehensive Stroke Center*, available at: https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx; *Certification for Primary Stroke Centers*, available at: https://www.jointcommission.org/certification/primary_stroke_centers.aspx; *Certification for Thrombectomy-Capable Stroke Centers*, available at: https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx, (last visited Mar. 29, 2019).

[23] Fla. Admin. Code R. 59A-3.066(2), (2019).

[24] Fla. Admin. Code R. 59A-3.246(4)(a), (2019).

[25] Fla. Admin. Code R. 59A-3.346(4)(b), (2019).

[26] Agency for Health Care Administration, Facility/Provider Definitions, *Acute Stroke Ready Center*, available at: http://www.floridahealthfinder.gov/about-ahca/facility-locator-glossary.aspx (last visited Mar. 29, 2019).

[27] Section 395.3038, F.S.

[28] Mark J. Alberts, et al, *Formation and Function of Acute Stroke–Ready Hospitals Within a Stroke System of Care Recommendations From the Brain Attack Coalition*, Stroke, Vol. 44, Issue 12 (Nov. 25, 2013), available at: http://stroke.ahajournals.org/content/44/12/3382.full, (last visited Mar. 29, 2019).

expertise to provide ongoing care for a stroke.[29] In such settings, there is a need to distinguish between those that offer enhanced care and expertise for acute stroke versus those with only basic or no organized abilities and expertise.[30]

An ASRC must have an acute stroke team available 24 hours a day, 7 days a week, and be capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called. An ASRC team must consist of a physician and one or more of the following:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

An ASRC must designate a physician with knowledge of cerebrovascular disease to serve as the ASRC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director of an ASRC are determined by the hospital governing board.

An ASRC must have the following services available 24 hours a day, 7 days a week:

- A dedicated emergency department;
- Clinical laboratory services;[31]
- Diagnostic imaging capability for a head computed tomography (CT) and magnetic resonance imaging (MRI);
- Intravenous thrombolytics available;
- Anticoagulate reversal medication available;
- Neurologist services available in person or via telemedicine; and
- A transfer agreement with a PSC or CSC.[32]

Primary Stroke Centers (PSC)

A PSC certification recognizes hospitals that meet standards to support better outcomes for stroke care.[33] Such hospitals must have:

- A dedicated stroke-focused program;
- Be staffed by qualified medical professionals trained in stroke care; and
- Provide individualized care to meet stroke patients' needs based on recommendations of the Brain Attack Coalition and guidelines published by the American Heart Association and American Stroke Association or equivalent guidelines.[34]

These hospitals must also collect and utilize performance data to improve quality of care for stroke patients.[35]

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[29] Id.
[30] Id.
[31] Fla. Admin. Code R. 59A-3.255(6)(g), (2019).
[32] Fla. Admin. Code R. 59A-3.246(4)(c),5., (2019).
[33] American Heart Association, *Facts*: *Primary Stroke Centers*, available at: https://www.yourethecure.org/facts-primary-stroke-centers (last visited Mar. 29, 2019).
[34] Id.
[35] *Supra* note 28.

In order for the AHCA to designate a hospital program as a PSC, the hospital program must be certified by the Joint Commission as a PSC or meet the certification criteria applicable to PSCs as outlined in the Joint Commission Disease-Specific Care Certification Manual, 2nd Edition.[36] The manual requires a PSC to:[37]

- Use a standardized method of delivering care;
- Support patient self-management activities;
- Tailor treatment and intervention to individual needs;
- Promote the flow of patient information across settings and providers, while protecting patient rights, security and privacy;
- Analyze and use standardized performance measure data to continually improve treatment plans; and
- Demonstrate the hospital's application of and compliance with clinical practice guidelines published by the American Heart Association and American Stroke Association or equivalent, evidence-based guidelines.[38]

A PSC must have an acute stroke team available 24 hours a day, 7 days a week, capable of responding to patients who are in the emergency department or an inpatient unit within 15 minutes of being called. A PSC team must consist of a physician and one or more of the following:

- A registered professional nurse;
- An advanced registered nurse practitioner; or
- A physician assistant.

A PSC must designate a physician with knowledge of cerebrovascular disease to serve as the PSC medical director. The medical director is responsible for implementing the stroke services protocols. The qualifications for the medical director are determined by the hospital's governing board.

A PSC must have the following services available 24 hours a day, 7 days a week:

- A dedicated emergency department;
- Clinical laboratory services;[39]
- Diagnostic imaging to include head CT, CT angiography (CTA), brain and cardiac magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and transthoracic and/or transesophageal echocardiography;
- Intravenous thrombolytics;
- Anticoagulate reversal medication available for administration; and
- Neurologist services, available in person or via tele-medicine.

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[36] The standards are published in the 2019 *Disease-Specific Care Review Process Guide*, available at: https://www.jointcommission.org/assets/1/6/2019_Disease_Specific_Care_Organization_RPG.pdf (last visited Mar. 29, 2019).
[37] *Id.*
[38] The Joint Commission, *Discover the Most Comprehensive Stroke Certifications* (March, 2019), available at: https://www.jointcommission.org/certification/primary_stroke_centers.aspx (last visited Mar. 29, 2019).
[39] *See* Fla. Admin. Code R. 59A-3.255(6)(g), (2019), for specific laboratory requirements.

The following services may be available on-site or via a transfer agreement:
- Neurosurgical services within two hours of being deemed clinically necessary;
- Physical, occupational, or speech therapy; and
- Neurovascular interventions for aneurysms, stenting of carotid arteries, carotid endartectomy, and endovascular therapy.

A PSC must develop a quality improvement program designed to analyze data, correct errors, identify system improvements, and ongoing improvement in patient care and delivery of services.
A multidisciplinary institutional Quality Improvement Committee must monitor quality benchmarks and review clinical complications on a regular basis. Specific benchmarks, outcomes, and indicators must be defined, monitored, and reviewed by the Quality Improvement Committee on a regular basis for quality assurance purposes.[40]

Comprehensive Stroke Centers (CSC)

A CSC certification recognizes hospitals that meet standards to treat the most complex stroke cases.[41] These hospitals must meet all the criteria of a PSC. They must also have advanced imaging techniques and personnel trained in vascular neurology, neurosurgery, and endovascular procedures available 24 hours a day, 7 days a week, as well as neuroscience intensive care unit (ICU) and experience and expertise treating patients with large ischemic strokes, intracerebral hemorrhage, and subarachnoid hemorrhage.

In order for the AHCA to designate a hospital program as a CSC, the hospital program must have received PSC designation and also have the following:
- Personnel with clinical expertise in specified disciplines available;[42]
- Advanced diagnostic capabilities;[43]
- Neurosurgical and endovascular interventions available;[44]
- Specialized infrastructure; and
- Quality improvement and clinical outcomes measurements.[45]

The specialized infrastructure includes extensive requirements that the EMS and CSC leadership are linked to ensure:
- EMS use a stroke triage assessment tool;
- EMS patient assessment and management at the scene is consistent with evidence-based practice;
- Inter-facility transfers; and

[40] Fla. Admin. Code R.59A-3.246(4)(d), (2019).
[41] The American Heart Association, *Get with the Guidelines – Stroke Clinical Tools*, available at: https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke/get-with-the-guidelines-stroke-clinical-tools (last visited Mar. 29, 2019).
[42] *See* Fla. Admin. Code R. 59A-3.246(4)(e), (2019), for specific qualifications. Medical personnel with neurosurgical expertise must be available in a CSC on a 24 hours per day, 7 days per week basis and in-house within two hours, and neurologist(s) with special expertise in the management of stroke patients should be available 24 hours per day, 7 days per week.
[43] Id.
[44] *Supra* note 38.
[45] Id.

- Ongoing communication with EMS providers regarding availability of services.

A CSC must maintain:
- An acute stroke team available 24 hours a day, 7 days a week;
- A system for facilitating inter-facility transfers;
- Defined access telephone numbers in a system for accepting appropriate transfers;
- Specialized inpatient units including an ICU with medical and nursing personnel who have special training, skills, and knowledge in the management of patients with all forms of neurological or neurosurgical conditions that require intensive care;
- An acute stroke unit with medical and nursing personnel who have training, skills, and knowledge sufficient to care for patients with neurological conditions, particularly acute stroke patients, and who are appropriately trained in neurological assessment and management;
- Inpatient post-stroke rehabilitation and ensure continuing arrangements post-discharge for rehabilitation needs and medical management;
- The education of its medical and paramedical professionals by offering ongoing professional education for all disciplines;
- An ongoing effort to educate inpatients, their families, and the public about risk factor reduction or management, primary and secondary prevention, the warning signs and symptoms of stroke, and medical management and rehabilitation for stroke patients;
- A career development track to develop neuroscience nursing, particularly in the area of cerebrovascular disease; and
- Professional and administrative infrastructure necessary to conduct clinical trials and should have participated in stroke clinical trials within the last year and actively participate in ongoing clinical stroke trials.[46]

Thrombectomy-Capable Stroke Centers (TSC)

The Joint Commission, in collaboration with the American Heart Association and American Stroke Association, is offering a new advanced stroke certification for TSCs in response to the need to identify hospitals that meet rigorous standards for performing endovascular thrombectomy (EVT).[47]

To achieve TSC certification, a hospital must:
- Demonstrate compliance with the new standards for TSC certification;[48]

[46] Id.
[47] The Joint Commission, *Certification for Thrombectomy-Capable Stroke Centers*, available at: https://www.jointcommission.org/certification/certification_for_thrombectomycapable_stroke_centers.aspx (last visited Mar. 29, 2019)
[48] All certified Thrombectomy-Capable Stroke Center (TSC) programs will be required to collect and report data for the eight Joint Commission stroke (STK) measures in addition to five selected comprehensive stroke (CSTK) measures relating to ischemic strokes for a total performance measurement requirement of 13 measures. In addition to collecting and reporting this data, organizations are expected to use this information for ongoing performance improvement efforts. The Joint Commission, *Thrombectomy-Capable Stroke Performance Measurement Requirements*, available at: https://www.jointcommission.org/certification/thrombectomycapable_stroke_performance_measurement_requirements.aspx (last visited Mar. 29, 2019)

- Meet the minimum mechanical thrombectomy volume requirements, outlined in the following chart:

Joint Commission Quality Measures for Disease-Specific Care Certification[49]

Measure Set No.	Measure Short Name	Ischemic Stroke	Hemorrhagic Stroke
STK-1	Venous Thromboembolism (VTE) Prophylaxis	X	X
STK-2	Discharged on Antithrombotic Therapy	X	
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	X	
STK-4	Thrombolytic Therapy	X	
STK-5	Antithrombotic Therapy By End of Hospital Day 2	X	
STK-6	Discharged on Statin Medication	X	
STK-8	Stroke Education	X	X
STK-10	Assessed for Rehabilitation	X	X

- Demonstrate the ability to perform mechanical thrombectomy, 24 hours a day, 7 days a week;
- Maintain dedicated intensive care beds for acute ischemic stroke patients;
- Meet the expectations for the availability of staff and practitioners closely aligned with CSC expectations;
- Collect and review data regarding adverse patient outcomes following mechanical thrombectomy; and
- Collect data for 13 standardized performance measures listed in the chart above.[50]

Stroke Center Inventory

The AHCA maintains a list of hospitals offering stroke services.[51] The list of hospitals meeting the criteria as a ASRC, PSC, or CSC is published on the AHCA's website.[52,53]There are also 286 EMS providers[54] that report patient stroke data to the DOH.[55] However, the data are not standardized, and many of the data that the DOH currently collects come from voluntary participation in the DOH's EMS Tracking and Reporting System (EMSTARS) program[56] and

[49] Id.
[50] *Infra* note 51.
[51] Section 395.3038, F.S.
[52] *Supra* note 211.
[53] Id. A list of hospitals with a stroke center designation is also available through the facility locator tool on: www.floridahealthfinder.gov, (last visited Mar. 12, 2019).
[54] Department of Health, *EMS Provider Licensure Report*, available at: http://www.floridahealth.gov/licensing-and-regulation/ems-service-provider-regulation-and-compliance/ems-providers.html (last visited Mar. 29, 2019).
[55]Agency For Health Care Administration, *Hospital ER Services*, available at: http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Hospital_ER_Services.pdf, (last visited Mar. 29, 2019).
[56] The EMSTARS program allows emergency medical providers to capture incident level patient care records for every emergency activation.

only includes data on response, provider impression, procedures and medication, and destination.[57]

Health care records submitted to the DOH from licensed EMS providers are confidential and exempt from public records requests under s. 401.30(4), F.S.

Stroke Patient Transportation

The DOH has also developed a stroke assessment tool.[58] The tool is available on the DOH's website and is provided to EMS providers.[59] Each licensed EMS provider must use a stroke triage assessment tool that is substantially similar to the DOH's stroke triage assessment tool.[60] Annually, by June 1, the DOH sends the list of ASRCs, PSCs, and CSCs to the medical director of each licensed EMS provider in Florida.[61]

III. Effect of Proposed Changes:

Section 1 amends s. 395.3038, F.S., to add Thrombectomy-Capable Stroke Centers (TSC) to the AHCA's list of certified stroke centers.

The bill requires that listed hospitals must be certified by a nationally recognized certifying organization as meeting the criteria for an ASRC, PSC, TSC, or CSC. The AHCA's list must include only those hospitals that have submitted documentation to the AHCA verifying their certification as an ASRC, PSC, TSC or CSC. That documentation may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy (EVT) consistent with the standards identified by a nationally recognized, guidelines-based organization approved by the AHCA.

The bill eliminates the use of an affidavit attesting that the hospital's stroke program meets the criteria for one of the stroke center designations, as specified by AHCA rule, as an alternate method for the hospital to be listed.

The bill directs that if a hospital chooses to no longer be certified by a nationally recognized certifying organization, or has not attained national certification as an ASRC, PSC, CSC, or TSC, the hospital must notify the AHCA and the AHCA must immediately remove the hospital from its list of stroke centers.

The bill removes AHCA's rule-making authority to establish criteria for an ASRC, PSC, and CSC, which were required to be substantially similar to the certification standards for the same categories of stroke centers of a nationally recognized accrediting organization.

[57] *Supra* note 55.
[58] Section 395.3041(2), F.S.
[59] Section 395.3041(2), F.S.
[60] Id.
[61] Section 395.3041(1), F.S.

Section 2 amends s. 395.30381, F.S., to require that TCSs, in addition to ASRCs, PSCs, and CSCs, regularly report information containing nationally recognized stroke performance measures to the statewide stroke registry.

Section 3 amends s. 395.3039, F.S., to prohibit a hospital from advertising that it is a state-listed ASRC, PSC, CSC, or TSC, unless the hospital has submitted documentation to the AHCA verifying that it is certified and meets the certification criteria of a nationally recognized certifying organization.

Section 4 amends s. 395.3041, F.S., to direct the DOH to include data from TSCs in its annual list to the medical directors of licensed EMS providers. The bill directs the medical directors of licensed EMS providers to develop and implement transportation and rerouting protocols, in addition to assessment and treatment protocols, for stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs. The protocols must include plans for the triage and transport of suspected stroke patients, including, but not limited to, patients who may have an emergent large vessel occlusion, to an appropriate facility within a specified timeframe after such patients exhibit the sudden onset of stroke-related symptoms.

The bill directs the DOH and the medical directors of licensed EMS providers to specifically consider the capability of an emergency receiving facility to improve outcomes for patients who are suspected, based on clinical severity, of having an emergent large vessel occlusion in developing the protocols.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals that maintain ASRCs, PSCs, CSCs, or TSCs, are required under CS/SB 1460 to be certified by a nationally recognized certifying organization and may incur a cost for their application for certification. They may need to purchase new software and incur labor costs to collect, maintain, and send the required data to the DOH. Such costs, if any, are indeterminate.

C. Government Sector Impact:

The bill has an insignificant fiscal impact on the Agency for Health Care Administration.[62]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.3038, 395.30381, 395.3039, and 395.3041.

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 18, 2019:
The CS:

- Removes specific entities that may certify that an ASRCs, PSCs, CSCs, or TSCs meets the standards of a specific type of stroke center and requires only that the certifying entity must be a nationally recognized, guidelines-based organization approved by the AHCA; and
- Removes the DOH from the protocol development and implementation process with licensed EMS medical directors for transportation and rerouting of stroke patients with the intent to reroute them to ASRCs, PSCs, CSCs, and TSCs.

[62] Agency for Health Care Administration, *SB 1460 2019 Agency Legislative Bill Analysis- Fiscal Analysis* (February 26, 2019) (on file with the Appropriations Subcommittee on Health and Human Services).

B. Amendments:

None.

538518

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book) recommended the following:

Senate Amendment

Delete lines 43 - 49

and insert:

organization approved by the agency. Each hospital that has attested in an affidavit to the agency that it meets the criteria in this subsection must be certified ~~that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as an~~

538518

~~acute stroke ready center, a primary stroke center, or a comprehensive stroke center~~ by a nationally recognized accrediting organization by July 1, 2021.

835638

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/09/2019	.	
	.	
	.	
	.	

Appropriations Subcommittee on Health and Human Services (Book) recommended the following:

Senate Amendment

Delete line 119

and insert:

protocols, the medical director of each

By the Committee on Health Policy; and Senators Book and Powell

588-03172-19 20191460c1

A bill to be entitled

An act relating to stroke centers; amending s. 395.3038, F.S.; revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; removing provisions requiring the agency to adopt rules establishing the criteria for such list; amending s. 395.30381, F.S.; revising provisions relating to the statewide stroke registry to conform to changes made by the act; amending s. 395.3039, F.S.; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act; amending s. 395.3041, F.S.; requiring the medical director of each licensed emergency medical services provider to develop and implement protocols for the assessment, treatment, transport, and rerouting of suspected stroke patients to certain stroke centers; requiring that such protocols include specified plans for the triage and transport of suspected stroke patients; providing an effective date.

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

Section 1. Subsection (1), paragraph (a) of subsection (2), and subsection (3) of section 395.3038, Florida Statutes, are amended to read:

395.3038 State-listed stroke centers; notification of hospitals.—

588-03172-19 20191460c1

(1) The agency shall make available on its website and to the department a list of the name and address of each hospital that is certified by a nationally recognized certifying organization as ~~meets the criteria for~~ an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center. The list of stroke centers must include only those hospitals that have submitted documentation to the agency verifying their certification as an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, which may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy consistent with the standards identified by a nationally recognized guidelines-based organization approved by the agency ~~that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as an acute stroke ready center, a primary stroke center, or a comprehensive stroke center by a nationally recognized accrediting organization~~.

(2)(a) If a hospital no longer chooses to be certified by a nationally recognized certifying organization or has not attained certification consistent with ~~meet~~ the criteria in subsection (1) as ~~for~~ an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, the hospital shall notify the agency and the agency shall immediately remove the hospital from the list of stroke centers.

~~(3) The agency shall adopt by rule criteria for an acute~~

~~stroke ready center, a primary stroke center, and a comprehensive stroke center which are substantially similar to the certification standards for the same categories of stroke centers of a nationally recognized accrediting organization.~~

Section 2. Section 395.30381, Florida Statutes, is amended to read:

395.30381 Statewide stroke registry.—

(1) Subject to a specific appropriation, the department shall contract with a private entity to establish and maintain a statewide stroke registry to ensure that the stroke performance measures required to be submitted under subsection (2) are maintained and available for use to improve or modify the stroke care system, ensure compliance with standards and nationally recognized guidelines, and monitor stroke patient outcomes.

(2) Each acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, and comprehensive stroke center shall regularly report to the statewide stroke registry information containing ~~specified by the department, including~~ nationally recognized stroke performance measures.

(3) The department shall require the contracted private entity to use a nationally recognized platform to collect data from each stroke center on the stroke performance measures required in subsection (2). The contracted private entity shall provide regular reports to the department on the data collected.

(4) A ~~No~~ liability of any kind or character for damages or other relief shall not arise or be enforced against any acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, or comprehensive stroke center by reason of having provided such information to the statewide stroke

registry.

Section 3. Section 395.3039, Florida Statutes, is amended to read:

395.3039 Advertising restrictions.—~~A~~ person may not advertise to the public, by way of any medium whatsoever, that a hospital is a state-listed ~~primary or comprehensive~~ stroke center unless the hospital has submitted documentation to the agency verifying that it is certified and meets the criteria ~~provided notice to the agency~~ as required in s. 395.3038 ~~by this act~~.

Section 4. Subsections (1), (3), and (4) of section 395.3041, Florida Statutes, are amended to read:

395.3041 Emergency medical services providers; triage and transportation of stroke victims to a stroke center.—

(1) By June 1 of each year, the department shall send the list of acute stroke ready centers, primary stroke centers, thrombectomy-capable stroke centers, and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in the ~~this~~ state.

(3) The medical director of each licensed emergency medical services provider shall develop and implement assessment, treatment, transport, and rerouting ~~transport-destination~~ protocols for stroke patients with the intent to assess, treat, ~~and~~ transport, and reroute stroke patients to acute stroke ready centers, primary stroke centers, thrombectomy-capable stroke centers, and comprehensive stroke centers. The protocols must include plans for the triage and transport of suspected stroke patients, including, but not limited to, patients who may have an emergent large vessel occlusion, to an appropriate facility

within a specified timeframe after such patients exhibit the sudden onset of stroke-related symptoms. In developing the protocols, the department and the medical director of each licensed emergency medical services provider must consider the capability of an emergency receiving facility to improve outcomes for patients who are suspected, based on clinical severity, of having an emergent large vessel occlusion ~~the most appropriate hospital~~.

(4) Each emergency medical services provider licensed under chapter 401 must comply with ~~all sections of~~ this section and ss. 395.3038-395.3039 ~~act~~.

Section 5. This act shall take effect July 1, 2019.

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Appropriations Subcommittee on Health and Human Services **Judge:**

Started: 4/4/2019 12:32:28 PM
Ends: 4/4/2019 1:59:45 PM Length: 01:27:18

12:34:31 PM Sen. Bean (Chair)
12:35:00 PM Sen. Book
12:36:32 PM Sen. Bean (Chair)
12:36:56 PM S 1300
12:38:32 PM Sen. Rader
12:39:10 PM Sen. Bean (Chair)
12:39:25 PM S 778
12:39:27 PM Sen. Baxley
12:39:53 PM Am. 712346
12:39:55 PM S 778 (cont.)
12:41:27 PM Sen. Bean (Chair)
12:41:28 PM S 1436
12:41:48 PM Sen. Gibson
12:42:26 PM Am. 174138
12:42:30 PM S 1436 (cont.)
12:43:56 PM S 7078
12:45:08 PM Sen. Harrell
12:46:02 PM Am. 195108
12:46:13 PM Sen. Harrell
12:46:39 PM Philip Gold, Attorney, FJA
12:47:55 PM Sen. Rouson
12:48:21 PM P. Gold
12:49:00 PM Sen. Harrrell
12:49:24 PM Am. 310648
12:49:31 PM Sen. Harrell
12:49:52 PM Sen. Flores
12:50:05 PM Sen. Harrell
12:50:40 PM Sen. Flores
12:51:30 PM Am. 224512
12:51:41 PM Sen. Harrell
12:52:26 PM Sen. Bean (Chair)
12:52:52 PM Philip Gold, Attorney, FJA
12:54:40 PM Sen. Harrell
12:55:13 PM Am. 870336
12:55:20 PM Sen. Harrell
12:56:05 PM Sen. Rader
12:56:28 PM Sen. Harrell
12:57:54 PM Sen. Flores
12:59:18 PM Sen. Harrell
1:01:04 PM Cynthia Henderson
1:01:17 PM Zayne Smith, Associate State Director, AARP Florida (waives in support)
1:01:55 PM S 7078 (cont.)
1:02:03 PM Sen. Flores
1:04:18 PM Sen. Farmer
1:05:59 PM Sen. Harrell
1:08:49 PM Sen. Bean (Chair)
1:08:50 PM Tab 1 - Senate Confirmation Hearing
1:10:43 PM Mary Mayhew, Secretary, AHCA
1:15:56 PM Sen. Rader
1:16:32 PM M. Mayhew
1:19:24 PM Sen. Rader
1:22:22 PM M. Mayhew

1:29:22 PM Sen. Rader
1:30:09 PM M. Mayhew
1:31:22 PM Sen. Rouson
1:32:09 PM M. Mayhew
1:33:17 PM Sen. Rouson
1:34:10 PM M. Mayhew
1:36:55 PM Sen. Flores
1:39:19 PM M. Mayhew
1:40:12 PM Sen. Book
1:41:12 PM M. Mayhew
1:43:30 PM Sen. Book
1:44:15 PM M. Mayhew
1:45:37 PM Sen. Rader
1:46:34 PM M. Mayhew
1:47:17 PM Sen. Bean (Chair)
1:47:45 PM Greg Pound
1:49:19 PM Karen Woodall, Executive Director, Florida Center for Fiscal and Economic Policy (waives in opposition)
1:49:48 PM Justin Senior, Ceo, SNHAF (waives in support)
1:49:59 PM Peter Lohrengel, Executive Director, Florida Society of Ambulatory Surgical Center (waives in support)
1:50:09 PM Barbara Palmer, Director, APD (waives in support)
1:50:14 PM Tom Parker, Director of Reimbursement, Florida Healthcare Administration (waives in support)
1:50:22 PM Bruce Rueben, President of Florida Hospital Association (waives in support)
1:50:28 PM Sen. Farmer
1:51:19 PM Sen. Bean (Chair)
1:51:25 PM Sen. Rader
1:53:45 PM Sen. Hooper
1:55:12 PM Sen. Farmer
1:55:48 PM Sen. Rouson
1:58:15 PM Sen. Hooper
1:59:09 PM Sen. Bean (Chair)