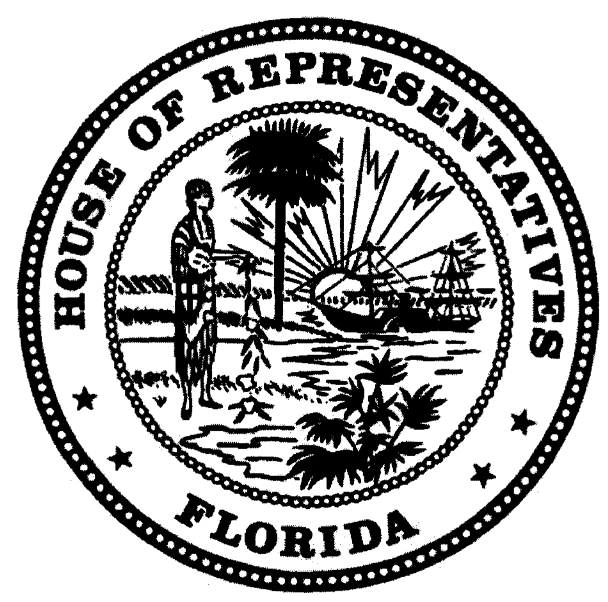

Health & Human Services Committee

Thursday, March 16, 2017
12:00 PM – 3:00 PM
Morris Hall (17 HOB)

Richard Corcoran
Speaker

W. Travis Cummings
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time:	Thursday, March 16, 2017 12:00 pm
End Date and Time:	Thursday, March 16, 2017 03:00 pm
Location:	Morris Hall (17 HOB)
Duration:	3.00 hrs

Consideration of the following bill(s):

HB 59 Adult Cardiovascular Services by Pigman
CS/HB 129 Health Care Practitioner Regulation by Health Quality Subcommittee, Plasencia
HB 145 Recovery Care Services by Renner, Fitzenhagen
CS/HB 161 Direct Primary Care Agreements by Health Innovation Subcommittee, Burgess, Miller, M.
CS/HB 209 Medical Faculty Certification by Health Quality Subcommittee, Miller, A.
CS/HB 217 Children Obtaining Driver Licenses by Children, Families & Seniors Subcommittee, Sullivan, Albritton
CS/HB 375 Patient Safety Culture Surveys by Health Care Appropriations Subcommittee, Grant, M.
HB 589 Prescription Drug Price Transparency by Yarborough
CS/HB 593 Restrictions on Use of Public Assistance Benefits by Children, Families & Seniors Subcommittee, Massullo, Fine
HB 7009 Ratification of Rules of the Board of Medicine by Health Quality Subcommittee, Massullo
HB 7041 Pub. Rec. and Meetings/Peer Review Panel/James & Esther King Biomedical Research Program & William G. "Bill" Bankhead, Jr., & David Coley Cancer Research Program by Oversight, Transparency & Administration Subcommittee, Pigman

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Wednesday, March 15, 2017.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, March 15, 2017.

NOTICE FINALIZED on 03/14/2017 3:44PM by Iseminger.Bobbye

HB 59

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 59 Adult Cardiovascular Services
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	15 Y, 0 N	Langston	Poche
2) Health Care Appropriations Subcommittee	15 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease. PCI uses a catheter to insert a stent to reopen blood vessels in the heart that have been narrowed by plaque build-up.

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II of chapter 408, F.S. Adult cardiovascular services (ACS) were previously regulated through AHCA's Certificate-of-Need (CON) program. Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services in 2007. Hospitals are now approved to provide these services by AHCA through the licensure process.

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open-heart surgery capability. Level I ACS programs must comply with national guidelines that apply to diagnostic cardiac catheterization services and PCI. Additionally, they must comply with national reporting requirements and meet specified staffing requirements. For example, nursing and technical catheterization laboratory staff in a Level I ACS program must have 500 hours of experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS program.

Licensed Level II ACS programs provide the same services as a Level I ACS program, but have on-site open-heart surgery capability. In addition to Level I requirements, Level II programs must comply with additional requirements for staffing, physician training and experience, operating procedures, equipment, physical plant, patient selection criteria, and reporting requirements.

HB 59 expands where nursing and technical staff may obtain their prerequisite experience. It authorizes them to obtain their 500 hours of prerequisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level I ACS program, if, throughout the training period, the program:

- Has an annual volume of 500 or more PCIs;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than five percent for PCIs; and
- Performs diverse cardiac procedures.

The bill does not have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, and other definitive medical treatment.[2]

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals; these rules must include minimum standards to ensure:

- 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.[3]

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Percutaneous Cardiac Intervention

Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.[4] PCI uses a catheter to insert a stent in the heart to reopen blood vessels that have been narrowed by plaque build-up, a condition known as atherosclerosis.[5] The catheter is threaded through blood vessels into the heart where the coronary artery is narrowed.[6] Once in place, a balloon tip covered with a stent is inflated to compress the plaque and expand the stent.[7] When the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn, leaving the stent to hold the artery open.[8]

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[1] S. 395.002(12), F.S.
[2] Id.
[3] S. 395.1055(1), F.S.
[4] George A Stouffer, III, and Pradeep K Yadav, *Percutaneous Coronary Intervention (PCI)*, MEDSCAPE, Oct. 12, 2016, available at http://emedicine.medscape.com/article/161446-overview (last visited March 10, 2017).
[5] Percutaneous coronary intervention (PCI or angioplasty with stent), Heart and Stroke, available at https://www.heartandstroke.ca/heart/treatments/surgery-and-other-procedures/percutaneous-coronary-intervention (last visited March 10, 2017).
[6] Id.
[7] Id.
[8] Id.

Regulation of Adult Cardiovascular Services

Adult cardiovascular services (ACS), including PCI, were previously regulated through the Certificate-of-Need (CON)[9] program. In 2007, Florida eliminated CON review for adult cardiac catheterization and adult open-heart surgery services[10] and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program.[11] However, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[12]

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS. A level I program is authorized to perform adult PCI without onsite cardiac surgery and a level II program is authorized to perform PCI with onsite cardiac surgery.[13]

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms,[14] for diagnosing congenital or acquired cardiovascular diseases, or for measuring blood pressure flow.[15] It also includes the selective catheterization of the coronary ostia[16] with injection of contrast medium into the coronary arteries.[17]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform only diagnostic procedures;[18] the license does not allow for the performance of therapeutic procedures.[19] [20] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.[21]

[9] The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. To obtain a CON a facility must demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program under s. 408.036(3), F.S., it must undergo a full comparative review or an expedited review.
[10] Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.
[11] Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla.
[12] S. 408.0361(2), F.S.
[13] S. 408.0361(3)(a), F.S.
[14] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.
[15] Rule 59A-3.2085(13)(b)1., F.A.C.
[16] A coronary ostia is either of the two openings in the aortic sinuses – the pouches behind each of the three leaflets of the aortic valve – that mark the origins of the left and right coronary arteries.
[17] Rule 59A-3.2085(13)(b)1., F.A.C.
[18] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.
[19] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administration of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.
[20] S. 408.0361(1)(b), F.S.
[21] S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214, available at http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000 (last visited March 10, 2017). These guidelines address, among other things, clinical proficiency, patient outcomes,

As of December 1, 2016, there are 22 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[22]

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open-heart surgery capability.[23] For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease;[24] and that it has formalized, written transfer agreement with a hospital that has a Level II program.[25]

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[26] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[27] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[28]

Level I ACS programs must meet the following staffing requirements.

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.

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equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

[22] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last visited March 10, 2017).

[23] Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.

[24] Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."

[25] S. 408.0361(3)(b), F.S.

[26] Rule 59A-3.2085(16)(a)5., F.A.C.

[27] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)* available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last visited March 10, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

[28] Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

- Nursing and technical catheterization laboratory staff must:
  - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
  - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[29]

As of December 1, 2016, there are 54 general acute care hospitals with a Level I ACS program in Florida.[30]

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, and also have on-site open-heart surgery capability.[31] For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.[32]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with guidelines from the American College of Cardiology and the American Heart Association, which include standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[33] Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[34] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[35]

As of December 1, 2016, there are 77 general acute care hospitals[36] with a Level II ACS program in Florida.[37]

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[29] Rule 59A-3.2085(16)(b), F.A.C.

[30] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last visited March 10, 2017).

[31] Rule 59A-3.2085(17)(a), F.A.C.

[32] S. 408.0361(3)(c), F.S.

[33] Rule 59A-3.2085(16)(a)5., F.A.C. A Level II ASC must comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons.

[34] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.

[35] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf (last visited February 7, 2017).

[36] 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of SB 58 2017 Legislative Session*, Nov. 28, 2016 (on file with Health Innovation Subcommittee staff).

PCI Best Practices

In 2014, the Society for Cardiovascular Angiography and Interventions, the ACC and AHA issued an Expert Consensus document on PCI without on-site surgical backup, which acknowledged advances and best practices in PCI performed in hospitals without on-site surgery (Level I facilities).[38] The Expert Consensus document noted that while PCI peaked in 2006, PCIs at hospitals without on-site surgery have increased since 2007.[39] The Expert Consensus document recommends the PCI programs without on-site surgery have experienced nursing and technical laboratory staff with training in interventional laboratories.[40] The Expert Consensus document continues to recommend PCI procedures should not be performed in facilities performing fewer than 200 procedures, with few exceptions.[41] The Expert Consensus document also recommends that a 95% success rate and a less than 5% complication rate are more important factors than overall volume of procedures performed.[42]

Effect of the Bill

Regulation of Adult Cardiovascular Services

Nursing and Technical Staff Experience

HB 59 requires AHCA's licensure rules for hospitals providing Level I ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring PCI in dedicated cardiac interventional laboratories or surgical centers. Level II facilities must meet requirements applicable to Level I facilities, so these changes will apply to all hospitals providing ACS.

Nursing and Technical Staff Experience

Previously all nursing and technical staff had to obtain their perquisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level II ACS. The bill offers an alternate location where to obtain the prerequisite experience, if certain qualifications are met. They may now obtain their 500 hours of prerequisite experience in a dedicated cardiac interventional laboratory at a hospital with a Level I ACS program, if, throughout the training period, the Level I ACS program:

- Has an annual volume of 500 or more PCI;
- Achieves a demonstrated success rate of 95 percent or greater for PCIs;
- Experiences a complication rate of less than 5 percent for PCIs; and
- Performs diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

The bill will enable Level I ACS programs to train their nursing and technical catheterization laboratory staff at their facilities instead of requiring that their staff be trained in a Level II ACS program.

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[37] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last visited March 10, 2017).
[38] Gregory J. Dehmer, et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., Mar. 17, 2014.
[39] Id.
[40] Id.
[41] Id. The Expert Consensus document cites data from a 2010-2011 National Cardiovascular Data Registry showing that half (49%) of reporting facilities performed fewer than 400 PCIs annually and of these, 65% of the facilities without on-site surgery backup had an annual case volume of less than 200 PCIs.
[42] Supra, note 38.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 2: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to adult cardiovascular services;
3 amending s. 408.0361, F.S.; expanding rulemaking
4 criteria for the Agency for Health Care Administration
5 for licensure of hospitals performing percutaneous
6 cardiac intervention procedures; providing an
7 effective date.
8
9 Be It Enacted by the Legislature of the State of Florida:
10
11 Section 1. Paragraph (b) of subsection (3) of section
12 408.0361, Florida Statutes, is amended to read:
13 408.0361 Cardiovascular services and burn unit licensure.—
14 (3) In establishing rules for adult cardiovascular
15 services, the agency shall include provisions that allow for:
16 (b) For a hospital seeking a Level I program,
17 demonstration that, for the most recent 12-month period as
18 reported to the agency, it has provided a minimum of 300 adult
19 inpatient and outpatient diagnostic cardiac catheterizations or,
20 for the most recent 12-month period, has discharged or
21 transferred at least 300 inpatients with the principal diagnosis
22 of ischemic heart disease and that it has a formalized, written
23 transfer agreement with a hospital that has a Level II program,
24 including written transport protocols to ensure safe and
25 efficient transfer of a patient within 60 minutes. However, a

26 hospital located more than 100 road miles from the closest Level
27 II adult cardiovascular services program does not need to meet
28 the 60-minute transfer time protocol if the hospital
29 demonstrates that it has a formalized, written transfer
30 agreement with a hospital that has a Level II program. The
31 agreement must include written transport protocols to ensure the
32 safe and efficient transfer of a patient, taking into
33 consideration the patient's clinical and physical
34 characteristics, road and weather conditions, and viability of
35 ground and air ambulance service to transfer the patient. At a
36 minimum, the rules for adult cardiovascular services must
37 require nursing and technical staff to have demonstrated
38 experience in handling acutely ill patients requiring
39 intervention based on the staff member's previous experience in
40 dedicated cardiac interventional laboratories or surgical
41 centers. If a staff member's previous experience is in a
42 dedicated cardiac interventional laboratory at a hospital that
43 does not have an approved adult open-heart-surgery program, the
44 staff member's previous experience qualifies only if, at the
45 time the staff member acquired his or her experience, the
46 dedicated cardiac interventional laboratory:
47 1. Had an annual volume of 500 or more percutaneous
48 cardiac intervention procedures;
49 2. Achieved a demonstrated success rate of 95 percent or
50 greater for percutaneous cardiac intervention procedures;

51 3. Experienced a complication rate of less than 5 percent
52 for percutaneous cardiac intervention procedures; and
53 4. Performed diverse cardiac procedures, including, but
54 not limited to, balloon angioplasty and stenting, rotational
55 atherectomy, cutting balloon atheroma remodeling, and procedures
56 relating to left ventricular support capability.
57 Section 2. This act shall take effect July 1, 2017.

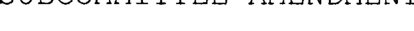
COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	______

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee
3 Representative Pigman offered the following:
4
5 **Amendment (with title amendment)**
6 Between lines 10 and 11, insert:
7 Section 1. Subsection (9) of section 395.1055, Florida
8 Statutes, is renumbered as subsection (11), and a new subsection
9 (9) and (10) are created to read:
10 (9) Pediatric cardiac programs.—
11 (a) Each provider of pediatric cardiac catheterization
12 services and pediatric open-heart surgery shall comply with
13 rules adopted by the agency establishing licensure standards for
14 those programs.

15 (b) In establishing licensure standards for a pediatric
16 cardiac catheterization program, the rules, at a minimum, must
17 require:
18 1. The program to be located in a facility in which
19 pediatric open-heart surgery is being performed and which is
20 completely equipped to provide necessary medical and surgical
21 care to the patient. The facility must be accredited by the
22 Joint Commission.
23 2. The cardiac catheterization team to include sufficient
24 medical and support staff to provide necessary medical and
25 surgical care to the patient.
26 3. The program to mobilize the pediatric cardiac
27 catheterization team within a specified period of time for an
28 emergency procedure.
29 4. The facility where the program is located to offer a
30 range of non-invasive cardiac and diagnostic services,
31 including, but not limited to:
32 a. Hematology studies or coagulation studies;
33 b. Electrocardiography;
34 c. Chest x-ray;
35 d. Blood gas studies;
36 e. Clinical pathology studies and blood chemistry
37 analysis;
38 f. A special procedure x-ray room;

39 g. A film storage and darkroom for proper processing of
40 films;
41 h. X-ray equipment with cineangiocardiography
42 capabilities;
43 i. An image intensifier;
44 j. An automatic injector;
45 k. A diagnostic x-ray examination table for special
46 procedures;
47 l. A blood gas analyzer;
48 m. A multichannel polygraph; and
49 n. Emergency equipment including a temporary pacemaker
50 unit with catheters, ventilator assistance devices, and a DC
51 defibrillator.
52 (c) In establishing licensure standards for a pediatric
53 open-heart surgery program, the rules, at a minimum, must
54 require:
55 a. The pediatric open-heart surgery team to include
56 sufficient surgical and support staff to provide necessary
57 medical and surgical care to the patient.
58 b. The program to:
59 1. Be available for nonemergent open-heart surgery 8 hours
60 per day, 5 days per week;
61 2. Be capable of mobilizing the surgical and medical
62 support teams within a specified period of time for emergency
63 cases; and



64 3. Provide 24 hour coverage by a physician or staff.
65 c. Post-operative care to be provided under the direction
66 of the cardiovascular surgeon who performed the surgery, in
67 communication with and support of the post-operative
68 cardiovascular team as prescribed by rule. Members of the team
69 must be on call or otherwise available for an emergency. A
70 patient must be cared for in an intensive care unit that
71 provides 24 hour per day nursing care with at least one
72 registered nurse for every two patients during the first hours
73 of post-operative care. Post-operative care must also include
74 coverage for operation of the cardiopulmonary bypass pump 24
75 hours per day.
76 d. Each pediatric open-heart surgery program to have the
77 capability to provide a full range of open-heart surgery
78 operations, including:
79 1. Repair or replacement of a heart valve;
80 2. Repair of a congenital heart defect;
81 3. Repair or reconstruction of an intrathoracic vessel;
82 and
83 4. Treatment of cardiac trauma.
84 e. A licensed facility with a pediatric open-heart surgery
85 program to provide the following services:
86 1. Availability of consultation in cardiology, hematology,
87 nephrology, pulmonary medicine, treatment of infectious
88 diseases, and other appropriate pediatric subspecialties;

89 2. Pathology, including anatomical, clinical, blood bank,
90 and coagulation laboratory services;
91 3. Anesthesiology, including respiratory therapy;
92 4. Radiology, including diagnostic nuclear medicine;
93 5. Neurology;
94 6. Inpatient cardiac catheterization;
95 7. Non-invasive cardiographics, including
96 electrocardiography, exercise stress testing, and
97 echocardiography;
98 8. Intensive care; and
99 9. Emergency care available 24 hours per day for cardiac
100 emergencies.
101 (d) Hospitals licensed for pediatric cardiac
102 catheterization programs shall participate in the clinical
103 outcome report system operated by the Society of Thoracic
104 Surgeons.
105 (10) Pediatric cardiac technical advisory panel.—
106 (a) The agency shall establish a technical advisory panel
107 to develop procedures and standards for measuring outcomes of
108 pediatric cardiac catheterization programs and pediatric open-
109 heart surgery programs.
110 (b) Voting members of the panel shall include:
111 1. A pediatric cardiac surgeon or pediatric cardiologist,
112 or a designated alternate, from each of the following pediatric
113 cardiac centers:

114 a. Johns Hopkins All Children's Hospital in St.
115 Petersburg;
116 b. Arnold Palmer Hospital for Children in Orlando;
117 c. Joe DiMaggio Children's Hospital in Hollywood;
118 d. Nicklaus Children's Hospital in Miami;
119 e. St. Joseph's Children's Hospital in Tampa;
120 f. University of Florida, Shands Children's Hospital in
121 Gainesville;
122 g. University of Miami, Holtz Children's Hospital in
123 Miami;
124 h. Wolfson Children's Hospital in Jacksonville;
125 i. Florida Hospital, Disney Children's Hospital in
126 Orlando; and
127 j. Nemours Children's Hospital in Orlando.
128 2. An at-large member appointed by the Secretary of the
129 Agency for Health Care Administration, who is either a pediatric
130 cardiologist or adult cardiologist with a special interest in
131 the care of adults with congenital heart disease.
132 (c) Nonvoting members of the panel shall include:
133 1. The Secretary of the Agency for Health Care
134 Administration, or designee;
135 2. The Surgeon General, or his or her designee;
136 3. The Deputy Secretary of Children's Medical Services, or
137 designee;

138 (d) The Secretary of the Agency for Health Care
139 Administration may appoint up to four additional nonvoting
140 members from the following organizations:
141 1. The Florida Association of Children's Hospitals;
142 2. The Florida Chapter of the American Academy of
143 Pediatrics;
144 3. The Florida Society of Thoracic and Cardiovascular
145 Surgeons;
146 4. The Florida Chapter of the American College of
147 Cardiology; or
148 5. The Florida Chapter of the American Heart Association.
149 (e) Based on recommendations from the panel, the agency
150 shall develop and adopt rules for pediatric cardiac
151 catheterization programs and pediatric open-heart surgery
152 programs, consistent with the licensure requirements in
153 subsection (9), that include at least the following:
154 1. Outcome standards specifying expected levels of
155 performance in pediatric cardiac programs, using a risk
156 adjustment procedure that accounts for the variations in
157 severity and case mix. Such standards may include, but are not
158 limited to, in-hospital mortality, infection rates, and returns
159 to surgery.
160 2. Specific steps to be taken by the agency and licensed
161 facilities that do not meet the outcome standards within
162 specified time periods, including time periods for detailed case

163 reviews and development and implementation of corrective action
164 plans.
165 Section 2. Paragraph (k) is added to subsection (3) of
166 section 408.05, Florida Statutes, to read:
167 408.05 Florida Center for Health Information and
168 Transparency.—
169 (3) HEALTH INFORMATION TRANSPARENCY.—In order to
170 disseminate and facilitate the availability of comparable and
171 uniform health information, the agency shall perform the
172 following functions:
173 (k) Contract with the Society of Thoracic Surgeons to
174 obtain data submitted pursuant to s. 395.1055(9)(d) for
175 publication on the agency's website in a manner that will allow
176 consumers to be informed of aggregate data and to compare
177 programs.
178
179 ---
180 **T I T L E A M E N D M E N T**
181 Remove line 2 and insert:
182 An act relating to cardiac programs; amending s. 395.1055, F.S.;
183 requiring the Agency for Health Care Administration to adopt
184 rules establishing standards for pediatric cardiac programs
185 offered in licensed facilities, including, but not limited to,
186 pediatric cardiac catheterization and pediatric open-heart
187 surgery programs; establishing minimum standards for rules for

188 pediatric cardiac catheterization programs and pediatric open-
189 heart surgery programs; requiring reporting of outcomes measures
190 by pediatric cardiac catheterization programs; creating
191 pediatric cardiac technical advisory panel; specifying voting
192 and nonvoting membership of the panel; requiring the agency to
193 work with the panel to develop outcome measures for pediatric
194 cardiac catheterization programs; amending s. 408.05, F.S.;
195 requiring the agency to contract with the Society of Thoracic
196 Surgeons for collection of certain data for publication on the
197 agency's website for general and comparative purposes;

CS/HB 129

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 129 Health Care Practitioner Regulation
SPONSOR(S): Health Quality Subcommittee; Plasencia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Advanced registered nurse practitioners (ARNPs) are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing or medical acts that are authorized pursuant to a written protocol with a physician. ARNPs may only sign those documents that are directly related to the performance of the nursing or medical acts authorized pursuant to a protocol, unless otherwise prohibited by law.

Physician assistants (PAs) complete specialized education that prepares them to perform medical services and practice as a part of a health care team. PAs practice under the delegated authority of a supervising physician. A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and do not, by law, require a physician's signature.

ARNPs and PAs provide comprehensive health care to patients within the scope of their education, certification, and delegated authority. Certain laws require that particular documents associated with the care that an ARNP or PA provides include a physician's signature to be recognized, even if the physician does not provide care to the patient. CS/HB 129 authorizes ARNPs and PAs to sign, certify, stamp, verify, or endorse any document required by law to be signed by a physician. Such documents include the disability certification for certain tax exemptions, a death certificate, and a certificate to initiate an involuntary examination under the Baker Act.

The Health Care Clinic Act (Act) was enacted in 2003 to reduce fraud and abuse in the personal injury protection insurance system. Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics ensures that such clinics meet basic standards, and provide administrative oversight.

Health care clinics must appoint a medical director that agrees in writing to accept legal responsibility for performing certain administrative activities on behalf of the clinic. A medical director must be a licensed allopathic, osteopathic, chiropractic, or podiatric physician, except for limited circumstances.

The bill authorizes an ARNP or a PA to serve as the medical director of a health care clinic.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Advanced Registered Nurse Practitioners

Advanced registered nurse practitioners (ARNPs) are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board of Nursing (BON) licenses, regulates, and administratively disciplines ARNPs. As of February 2017, there are 26,691 active licensed ARNPs.[1]

To be certified as an ARNP, the applicant must be licensed as a registered nurse, have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills, and submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[2] A nursing specialty board must:

- Attest to the competency of nurses in a clinical specialty area;
- Require nurses to take a written examination prior to certification;
- Require nurses to complete a formal program prior to eligibility for examination;
- Maintain program accreditation or review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing specialty.[3]

ARNPs may perform advanced or specialized nursing to include, in addition to practices of professional nursing[4] that registered nurses are authorized to perform, advanced-level nursing acts approved by the BON as appropriate for ARNPs to perform by virtue of their post-basic specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician's protocol.[5]

Within the framework of the written protocol, an ARNP may:

- Prescribe, dispense, administer, or order any drug;[6]
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by Board rule;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty; and
- Perform medical acts authorized as authorized within the framework of an established supervisory physician's protocol.[7]

An ARNP may sign only those documents that are directly related to the performance of authorized nursing or medical acts performed pursuant to a physician's protocol and which do not, by law, require a physician's signature. Under current law, an ARNP may not sign, among other things, a certificate to

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[1] E-mail correspondence with the Department of Health dated February 2, 2017, (on file with the staff of the Health and Human Services Committee).
[2] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[3] Rule 64B9-4.002(3), F.A.C.
[4] The practice of professional nursing means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skills based on the applied principles of psychological, biological, physical, and social sciences. Section 464.003(20), F.S.
[5] Section 464.003(2), F.S.
[6] ARNP prescribing authority for controlled substances is limited to a 7-day, except that this restriction does not apply to psychiatric medicines prescribed by psychiatric nurses. Only psychiatric nurses may prescribe psychiatric controlled substances to children younger than 18.
[7] Sections 464.012(3),(4), and 464.003, F.S.

initiate an involuntary examination of a person under the Baker Act,[8] a death certificate,[9] a certification of a disability for certain tax exemptions,[10] or for the release of persons in receiving facilities under the Baker Act.[11]

Physician Assistants

Under Florida law, physician assistants are governed by the physician practice acts for medical doctors and doctors of osteopathic medicine. PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. As of February 2017, there are 7,527 active licensed PAs.[12]

An applicant for a PA license must apply to the Department of Health (DOH). DOH must issue a license to a person certified by the Council as having met all of the following requirements:

- Satisfactorily passes the National Commission on Certification of Physician Assistants exam;
- Completes an application form and remit the registration fee;
- Completes an approved PA training program;
- Provides an acknowledgement of any prior felony convictions;
- Provides an acknowledgement of any revocation or denial of licensure or certification in any state; and
- If the applicant wishes to apply for prescribing authority, submits of a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.[13]

In Florida, a PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be qualified in the medical area in which the PA is practicing and is responsible and liable for the performance, acts, and omissions of the PA.[14]

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[15]

A supervising physician may only delegate tasks and procedures to the PA which are within the supervising physician's scope of practice.[16] The decision to permit the PA to perform a task or

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[8] Section 394.463, F.S.
[9] Section 382.008, F.S.
[10] Section 196.101, F.S.
[11] *Supra* note 8
[12] E-mail correspondence with the Department of Health dated February 2, 2017, (on file with the staff of the Health and Human Services Committee).
[13] *See* s. 458.347 and s. 459.022, F.S.
[14] Sections 458.347(3), F.S., and 459.022(3), F.S.; and Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.
[15] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.
[16] *Supra* note 13.

procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[17]

A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;[18]
- Order any medication for administration for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;[19] and
- Any other services that are not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[20]

A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and which do not, by law, require a physician's signature. Under current law, a PA may not sign, among other things, a certificate to initiate an involuntary examination of a person under the Baker Act,[21] a death certificate,[22] a certification of a disability for certain tax exemptions,[23] or for the release of persons in receiving facilities under the Baker Act.[24]

Health Care Clinics

The Health Care Clinic Act (Act), ss. 400.990 – 400.995, F.S., was enacted in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system.[25] Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics ensures that such clinics meet basic standards, and provide administrative oversight.

Any entity that meets the definition of a health care clinic must be licensed as a health care clinic. Although all clinics must be licensed by AHCA, the Act creates many exceptions from the health care clinic licensure requirements.[26] There are currently 10,238 entities with Certificates of Exemption under the Act.[27] To be licensed, an entity must submit a completed application form to AHCA[28] and must:

- Submit to a Level 2 background screening including owners and certain employees and officers of the entity;
- Provide a description or explanation of any exclusions, suspensions, or terminations of the applicant from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment programs;

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[17] "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. *Supra* note15.
[18] Sections 458.347(4)(f), F.S., and 459.022(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.
[19] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.
[20] Sections 458.347(4) and 459.022(e), F.S.
[21] *Supra* note 8.
[22] *Supra* note 9.
[23] *Supra* note 10.
[24] *Supra* note 8.
[25] Chapter 2003-411, Laws of Fla. PIP insurance is no fault auto insurance that provides certain benefits for individuals injured as a result of a motor vehicle accident. All motor vehicles registered in this state must have PIP insurance.
[26] Section 400.9905(4), F.S.
[27] *Id.*
[28] Section 408.806, F.S.

- Demonstrate financial ability to operate by showing that the applicant's assets, credits, and projected revenues will meet or exceed projected liabilities and expense[29] or provide a surety bond of at least $500,000 payable to AHCA;[30]
- Provide proof of the applicant's legal right to occupy the property in which the clinic is located; and
- Provide proof of any required insurance.[31]

AHCA has 60 days after the receipt of the completed application for licensure to approve or deny the application. Licenses must be renewed biennially. There are currently 2,016 licensed health care clinics.[32]

Each clinic must appoint a medical or clinical director. A medical director must be a physician employed or under contract with a clinic and who maintains an unencumbered licensed as an allopathic physician, osteopathic physician, chiropractor, or podiatrist.[33] In lieu of a medical director, a health care clinic may appoint a clinical director if the clinic does not provide services that are regulated by one of the aforementioned physician practice acts.

The medical or clinical director must agree in writing to accept the legal responsibility for the following activities on behalf of the clinic:

- Display signs that identify the medical or clinical 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 that the billings are not fraudulent or unlawful;
- Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.[34]

If the health care clinic's medical director is a physician, it may provide any health care service or treatment that a physician is authorized to provide. However, if the health care clinic employs another health care practitioner as its clinic director, the health care services it may offer is limited to those services within the scope of practice of that health care practitioner's license.[35] For example, if the clinic director is a licensed under ch. 463, F.S., as an optometrist, the health care clinic services would be limited to optometric services.

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[29] Section 408.8069, F.S. This also includes providing AHCA with financial statements, including balance sheet, income and expense statement, a statement of cash flow for the first 2 years of operation that provides evidence that the applicant has sufficient assets, credits, and projected revenues to cover liabilities and expenses, and a statement of the applicant's startup costs and sources of funds through the breakeven point.
[30] Section 408.8069, F.S.
[31] Section 408.810, F.S.
[32] E-mail correspondence with AHCA staff dated February 16, 2017, (on file with the Health Quality Subcommittee).
[33] Section 400.9905(5), F.S.
[34] Section 400.9935, F.S.
[35] Section 400.9905 (5), F.S.

Effect of Proposed Changes

CS/HB 129 authorizes ARNPs and PAs to serve as health care clinic medical directors if employed or under contract with the clinic. To serve as a medical director, an ARNP must have an active and unencumbered license under ch. 464, F.S., and be certified under s. 464.012, F.S.; a PA must have an active and unencumbered license under ch. 458, F.S. or ch. 459, F.S.

Currently, ARNPs and PAs may only sign documents related to the performance of medical services as authorized by a supervising physician, if the document does not, by law, require a physician's signature. If an ARNP or PA provided the medical service for which the physician signature is required, a supervising physician must provide the signature or the patient must visit a physician to obtain such signature. The bill also authorizes ARNPs and PAs to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician. This includes, among other things, signing a certificate to initiate an involuntary examination of a person under the Baker act, signing for the release of persons in receiving facilities under the Baker Act, or signing death certificates. Therefore, if an ARNP or PA provides the health care services for which a document requires a physician's signature, the ARNP or PA may sign the document.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 400.9905, F.S., relating to definitions.
Section 2: Amends s. 458.347, F.S., relating to physician assistants.
Section 3: Amends s. 459.022, F.S., relating to physician assistants.
Section 4: Amends s. 464.012, F.S., relating to certification of advanced nurse practitioners; fees; controlled substance prescribing.
Section 5: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

   None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 22, 2016, the Health Quality Subcommittee adopted an amendment that authorized a physician assistant (PA) to serve as a medical director of a health care clinic. The amendment authorized a physician to delegate to a PA the authority to sign, certify, stamp, verify, or endorse any document that is required by law to be signed, certified, stamped, verified, or endorsed by a physician.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

1 A bill to be entitled
2 An act relating to health care practitioner
3 regulation; amending s. 400.9905, F.S.; revising the
4 definition of the term "medical director" to include
5 certain physician assistants and advanced registered
6 nurse practitioners; amending ss. 458.347 and 459.022,
7 F.S.; authorizing a physician assistant to sign,
8 certify, stamp, verify, or endorse a document that
9 requires the signature, certification, stamp,
10 verification, or endorsement of a physician; amending
11 s. 464.012, F.S.; authorizing an advanced registered
12 nurse practitioner to sign, certify, stamp, verify, or
13 endorse a document that requires the signature,
14 certification, stamp, verification, or endorsement of
15 a physician; providing an effective date.
16
17 Be It Enacted by the Legislature of the State of Florida:
18
19 Section 1. Subsection (5) of section 400.9905, Florida
20 Statutes, is amended to read:
21 400.9905 Definitions.—
22 (5) "Medical director" means:
23 (a) A physician or physician assistant who is employed or
24 under contract with a clinic and who maintains a full and
25 unencumbered physician license in accordance with chapter 458,

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

26 chapter 459, chapter 460, or chapter 461 or a full and
27 unencumbered physician assistant license in accordance with
28 chapter 458 or chapter 459; or
29 (b) An advanced registered nurse practitioner who is
30 employed or under contract with a clinic, maintains a full and
31 unencumbered license to practice professional nursing in
32 accordance with chapter 464, and who is certified under s.
33 464.012.
34
35 If a ~~However, if the~~ clinic does not provide services pursuant
36 to any of the ~~respective~~ physician or nurse practices acts
37 specified ~~listed~~ in this subsection, it may appoint a Florida-
38 licensed health care practitioner who does not provide services
39 pursuant to those ~~the respective physician practices~~ acts ~~listed~~
40 ~~in this subsection~~ to serve as a clinic director who is
41 responsible for the clinic's activities. A health care
42 practitioner may not serve as the clinic director if the
43 services provided at the clinic are beyond the scope of that
44 practitioner's license; however, ~~except that~~ a licensee
45 specified in s. 456.053(3)(b) who provides only services
46 authorized under that paragraph ~~pursuant to s. 456.053(3)(b)~~ may
47 serve as clinic director of an entity providing such services ~~as~~
48 ~~specified in s. 456.053(3)(b)~~.
49 Section 2. Paragraph (i) is added to subsection (4) of
50 section 458.347, Florida Statutes, to read:

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

51 458.347 Physician assistants.—
52 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—
53 (i) A supervisory physician may delegate to a licensed
54 physician assistant the authority to sign, certify, stamp,
55 verify, or endorse a document that requires the signature,
56 certification, stamp, verification, or endorsement of a
57 physician.
58 Section 3. Paragraph (h) is added to subsection (4) of
59 section 459.022, Florida Statutes, to read:
60 (h) A supervisory physician may delegate to a licensed
61 physician assistant the authority to sign, certify, stamp,
62 verify, or endorse a document that requires the signature,
63 certification, stamp, verification, or endorsement of a
64 physician.
65 Section 4. Paragraph (f) is added to subsection (3) of
66 section 464.012, Florida Statutes, to read:
67 464.012 Certification of advanced registered nurse
68 practitioners; fees; controlled substance prescribing.—
69 (3) An advanced registered nurse practitioner shall
70 perform those functions authorized in this section within the
71 framework of an established protocol that is filed with the
72 board upon biennial license renewal and within 30 days after
73 entering into a supervisory relationship with a physician or
74 changes to the protocol. The board shall review the protocol to
75 ensure compliance with applicable regulatory standards for

76 protocols. The board shall refer to the department licensees
77 submitting protocols that are not compliant with the regulatory
78 standards for protocols. A practitioner currently licensed under
79 chapter 458, chapter 459, or chapter 466 shall maintain
80 supervision for directing the specific course of medical
81 treatment. Within the established framework, an advanced
82 registered nurse practitioner may:
83 (f) Sign, certify, stamp, verify, or endorse a document
84 that requires the signature, certification, stamp,
85 verification, or endorsement of a physician.
86 Section 5. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__	(Y/N)
ADOPTED AS AMENDED	__	(Y/N)
ADOPTED W/O OBJECTION	__	(Y/N)
FAILED TO ADOPT	__	(Y/N)
WITHDRAWN	__	(Y/N)
OTHER	____	

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee
3 Representative Plasencia offered the following:
4
5 **Amendment (with title amendment)**
6 Remove lines 57-85 and insert:
7 physician, except that the supervisory physician may not
8 delegate the authority to issue a written approval to release a
9 patient from a receiving facility or its contractor under s.
10 394.463(2)(f).
11 Section 3. Paragraph (h) is added to subsection (4) of
12 section 459.022, Florida Statutes, to read:
13 (h) A supervisory physician may delegate to a licensed
14 physician assistant the authority to sign, certify, stamp,
15 verify, or endorse a document that requires the signature,
16 certification, stamp, verification, or endorsement of a

17 physician, except that the supervisory physician may not
18 delegate the authority to issue a written approval to release a
19 patient from a receiving facility or its contractor under s.
20 394.463(2)(f).
21 Section 4. Paragraph (f) is added to subsection (3) of
22 section 464.012, Florida Statutes, to read:
23 464.012 Certification of advanced registered nurse
24 practitioners; fees; controlled substance prescribing.—
25 (3) An advanced registered nurse practitioner shall
26 perform those functions authorized in this section within the
27 framework of an established protocol that is filed with the
28 board upon biennial license renewal and within 30 days after
29 entering into a supervisory relationship with a physician or
30 changes to the protocol. The board shall review the protocol to
31 ensure compliance with applicable regulatory standards for
32 protocols. The board shall refer to the department licensees
33 submitting protocols that are not compliant with the regulatory
34 standards for protocols. A practitioner currently licensed under
35 chapter 458, chapter 459, or chapter 466 shall maintain
36 supervision for directing the specific course of medical
37 treatment. Within the established framework, an advanced
38 registered nurse practitioner may:
39 (f) Sign, certify, stamp, verify, or endorse a document
40 that requires the signature, certification, stamp,
41 verification, or endorsement of a physician. However, an

42 advanced registered nurse practitioner may not issue a written
43 approval to release a patient from a receiving facility or its
44 contractor under s. 394.463(2)(f), unless he or she is a
45 psychiatric nurse as defined in s. 395.455(35), and is acting
46 within the authority granted under s. 394.463.
47
48 ---
49 **T I T L E A M E N D M E N T**
50 Remove lines 10-15 and insert:
51 Verification, or endorsement or a physician; providing an
52 exception; amending s. 464.012, F.S.; authorizing an advanced
53 registered nurse practitioner to sign, certify, stamp, verify,
54 or endorse a document that requires the signature,
55 certification, stamp, verification, or endorsement of a
56 physician; providing an exception; providing an effective date.

HB 145

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 145 Recovery Care Services
SPONSOR(S): Renner; Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 222

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	15 Y, 0 N	Poche	Poche
2) Health Care Appropriations Subcommittee	12 Y, 3 N	Clark	Pridgeon
3) Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

Pursuant to s. 395.002(3), F.S., an ambulatory surgical center (ASC) is a facility that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.

Federal Medicare reimbursement is generally limited to stays of no more than 24 hours. HB 145 changes the allowable length of stay in an ASC from less than one working day to no more than 24 hours, which is the federal Medicare length of stay standard.

HB 145 creates a new license for a Recovery Care Center (RCC), defined as a facility the primary purpose of which is to provide recovery care services, to which a patient is admitted and discharged within 72 hours, and which is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to a RCC. A patient may receive recovery care services in a RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving out-patient medical treatment such as chemotherapy.

The new RCC license is modeled after the current licensing procedures for hospitals and ASCs, subjecting RCCs to similar regulatory standards, inspections, and rules. RCCs must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital.

The bill has an indeterminate, but likely insignificant, fiscal impact that can be managed within existing Agency for Health Care Administration resources.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Ambulatory Surgical Centers (ASCs)

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[1]

Currently, there are 432 licensed ASCs in Florida.[2] Of the 306 licensed hospitals in the state, 218 report providing outpatient surgical services.[3]

In 2015, there were 3,029,199 visits to ASCs in Florida.[4] Visits occur at hospital-based outpatient facilities or freestanding ASCs. Hospital-based outpatient facilities accounted for 47 percent and freestanding ASCs accounted for 53 percent of the total number of visits.[5] Of the $37.9 billion in total charges for ambulatory procedures in 2015, hospital-based outpatient facilities accounted for 76 percent of the charges, while freestanding ASCs accounted for 24 percent.[6] The average charge at the hospital-based facilities, $20,444, was more than three times larger than the average charge at the freestanding ASCs, $5,561.[7]

In Florida, for 2015, the top five medical procedures, by total charges, at a freestanding ASC and hospital-based outpatient facility were:

- Esophagogastroduodenoscopy with biopsy;
- Cataract surgery with IOL implant;
- Colonoscopy and biopsy;
- Diagnostic colonoscopy; and
- Colonoscopy with lesion removal.[8]

The following chart shows the total number of visits for each of the top five medical procedures and the average charge for each procedure[9]:

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[1] S. 395.002(3), F.S.
[2] Agency for Health Care Administration, *All Florida Ambulatory (Outpatient) Surgery Centers Results*, available at http://www.floridahealthfinder.gov/CompareCare/ListFacilities.aspx (last viewed February 5, 2017).
[3] Agency for Health Care Administration, *2017 Agency Legislative Bill Analysis-HB 145*, page 2, January 4, 2017 (on file with Health and Human Services Committee staff).
[4] Agency for Health Care Administration, *Presentation on Ambulatory Surgical Centers- Health Innovation Subcommittee*, slide 10, January 25, 2017 (on staff with Health and Human Services Committee staff).
[5] Office of Program Policy and Government Accountability, *Presentation on Ambulatory Surgical Centers and Recovery Care Centers-Health Innovation Subcommittee*, slide 4, January 25, 2017 (on staff with Health and Human Services Committee staff).
[6] Id. at slide 5.
[7] Id.
[8] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Current Procedural Terminology Code and Facility Type*, available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed on February 5, 2017).
[9] Id.

Procedure	Total Visits	Average Charge
Esophagogastroduodenoscopy with biopsy	241,006	$4,930
Cataract surgery with IOL implant	229,289	$4,535
Colonoscopy and biopsy	185,707	$4,345
Diagnostic colonoscopy	202,687	$3,411
Colonoscopy with lesion removal	153,917	$4,404

In 2015, payment for visits to freestanding ASCs and hospital-based outpatient facilities was made mainly by commercial insurance and regular Medicare. Commercial insurance paid $15.5 billion or 41 percent of charges, while Medicare paid $10.8 billion or 31 percent of charges.[10] The next three top payer groups, Medicare managed care, Medicaid managed care, and self-pay, accounted for a combined $8.6 billion or 22.9 percent of charges.[11]

ASC Licensure

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.[12] Applicants for ASC licensure must submit certain information to AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Proof of registration of articles of incorporation; and
- A zoning certificate or proof of compliance with zoning requirements.[13]

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

- Governing body bylaws, rules, and regulations;
- Medical staff bylaws, rules, and regulations;
- A roster of medical staff members;
- A nursing procedure manual;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- The comprehensive Emergency Management Plan.[14]

AHCA is authorized to adopt rules for hospitals and ASCs.[15] Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals,[16] but the rules for all hospitals and ASCs must 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;

[10] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Patient, Primary Payer, and Average Charges* http://www.floridahealthfinder/gov/QueryTool/QTResults.aspx?T=O (last viewed February 5, 2017).
[11] Id.
[12] SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[13] Rule 59A-5.003(4), F.A.C.
[14] Rule 59A-5.003(5), F.A.C.
[15] S. 395.1055, F.S.
[16] S. 395.1055(2), F.S.

- 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

The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, and laboratory and radiologic services.[17] In providing these services, ACSs are required to have certain professional staff available, including:

- A registered nurse to serve as an operating room circulating nurse;[18]
- An anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician in the ASC during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged;[19] and
- A registered professional nurse in the recovery area during the patient's recovery period.[20]

Infection Control Rules

ASCs are required to establish infection control programs, which must include written policies and procedures reflecting the scope of the program.[21] The written policies and procedures must be reviewed at least every two years by the infection control program members.[22] The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;[23]
- A system for identifying, reporting, evaluating and maintaining records of infections;[24]
- Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the ASC;[25] and
- Development and coordination of training programs in infection control for all personnel.[26]

Emergency Management Plan Rules

ASCs are required to develop and adopt written comprehensive emergency management plans for emergency care during an internal or external disaster or emergency.[27] Some of the elements that must be in the plan include:

- Provisions for internal and external disasters, and emergencies;
- A description of the center's role in a community wide comprehensive emergency management plan;
- Information about how the center plans to implement specific procedures outlined in its plan;
- Precautionary measures, including voluntary cessation of center operations, to be taken by the center in preparation and response to warnings of inclement weather, including hurricanes and tornadoes, or other potential emergency conditions;

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[17] Rule 59A-5.0085, F.A.C.
[18] Rule 59A-5.0085(3)(c), F.A.C.
[19] Rule 59A-5.0085(2)(b), F.A.C.
[20] Rule 59A-5.0085(3)(d), F.A.C.
[21] Rule 59A-5.011(1), F.A.C.
[22] Rule 59A-5.011(2), F.A.C.
[23] Rule 59A-5.011(1)(a), F.A.C.
[24] Rule 59A-5.011(1)(b), F.A.C.
[25] Rule 59A-5.011(1)(c), F.A.C.
[26] Rule 59A-5.011(1)(d), F.A.C.
[27] Rule 59A-5.018(1), F.A.C.

- Provisions for coordinating with hospitals that would receive patients to be transferred;
- Provisions for the management of staff, including the distribution and assignment of responsibilities and functions, and the assignment of staff to accompany patients to a hospital or subacute care facility;
- Provisions for the management of patients who may be treated at the center during an internal or external disaster or emergencies, including control of patient information and medical records, individual identification of patients, transfer of patients to hospital(s) and treatment of mass casualties;
- Provisions for contacting relatives and necessary persons advising them of patient location changes; and
- A provision for educating and training personnel in carrying out their responsibilities in accordance with the adopted plan.

The ASC must review the plan and update it annually.[28]

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission for Health Care Organizations, the Accreditation Association for Ambulatory Health Care, or the American Osteopathic Association Healthcare Facilities Accreditation Program.[29] AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs.[30] AHCA must accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report document that the ASC is in substantial compliance with state licensure requirements.[31] AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.[32]

AHCA is also required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements.[33] 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.[34]

Of the 432 licensed ASCs in Florida, as of December 2016, 304 were accredited by the Accreditation Association for Ambulatory Health Care and 83 by the Joint Commission.[35]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines an "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[36] following an admission.[37]

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[28] Rule 59A-5.018(2)(a), F.A.C.

[29] Rule 59A-5.004(3), F.A.C.; Agency for Health Care Administration, Ambulatory Surgical Center, *Accrediting Organizations for Ambulatory Surgical Centers*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ambulatory.shtml (last viewed February 5, 2017).

[30] Rule 59A-5.004(1) and (2), F.A.C.

[31] Rule 59A-5.004(3), F.A.C.

[32] Rule 59A-5.004(5), F.A.C.

[33] Rule 59A-5.004(1), F.S., and s. 395.0161, F.S.

[34] S. 395.0161(2), F.S.

[35] Supra, FN 3.

[36] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 137, 04-01-15), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf (last viewed February 5, 2017); Exceeding the 24-hour time frame is expected to be a rare occurrence and each rare occurrence is expected to be

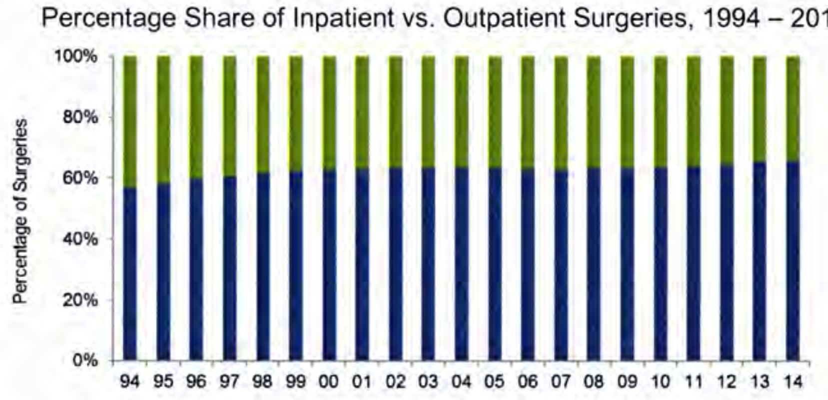
CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency that CMS determines provides reasonable assurance that the conditions are met.[38] All of the CMS conditions for coverage requirements are included in Chapter 59A-5, F.A.C., and apply to all ASCs. The conditions for coverage require:

- A governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- A quality assessment and performance improvement program;
- A transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- A disaster preparedness plan;
- An organized medical staff;
- A fire control plan;
- A sanitary environment;
- An infection control program; and
- A procedure for patient admission, assessment and discharge.

ASC Cost of Care and Quality Outcomes

There has been tremendous growth in the outpatient surgery segment of health care in the U.S., facilitated by advances in technology. From 1981 through 2005, the number of outpatient surgeries increased ten-fold.[39] Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.[40]

Percentage Share of Inpatient vs. Outpatient Surgeries, 1994 – 2014[41]



The increased use of outpatient surgery may help lower health care costs and meet increased patient demand for outpatient surgery, which is frequently more convenient for patients and their families and allows for less stressful recovery.

demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with regulations. In addition, review of the cases that exceed the time frame may also reveal noncompliance with conditions for coverage related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

[37] 42 C.F.R. §416.2

[38] 42 C.F.R. §416.26(a)(1)

[39] Munnich E. and Parente S., *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, Health Affairs 33;5: 764-69, 764 (2014).

[40] Munnich E. and Parente S., *Returns to Specialization: Evidence from the Outpatient Surgery Market*, pg. 1 (April 2014); Chart data is from an analysis of the American Hospital Association Annual Survey data from 2014 for community hospitals.

[41] David M. Shapiro, Presentation on Issues and Trends in Ambulatory Surgery, slide 5, Health Innovation Subcommittee, January 25, 2017 (on file with Health and Human Services Committee staff).

ASC Cost of Care

Despite the volume of outpatient surgeries today, there is little research on cost savings associated with ASCs.[42] Research does show that procedures in ASCs are 25 percent faster on average than hospital-based outpatient facilities, driven mainly by technological, system and process efficiencies in ASCs.[43] The same study also found that ASC efficiency generated a savings of $363-$1,000 per outpatient case.[44]

In 2014, the Office of the Inspector General for the U.S. Department of Health and Human Services studied the cost efficiency associated with Medicare beneficiaries obtaining surgical services in an outpatient setting.[45] The OIG found that Medicare saved almost $7 billion during calendar years (CYs) 2007 through 2011 and could potentially save $12 billion from CYs 2012 through 2017 due primarily to the lower rates for surgical procedures done in ASCs.[46] The OIG also found that Medicare beneficiaries realized savings of $2 billion in the form of reduced co-payment obligations in the ASC setting.[47] In addition, Medicare could generate savings of as much as $15 billion for CYs 2012 through 2017 if CMS reduced hospital outpatient department payment rates for ASC-approved procedures to ASC payment levels.[48] Beneficiaries, in turn, would save $3 billion.[49]

A review of commercial medical claims data found that U.S. healthcare costs are reduced by more than $38 billion per year due to the availability of ASCs for outpatient procedures.[50] More than $5 billion of the cost reduction accrued to the patient through lower deductible and coinsurance payments.[51] This cost reduction is driven by the fact that, in general, ASC prices are significantly lower than hospital outpatient department prices for the same procedure in all markets, regardless of payer. The study also looks at the potential savings that could be achieved if additional procedures were redirected to ASCs. As much as $55 billion could be saved annually depending on the percentage of procedures that migrate to ASCs and the mix of ASCs selected instead of HOPDs.[52]

An analysis by the Ambulatory Surgery Center Association of 2014 data from the Center for Medicaid and Medicare Services focused on the impact of Florida ASCs to Medicare. Specifically, the analysis found:

- Medicare saved more than $84 million on cataract procedures because beneficiaries elected to have those procedures performed in an ASC.
- Florida patients saved more than $23.4 million by having upper GI procedures in an ASC.
- Medicare saved an additional $42.6 million on colonoscopies performed in ASCs.[53]

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[42] Supra, FN 41 at slide 2.

[43] Elizabeth L. Munnich, University of Louisville, Louisville, Kentucky, Presentation on Measuring Cost and Quality in Ambulatory Surgical Centers-Health Innovation Subcommittee, slide 5, January 25, 2017 (on file with Health and Human Services Committee staff); Trentman T., et al, *Outpatient surgery performed in an ambulatory surgery center versus a hospital: comparison of perioperative time intervals*, Amer. J. Surgery 100; 1: 64-67 (July 2010).

[44] Supra, FN 39 at pg. 767; The savings calculation is based on the estimated charges for operating room time, set at $29 to $80 per minute, not including surgeon and anesthesia provider fees. Macario A. *What does one minute of operating room time cost?* J Clin Anesth. 2010;22(4):233–6.

[45] U.S. Department of Health and Human Services, Office of Inspector General, *Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, Audit A-05-12-00020 (April 16, 2014).

[46] Id. at pg. i.

[47] Id. at pg. ii.

[48] Id.

[49] Id.

[50] Healthcare Bluebook and HealthSmart, *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, page 7 (June 2016), available at http://www.ascassociation.org/asca/communities/community-home/librarydocuments/viewdocument?DocumentKey=61197e80-d852-4004-860a-2424968b005b (last viewed February 7, 2017).

[51] Id.

[52] Id.

[53] Dr. David Shapiro, Florida Society of Ambulatory Surgery Centers, *Issues and Trends in Ambulatory Surgery-A Presentation to the Florida House of Representatives Health Innovation Subcommittee*, slide 8, January 25, 2017 (on file with Health and Human Services Committee staff).

ASC Quality Outcomes

The body of evidence shows that patients undergoing outpatient surgery in an ASC have the same or better outcomes as patients undergoing surgery at a hospital-based outpatient department.[54] Another study showed that patients who underwent a high volume procedure in an ASC were less likely than those treated in a hospital-based outpatient department to visit an ER or be admitted to the hospital following surgery.[55] The finding held true across timeframe since surgery and for low and high risk patients. Researchers concluded that ASCs provide high volume services more efficiently that hospital-based outpatient departments, but not at the expense of quality of care.[56]

One study found patient satisfaction with care received at ASCs across the country measured at 92 percent.[57]

Recovery Care Centers

Recovery care centers (RCCs) are entities that provide short-term nursing care, support, and pain control for patients that do not require acute hospitalization.[58] RCC patients are typically healthy persons that have had elective surgery. RCCs can be either freestanding or attached to an ASC or hospital. In practice, RCCs typically provide care to patients transferred from an ASC following surgery, which allows the ASC to perform more complex procedures.[59]

RCCs are not eligible for Medicare reimbursement.[60] However, RCCs may receive payments from Medicaid programs.

Three states, Arizona, Connecticut, and Illinois, have specific licenses for RCCs.[61] Other states license RCCs as nursing facilities or hospitals.[62] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[63]

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[54] Office of Program Policy and Government Accountability, Research Memorandum, *Ambulatory Surgical Centers and Recovery Care Centers*, January 19, 2016 (on file with Health and Human Services Committee staff). The OPPAGA research literature review found nine studies supporting the conclusion that ASCs provide more timely service to patients and have low rates of unexpected safety events. The review also found five studies concluding that the increase in patient volume to ASCs was not associated with an increase in hospital admissions or patient mortality. *Outpatient Surgery Performed in an Ambulatory Surgery Center Versus a Hospital: Comparison of Perioperative Time Intervals* (Trentman et al., 2010); *A Comparative Study of Quality Outcomes in Freestanding Ambulatory Surgery Centers and Hospital-Based Outpatient Departments: 1997-2004* (Chukmaitov et al., 2008); *Comparing Quality at an Ambulatory Surgery Center and a Hospital-Based Facility: Preliminary Findings* (Grisel and Arjmand, 2009); *Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery* (Hollenbeck et al., 2015); *Changing Access to Emergency Care for Patients Undergoing Outpatient Procedures at Ambulatory Surgery Centers: Evidence From Florida* (Neuman et al., 2011); and *Hospital-Based, Acute Care After Ambulatory Surgery Center Discharge* (Fox et al., 2014).

[55] Supra, FN 41 at pgs. 26-29; Fleisher LA, Pasternak LR, Herbert R, Anderson GF. *Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care.* Arch Surg. 2004 Jan;139(1):67-72.

[56] Supra, FN 41 at slide 8.

[57] *Press Ganey Outpatient Pulse Report 2008*. Represents the experiences of 1,039,289 patients treated at 1,218 facilities nationwide between January 1 and December 31, 2007.

[58] Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare Payment for Post-Surgical Recovery Care Centers*, (2000), available at https://permanent.access.gpo.gov/lps20907/nov2000medpay.pdf (last viewed February 5, 2017).

[59] Id. at pg. 4.

[60] Supra, FN 57.

[61] Ariz. Rev. Stat. Ann.§§ 36-448.51-36-448.55; Conn. Conn. Agencies Regs § 19A-495-571; 210 Ill. Comp. Stat. Ann. 3/35. In 2009, Illinois limited the total number of RCCs to those centers holding a certificate of need for beds as of January 1, 2008. The five existing RCCs were grandfathered in and continue to be regulated under 77 Ill. Admin. Code 210.

[62] Sandra Lee Breisch, *Profits in Short Stays*, Am. Acad. of Orthopedic Surgeons Bulletin (June, 1999), available at http://www2.aaos.org/bulletin/jun99/asc.htm (last viewed February 5, 2017).

[63] Supra FN 57, at pg. 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[64]	Connecticut[65]	Illinois[66]
Licensure Required	X	X	X
Written Policies	X	X	X
Maintain Medical Records	X	X	X
Patient's Bill of Rights	X	X	X
Allows Freestanding Facility or Attached	Not Addressed.	X	X
Length of Stay	Not Addressed.	Expected 3 days Maximum 21 days	Expected 48 hours Maximum 72 hours
Emergency Care Transfer Agreement	For care not provided by the RCC.	With a hospital and an ambulance service.	With a hospital within 15 minutes travel time.
Prohibited Patients	Patients needing: • Intensive care • Coronary care • Critical care	Patients needing: • Intensive care • Coronary care • Critical care	• Patients with chronic infectious conditions • Children under age 3
Prohibited Services	• Surgical • Radiological • Pediatric • Obstetrical	• Surgical • Radiological • Pre-adolescent pediatric • Hospice • Obstetrical services over 24 week gestation • Intravenous therapy for non-hospital based RCC	• Blood administration (only blood products allowed)
Required Services	• Laboratory • Pharmaceutical • Food	• Pharmaceutical • Dietary • Personal care • Rehabilitation • Therapeutic • Social work	• Laboratory • Pharmaceutical • Food • Radiological
Bed Limitation	Not Addressed.	Not Addressed.	20
Required Staff	• Governing authority • Administrator	• Governing body • Administrator	• Consulting committee
Required Medical Personnel	• At least two physicians • Director of nursing	• Medical advisory board • Medical director • Director of nursing	• Medical director • Nursing supervisor
Required Personnel When Patients Are Present	• Director of nursing 40 hours per week • One registered nurse • One other nurse	• Two persons for patient care	• One registered nurse • One other nurse

[64] Ariz. Rev. Stat. Ann. §§ 36-448.51-36-448.55; Ariz. Admin. Code §§ R9-10-501-R9-10-518 (updated in 2013, formerly R9-10-1401-R9-10-1412).
[65] Conn. Agencies Regs. § 19A-495-571.
[66] 210 Ill. Comp. Stat. Ann. 3/35; Ill. Admin. Code tit. 77, §§ 210.2500 & 210.2800.

Effect of Proposed Changes

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and cannot stay overnight. Medicare reimbursement policy limits the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to permit a patient to stay at an ASC for no longer than 24 hours. The change conforms to the Medicare length of stay requirement.

The bill creates a new license for a Recovery Care Center (RCC). The new RCC license is modeled after the current licensure program for hospitals and ASCs in Chapters 395 and 408, F.S. An applicant for RCC licensure must follow the general licensing procedures in Chapter 408, Part II. Additionally, the applicant will be subject to the license, inspection, safety, facility, and other requirements of Chapter 395, Part I.

The bill defines a RCC as a facility whose primary purpose is to provide recovery care services, to which the patient is admitted and discharged within 72 hours, and is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable not in need of acute hospitalization by their attending or referring physician prior to admission to a RCC. A patient may receive recovery care services in a RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving an out-patient medical treatment, such as chemotherapy.

A RCC must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital. Further, AHCA is authorized to adopt rules regarding RCC admission and discharge procedures.

Section 395.1055, F.S., directs AHCA to adopt rules for hospitals and ASCs that set standards to ensure patient safety, including requirements for:

- Staffing;
- Infection control;
- Housekeeping;
- Medical records;
- Emergency management;
- Inspections;
- Accreditation;
- Organization, including a governing body and organized medical staff;
- Departments and services;
- Quality assessment and improvement;
- Minimum space; and
- Equipment and furnishings.

The bill authorizes AHCA to adopt, by rule, appropriate standards for RCCs pursuant to s. 395.1055, F.S. In addition, the bill requires AHCA to adopt rules to set standards for dietetic departments, proper use of medications, and pharmacies in RCCs.

The license fee for a RCC will be set by rule by AHCA and must be at least $1,500.[67]

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.001, F.S., related to legislative intent.
Section 2: Amends s. 395.002, F.S., related to definitions.
Section 3: Amends s. 395.003, F.S., related to licensure; denial, suspension, and revocation.
Section 4: Creates s. 395.0171, F.S., related to recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.
Section 5: Amends s. 395.1055, F.S., related to rules and enforcement.
Section 6: Amends s. 395.10973, F.S., related to powers and duties of the agency.
Section 7: Amends s. 408.802, F.S., related to applicability.
Section 8: Amends s. 408.820, F.S., related to exemptions.
Section 9: Amends 385.211, F.S., related to refractory and intractable epilepsy treatment and research at recognized medical centers.
Section 10: Amends s. 394.4787, F.S., related to definitions.
Section 11: Amends s. 409.975, F.S., related to managed care plan accountability.
Section 12: Amends s. 627.64194, F.S., related to coverage requirements for services provided by nonparticipating providers; payment collection limitations.
Section 13: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. Applicants for licensure as a RCC will be subject to the Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews, an application fee of at least $1,500, and a licensure inspection fee of $400.[68]

2. Expenditures:

   The bill requires AHCA to regulate RCCs in accordance with Chapters 395 and 408, F.S., and any rules adopted by the agency. The fees associated with the new license are anticipated to cover the expenses incurred by AHCA in enforcing and regulating the new license. No additional staff will be required as existing regulatory staff is sufficient to absorb the workload associated with up to 10 licensees.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[67] S. 395.004, F.S.
[68] Supra, FN 3 at page 6.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals needing surgery may save money by being able to stay longer in an ASC or stay in a RCC rather than having the original procedure in a hospital and remaining in the hospital to recover merely because the recovery time will be longer than the ASC limit would allow.

Being able to keep patients longer may have a positive fiscal impact on the ASC by being able to perform more complex procedures.

Hospitals may experience a negative fiscal impact if more patients receive care in an ASC or RCC.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to recovery care services; amending s.
3 395.001, F.S.; providing legislative intent regarding
4 recovery care centers; amending s. 395.002, F.S.;
5 revising and providing definitions; amending s.
6 395.003, F.S.; including recovery care centers as
7 facilities licensed under chapter 395, F.S.; creating
8 s. 395.0171, F.S.; providing admission criteria for a
9 recovery care center; requiring emergency care,
10 transfer, and discharge protocols; authorizing the
11 Agency for Health Care Administration to adopt rules;
12 amending s. 395.1055, F.S.; authorizing the agency to
13 establish separate standards for the care and
14 treatment of patients in recovery care centers;
15 amending s. 395.10973, F.S.; directing the agency to
16 enforce special-occupancy provisions of the Florida
17 Building Code applicable to recovery care centers;
18 amending s. 408.802, F.S.; providing applicability of
19 the Health Care Licensing Procedures Act to recovery
20 care centers; amending s. 408.820, F.S.; exempting
21 recovery care centers from specified minimum licensure
22 requirements; amending ss. 385.211, 394.4787, 409.975,
23 and 627.64194, F.S.; conforming cross-references;
24 providing an effective date.
25

26 Be It Enacted by the Legislature of the State of Florida:
27
28 Section 1. Section 395.001, Florida Statutes, is amended
29 to read:
30 395.001 Legislative intent.—It is the intent of the
31 Legislature to provide for the protection of public health and
32 safety in the establishment, construction, maintenance, and
33 operation of hospitals, ambulatory surgical centers, <u>recovery
34 care centers,</u> and mobile surgical facilities by providing for
35 licensure of same and for the development, establishment, and
36 enforcement of minimum standards with respect thereto.
37 Section 2. Subsections (3), (16), and (23) of section
38 395.002, Florida Statutes, are amended, subsections (25) through
39 (33) are renumbered as subsections (27) through (35),
40 respectively, and new subsections (25) and (26) are added to
41 that section, to read:
42 395.002 Definitions.—As used in this chapter:
43 (3) "Ambulatory surgical center" or "mobile surgical
44 facility" means a facility the primary purpose of which is to
45 provide elective surgical care, in which the patient is admitted
46 ~~to~~ and discharged ~~from such facility~~ within <u>24 hours</u> ~~the same
47 working day and is not permitted to stay overnight~~, and which is
48 not part of a hospital. However, a facility existing for the
49 primary purpose of performing terminations of pregnancy, an
50 office maintained by a physician for the practice of medicine,

CODING: Words ~~stricken~~ are deletions; words <u>underlined</u> are additions.

51 or an office maintained for the practice of dentistry may ~~shall~~
52 not be construed to be an ambulatory surgical center, provided
53 that any facility or office which is certified or seeks
54 certification as a Medicare ambulatory surgical center shall be
55 licensed as an ambulatory surgical center pursuant to s.
56 395.003. Any structure or vehicle in which a physician maintains
57 an office and practices surgery, and which can appear to the
58 public to be a mobile office because the structure or vehicle
59 operates at more than one address, shall be construed to be a
60 mobile surgical facility.
61 (16) "Licensed facility" means a hospital, ambulatory
62 surgical center, recovery care center, or mobile surgical
63 facility licensed in accordance with this chapter.
64 (23) "Premises" means those buildings, beds, and equipment
65 located at the address of the licensed facility and all other
66 buildings, beds, and equipment for the provision of hospital,
67 ambulatory surgical, recovery, or mobile surgical care located
68 in such reasonable proximity to the address of the licensed
69 facility as to appear to the public to be under the dominion and
70 control of the licensee. For any licensee that is a teaching
71 hospital as defined in s. 408.07(45), reasonable proximity
72 includes any buildings, beds, services, programs, and equipment
73 under the dominion and control of the licensee that are located
74 at a site with a main address that is within 1 mile of the main
75 address of the licensed facility; and all such buildings, beds,

76 and equipment may, at the request of a licensee or applicant, be
77 included on the facility license as a single premises.
78 (25) "Recovery care center" means a facility the primary
79 purpose of which is to provide recovery care services, in which
80 a patient is admitted and discharged within 72 hours, and which
81 is not part of a hospital.
82 (26) "Recovery care services" means postsurgical and
83 postdiagnostic medical and general nursing care provided to a
84 patient for whom acute care hospitalization is not required and
85 an uncomplicated recovery is reasonably expected. The term
86 includes postsurgical rehabilitation services. The term does not
87 include intensive care services, coronary care services, or
88 critical care services.
89 Section 3. Subsection (1) of section 395.003, Florida
90 Statutes, is amended to read:
91 395.003 Licensure; denial, suspension, and revocation.—
92 (1)(a) The requirements of part II of chapter 408 apply to
93 the provision of services that require licensure pursuant to ss.
94 395.001-395.1065 and part II of chapter 408 and to entities
95 licensed by or applying for such licensure from the Agency for
96 Health Care Administration pursuant to ss. 395.001-395.1065. A
97 license issued by the agency is required in order to operate a
98 hospital, ambulatory surgical center, recovery care center, or
99 mobile surgical facility in this state.
100 (b)1. It is unlawful for a person to use or advertise to

101 the public, in any way or by any medium whatsoever, any facility
102 as a "hospital," "ambulatory surgical center," "recovery care
103 center," or "mobile surgical facility" unless such facility has
104 first secured a license under the provisions of this part.
105 2. This part does not apply to veterinary hospitals or to
106 commercial business establishments using the word "hospital,"
107 "ambulatory surgical center," "recovery care center," or "mobile
108 surgical facility" as a part of a trade name if no treatment of
109 human beings is performed on the premises of such
110 establishments.
111 (c) Until July 1, 2006, additional emergency departments
112 located off the premises of licensed hospitals may not be
113 authorized by the agency.
114 Section 4. Section 395.0171, Florida Statutes, is created
115 to read:
116 395.0171 Recovery care center admissions; emergency and
117 transfer protocols; discharge planning and protocols.—
118 (1) Admissions to a recovery care center are restricted to
119 patients who need recovery care services.
120 (2) Each patient must be certified by his or her attending
121 or referring physician or by a physician on staff at the
122 facility as medically stable and not in need of acute care
123 hospitalization before admission.
124 (3) A patient may be admitted for recovery care services
125 upon discharge from a hospital or an ambulatory surgery center.

126 A patient may also be admitted postdiagnosis and posttreatment
127 for recovery care services.
128 (4) A recovery care center must have emergency care and
129 transfer protocols, including transportation arrangements, and
130 referral or admission agreements with at least one hospital.
131 (5) A recovery care center must have procedures for
132 discharge planning and discharge protocols.
133 (6) The agency may adopt rules to implement this section.
134 Section 5. Subsections (2) and (8) of section 395.1055,
135 Florida Statutes, are amended, and subsection (10) is added to
136 that section, to read:
137 395.1055 Rules and enforcement.—
138 (2) Separate standards may be provided for general and
139 specialty hospitals, ambulatory surgical centers, recovery care
140 centers, mobile surgical facilities, and statutory rural
141 hospitals as defined in s. 395.602.
142 (8) The agency may not adopt any rule governing the
143 design, construction, erection, alteration, modification,
144 repair, or demolition of any public or private hospital,
145 intermediate residential treatment facility, recovery care
146 center, or ambulatory surgical center. It is the intent of the
147 Legislature to preempt that function to the Florida Building
148 Commission and the State Fire Marshal through adoption and
149 maintenance of the Florida Building Code and the Florida Fire
150 Prevention Code. However, the agency shall provide technical

151 assistance to the commission and the State Fire Marshal in
152 updating the construction standards of the Florida Building Code
153 and the Florida Fire Prevention Code which govern hospitals,
154 intermediate residential treatment facilities, recovery care
155 centers, and ambulatory surgical centers.
156 (10) The agency shall adopt rules for recovery care
157 centers which include fair and reasonable minimum standards for
158 ensuring that recovery care centers have:
159 (a) A dietetic department, service, or other similarly
160 titled unit, either on the premises or under contract, which
161 shall be organized, directed, and staffed to ensure the
162 provision of appropriate nutritional care and quality food
163 service.
164 (b) Procedures to ensure the proper administration of
165 medications. Such procedures shall address the prescribing,
166 ordering, preparing, and dispensing of medications and
167 appropriate monitoring of the effects of such medications on the
168 patient.
169 (c) A pharmacy, pharmaceutical department, or
170 pharmaceutical service, or similarly titled unit, on the
171 premises or under contract.
172 Section 6. Subsection (8) of section 395.10973, Florida
173 Statutes, is amended to read:
174 395.10973 Powers and duties of the agency.—It is the
175 function of the agency to:

176 (8) Enforce the special-occupancy provisions of the
177 Florida Building Code which apply to hospitals, intermediate
178 residential treatment facilities, recovery care centers, and
179 ambulatory surgical centers in conducting any inspection
180 authorized by this chapter and part II of chapter 408.
181 Section 7. Subsection (30) is added to section 408.802,
182 Florida Statutes, to read:
183 408.802 Applicability.—The provisions of this part apply
184 to the provision of services that require licensure as defined
185 in this part and to the following entities licensed, registered,
186 or certified by the agency, as described in chapters 112, 383,
187 390, 394, 395, 400, 429, 440, 483, and 765:
188 (30) Recovery care centers, as provided under part I of
189 chapter 395.
190 Section 8. Subsection (29) is added to section 408.820,
191 Florida Statutes, to read:
192 408.820 Exemptions.—Except as prescribed in authorizing
193 statutes, the following exemptions shall apply to specified
194 requirements of this part:
195 (29) Recovery care centers, as provided under part I of
196 chapter 395, are exempt from s. 408.810(7)-(10).
197 Section 9. Subsection (2) of section 385.211, Florida
198 Statutes, is amended to read:
199 385.211 Refractory and intractable epilepsy treatment and
200 research at recognized medical centers.—

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

201 (2) Notwithstanding chapter 893, medical centers
202 recognized pursuant to s. 381.925, or an academic medical
203 research institution legally affiliated with a licensed
204 children's specialty hospital as defined in s. 395.002(30)
205 ~~395.002(28)~~ that contracts with the Department of Health, may
206 conduct research on cannabidiol and low-THC cannabis. This
207 research may include, but is not limited to, the agricultural
208 development, production, clinical research, and use of liquid
209 medical derivatives of cannabidiol and low-THC cannabis for the
210 treatment for refractory or intractable epilepsy. The authority
211 for recognized medical centers to conduct this research is
212 derived from 21 C.F.R. parts 312 and 316. Current state or
213 privately obtained research funds may be used to support the
214 activities described in this section.
215 Section 10. Subsection (7) of section 394.4787, Florida
216 Statutes, is amended to read:
217 394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788,
218 and 394.4789.—As used in this section and ss. 394.4786,
219 394.4788, and 394.4789:
220 (7) "Specialty psychiatric hospital" means a hospital
221 licensed by the agency pursuant to s. 395.002(30) ~~395.002(28)~~
222 and part II of chapter 408 as a specialty psychiatric hospital.
223 Section 11. Paragraph (b) of subsection (1) of section
224 409.975, Florida Statutes, is amended to read:
225 409.975 Managed care plan accountability.—In addition to

226 the requirements of s. 409.967, plans and providers
227 participating in the managed medical assistance program shall
228 comply with the requirements of this section.
229 (1) PROVIDER NETWORKS.—Managed care plans must develop and
230 maintain provider networks that meet the medical needs of their
231 enrollees in accordance with standards established pursuant to
232 s. 409.967(2)(c). Except as provided in this section, managed
233 care plans may limit the providers in their networks based on
234 credentials, quality indicators, and price.
235 (b) Certain providers are statewide resources and
236 essential providers for all managed care plans in all regions.
237 All managed care plans must include these essential providers in
238 their networks. Statewide essential providers include:
239 1. Faculty plans of Florida medical schools.
240 2. Regional perinatal intensive care centers as defined in
241 s. 383.16(2).
242 3. Hospitals licensed as specialty children's hospitals as
243 defined in s. 395.002(30) ~~395.002(28)~~.
244 4. Accredited and integrated systems serving medically
245 complex children which comprise separately licensed, but
246 commonly owned, health care providers delivering at least the
247 following services: medical group home, in-home and outpatient
248 nursing care and therapies, pharmacy services, durable medical
249 equipment, and Prescribed Pediatric Extended Care.
250

251 Managed care plans that have not contracted with all statewide
252 essential providers in all regions as of the first date of
253 recipient enrollment must continue to negotiate in good faith.
254 Payments to physicians on the faculty of nonparticipating
255 Florida medical schools shall be made at the applicable Medicaid
256 rate. Payments for services rendered by regional perinatal
257 intensive care centers shall be made at the applicable Medicaid
258 rate as of the first day of the contract between the agency and
259 the plan. Except for payments for emergency services, payments
260 to nonparticipating specialty children's hospitals shall equal
261 the highest rate established by contract between that provider
262 and any other Medicaid managed care plan.
263 Section 12. Paragraphs (b) and (e) of subsection (1) of
264 section 627.64194, Florida Statutes, are amended to read:
265 627.64194 Coverage requirements for services provided by
266 nonparticipating providers; payment collection limitations.—
267 (1) As used in this section, the term:
268 (b) "Facility" means a licensed facility as defined in s.
269 395.002(16) and an urgent care center as defined in s.
270 395.002(32) ~~395.002(30)~~.
271 (e) "Nonparticipating provider" means a provider who is
272 not a preferred provider as defined in s. 627.6471 or a provider
273 who is not an exclusive provider as defined in s. 627.6472. For
274 purposes of covered emergency services under this section, a
275 facility licensed under chapter 395 or an urgent care center

276 defined in s. 395.002(32) ~~395.002(30)~~ is a nonparticipating
277 provider if the facility has not contracted with an insurer to
278 provide emergency services to its insureds at a specified rate.
279 Section 13. This act shall take effect July 1, 2017.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 161 Direct Primary Care Agreements
SPONSOR(S): Health Innovation Subcommittee, Burgess, Jr.
TIED BILLS: **IDEN./SIM. BILLS:** SB 240

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	15 Y, 0 N, As CS	Poche	Poche
2) Health & Human Services Committee		Poche MW	Calamas CEC

SUMMARY ANALYSIS

Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the primary care provider-patient relationship. Through a contractual agreement, a patient pays a monthly fee, usually between $25 and $100 per individual, to the primary care provider for defined primary care services. After paying the fee, a patient can utilize all services under the agreement at no extra charge. Some DPC practices also include routine preventative services, women's health services, pediatric care, urgent care, wellness education, chronic disease management, and home visits. The Office of Insurance Regulation does not currently regulate DPC agreements.

CS/HB 161 provides that a direct primary care agreement (agreement) and the act of entering into such an agreement are not insurance and not subject to regulation under the Florida Insurance Code (Code), including chapter 636, F.S. The bill also exempts a primary care provider, which includes a primary care group practice, or his or her agent, from any certification or licensure requirements in the Code for marketing, selling, or offering to sell an agreement. An agreement must:

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, or the patient's legal representative;
- Allow either party to terminate the agreement by written notice followed by, at least, a 30 day waiting period;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of services that are covered by the monthly fee;
- Specify the monthly fee and any fees for services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Provide for a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason;
- State that the agreement is not health insurance and that the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement for any primary care services covered by the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's obligations under chapter 440, F.S.

The bill does not have a fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Office of Insurance Regulation

The Florida Office of Insurance Regulation (OIR) regulates the business of insurance in the state, in accordance with the Florida Insurance Code (Code). The specific chapters under the Code are:

Chapter 624, F.S. – Insurance Code: Administration and General Provisions
Chapter 625, F.S. – Accounting, Investments, and Deposits by Insurers
Chapter 626, F.S. – Insurance Field Representatives and Operations
Chapter 627, F.S. – Insurance Rates and Contracts
Chapter 628, F.S. – Stock and Mutual Insurers; Holding Companies
Chapter 629, F.S. – Reciprocal Insurers
Chapter 630, F.S. – Alien Insurers: Trusteed Assets; Domestication
Chapter 631, F.S. – Insurer Insolvency; Guaranty of Payment
Chapter 632, F.S. – Fraternal Benefit Societies
Chapter 634, F.S. – Warranty Associations
Chapter 635, F.S. – Mortgage Guaranty Insurance
Chapter 636, F.S. – Prepaid Limited Health Service Organizations and Discount Medical Plan Organizations
Chapter 641, F.S. – Health Care Service Programs
Chapter 648, F.S. – Bail Bond Agents
Chapter 651, F.S. – Continuing Care Contracts

The Life and Health Unit (Unit) of OIR provides financial oversight of health insurers, health maintenance organizations, and other regulated entities providing health care coverage. The Unit also reviews and approves some health care coverage products offered in the state. The following chart shows the type and number of each entity in the state:[1]

Authority Category	Authorities
Health Insurers	378
Third Party Administrators	302
Continuing Care Retirement Communities	76
Discount Medical Plan Organizations	38
Health Maintenance Organizations	35
Fraternal Benefit Societies	38
Prepaid Limited Health Service Organizations/Prepaid Health Clinics	24

Direct Primary Care

Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the primary care provider-patient relationship. Through a contractual agreement, a patient pays a

[1] Email correspondence from OIR staff dated February 3, 2017, reflecting the number of entities in the state as of February 2, 2017 (on file with Health and Human Services Committee staff).

monthly fee, usually between $50 and $100 per individual,[2] to the primary care provider for defined primary care services. Theses primary care services may include:

- Office visits;
- Annual physical examination;
- Routine laboratory tests;
- Vaccinations;
- Wound care;[3]
- Splinting or casting of fractured or broken bones;
- Other routine testing, e.g. echocardiogram and colon cancer screening; or
- Other medically necessary primary care procedures.

After paying the fee, a patient can access all services under the agreement at no extra charge. Some DPC practices also include routine preventative services, like laboratory tests, mammograms, Pap screenings, vaccinations, and home visits.[4] A primary care provider DPC model can be designed to address the large majority of health care issues, including women's health services, pediatric care, urgent care, wellness education, and chronic disease management.

In the DPC practice model, the primary care provider eliminates practice overhead costs associated with filing claims, coding, refiling claims, write-offs, appealing denials, and employing billing staff. The cost and time savings can be reinvested in the practice, allowing more time with patients to address their primary care needs.

There are an estimated 4,400 direct primary care physicians nationwide, up from 756 in 2010.[5] The following chart illustrates the concentration of DPC practices in the United States:[6]

[2] A recent study of 141 DPC practices found the average monthly fee to be $77.38. Philip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med., November-December 2015, Vol. 28 No. 6, pg. 797; approximately two thirds of DPC practices charge less than $135 per month. Jen Wieczner, *Is Obamacare Driving Doctors to Refuse Insurance?*, Wall St. J. Marketwatch, Nov. 12, 2013, available at: http://www.marketwatch.com/story/is-direct-primary-care-for-you-2013-11-12 (last visited February 5, 2017).

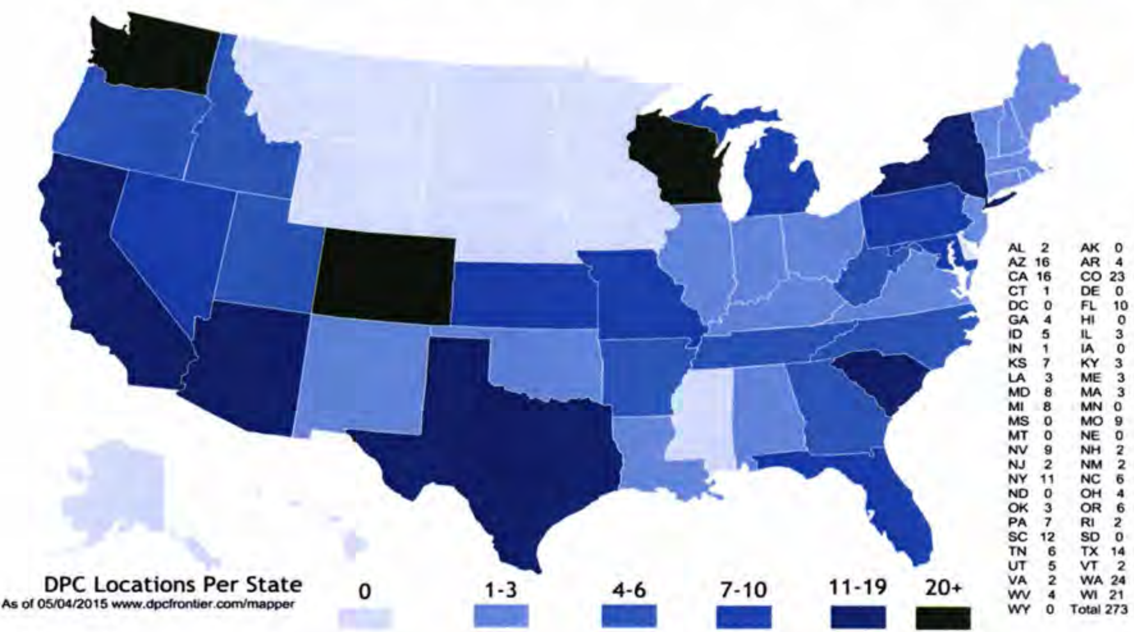
[3] E.g., stitches and sterile dressings.

[4] Direct Primary Care Journal, *DPC Journal Releases Two-Year Industry Analysis of Direct Primary Care Marketplace; Shows Trends, Demographics, DPC Hot Zones*, available at: http://directprimarycarejournal.com/2015/08/24/dpc-journal-releases-two-year-industry-analysis-of-direct-primary-care-marketplace-shows-trends-demographics-dpc-hot-zones/ (last viewed February 5, 2017).

[5] Daniel McCorry, *Direct Primary Care: An Innovative Alternative to Conventional Health Insurance*, The Heritage Foundation Backgrounder, No. 2939 (Aug. 6, 2014), available at: http://report.heritage.org/bg2939 (last viewed January 23, 2016).

[6] Supra, FN 2, Eskew and Klink.

Direct Primary Care Practice Distribution



As of June 2016, sixteen states have approved legislation which defines DPC agreements or services as outside the scope of state regulation[7]:

- Washington
- West Virginia
- Oregon
- Utah
- Arizona
- Louisiana
- Michigan
- Mississippi
- Idaho
- Oklahoma
- Kansas
- Missouri
- Texas
- Nebraska
- Tennessee
- Wyoming[8]

Florida statutes do not specifically address DPC agreements, and OIR has not asserted regulatory authority over them. There is uncertainty about whether OIR might assert such authority in the future. In the event that OIR found that DPC agreements constitute insurance plans subject to regulation under the Insurance Code, the agreements could be subject to the insurance premium tax. In addition, DPC

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[7] Direct Primary Care Coalition, *On the Move in the States with DPC*, available at: http://www.dpcare.org (last viewed February 5, 2017).

[8] In November 2016, New Jersey implemented a DPC pilot program for members of the New Jersey State Health Benefits Program and the School Employees' Health Benefits Program. DPC practices were established in three towns across the state, with a fourth location opening in early 2017. The goal is to provide DPC services to 60,000 state and school systems employees in the first three years of the program.

would be required to meet all other applicable regulations, including reserve requirements, rate and form reviews by OIR, and regulations governing ownership and administration of the DPC arrangement.

DPC and Health Care Reform

The Patient Protection and Affordable Care Act (PPACA)[9] addresses the DPC practice model. The individual responsibility provision of PPACA requires individuals to obtain health insurance coverage that meets minimum essential coverage standards in the law. Failure to do so results in tax penalties.

Direct primary care arrangements alone do not constitute minimum essential coverage because they do not cover catastrophic medical events. A qualified health plan under PPACA is permitted to offer coverage through a DPC medical home plan if it provides essential health benefits and meets all other criteria in the law.[10] Patients who are enrolled in a DPC medical home plan may be compliant with the individual mandate if they have coverage for other services, such as a wraparound catastrophic health policy to cover treatment for serious illnesses, like cancer, or severe injuries that require lengthy hospital stays and rehabilitation.[11] In Colorado and Washington, qualified health plans are offering DPC medical home coverage on each state-based health insurance exchange.[12]

Effect of Proposed Changes

CS/HB 161 provides that a direct primary care agreement is not insurance and entering into such an agreement is not the business of insurance. It exempts both the agreement and the activity from the Code, including chapter 636, F.S. Through the exemption, the bill eliminates any authority of OIR to regulate a direct primary care agreement or entering into such an agreement. The bill also exempts a primary care provider, or his or her agent, from certification or licensing requirements under the Code to market, sell, or offer to sell a direct primary care agreement.

The bill requires a direct primary care agreement to:

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, the patient's legal representative, or an employer;
- Allow either party to terminate the agreement by written notice followed by, at least, a 30 day waiting period;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of services that are covered by the monthly fee;
- Specify the monthly fee and any fees for services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Provide for a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason;
- State that the agreement is not health insurance and that the primary care provider will not bill the patient's health insurance policy or plan for services covered under the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's obligations under chapter 440, F.S.

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[9] Pub. L. No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).
[10] 42 U.S.C. §1802 (a)(3); 45 C.F.R. §156.245
[11] 42 U.S.C. §18021(a)(3); The Secretary of the U.S. Department of Health and Human Services is required to promulgate rules to guide insurers in developing DPC medical home products that provide minimum essential coverage. As of the date of this analysis, those rules have not been promulgated.
[12] Jay Keese, Direct Primary Care Coalition, *Direct Primary Care*, PowerPoint presentation before the House Health Innovation Subcommittee, slide 2, February 17, 2015 (on file with Health and Human Services Committee staff).

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Creates s. 624.27, F.S., relating to application of code as to direct primary care agreements.
Section 2: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   On February 24, 2017, the Revenue Estimating Conference (REC) considered the fiscal impact of CS/HB 161. The REC concluded that the bill has no impact on the Insurance Premium Tax Group trust fund.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill removes any regulatory uncertainty as to the status of a direct primary care agreement as insurance. Primary care providers may choose to invest in establishing direct primary care practices throughout the state to provide primary care services, which would increase access to such services, without concern of facing regulatory action by OIR.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 15, 2017, the Health Innovation Subcommittee adopted one amendment to HB 161. The amendment required the direct primary care agreement to include a notice provision, in at least 12-point type in a contrasting color on the signature page, stating that the agreement is not workers' compensation insurance and may not replace an employer's obligations under chapter 440, F.S., the workers' compensation statute.

The analysis is drafted to the committee substitute as passed by the Health Innovation Subcommittee.

1 A bill to be entitled
2 An act relating to direct primary care agreements;
3 creating s. 624.27, F.S.; providing definitions;
4 specifying that a direct primary care agreement does
5 not constitute insurance and is not subject to the
6 Florida Insurance Code; specifying that entering into
7 a direct primary care agreement does not constitute
8 the business of insurance and is not subject to the
9 code; providing that a certificate of authority is not
10 required to market, sell, or offer to sell a direct
11 primary care agreement; specifying requirements for a
12 direct primary care agreement; providing an effective
13 date.
14
15 Be It Enacted by the Legislature of the State of Florida:
16
17 Section 1. Section 624.27, Florida Statutes, is created to
18 read:
19 624.27 Direct primary care agreements; exemption from
20 code.—
21 (1) As used in this section, the term:
22 (a) "Direct primary care agreement" means a contract
23 between a primary care provider and a patient, the patient's
24 legal representative, or an employer, which meets the
25 requirements of subsection (4) and does not indemnify for

26 services provided by a third party.
27 (b) "Primary care provider" means a health care provider
28 licensed under chapter 458, chapter 459, chapter 460, or chapter
29 464, or a primary care group practice, that provides medical
30 services to patients which are commonly provided without
31 referral from another health care provider.
32 (c) "Primary care service" means the screening,
33 assessment, diagnosis, and treatment of a patient conducted
34 within the competency and training of the primary care provider
35 for the purpose of promoting health or detecting and managing
36 disease or injury.
37 (2) A direct primary care agreement does not constitute
38 insurance and is not subject to the Florida Insurance Code,
39 including chapter 636. The act of entering into a direct primary
40 care agreement does not constitute the business of insurance and
41 is not subject to the Florida Insurance Code, including chapter
42 636.
43 (3) A primary care provider or an agent of a primary care
44 provider is not required to obtain a certificate of authority or
45 license under the Florida Insurance Code, including chapter 636,
46 to market, sell, or offer to sell a direct primary care
47 agreement.
48 (4) For purposes of this section, a direct primary care
49 agreement must:
50 (a) Be in writing.

51 (b) Be signed by the primary care provider or an agent of
52 the primary care provider and the patient, the patient's legal
53 representative, or an employer.
54 (c) Allow a party to terminate the agreement by giving the
55 other party at least 30 days' advance written notice. The
56 agreement may provide for immediate termination due to a
57 violation of the physician-patient relationship or a breach of
58 the terms of the agreement.
59 (d) Describe the scope of primary care services that are
60 covered by the monthly fee.
61 (e) Specify the monthly fee and any fees for primary care
62 services not covered by the monthly fee.
63 (f) Specify the duration of the agreement and any
64 automatic renewal provisions.
65 (g) Offer a refund to the patient, the patient's legal
66 representative, or an employer of monthly fees paid in advance
67 if the primary care provider ceases to offer primary care
68 services for any reason.
69 (h) Contain, in contrasting color and in at least 12-point
70 type, the following statements on the signature page:
71 1. This agreement is not health insurance and the primary
72 care provider will not file any claims against the patient's
73 health insurance policy or plan for reimbursement of any primary
74 care services covered by the agreement.
75 2. This agreement does not qualify as minimum essential

76 coverage to satisfy the individual shared responsibility
77 provision of the Patient Protection and Affordable Care Act, 26
78 U.S.C. s. 5000A.
79 3. This agreement is not workers' compensation insurance
80 and does not replace an employer's obligations under chapter
81 440.
82 Section 2. This act shall take effect July 1, 2017.

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

CS/HB 209

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 209 Medical Faculty Certification
SPONSOR(S): Health Quality Subcommittee; Miller
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Siples	McElroy
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

A medical faculty certificate allows medical school faculty physicians to practice medicine in Florida without passing a licensure examination. A physician who receives a medical faculty certificate has all rights and responsibilities as other licensed physicians, except the certificateholder may only practice in conjunction with a full-time faculty position at an accredited medical school and its affiliated clinical facilities or teaching hospitals. Currently, medical faculty certificates are authorized for physicians teaching in any one of Florida's eight Florida medical schools.

CS/HB 209 expands the current medical faculty certificate eligibility criteria by allowing a medical faculty certificate to be issued to an individual who has been offered and has accepted a full-time faculty appointment to teach in a program of medicine at the Johns Hopkins All Children's Hospital in St. Petersburg, Florida. The bill also limits the number of extended medical faculty certificateholders allowed at the Johns Hopkins All Children's Hospital in St. Petersburg, Florida, to 30 persons, which is consistent with limitations for all but one of the other institutions eligible for such certificates.

Currently, a dean of a medical school or a director of a teaching hospital may request that a physician be authorized to provide medical care or treatment for educational purposes for a single period of time, not to exceed 180 consecutive days. Such physician must register with the department and demonstrate financial responsibility. The bill authorizes the medical director of a specialty-licensed children's hospital licensed under ch. 395, F.S., that is affiliated with an accredited medical school and its affiliated clinics, to request temporary registration for a physician who is not licensed in Florida and authorization to provide medical care or treatment for educational purposes.

There is an insignificant, negative fiscal impact on the Department of Health and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Medical Faculty Certificates

The Board of Medicine within the Department of Health's Division of Medical Quality Assurance may issue medical faculty certificates to physicians allowing them to practice medicine in Florida without sitting for and successfully passing a national examination.[1] These physicians have the same rights and responsibilities as other licensed physicians, except they may only practice in conjunction with a full-time faculty position at an accredited medical school and its affiliated clinical facilities or teaching hospitals.

To be eligible to receive a medical faculty certificate a physician must:[2]

- Be a graduate of an accredited medical school or its equivalent, or a graduate of a foreign medical school listed with the World Health Organization;
- Hold a valid, current license to practice medicine in another jurisdiction;
- Complete the application form and remit a nonrefundable application fee not to exceed $500;
- Complete an approved residency or fellowship of at least one year or equivalent training;
- Be at least 21 years of age;
- Be of good moral character;
- Not have committed any act in Florida or any other jurisdiction which would constitute the basis for disciplining a physician;
- Have completed, before medical school, the equivalent of 2 academic years of preprofessional, postsecondary education, as determined by the Board of Medicine;[3] and
- Have accepted a full-time faculty appointment to teach in a program of medicine at:
    - The University of Florida;
    - The University of Miami;
    - The University of South Florida;
    - The Florida State University;
    - The Florida International University;
    - The University of Central Florida;
    - The Mayo Clinic College of Medicine in Jacksonville, Florida; or
    - The Florida Atlantic University.

Currently, a medical faculty certificate holder is required to pay an application fee of $500, and $424 for the issuance of the initial certificate.[4] The initial certificate is valid for 2 years, or until the applicant terminates the relationship with the medical school or teaching institution, whichever occurs sooner. To renew (or extend) a certificate, an applicant must submit an approved form, remit a renewal fee of $360,[5] and submit a letter from the dean of the medical school stating that the applicant is a distinguished medical scholar and an outstanding practicing physician.[6]

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[1] There are several different types of national examinations for medical doctors: a State Board Examination, National Board of Medical Examiners, United States Medical Licensing Examination, Federation Licensing Examination (FLEX), and Special Purpose Examination (SPEX).

[2] Section 458.3145(1), F.S.

[3] This education requirement is only applicable to applicants who have graduated from medical school after October 1, 1992. Section 458.3145(1)(h), F.S.

[4] Rule 64B8-3.002, F.A.C.

[5] However, for a medical faculty certificate renewed during calendar years 2015 and 2016, the renewal fee was $250. Rule 64B8-3.003, F.A.C.

[6] Section 458.3145(2), F.S.

There is no limit on the number of initial certificates a medical school or teaching institution may receive. However, the number of medical faculty certificates that may be renewed by each medical school or teaching institution is statutorily limited.[7] All medical schools, except the Mayo Clinic College of Medicine in Jacksonville, Florida, are limited to 30 renewed medical faculty certificates. The Mayo Clinic College of Medicine is limited to 10 renewed medical faculty certificates. The H. Lee Moffitt Cancer Center and Research Institute is also permitted to have up to 30 renewed faculty certificates.[8]

An annual review of each medical faculty certificate recipient is made by the dean of the certificate recipient's accredited 4-year medical school and reported to the Board of Medicine within the Department of Health on an annual basis.[9] According to the Department of Health, as of February 8, 2017, the Board of Medicine oversees 51 active medical faculty certificates.[10]

Temporary Registration of Physicians for Educational Purposes

The Board of Medicine may authorize any physician to provide medical care or treatment in connection with the education of students, residents, or faculty, upon the request of a Florida medical school dean or the medical director of a teaching hospital.[11] The physician must register with the Board of Medicine and demonstrate financial responsibility. The physician may only perform such medical care or treatment for a single period of time, which may not exceed 180 consecutive days. No more than three physicians per year, per institution may be registered to provide such services. DOH has issued four temporary registrations of physicians for educational purposes since 2013.[12]

Johns Hopkins All Children's Pediatric Residency Program

The All Children's Hospital was founded in 1926 to care for children with polio and other crippling diseases, without regard for a patient's race, creed, or ability to pay.[13] After the development of the polio vaccine, the hospital changed its focus and dedicated itself to meeting a wide range of medical needs of infants, children, and teens. In April 2011, the hospital became fully integrated into the Johns Hopkins Health System.

Johns Hopkins Medicine is located in Baltimore, Maryland, and consists of Johns Hopkins Health System and Johns Hopkins University School of Medicine. The Johns Hopkins University School of Medicine has approximately 1,200 medical and doctoral students, 2,800 full-time faculty, and 1,200 part-time faculty.[14]

In July 2014, the Johns Hopkins All Children's Pediatric Residency Program received its first class of residents.[15] The focus of the residency program is to train pediatricians that will be prepared for the changing world of healthcare, and offer residents early and frequent opportunities to participate in clinical research under the mentorship of the Johns Hopkins All Children's Hospital and the faculty of the Johns Hopkins University School of Medicine.[16] Among the specialties services offered are a heart

[7] Section 458.3145(4), F.S.
[8] *Id.*
[9] Section 458.3145(5), F.S.
[10] E-mail correspondence with Department of Health staff dated February 8, 2017, on file with the Health and Human Services Committee.
[11] Section 458.3145(6), F.S.
[12] E-mail correspondence with Department of Health staff dated March 13, 2017, on file with the Health and Human Services Committee.
[13] Johns Hopkins Medicine, "A Bright Future for Johns Hopkins All Children's Hospital," *available at* https://www.hopkinsallchildrens.org/about-us/johns-hopkins-medicine (last visited March 10, 2017).
[14] Johns Hopkins Medicine, *Excellence and Discovery: An Overview*, p. 13, *available at* http://www.hopkinsmedicine.org/about/downloads/jhm-overview.pdf (last visited March 10, 2017).
[15] Johns Hopkins Medicine, Office of Medical Education, "About Johns Hopkins All Children's Pediatric Residency Program," *available at* http://ome.allkids.org/residency (last visited March 10, 2017).
[16] Johns Hopkins Medicine, Office of Medical Education, "Johns Hopkins All Children's Hospital Pediatric Residency Frequently Asked Questions," *available at* http://ome.allkids.org/faq (last visited March 10, 2017).

institute, a cancer & blood disorder institute, an institute for brain protection sciences, a maternal, fetal, and neonatal institute, pediatric surgery, and other specialty services.[17]

Currently, physicians teaching at the hospital may not obtain a medical faculty certificate because the Johns Hopkins All Children's Hospital in St. Petersburg, Florida, in not included in the list of institutions whose full-time employees are eligible to apply for a medical faculty certificate under s. 458.3145, F.S.

Effect of Proposed Changes

Medical Faculty Certificates

The bill expands the current medical faculty certificate eligibility by allowing a medical faculty certificate to be issued without examination to an individual who has been offered and has accepted a full-time faculty appointment to teach in a program of medicine at the Johns Hopkins All Children's Hospital in St. Petersburg, Florida. The bill also limits the number of medical faculty certificates the Board of Medicine may issue to eligible faculty at the Johns Hopkins All Children's Hospital in St. Petersburg, Florida, to 30 persons, which is consistent with limitations for all but one of the other institutions eligible for such certificates.

Temporary Registration of Physicians for Educational Purposes

Under current law, a dean of a Florida medical school located the medical directors of statutory teaching hospitals in this state may request registration and authorization of a physician to provide medical care or treatment, in connection with the education of students, residents, or faculty. The physician registers with Board of Medicine and demonstrates financial responsibility[18] and may not provide such services for more than 180 executive days. The bill expands the temporary registration to include physicians providing medical care or treatment at a specialty-licensed children's hospital licensed under ch. 395, F.S., that is affiliated with an accredited medical school and its affiliated clinics, for educational purposes.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.3145, F.S., relating to medical faculty certificate.
Section 2: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Division of Medical Quality Assurance within the Department of Health may see an increase in workload from processing additional medical faculty certificates and certificate renewals. However, the application fee of $500, the initial license fee of $424, and the renewal license fee of $360 should support the workload increase.

[17] Johns Hopkins Medicine, *Specialty Services Facts: Johns Hopkins All Children's Hospital*, October 2016, *available at* http://www.hopkinsmedicine.org/about/downloads/all_childrens_hospital.pdf (last visited March 10, 2017).

[18] Under s. 458.320, F.S., a physician must maintain liability coverage of at least $100,000, with a minimum annual aggregate of at least $300,000, or an escrow account or irrevocable credit of letter for the same amounts.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 15, 2017, the Health Quality Subcommittee adopted an amendment that authorizes the medical director of a specialty-licensed children's hospital licensed under chapter 395 that is affiliated with an accredited medical school and its affiliated clinics, to request for a physician who is not licensed in Florida be temporarily registered and allowed to provide medical care or treatment for educational purposes.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

1 A bill to be entitled
2 An act relating to medical faculty certification;
3 amending s. 458.3145, F.S.; revising the list of
4 schools at which certain faculty members are eligible
5 to receive a medical faculty certificate; authorizing
6 a certificateholder to practice at certain specialty-
7 licensed children's hospitals; revising provisions to
8 allow the medical director of certain specialty-
9 licensed children's hospitals to request the provision
10 of medical care and treatment in connection with
11 education; providing an effective date.
12
13 Be It Enacted by the Legislature of the State of Florida:
14
15 Section 1. Section 458.3145, Florida Statutes, is amended
16 to read:
17 458.3145 Medical faculty certificate.—
18 (1) A medical faculty certificate may be issued without
19 examination to an individual who:
20 (a) Is a graduate of an accredited medical school or its
21 equivalent, or is a graduate of a foreign medical school listed
22 with the World Health Organization;
23 (b) Holds a valid, current license to practice medicine in
24 another jurisdiction;
25 (c) Has completed the application form and remitted a

26 nonrefundable application fee not to exceed $500;
27 (d) Has completed an approved residency or fellowship of
28 at least 1 year or has received training which has been
29 determined by the board to be equivalent to the 1-year residency
30 requirement;
31 (e) Is at least 21 years of age;
32 (f) Is of good moral character;
33 (g) Has not committed any act in this or any other
34 jurisdiction which would constitute the basis for disciplining a
35 physician under s. 458.331;
36 (h) For any applicant who has graduated from medical
37 school after October 1, 1992, has completed, before entering
38 medical school, the equivalent of 2 academic years of
39 preprofessional, postsecondary education, as determined by rule
40 of the board, which must include, at a minimum, courses in such
41 fields as anatomy, biology, and chemistry; and
42 (i) Has been offered and has accepted a full-time faculty
43 appointment to teach in a program of medicine at:
44 1. The University of Florida;
45 2. The University of Miami;
46 3. The University of South Florida;
47 4. The Florida State University;
48 5. The Florida International University;
49 6. The University of Central Florida;
50 7. The Mayo Clinic College of Medicine in Jacksonville,

51 Florida; ~~or~~
52 8. The Florida Atlantic University; or
53 9. The Johns Hopkins All Children's Hospital in St.
54 Petersburg, Florida.
55 (2) The certificate authorizes the holder to practice only
56 in conjunction with his or her faculty position at an accredited
57 medical school and its affiliated clinical facilities or
58 teaching hospitals that are registered with the Board of
59 Medicine as sites at which holders of medical faculty
60 certificates will be practicing, or a specialty-licensed
61 children's hospital licensed under chapter 395 that is
62 affiliated with an accredited medical school and its affiliated
63 clinics. Such certificate automatically expires when the
64 holder's relationship with the medical school is terminated or
65 after a period of 24 months, whichever occurs sooner, and is
66 renewable every 2 years by a holder who applies to the board on
67 a form prescribed by the board and provides certification by the
68 dean of the medical school that the holder is a distinguished
69 medical scholar and an outstanding practicing physician.
70 (3) The holder of a medical faculty certificate issued
71 under this section has all rights and responsibilities
72 prescribed by law for the holder of a license issued under s.
73 458.311, except as specifically provided otherwise by law. Such
74 responsibilities include compliance with continuing medical
75 education requirements as set forth by rule of the board. A

76 hospital or ambulatory surgical center licensed under chapter
77 395, health maintenance organization certified under chapter
78 641, insurer as defined in s. 624.03, multiple-employer welfare
79 arrangement as defined in s. 624.437, or any other entity in
80 this state, in considering and acting upon an application for
81 staff membership, clinical privileges, or other credentials as a
82 health care provider, may not deny the application of an
83 otherwise qualified physician for such staff membership,
84 clinical privileges, or other credentials solely because the
85 applicant is a holder of a medical faculty certificate under
86 this section.
87 (4) In any year, the maximum number of extended medical
88 faculty certificateholders as provided in subsection (2) may not
89 exceed 30 persons at each institution named in subparagraphs
90 (1)(i)1.-6., 8., and 9. ~~and 8.~~ and at the facility named in s.
91 1004.43 and may not exceed 10 persons at the institution named
92 in subparagraph (1)(i)7.
93 (5) Annual review of all such certificate recipients will
94 be made by the deans of the accredited 4-year medical schools
95 provided in paragraph (1)(i) of this section ~~within this state~~
96 and reported to the Board of Medicine.
97 (6) Notwithstanding subsection (1), any physician, when
98 providing medical care or treatment in connection with the
99 education of students, residents, or faculty at the request of
100 the dean of an accredited medical school within this state or at

101 the request of the medical director of a statutory teaching
102 hospital as defined in s. 408.07 or a specialty-licensed
103 children's hospital licensed under chapter 395 that is
104 affiliated with an accredited medical school and its affiliated
105 clinics, may do so upon registration with the board and
106 demonstration of financial responsibility pursuant to s.
107 458.320(1) or (2) unless such physician is exempt under s.
108 458.320(5)(a). The performance of such medical care or treatment
109 must be limited to a single period of time, which may not exceed
110 180 consecutive days, and must be rendered within a facility
111 registered under subsection (2) or within a statutory teaching
112 hospital as defined in s. 408.07. A registration fee not to
113 exceed $300, as set by the board, is required of each physician
114 registered under this subsection. However, no more than three
115 physicians per year per institution may be registered under this
116 subsection, and an exemption under this subsection may not be
117 granted to a physician more than once in any given 5-year
118 period.
119 Section 2. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	____

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee
3 Representative Miller, A. offered the following:
4
5 **Amendment (with title amendment)**
6 Between lines 14 and 15, insert:
7
8 Section 1. Subsection (1) of section 456.013, Florida
9 Statutes, is amended to read:
10 456.013 Department; general licensing provisions.—
11 (1)(a) Any person desiring to be licensed in a profession
12 within the jurisdiction of the department shall apply to the
13 department in writing to take the licensure examination. The
14 application shall be made on a form prepared and furnished by
15 the department. The application form must be available on the
16 World Wide Web and the department may accept electronically

17 submitted applications beginning July 1, 2001. The application
18 shall require the social security number of the applicant,
19 except as provided in paragraphs ~~paragraph~~ (b) and (c). The form
20 shall be supplemented as needed to reflect any material change
21 in any circumstance or condition stated in the application which
22 takes place between the initial filing of the application and
23 the final grant or denial of the license and which might affect
24 the decision of the department. If an application is submitted
25 electronically, the department may require supplemental
26 materials, including an original signature of the applicant and
27 verification of credentials, to be submitted in a nonelectronic
28 format. An incomplete application shall expire 1 year after
29 initial filing. In order to further the economic development
30 goals of the state, and notwithstanding any law to the contrary,
31 the department may enter into an agreement with the county tax
32 collector for the purpose of appointing the county tax collector
33 as the department's agent to accept applications for licenses
34 and applications for renewals of licenses. The agreement must
35 specify the time within which the tax collector must forward any
36 applications and accompanying application fees to the
37 department.

38 (b) If an applicant has not been issued a social security
39 number by the Federal Government at the time of application
40 because the applicant is not a citizen or resident of this
41 country, the department may process the application using a

42 unique personal identification number. If such an applicant is
43 otherwise eligible for licensure, the board, or the department
44 when there is no board, may issue a temporary license to the
45 applicant, which shall expire 30 days after issuance unless a
46 social security number is obtained and submitted in writing to
47 the department. Upon receipt of the applicant's social security
48 number, the department shall issue a new license, which shall
49 expire at the end of the current biennium.
50 (c) Notwithstanding any other provision of law, if an
51 applicant for a temporary certificate as set forth in s.
52 458.3137 has not been issued a social security number by the
53 Federal Government at the time of application because the
54 applicant is not a citizen or resident of this country, the
55 department shall process the application using a unique personal
56 identification number. If such applicant is otherwise eligible
57 for the temporary certificate, the board, or the department when
58 there is no board, shall issue the temporary certificate without
59 requiring the applicant to provide a social security number.
60 Section 2. Subsection (1) of section 458.3137, Florida
61 Statutes, is amended to read:
62 458.3137 Temporary certificate for visiting physicians to
63 obtain medical privileges for instructional purposes in
64 conjunction with certain plastic surgery or other medical or
65 surgical training programs and educational symposiums.—
66 (1) A physician who has been invited by:

67 (a) A plastic surgery or other medical or surgical
68 training program affiliated with a medical school in this state
69 which is accredited by the Accreditation Council for Graduate
70 Medical Education or the American Osteopathic Association or
71 which is part of a teaching hospital as defined in s. 408.07; ~~or~~
72 (b) A teaching hospital as defined in s. 408.07; or
73 (c ~~b~~) An educational symposium cosponsored by the American
74 Society of Plastic Surgeons, the Plastic Surgery Educational
75 Foundation, the American Society for Aesthetic Plastic Surgery,
76 or any other medical or surgical society in conjunction with a
77 medical school or teaching hospital as defined in s. 408.07,
78
79 may be issued a temporary certificate for limited privileges
80 solely for purposes of providing educational training in plastic
81 surgery or other medical or surgical procedures, as appropriate,
82 in accordance with the restrictions set forth in this section.
83
84 ---
85 **T I T L E A M E N D M E N T**
86 Between lines 2 and 3, insert:
87 amending s. 456.013, F.S.; providing criteria for an applicant
88 of a temporary certificate for visiting physicians to obtain
89 medical privileges for instructional purposes who has not been
90 issued a social security number; amending s. 458.337, F.S.;
91 revising the circumstances under which a visiting physician may

92 be issued a temporary certificate to obtain medical privileges
93 for instructional purposes;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 217 Children Obtaining Driver Licenses
SPONSOR(S): Children, Families & Seniors Subcommittee, Sullivan, Albritton and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 60

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	14 Y, 0 N, As CS	Tuszynski	Brazzell
2) Health Care Appropriations Subcommittee	14 Y, 0 N	Fontaine	Pridgeon
3) Health & Human Services Committee		Tuszynski TT	Calamas CC

SUMMARY ANALYSIS

Florida's dependency system safeguards child welfare by providing services to prevent child abandonment, abuse, and neglect. The Department of Children and Families (DCF) works in partnership with local communities and the courts to ensure the safety, timely permanency, and well-being of children in the dependency system.

Children in the dependency system sometimes face barriers to having everyday life experiences common to young people their age. Florida statute recognizes that children in the dependency system should have normal age-appropriate experiences. One typical experience for teenagers is obtaining a driver license, which can facilitate having a job, attending school, engaging socially, and contributing to the community.

The Florida Legislature authorized the Keys to Independence Act in 2014. This created a 3-year pilot program to help children in licensed foster care overcome barriers to getting a driver license, such as the costs of education, licensure, and insurance, by providing reimbursement.

HB 217 makes the Keys to Independence program permanent. The bill expands the program to include, under certain conditions, children in non-licensed out-of-home care who have reached permanency or turned 18.

The bill requires the child's transition plan and the court to address the child's obtaining a driver license.

The bill permits a guardian ad litem authorized by a minor's caregiver to sign for the minor's learner license and not assume any obligation or liability for damages caused by the minor.

The current program is funded with a recurring appropriation of $800,000 and will not require additional resources for this proposed expansion. The bill has no fiscal impact on local governments.

The bill has an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Child Welfare System

Florida's dependency system safeguards child welfare by providing services to prevent child abandonment, abuse, and neglect.[1] The Department of Children and Families (DCF) works in partnership with local communities and the courts to ensure the safety, timely permanency, and well-being of children in the dependency system.

DCF contracts for foster care and related services with lead agencies, also known as community-based care organizations (CBCs). The transition to outsourced provision of child welfare services was intended to increase local community ownership of service delivery and design.[2]

DCF, through the CBCs, administers a system of care[3] for children to:

- Prevent children's separation from their families;
- Intervene to allow children to remain safely in their own homes;
- Reunify families who have had children removed from their care, if possible and appropriate;
- Ensure safety and normalcy for children who are separated from their families;
- Enhance children's well-being of children through educational stability and timely health care;
- Provide permanency; and
- Develop their independence and self-sufficiency.

Normalcy and Driver Licenses

Children in the dependency system sometimes face barriers to participating in everyday life experiences common to young people their age. Florida statute recognizes that children in out-of-home care are entitled to age-appropriate extracurricular, enrichment, and social activities.[4]

Nationally, 24.5% of 16-year-olds, 44.9% of 17-year-olds, and 60.1% of 18-year-olds are licensed drivers.[5]

DCF contracts with a private not-for-profit to survey youth in foster care every six months and to publish findings.[6] The Spring 2016 survey reported very different numbers for foster care youth who have driver licenses:

- 0% of 16-year-olds (1 child of 235 surveyed);
- 5% of 17-year-olds (12 children of 235 surveyed); and
- 3% of the total number of children surveyed (13 of 470 surveyed).

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[1] S. 39.001(8), F.S.

[2] Community-Based Care, The Department of Children and Families, accessible at http://www.myflfamilies.com/service-programs/community-based-care (last accessed January 28, 2017).

[3] S. 409.145(1), F.S.

[4] S. 409.145(3)(b)(1), F.S.

[5] Sivak, M., Schoettle, B, *Recent Decreases in the Proportion of Persons with a Driver's License Across All Age Groups*, The University of Michigan Transportation Research Institute, January 2016, available at http://www.umich.edu/~umtriswt/PDF/UMTRI-2016-4.pdf (last accessed February 13, 2017).

[6] My Services, Florida's Youth Survey: Spring 2016, available at http://www.dcf.state.fl.us/programs/indliving/docs/My%20Services%20Spring%202016%20Final.pdf (last accessed February 13, 2017).

The children surveyed reported the following percentages of learner license holders:

- 10% of 15-year-olds (23 children of 242 surveyed);
- 15% of 16-year-olds (35 children of 235 surveyed);
- 18% of 17-year-olds (43 children of 235 surveyed); and
- 14% of the total number of children surveyed (101 of 712 surveyed).

Barriers to a child in licensed out-of-home care being able to obtain a driver license include the costs of driver education, licensure, and motor vehicle insurance.[7]

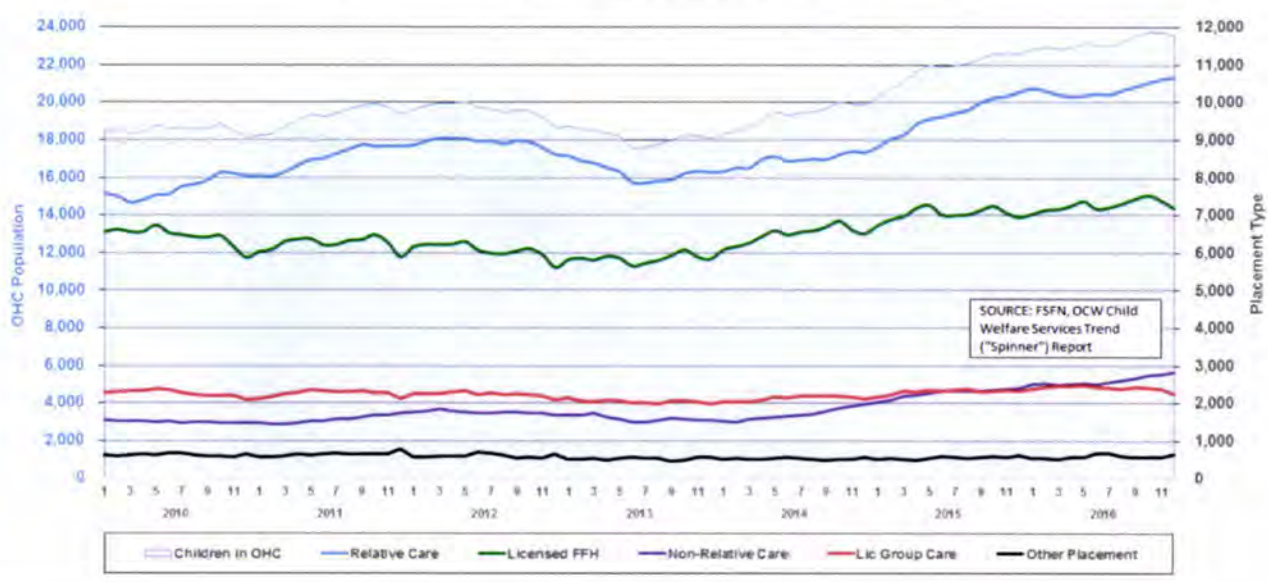
Types of Placement

While in-home services are preferred, the child welfare system finds appropriate out-of-home placements for those who cannot safely stay in their own homes. Placements that require licensure include family foster homes and residential child-caring agencies (group homes).[8] The following out-of-home placements do not require licensure by DCF:

- Relative caregivers, such as an aunt or grandmother;
- Non-relative caregivers, such as a neighbor or family friend;
- An adoptive home which has been approved by DCF or by a licensed child-placing agency for children placed for adoption; and
- Persons or neighbors who care for children in their homes for less than 90 days.[9]

Out-of-home placements in Florida have increased the last three years, particularly placements that do not require DCF licensure.[10] DCF reports that, according to the Florida Safe Families Network,[11] as of November 2016, approximately 3,000 children resided in out-of-home care who were in the eligible age range for the program, with almost 900 of those children in non-licensed placements.[12]

Children in Out-of-Home Care by Placement Type[13]



[7] S. 409.1454(1), F.S.; Keys to Independence, Legislative Report, June 2016, available at: https://www.dcf.state.fl.us/programs/childwelfare/docs/2016LMRs/Keys%20to%20Independence%20Annual%20Report.pdf (last accessed March 11, 2017).
[8] Id.
[9] S. 409.175, F.S.
[10] Department of Children and Families, Child Welfare Key Indicators Monthly Report, pg. 25, January 2017, available at: http://centerforchildwelfare.fmhi.usf.edu/qa/cwkeyindicator/KI_Monthly_Report_January_2017_Final.pdf (last accessed March 11, 2017).
[11] The FSFN system is the automated child welfare information system administered by the Department of Children and Families.
[12] Department of Children and Families, 2017 Agency Legislative Bill Analysis, HB 217, January 25, 2017.
[13] Supra, FN 10

Extended Foster Care

In 2014, the Legislature provided an option for extended foster care.[14] Previously, youth could not remain in foster care after their 18th birthday. Now, through extended foster care, they may remain in care until they turn 21 or, if enrolled in an eligible post-secondary institution, receive financial assistance until age 23 as they continue pursuing academic and career goals.[15] In extended foster care, young adults continue to receive case management services and other supports to provide them with a sound platform for success as independent adults.

Judicial Review

Children in foster care have judicial review hearings every 6 months. These hearings give the judge and all parties to a case an opportunity to review the case and the current status of permanency.[16] Prior to the judicial review hearing, DCF must provide the court and all parties a written report detailing many aspects of the child's placement and social well-being.

Keys to Independence Pilot Program

The Florida Legislature enacted the Keys to Independence Act in 2014 (Act),[17] which created a 3-year pilot program to help children in licensed foster care overcome barriers to getting a driver license, such as the costs of education, licensure, and insurance, by providing reimbursement.[18] The Act required DCF to contract with a not-for-profit entity whose mission is to support youth aging out of foster care to develop procedures for operating and administering the pilot program, to include:[19]

- Determining eligibility, including responsibilities for the child and caregivers.
- Developing application and payment forms.
- Notifying eligible children, caregivers, group homes, and residential programs of the pilot program.
- Providing technical assistance to lead agencies, providers, group homes, and residential programs to support removing obstacles that prevent children in foster care from driving.

Community Based Care of Central Florida (CBCCF) was selected to develop, implement, manage and market the statewide pilot with the goal of getting as many children in foster care driving as possible.[20] The pilot ends June 30, 2017.

In the pilot program, youth aged 15-21 in licensed out-of-home care may be reimbursed for fees associated with obtaining a driver license, such as:

- Learner license fee
- Driver license fee
- Testing fees
- 4-Hour Traffic Law & Substance Abuse Course
- Driver education course
- Monthly insurance premium
- Insurance deductible

[14] S. 39.6251, F.S.
[15] The Department of Children and Families, Extended Foster Care – My Future My Choice, available at: http://www.myflfamilies.com/service-programs/independent-living/extended-foster-care (last accessed March 10, 2017).
[16] S. 39.701, F.S.
[17] S. 409.1454, F.S.
[18] Keys to Independence, Legislative Report, June 2016, available at https://www.dcf.state.fl.us/programs/childwelfare/docs/2016LMRs/Keys%20to%20Independence%20Annual%20Report.pdf (last accessed March 10, 2017).
[19] S. 409.1454(5), F.S.
[20] Supra, FN 18 at pg. 3; *See* s. 409.1454(5), F.S.

Section 322.02(2), F.S., requires any individual under the age of 18 to hold a learner license for 12-months before testing for a driver license. The vast majority of youth enrolling in the Keys to Independence program enroll without a learner license (75%).[21]

Results of the Pilot

The program was advertised through many means, including a dedicated website, social media, targeted emails, and at trainings and outreach events held throughout the state. Program staff conducted in-person trainings in all CBC service areas, offering multiple presentations to groups of case managers, Guardians ad Litem, foster parents, residential providers, CBC staff and other stakeholders.[22]

As of December 31, 2016, 1,276 children in licensed out-of-home care were enrolled in the program. The chart below summarizes the results for the pilot by year.[23]

Keys to Independence Participants[24]			
Participation Area	Number of Participants		
	FY 2014-15 (Pilot Year 1)	FY 2015-16 (Pilot Year 2)	FY 2016-17 YTD[25] (Pilot Year 3)
Passed 4-Hour Traffic Law & Substance Abuse Course	45	126	109
Obtained Learner License	74	127	91
Took Driver Education Class	32	82	97
Obtained Driver License	30	65	59
Received Reimbursement for Insurance[26]	17	36	38

Keys to Independence Enrollment: Youth Ages 15-17 in Licensed Out-of-Home Care by CBC through December 1, 2016[27]					
Circuit	Counties	Lead Agency	# of Enrolled Children	Total Eligible	% Enrolled
1	Escambia, Okaloosa, Santa Rosa, Walton	Families First Network	24	96	25.0%
2, 14	Franklin, Gadsden, Jefferson, Leon, Liberty, Wakulla, Bay, Calhoun, Gulf, Holmes, Jackson, Washington	Big Bend CBC	23	53	43.4%

[21] Supra, FN 18 at pg. 3.
[22] Supra, FN 18 at pg. 7-8.
[23] Community Based Care Keys to Independence Program, *Mid-Year Snapshot*, December 2016 (on file with Children, Families, & Seniors Subcommittee).
[24] Email from David Finucane, Initiative Support Manager, Community Based Care of Central Florida, Re: Updated One Sheeter on Budget, (February 13, 2017).
[25] As of February 13, 2017.
[26] Insurance is reflective of those insurance policies for which the Keys to Independence program has provided reimbursement. Young adults over the age of 18 are not required to have auto insurance in the State of Florida unless they own a vehicle.
[27] Supra, FN 23.

Keys to Independence Enrollment: Youth Ages 15-17 in Licensed Out-of-Home Care by CBC through December 1, 2016[27]					
Circuit	Counties	Lead Agency	# of Enrolled Children	Total Eligible	% Enrolled
3, 8	Columbia, Dixie, Hamilton, Lafayette, Madison, Suwannee, Taylor, Alachua, Baker, Bradford, Gilchrist, Levy, Union	Partnership for Strong Families	16	34	47.1%
4	Clay	Kids First of Florida	10	14	71.4%
4	Duval, Nassau	Family Support Services of North Florida	47	52	90.4%
7	St, Johns	St. Johns County Board of Commissioners	8	9	88.9%
7	Flagler, Putnam, Volusia	Community Partnership of Children	58	61	95.1%
5	Citrus, Hernando, Lake, Marion, Sumter	Kids Central	76	82	92.7%
9	Orange, Osceola	CBC of Central Florida	71	92	77.2%
10	Hardee, Highlands, Polk	Heartland for Children	44	54	81.5%
18	Seminole	CBC of Central Florida	26	27	96.3%
18	Brevard	Brevard Family Partnership	16	41	39.0%
6	Pasco, Pinellas	Eckerd Community Alternatives	104	125	83.2%
12	DeSoto, Manatee, Sarasota	Sarasota Family YMCA	22	62	35.5%
13	Hillsborough	Eckerd Community Alternatives	95	132	72.0%
20	Charlotte, Collier, Glades, Hendry, Lee	Children's Network of Southwest Florida	38	97	39.2%
15	Palm Beach	ChildNet	32	104	30.8%
17	Broward	ChildNet	62	168	36.9%
19	Indian River, Martin, Okeechobee, St. Lucie	Devereux Families	29	34	85.3%
11, 16	Miami-Dade, Monroe	Our Kids of Miami-Dade/Monroe	40	174	23.0%
Statewide Total			**841**	**1511**	**55.6%**

Special Driver's License and Insurance Provisions for Foster Children and Foster Parents

Among the primary obstacles to these children being able to drive is the potential liability of the foster parents when the children drive vehicles owned by the foster parents and the attendant cost of insurance to protect foster parents from this liability.

Section 322.09(2), F.S., provides that any negligence or willful misconduct of the child operating a motor vehicle will be imputed to the adult who signed the application. That adult is jointly and severally liable with the child for any damages caused by the negligent or willful misconduct.

In 2001, s. 322.09, F.S., was amended to relieve foster parents or authorized representatives of a residential group home who sign for a foster child's license of liability for any damages or misconduct of the child.[28] While this provision addresses liability resulting directly from the signature on the driver license application, it does not address any vicarious liability that the foster parent may have because of the foster parent's ownership of the vehicle that the child drives.[29] This liability arises whenever an insured individual allows another to operate his or her motor vehicle and is independent of the provisions of s. 322.09, F.S. Thus, the foster parent who owns the motor vehicle continues to be subject to vicarious liability for the actions of the child while operating the foster parent's vehicle, in the same way the foster parent would be vicariously liable for the actions of any other person operating that vehicle. This vicarious liability is one of the risks for which insurance coverage is purchased.

Also in 2001, s. 627.746, F.S., was created to prohibit a motor vehicle insurance company from charging an additional premium on a motor vehicle owned by a foster parent for coverage of a child operating the vehicle while the child is holding a learner license.[30] This prohibition is only applicable until the child obtains a regular driver license.

Effect of the Bill

The bill makes the Keys to Independence program permanent. It expands eligibility to children in the dependency system placed in non-licensed out-of-home placements, such as with relative and non-relative caregivers.

The bill extends the ability to receive the benefits of the program to six months after having achieved permanency or turning 18 years of age. Young adults who have chosen to extend foster care[31] would need to demonstrate that the cost of obtaining a driver license is a barrier to obtaining employment or completing educational goals. For any child 15 years of age or older, the bill requires a determination that appropriate steps are being taken to obtain a driver license or learner license at judicial reviews. Review hearings after a child has reached 17 years of age will require written verification that information on how to obtain a driver license has been provided to the child and that the child's transition plan addresses the option to obtain a driver license.

The bill also requires the non-for-profit contracted to run the program to publicize, engage in outreach, and provide incentives to encourage youth to obtain driver licenses.

The bill also permits a guardian ad litem authorized by a caregiver to sign for a learner license and not assume any obligation or liability for any damages caused by the minor.

Finally, the bill reenacts multiple sections of statute to incorporate conforming changes.

The bill provides for an effective date of upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 409.1454, F.S., relating to motor vehicle insurance for children in care.
Section 2: Amends s. 39.6035, F.S., relating to transition plans.
Section 3: Amends s. 39.701, F.S., relating to judicial review.
Section 4: Amends s. 322.09, F.S., relating to application of minors; responsibility for negligence or misconduct of minor.
Section 5: Reenacts s. 409.1451, F.S., relating to the Road-to-Independence program.
Section 6: Reenacts s. 322.05, F.S., relating to persons not to be licensed.
Section 7: Reenacts s. 322.56, F.S., relating to contracts for administration of driver license examination.
Section 8: Provides for an effective date of upon becoming law.

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[28] Chapter 2001-83, Laws of Fla.
[29] See Hertz Corp. vs. Jackson, 617 So.2d 105 (Fla. 1993).
[30] Chapter 2001-83, Laws of Fla.
[31] S. 39.6251, F.S., allows a child, who meets certain criteria and who is living in licensed care when they turn 18 years of age, to elect to remain under the jurisdiction of the dependency court and in the care of DCF until 21 years of age.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The department anticipates that any increase in expenditures can be funded within existing resources.[32] The current program is funded with an annual appropriation of $800,000 from the General Revenue Fund and should require no additional resources for the proposed expansion.[33] Section 409.1454(4), F.S., limits program expenditures to available funding.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The program received a recurring $800,000 appropriation of general revenue funds pursuant to Chapter 2014-166, Laws of Florida. Actual program expenditures have been less than the recurring appropriation amount as shown in the table below.

Expenditures by Fiscal Year[34]			
	Actual Expenditures FY 2014-15	Actual Expenditures FY 2015-16	Projected Expenditures FY 2016-17
Fixed Expenses	$161,060	$225,923	$384,889
Cost-Reimbursed Expenses	$30,923	$104,262	$138,568
Total Expenses	**$191,983**	**$330,185**	**$523,457**

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to affect county or municipal governments.

[32] Department of Children and Families, Agency Analysis of 2017 House Bill 217, p. 4 (January 25, 2017).
[33] Supra, FN 24.
[34] Supra, FN 24.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 16, 2017, the Children, Families, and Seniors Subcommittee adopted an amendment that maintains the program in ch. 409, F.S., instead of moving it to ch. 39, F.S. This aligns the House bill with the Senate companion.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

1 A bill to be entitled
2 An act relating to children obtaining driver licenses;
3 amending s. 409.1454, F.S.; revising legislative
4 findings; revising a pilot program to make it
5 permanent; revising the applicability of the program
6 to children in out-of-home care; authorizing the
7 program to pay for a child to complete a driver
8 education program and obtain a driver license or the
9 related costs of licensure under certain
10 circumstances; revising the duties of the Department
11 of Children and Families under the program; deleting
12 the requirement for an annual report by the department
13 to the Governor and the Legislature; amending s.
14 39.6035, F.S.; revising a child's transition plan to
15 include options to use in obtaining a driver license
16 under certain circumstances; amending s. 39.701, F.S.;
17 revising a required determination made by the court
18 and a citizen review panel; requiring the department
19 to include specified information in the social study
20 report for judicial review under certain
21 circumstances; amending s. 322.09, F.S.; providing
22 that a guardian ad litem authorized by a minor's
23 caregiver to sign for the minor's learner's driver
24 license does not assume any obligation or liability
25 for damages; making technical changes; reenacting s.

26 409.1451(5)(a), F.S., relating to the Road-to-
27 Independence Program, to incorporate the amendment
28 made to s. 39.6035, F.S., in a reference thereto;
29 reenacting ss. 322.05(3), relating to issuance of
30 driver licenses to certain minors, and 322.56(8)(a),
31 F.S., relating to the administration of testing
32 programs for learner's driver licenses, to incorporate
33 the amendment made to s. 322.09, F.S., in references
34 thereto; providing an effective date.
35
36 Be It Enacted by the Legislature of the State of Florida:
37
38 Section 1. Section 409.1454, Florida Statutes, is amended,
39 to read:
40 409.1454 MOTOR VEHICLE INSURANCE AND DRIVER LICENSES FOR
41 CHILDREN IN CARE.—
42 (1) The Legislature finds that the costs of driver
43 education, licensure and costs incidental to licensure, and
44 motor vehicle insurance for a child in ~~licensed~~ out-of-home care
45 after such child obtains a driver license create ~~creates~~ an
46 additional barrier to engaging in normal age-appropriate
47 activities and gaining independence and may limit opportunities
48 for obtaining employment and completing educational goals. The
49 Legislature also finds that the completion of an approved driver
50 education course is necessary to develop safe driving skills.

51 (2) To the extent that funding is available, the
52 department shall establish a ~~3-year pilot~~ program to pay the
53 cost of driver education, licensure and other costs incidental
54 to licensure, and motor vehicle insurance for children in
55 ~~licensed~~ out-of-home care who have successfully completed a
56 driver education program.
57 (3) If a caregiver, or an individual or not-for-profit
58 entity approved by the caregiver, adds a child to his or her
59 existing insurance policy, the amount paid to the caregiver or
60 approved purchaser may not exceed the increase in cost
61 attributable to the addition of the child to the policy.
62 (4) Payment shall be made to eligible recipients in the
63 order of eligibility until available funds are exhausted. If a
64 child determined to be eligible reaches permanency status or
65 turns 18 years of age, the program may pay for that child to
66 complete a driver education program and obtain a driver license
67 for up to 6 months after the date the child reaches permanency
68 status or 6 months after the date the child turns 18 years of
69 age. A child continuing in care under s. 39.6251 may be eligible
70 to have the costs of licensure and costs incidental to licensure
71 paid if the child demonstrates that such costs are creating
72 barriers for obtaining employment or completing educational
73 goals.
74 (5) The department shall contract with a not-for-profit
75 entity whose mission is to support youth aging out of foster

76 care to develop procedures for operating and administering the
77 ~~pilot~~ program, including, but not limited to:
78 (a) Determining eligibility, including responsibilities
79 for the child and caregivers.
80 (b) Developing application and payment forms.
81 (c) Notifying eligible children, caregivers, group homes,
82 and residential programs of the ~~pilot~~ program.
83 (d) Providing technical assistance to lead agencies,
84 providers, group homes, and residential programs to support
85 removing obstacles that prevent children in foster care from
86 driving.
87 (e) Publicizing the program, engaging in outreach, and
88 providing incentives to youth participating in the program to
89 encourage the greatest number of eligible children to obtain
90 driver licenses.
91 ~~(6) By July 1, 2015, and annually thereafter for the~~
92 ~~duration of the pilot program, the department shall submit a~~
93 ~~report to the Governor, the President of the Senate, and the~~
94 ~~Speaker of the House of Representatives evaluating the success~~
95 ~~of and outcomes achieved by the pilot program. The report shall~~
96 ~~include a recommendation as to whether the pilot program should~~
97 ~~be continued, terminated, or expanded.~~
98 Section 2. Subsection (1) of section 39.6035, Florida
99 Statutes, is amended to read:
100 39.6035 Transition plan.—

101 (1) During the 180-day period after a child reaches 17
102 years of age, the department and the community-based care
103 provider, in collaboration with the caregiver and any other
104 individual whom the child would like to include, shall assist
105 the child in developing a transition plan. The required
106 transition plan is in addition to standard case management
107 requirements. The transition plan must address specific options
108 for the child to use in obtaining services, including housing,
109 health insurance, education, a driver license, and workforce
110 support and employment services. The plan must also consider
111 establishing and maintaining naturally occurring mentoring
112 relationships and other personal support services. The
113 transition plan may be as detailed as the child chooses. In
114 developing the transition plan, the department and the
115 community-based provider shall:
116 (a) Provide the child with the documentation required
117 pursuant to s. 39.701(3); and
118 (b) Coordinate the transition plan with the independent
119 living provisions in the case plan and, for a child with
120 disabilities, the Individuals with Disabilities Education Act
121 transition plan.
122 Section 3. Paragraph (c) of subsection (2) and paragraph
123 (a) of subsection (3) of section 39.701, Florida Statutes, are
124 amended to read:
125 39.701 Judicial review.—

126 (2) REVIEW HEARINGS FOR CHILDREN YOUNGER THAN 18 YEARS OF
127 AGE.—
128 (c) Review determinations.—The court and any citizen
129 review panel shall take into consideration the information
130 contained in the social services study and investigation and all
131 medical, psychological, and educational records that support the
132 terms of the case plan; testimony by the social services agency,
133 the parent, the foster parent or legal custodian, the guardian
134 ad litem or surrogate parent for educational decisionmaking if
135 one has been appointed for the child, and any other person
136 deemed appropriate; and any relevant and material evidence
137 submitted to the court, including written and oral reports to
138 the extent of their probative value. These reports and evidence
139 may be received by the court in its effort to determine the
140 action to be taken with regard to the child and may be relied
141 upon to the extent of their probative value, even though not
142 competent in an adjudicatory hearing. In its deliberations, the
143 court and any citizen review panel shall seek to determine:
144 1. If the parent was advised of the right to receive
145 assistance from any person or social service agency in the
146 preparation of the case plan.
147 2. If the parent has been advised of the right to have
148 counsel present at the judicial review or citizen review
149 hearings. If not so advised, the court or citizen review panel
150 shall advise the parent of such right.

151 3. If a guardian ad litem needs to be appointed for the
152 child in a case in which a guardian ad litem has not previously
153 been appointed or if there is a need to continue a guardian ad
154 litem in a case in which a guardian ad litem has been appointed.
155 4. Who holds the rights to make educational decisions for
156 the child. If appropriate, the court may refer the child to the
157 district school superintendent for appointment of a surrogate
158 parent or may itself appoint a surrogate parent under the
159 Individuals with Disabilities Education Act and s. 39.0016.
160 5. The compliance or lack of compliance of all parties
161 with applicable items of the case plan, including the parents'
162 compliance with child support orders.
163 6. The compliance or lack of compliance with a visitation
164 contract between the parent and the social service agency for
165 contact with the child, including the frequency, duration, and
166 results of the parent-child visitation and the reason for any
167 noncompliance.
168 7. The frequency, kind, and duration of contacts among
169 siblings who have been separated during placement, as well as
170 any efforts undertaken to reunite separated siblings if doing so
171 is in the best interest of the child.
172 8. The compliance or lack of compliance of the parent in
173 meeting specified financial obligations pertaining to the care
174 of the child, including the reason for failure to comply, if
175 applicable.

176 9. Whether the child is receiving safe and proper care
177 according to s. 39.6012, including, but not limited to, the
178 appropriateness of the child's current placement, including
179 whether the child is in a setting that is as family-like and as
180 close to the parent's home as possible, consistent with the
181 child's best interests and special needs, and including
182 maintaining stability in the child's educational placement, as
183 documented by assurances from the community-based care provider
184 that:
185 a. The placement of the child takes into account the
186 appropriateness of the current educational setting and the
187 proximity to the school in which the child is enrolled at the
188 time of placement.
189 b. The community-based care agency has coordinated with
190 appropriate local educational agencies to ensure that the child
191 remains in the school in which the child is enrolled at the time
192 of placement.
193 10. A projected date likely for the child's return home or
194 other permanent placement.
195 11. When appropriate, the basis for the unwillingness or
196 inability of the parent to become a party to a case plan. The
197 court and the citizen review panel shall determine if the
198 efforts of the social service agency to secure party
199 participation in a case plan were sufficient.
200 12. For a child who has reached 13 years of age but is not

201 yet 18 years of age, the adequacy of the child's preparation for
202 adulthood and independent living. For a child who is 15 years of
203 age or older, the court shall determine if appropriate steps are
204 being taken for the child to obtain a driver license or
205 learner's driver license.
206 13. If amendments to the case plan are required.
207 Amendments to the case plan must be made under s. 39.6013.
208 (3) REVIEW HEARINGS FOR CHILDREN 17 YEARS OF AGE.—
209 (a) In addition to the review and report required under
210 paragraphs (1)(a) and (2)(a), respectively, the court shall hold
211 a judicial review hearing within 90 days after a child's 17th
212 birthday. The court shall also issue an order, separate from the
213 order on judicial review, that the disability of nonage of the
214 child has been removed pursuant to ss. 743.044, 743.045,
215 743.046, and 743.047, and for any of these disabilities that the
216 court finds is in the child's best interest to remove. The court
217 shall continue to hold timely judicial review hearings. If
218 necessary, the court may review the status of the child more
219 frequently during the year before the child's 18th birthday. At
220 each review hearing held under this subsection, in addition to
221 any information or report provided to the court by the foster
222 parent, legal custodian, or guardian ad litem, the child shall
223 be given the opportunity to address the court with any
224 information relevant to the child's best interest, particularly
225 in relation to independent living transition services. The

226 department shall include in the social study report for judicial
227 review written verification that the child has:
228 1. A current Medicaid card and all necessary information
229 concerning the Medicaid program sufficient to prepare the child
230 to apply for coverage upon reaching the age of 18, if such
231 application is appropriate.
232 2. A certified copy of the child's birth certificate and,
233 if the child does not have a valid driver license, a Florida
234 identification card issued under s. 322.051.
235 3. A social security card and information relating to
236 social security insurance benefits if the child is eligible for
237 those benefits. If the child has received such benefits and they
238 are being held in trust for the child, a full accounting of
239 these funds must be provided and the child must be informed as
240 to how to access those funds.
241 4. All relevant information related to the Road-to-
242 Independence Program, including, but not limited to, eligibility
243 requirements, information on participation, and assistance in
244 gaining admission to the program. If the child is eligible for
245 the Road-to-Independence Program, he or she must be advised that
246 he or she may continue to reside with the licensed family home
247 or group care provider with whom the child was residing at the
248 time the child attained his or her 18th birthday, in another
249 licensed family home, or with a group care provider arranged by
250 the department.

251 5. An open bank account or the identification necessary to
252 open a bank account and to acquire essential banking and
253 budgeting skills.
254 6. Information on public assistance and how to apply for
255 public assistance.
256 7. A clear understanding of where he or she will be living
257 on his or her 18th birthday, how living expenses will be paid,
258 and the educational program or school in which he or she will be
259 enrolled.
260 8. Information related to the ability of the child to
261 remain in care until he or she reaches 21 years of age under s.
262 39.013.
263 9. A letter providing the dates that the child is under
264 the jurisdiction of the court.
265 10. A letter stating that the child is in compliance with
266 financial aid documentation requirements.
267 11. The child's educational records.
268 12. The child's entire health and mental health records.
269 13. The process for accessing his or her case file.
270 14. A statement encouraging the child to attend all
271 judicial review hearings occurring after the child's 17th
272 birthday.
273 <u>15. Information on how to obtain a driver license or</u>
274 <u>learner's driver license.</u>
275 Section 4. Subsection (4) of section 322.09, Florida

276 Statutes, is amended to read:
277 322.09 Application of minors; responsibility for
278 negligence or misconduct of minor.—
279 (4) Notwithstanding ~~the provisions of~~ subsections (1) and
280 (2), if a foster parent of a minor who is under the age of 18
281 years and is in foster care as defined in s. 39.01, an
282 authorized representative of a residential group home at which
283 such a minor resides, ~~or~~ the caseworker at the agency at which
284 the state has placed the minor<u>, or a guardian ad litem</u>
285 <u>specifically authorized by the minor's caregiver to sign for a</u>
286 <u>learner's driver license</u> signs the minor's application for a
287 learner's driver license, that foster parent, group home
288 representative, ~~or~~ caseworker<u>, or guardian ad litem</u> does not
289 assume any obligation or become liable for any damages caused by
290 the negligence or willful misconduct of the minor by reason of
291 having signed the application. <u>Before</u> ~~Prior to~~ signing the
292 application, the caseworker shall notify the foster parent or
293 other responsible party of his or her intent to sign and verify
294 the application.
295 Section 5. For the purpose of incorporating the amendment
296 made by this act to section 39.6035, Florida Statutes, in a
297 reference thereto, paragraph (a) of subsection (5) of section
298 409.1451, Florida Statutes, is reenacted to read:
299 409.1451 The Road-to-Independence Program.—
300 (5) PORTABILITY.—The services provided under this section

301 are portable across county lines and between lead agencies.
302 (a) The service needs that are identified in the original
303 or updated transition plan, pursuant to s. 39.6035, shall be
304 provided by the lead agency where the young adult is currently
305 residing but shall be funded by the lead agency who initiated
306 the transition plan.
307 Section 6. For the purpose of incorporating the amendment
308 made by this act to section 322.09, Florida Statutes, in a
309 reference thereto, subsection (3) of section 322.05, Florida
310 Statutes, is reenacted to read:
311 322.05 Persons not to be licensed.—The department may not
312 issue a license:
313 (3) To a person who is at least 16 years of age but who is
314 under 18 years of age, unless the parent, guardian, or other
315 responsible adult meeting the requirements of s. 322.09
316 certifies that he or she, or another licensed driver 21 years of
317 age or older, has accompanied the applicant for a total of not
318 less than 50 hours' behind-the-wheel experience, of which not
319 less than 10 hours must be at night. This subsection is not
320 intended to create a private cause of action as a result of the
321 certification. The certification is inadmissible for any purpose
322 in any civil proceeding.
323 Section 7. For the purpose of incorporating the amendment
324 made by this act to section 322.09, Florida Statutes, in a
325 reference thereto, paragraph (a) of subsection (8) of section

326 322.56, Florida Statutes, is reenacted to read:
327 322.56 Contracts for administration of driver license
328 examination.—
329 (8) The department shall contract with providers of
330 approved online traffic law and substance abuse education
331 courses to serve as third-party providers to conduct online, on
332 behalf of the department, examinations required pursuant to ss.
333 322.12 and 322.1615 to applicants for Class E learner's driver
334 licenses.
335 (a) The online testing program shall:
336 1. Use personal questions before the examination, which
337 the applicant is required to answer during the examination, to
338 strengthen test security to deter fraud;
339 2. Require, before the start of the examination, the
340 applicant's parent, guardian, or other responsible adult who
341 meets the requirements of s. 322.09 to provide the third-party
342 administrator with his or her driver license number and to
343 certify that the parent, guardian, or responsible adult will
344 monitor the applicant during the examination; and
345 3. Require, before issuance by the department of a
346 learner's driver license to an applicant who has passed an
347 online examination, the applicant's parent, guardian, or other
348 responsible adult who meets the requirements of s. 322.09 to
349 certify to the department that he or she monitored the applicant
350 during the online examination. This certification shall be

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

351 similar to the certification required by s. 322.05(3). This
352 subsection does not preclude the department from continuing to
353 provide written examinations at driver license facilities.
354 Section 8. This act shall take effect upon becoming a law.

CS/HB 375

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 375 Patient Safety Culture Surveys
SPONSOR(S): Health Care Appropriations Subcommittee; Grant, M. and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1434

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 4 N	Poche	Poche
2) Health Care Appropriations Subcommittee	10 Y, 4 N, As CS	Clark	Pridgeon
3) Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

CS/HB 375 requires the Agency for Health Care Administration (AHCA) to develop patient safety culture surveys to measure aspects of patient safety culture in hospitals and ambulatory surgical centers. The surveys will measure the frequency of adverse events, quality of handoffs and transitions, staff comfort in reporting a potential problem or error, the level of teamwork within hospital units and the facility as a whole, staff compliance with patient safety regulations and guidelines, staff's perception of facility support for patient safety, and staff's opinions on whether or not they would undergo a health care service or procedure at the facility. AHCA must review and analyze nationally recognized patient safety culture survey products, including, but not limited to, the surveys developed by the federal Agency for Healthcare Research and Quality and the Safety Attitudes Questionnaire developed by the University of Texas, to design the survey.

The bill requires facilities to annually conduct and submit the results of the AHCA-designed patient safety culture survey to the Florida Center for Health Information and Transparency, and authorizes AHCA to adopt rules for the survey and submission process. Submission of the culture survey is a condition of licensure. AHCA must include the survey results in the health care quality measures available to the public.

The bill also makes various conforming changes to reflect the provisions of the bill.

The bill provides an appropriation for AHCA to design and process the patient safety culture surveys. The bill provides an appropriation in the sum of $352,919 in recurring funds from the Health Care Trust Fund and one full-time equivalent (FTE) position with associated salary rate to implement the provisions contained within the bill.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Facility Regulation

Hospitals

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment.[2]

A specialty hospital, in addition to providing the same services as general hospitals, provides other services, including:

- A range of medical services restricted to a defined age or gender group;
- A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- Intensive residential treatment programs for children and adolescents.[3]

AHCA must maintain an inventory of hospitals with an emergency department.[4] The inventory must list all services within the capability of each hospital, and such services must appear on the face of the hospital's license. As of February 13, 2017, 218 of the 307 licensed hospitals in the state have an emergency department.[5]

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is $1,565.13 or $31.46 per bed, whichever is greater.[6] The survey fee is $400.00 or $12.00 per bed, whichever is greater.[7]

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.[8] The rules for general and specialty hospitals must include minimum standards to ensure:

- 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

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[1] S.395.002(12), F.S.
[2] Id.
[3] S. 395.002(28), F.S.
[4] S. 395.1041(2), F.S.
[5] Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals,* available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (reports generated on February 13, 2017).
[6] Rule 59A-3.006(3), F.A.C.
[7] S. 395.0161(3)(a), F.S.
[8] S. 395.1055(2), F.S.

- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[9]

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Ambulatory Surgical Centers (ASCs)

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[10] ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.[11] Applicants for ASC licensure must submit certain information to AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Proof of registration of articles of incorporation; and
- A zoning certificate or proof of compliance with zoning requirements.[12]

Upon receipt of an initial application, AHCA is required to conduct a survey to determine compliance with all laws and rules. ASCs 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
- The comprehensive Emergency Management Plan.[13]

AHCA is authorized to adopt rules for ASCs.[14] Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals,[15] but the rules for all ASCs must include the minimum standards listed above for hospitals.

The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.

Health Care Price and Quality Transparency

The United States is experiencing significant changes in health care payment and delivery. Record numbers of newly-insured persons are enrolled in both public and private health insurance. Americans bear a greater share of health care costs, and more participate in high deductible health plans. Clear, factual information about the cost and quality of health care is necessary for consumers to select value-driven health care options and for consumers and providers to be involved in and accountable for decisions about health and health care services. To promote consumer involvement, health care pricing and other data should be free, timely, reliable, and reflect individual health care needs and insurance coverage.

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[9] S. 395.1055(1), F.S.
[10] S. 395.002(3), F.S.
[11] SS. 395.001-1065, F.S., and Part II, Chapter 408, F.S.
[12] Rule 59A-5.003(4), F.A.C.
[13] Rule 59A-5.003(5), F.A.C.
[14] S. 395.1055, F.S.
[15] S. 395.1055(2), F.S.

Health Care Quality Transparency

Most Americans believe that the health care they receive is the best available, but the evidence shows otherwise.[16] Although the U.S. spends more than $3 trillion a year on health care,[17] 17.4 percent of the gross national product,[18] research shows that the quality of health care in America is, at best, imperfect, and, at worst, deeply flawed.[19] Issues with health care quality fall into three categories:

- Underuse. Many patients do not receive medically necessary care.
- Misuse. Each year, more than 100,000 Americans get the wrong care and are injured as a result. More than 1.5 million medication errors are made each year.
- Overuse. Many patients receive care that is not needed or for which there is an equally effective alternative that costs less money or causes fewer side effects.

Research indicates that quality of care in the U.S. is uneven. For example, Americans receive appropriate, evidence-based care when they need it only 55 percent of the time.[20] Similarly, more than 400,000 people die each year as a result of preventable hospital errors in the U.S.[21], and more than 75,000 people died in 2011 from an infection obtained while in the hospital.[22]

There are hundreds of health care quality measures developed, maintained, and evaluated for relevancy and accuracy by many different organizations, including the federal Agency for Healthcare Research and Quality, the National Quality Forum, and the National Committee for Quality Assurance. In general, health quality measures can be sorted into four categories:[23]

- **Structure measures**- assess the aspects of the health care setting, including facility, personnel, and policies related to the delivery of care.
    - Example- What is the nurse-to-patient ratio in a neonatal intensive care unit?
- **Process measures**- determine if the services provided to patients are consistent with routine clinical care.
    - Example- Does a doctor recommend prostate-specific antigen testing for his male patients at average risk for prostate cancer beginning at age 50?
- **Outcome measures**- evaluate patient health as a result of care received.
    - Example- What is the infection rate of patients undergoing cardiac surgery at a hospital?
- **Patient experience measures**- provide feedback on patients' experiences with the care received.
    - Example- Do patients recommend their doctor to others following a procedure?

Data on health care quality measures come from a number of sources. Some of the most common sources include:

- Health insurance claims and other administrative documents;

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[16] National Committee for Quality Assurance, *The Essential Guide to Health Quality*, page 6, available at http://www.ncqa.org/Portals/0/Publications/Resource/%20Library/NCQA_Primer_web.pdf (last viewed February 13, 2017).

[17] The Henry J. Kaiser Foundation, Peterson-Kaiser Health System Tracker, *Health Spending Explorer-U.S. Health Expenditures 1960-2014*, available at http://www.healthsystemtracker.org/interactive/health-spending-explorer/?display=U.S.%2520%2524%2520Billions&service=Hospitals%252CPhysicians%2520%2526%2520Clinics%252CPrescriptions%2520Drug (last viewed February 13, 2017).

[18] The World Bank, *Data-United States*, available at http://data.worldbank.org/country/united-states (last viewed February 13, 2017).

[19] Supra, FN 55.

[20] McGlynn, E.A., Asch, S.M., et al., *The quality of health care delivered to adults in the United States*, New England Journal of Medicine, 348(26): 2635-45, June 2, 2003.

[21] James, J., *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, Journal of Patient Safety, 9(3): 122-128 (September 2013).

[22] Centers for Disease Control, *Healthcare-associated infections (HAI), Data and Statistics-HAI Prevalence Survey*, available at http://www.cdc.gov/HAI/surveillance/index.html (last viewed February 13, 2017).

[23] U.S. Government Accountability Office, *Health Care Transparency-Actions Needed to Improve Cost and Quality Information for Consumers*, October 2014, pgs. 6-7 (citing quality measure categories established by the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse, available at http://qualitymeasures.ahrq.gov/tutorial/varieties.aspx).

- Disease registries, such as those maintained by the Agency for Toxic Substances and Disease Registry[24] in the Centers for Disease Control and national disease-specific registries, like the National Amyotrophic Lateral Sclerosis (ALS) Registry[25] and the Kaiser Permanente Autoimmune Disorder Registry[26];
- Medical records; and
- Qualitative data, including information from patient surveys, interviews, and focus groups.[27]

Standardized healthcare performance measures are used by a range of healthcare stakeholders for a variety of purposes. Measures help clinicians, hospitals, and other providers understand whether the care they provide their patients is optimal and appropriate, and if not, where to focus their efforts to improve. Public and private payers also use measures for feedback and benchmarking purposes, public reporting, and incentive-based payment. Lastly, measures are an essential part of making the cost and quality of healthcare more transparent to all, particularly for those who receive care or help make care decisions for loved ones. The Institute of Medicine's six domains of quality—safe, effective, patient-centered, timely, efficient, and equitable—are one way to organize the information.[28] Studies have found patients find effectiveness, safety, and patient-centeredness to be most meaningful in their consideration of health care options.[29]

As more and more health care consumers shop for their health care, value becomes more important than price alone. Determining value means comparing the cost of care with information on the quality or benefit of the service. Presenting health care price information without accompanying quality information leads consumers to assume that high-priced care is high quality care.[30] In fact, there is no evidence of a correlation between cost and quality in health care.[31]

Showing cost and quality information together helps consumers clearly see variation among providers.[32] Further, it helps consumers understand that high costs do not necessarily mean high quality—high-quality care is available without paying the highest price.[33] One way to accomplish this would be to present comparative quality and cost information on one, consumer-friendly website, using several specific measures or scores so multiple metrics can be compared at the same time.[34]

Florida Center for Health Information and Transparency

The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system (information system) that includes the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data. The Florida Center is housed within AHCA and is funded through appropriations in the General Appropriations Act, through grants, gifts, and other payments, and through fees charged for services. Offices within the Florida Center, which serve different functions, are:

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[24] For more information, visit www.atsdr.cdc.gov/.
[25] For more information, visit https://wwwn.cdc.gov/ALS/Default.aspx.
[26] For more information, visit https://www.dor.kaiser.org/external/DORExternal/aidr/index.aspx.
[27] Supra, FN 23 at page 11.
[28] Institute of Medicine, *Report: Crossing the Quality Chasm: A New Health System for the 21st Century*, March 1, 2001, available at http://ion.nationalacademies.org/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf (last viewed February 13, 2017).
[29] Hibbard, JH, Greene, J, Daniel D., *What is Quality Anyway? Performance Reports That Clearly Communicate to Consumers the Meaning of Quality Care*, Med. Care Res. Rev., 67(3): 275-293 (2010).
[30] Public Agenda and Robert Wood Johnson Foundation, *How Much Will It Cost? How Americans Use Prices in Health Care*, March 2015, page 5, available at http://www.publicagenda.org/files/HowMuchWillItCost_PublicAgenda_2015.pdf.
[31] Carman, KL, Maurer M., et al., *Evidence That Consumers Are Skeptical About Evidence-Based Health Care*, Health Affairs, 29(7): 1400-1406 (2010).
[32] American Institute of Research, The Robert Wood Johnson Foundation, *How to Report Cost Data to Promote High-Quality, Affordable Choices: Findings from Consumer Testing*, February 2014, available at http://www.rwjf.org/content/dam/farm/reports/issue_brief/2014/rwjf410706 (last viewed February 13, 2017).
[33] Id.
[34] Id.

- Data Collection and Quality Assurance, which collects patient discharge data from all licensed acute care hospitals (including psychiatric and comprehensive rehabilitation units), comprehensive rehabilitation hospitals, ambulatory surgical centers and emergency departments.
- Risk Management and Patient Safety, which conducts in-depth analyses of reported incidents to determine what happened and how the facility responded to the incident.
- Data Dissemination and Communication, which maintains AHCA's health information website, provides technical assistance to data users, and creates consumer brochures and other publications.
- Health Information Exchange and Policy Analysis, which monitors innovations in health information technology, informatics, and the exchange of health information and provides a clearinghouse of technical resources on health information exchange, electronic prescribing, privacy and security, and other relevant issues.

The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ASC, emergency department, and comprehensive rehabilitation hospital on a quarterly basis. The data is validated for accuracy and maintained in three major databases: the hospital inpatient database, the ambulatory surgery database, and the emergency department database.

The hospital inpatient database contains records for each patient stay at Florida acute care facilities, including long-term care hospitals and psychiatric hospitals. These records contain extensive patient information including discharge records, patient demographics, admission information, medical information, and charge data. This database also includes comprehensive inpatient rehabilitation data on patient-level discharge information from Florida's licensed freestanding comprehensive inpatient rehabilitation hospitals and acute care hospital distinct part rehabilitation units.

The ambulatory surgery database contains "same-day surgery" data on reportable patient visits to Florida health care facilities, including freestanding ambulatory surgery centers, short-term acute care hospitals, lithotripsy centers, and cardiac catheterization laboratories. Ambulatory surgery data records include, but are not limited to, patient demographics, medical information, and charge data.

The emergency department database collects reports of all patients who visited an emergency department, but were not admitted for inpatient care. Reports are electronically submitted to the AHCA and include the hour of arrival, the patient's chief complaint, principal diagnosis, race, ethnicity, and external causes of injury.

Florida law requires the Florida Center to identify available data sets, compile new data when specifically authorized by the Legislature, and promote the use of extant health-related data and statistics. The Florida Center maintains data sets in existence before July 1, 2016, and may collect or compile data on:

- Health resources, including licensed health care practitioners, by specialty and type of practice. and including information collected by the Department of Health.
- Health service inventories, including acute care, long-term care, and other institutional care facilities and specific services provided by hospitals, nursing homes, home health agencies, and other licensed health care facilities.
- Service utilization for licensed health care facilities.
- Health care costs and financing, including trends in health care prices and costs, the sources of payment for health care services, and federal, state, and local expenditures for health care.
- The extent of public and private health insurance coverage in this state; and
- Specific quality-of-care initiatives involving various health care providers when extant data is not adequate to achieve the objectives of the initiative.

The Florida Center maintains www.FloridaHealthFinder.gov, which was established to assist consumers in making informed health care decisions and lead to improvements in quality of care in Florida. The website provides a wide array of search and comparative tools to the public which allow easy access to information on hospitals, ambulatory surgery centers, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. The website also provides tools to researchers and professionals to allow specialized data queries, but requires users to have some knowledge of medical coding and terminology. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator, hospital and ambulatory surgery centers performance data, data on mortality, complication, and infection rates for hospitals, and a facility/provider locator. AHCA is frequently improving the functionality of the website by adding more information and search capabilities.

Patient Safety Culture Surveys[35]

Patient safety culture can be defined as the set of values, beliefs, and norms about what is important, how to behave, and what attitudes are appropriate when it comes to patient safety in a workgroup or organization.[36] In a safe culture, employees are guided by an organization-wide commitment to safety in which each member upholds their own safety norms and those of their co-workers. Safety culture is increasingly recognized as an important strategy to improving deficits in patient safety. The question for health care facilities is how to measure the patient safety climate in the facility.

Agency for Healthcare Research and Quality Hospital and ASC Patient Safety Culture Survey

In 2004, the federal Agency for Healthcare Research and Quality (AHRQ) released the Hospital Survey on Patient Safety Culture, a staff survey designed to help hospitals assess the culture of safety in their institutions by measuring how their staff perceive various aspects of patient safety culture.[37] The survey has since been implemented in hundreds of hospitals across the United States, and in other countries.

The survey[38] asks respondents to indicate to what degree they agree or disagree with a statement, how often something occurs, or provide a specific number or grade. Excerpts of the survey follow.

- Teamwork Within Units
    - People support one another in this unit.
    - When a lot of work needs to be done quickly, we work together as a team to get the work done.
    - In this unit, people treat each other with respect.
    - When one area in this unit gets really busy, others help out.
- Supervisor/Manager Expectations & Actions Promoting Patient Safety
    - My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.
    - My supervisor/manager seriously considers staff suggestions for improving patient safety.
    - Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.
    - My supervisor/manager overlooks patient safety problems that happen over and over.

[35] Besides the two patient safety culture surveys highlighted is this section, other measures of safety climate include, but are not limited to, Zohar's (2000) assessment of unit safety climate; Zohar and Luria's (2005) measure of unit climate; Hofmann and Stetzer's (1996, 1998) measure of safety climate including safe practices, safety policies, and/or safety requirements; and Hofmann, Morgeson, and Gerras' (2003) measure of safety climate.
[36] International Nuclear Safety Advisory Group, *Safety Culture*, 1991;75-INSAG-4:1-44.
[37] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, *Hospital Survey on Patient Safety Culture*, available at http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/index.html (last viewed February 13, 2017). Besides hospitals, AHRQ developed patient safety culture surveys for hospitals, nursing homes, ambulatory outpatient medical offices, community pharmacies, and ambulatory surgery centers.
[38] The survey is available at http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/hospital/resources/hospscanform.pdf.

- Management Support for Patient Safety
  - Hospital management provides a work climate that promotes patient safety.
  - The actions of hospital management show that patient safety is a top priority.
  - Hospital management seems interested in patient safety only after an adverse event happens.
- Communication Openness
  - Staff will freely speak up if they see something that may negatively affect patient care.
  - Staff feels free to question the decisions or actions of those with more authority.
  - Staff is afraid to ask questions when something does not seem right.
- Handoffs & Transitions
  - Things "fall between the cracks" when transferring patients from one unit to another.
  - Important patient care information is often lost during shift changes.
  - Problems often occur in the exchange of information across hospital units.
  - Shift changes are problematic for patients in this hospital.
- Patient Safety Grade- Excellent, Very Good, Acceptable, Poor, Failing
  - Please give your work area/unit in this hospital an overall grade on patient safety.

In 2006, AHRQ developed a comparative database on the survey, comprised of data from U.S. hospitals that administered the survey and voluntarily submitted the data.[39] The database allows hospitals wishing to compare their patient safety culture survey results to those of other hospitals in support of patient safety culture improvement.[40] In 2016, 680 hospitals submitted survey results to the database.[41] The database also includes a chapter on trending that presents results showing change over time for 326 hospitals that administered the survey and submitted data at least in 2014 and 2016.[42] The trends and findings include:

- The average percent positive scores across the 12 patient safety culture composites increased by 1 percentage point.
- For hospitals that increased on Patient Safety Grade, scores for "Excellent" or "Very Good" increased on average by 6 percent.
- For hospitals that increased on the number of respondents who reported at least one event in the past 12 months, the average increase was 5 percent.

AHRQ also developed the Ambulatory Surgery Center Survey on Patient Safety Culture in response to interest from ambulatory surgery centers (ASCs) in assessing patient safety culture in their facilities. This survey is designed specifically for ASC staff and asks for their opinions about the culture of patient safety in their facility.[43] In 2014, AHRQ conducted a pilot study on the use of the Patient Safety Culture survey in 59 ASCs.[44] The pilot study was intended to help ASCs assess the extent to which their culture emphasizes the importance of patient safety by viewing the patient safety culture survey results of the ASCs participating in the study.[45] The study was also used to prove the reliability and structure of the questions and items contained the in the survey. Based on the testing and input from AHRQ and a technical expert panel, the survey was determined to be reliable and it was made available for industry use.

University of Texas Safety Attitudes Questionnaire

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[39] Supra, FN 36.
[40] Id.
[41] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2016 User Comparative Database Report-Hospital Survey on Patient Safety Culture*, available at https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/hospital/2016/2016_hospitalsops_report_pt1.pdf (last viewed February 13, 2017).
[42] Id.
[43] The survey is available at http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/asc/resources/ascsurvey.pdf.
[44] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, *Results From the 2014 AHRQ Ambulatory Surgery Center Survey on Patient Safety Culture Pilot Study*, available at https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient safety/patientsafetyculture/asc/resources/asc_pilotstudy.pdf (last viewed February 13, 2017).
[45] Id. at pg. 1.

Another patient safety culture survey widely used by hospitals and other facilities to measure patient safety culture is the Safety Attitudes Questionnaire (SAQ) developed by researchers at the University of Texas. The SAQ was adapted from two other safety surveys from the aviation industry- the Flight Management Attitudes Questionnaire and its predecessor, the Cockpit Management Attitudes Questionnaire, developed over 30 years ago. The aviation questionnaires were created after researchers found that most airline accidents were due to breakdowns in interpersonal aspects of crew performance such as teamwork, speaking up, leadership, communication, and collaborative decision making. The FMAQ measures crew member attitudes about these topics, and was found to reliable, sensitive to change, and predictive of flight crew performance. Researchers also found that many of the items contained in the aviation questionnaires were useful in measuring attitudes about the same topics in a medical setting, so the SAQ was developed.

The SAQ was specifically designed to measure safety culture at both the individual and group level. Both the healthcare version (SAQ) and aviation version (FMAQ) of this survey instrument were shown to identify variability within and between hospitals and airlines[46]. The SAQ went through full derivation and validation testing, and was determined to be both a valid and reliable measurement tool for determining patient safety culture.[47]

The SAQ is a one-page, 60 item survey instrument that assesses safety culture across six factors—perceptions of management, job satisfaction, working conditions, stress recognition, teamwork climate and safety climate.[48] The SAQ defines safety climate as perceptions of a strong and proactive organizational commitment to safety, as one aspect of overall safety culture. Each item is measured on a 5-point Likert scale, from disagree strongly to agree strongly, which is then converted to a 0–100 scale. The scaled scores correspond to the patient safety climate in a facility. The SAQ has been adapted for use in intensive care units, operating rooms, general inpatient settings, and ambulatory clinics.[49]

Research on Patient Safety Culture Surveys

Since 2000, a robust body of research has emerged to measure the effectiveness of patient safety culture surveys in identifying areas of improvement in hospitals, ASCs, and other health care settings. This research has found that facilities with a poor patient safety climate have poor or less desirable patient outcomes following treatment in those facilities. For example, in one study, the SAQ (operating version) was given to 60 hospitals in 16 states to administer to each hospital's operating room caregivers.[50] When the results of the surveys were compared with a chart showing surgical complication rates for each hospital participating in the study, the charts were nearly identical. The study showed that there was a correlation between patient safety culture in a hospital and patient outcomes.[51]

Another study examined the patient safety culture at 30 intensive care units (ICUs) across the country to determine if there was a correlation between safety culture and patient outcomes, specifically hospital mortality and length of stay.[52] Using the SAQ-ICU version, the study found that lower perceptions of management among ICU personnel were significantly associated with higher hospital

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[46] Pronovost P, Sexton B. *Assessing safety culture: guidelines and recommendations*. Qual Saf Health Care 2005;14:231–3; see also Sexton JB, Thomas EJ. *Measurement: Assessing Safety Culture*. In: Leonard M, Frankel A, Simmonds T (eds). *Achieving Safe and Reliable Healthcare: Strategies and Solutions*. Chicago, IL: Health Administration Press, 2004, pp. 115–27.
[47] Sexton JB, Helmreich RL, Neilands TB et al. *The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research*. BMC Health Serv Res 2006;6:44.
[48] Huang, D., Clermont, G. *Intensive care unit safety culture and outcomes: a U.S. multicenter study*. Intl. J. Quality in Health Care 2010;22:151-161.
[49] For each version of the SAQ, item content is the same, with minor modifications to reflect the clinical area.
[50] Makary M., Sexton B. *Patient safety in surgery*. Annals of Surgery 2006; 243:628-35.
[51] Makary, M. *Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care* pgs. 90-92 (2012).
[52] Supra, FN 47.

mortality.[53] In fact, for every 10 percent decrease in an ICU's percentage of positive scores associated with perceptions of management, the odds of patient death in the ICU increased 1.24 times.[54] Also, the study found that lower safety climate, perceptions of management, and job satisfaction were significantly associated with increased lengths of stay in the hospital.[55] Other studies have also found a correlation between positive teamwork attitudes and patient outcomes in ICUs.[56]

Facilities whose frontline health care workers and managers score higher on patient safety climate surveys have been found to have lower rates of adverse patient safety indicators, such as postoperative sepsis, pressure ulcers, and inpatient falls resulting in a fractured hip.[57] Another study found a correlation between poor safety climate scores and high burnout rates among NICU nurses.[58] An additional study found that positive teamwork attitudes measured by patient safety culture survey tools are associated with better patient outcomes in pediatric surgery.[59]

Effect of Proposed Changes

HB 375 requires AHCA to develop hospital and ASC patient safety culture surveys to measure aspects of patient safety culture, including frequency of adverse events, quality of handoffs and transitions, comfort in reporting a potential problem or error, the level of teamwork within hospital units and the facility as a whole, staff compliance with patient safety regulations and guidelines, staff's perception of facility support for patient safety, and staff's opinions on whether or not they would undergo a health care service or procedure at the facility. AHCA must review and analyze nationally recognized patient safety culture survey products, including but not limited to the patient safety surveys developed by the federal Agency for Healthcare Research and Quality and the University of Texas to develop the survey.

The bill requires facilities to annually conduct the survey and submit the results to the Florida Center, and authorizes AHCA to adopt rules for the survey and submission process. Submission of the culture survey is a condition of licensure. AHCA must include the survey results in the health care quality measures available to the public. Consumers may use the survey results to make decisions on which hospital or ASC is best their treatment needs, or the treatment needs of their family members.

Finally, the bill also makes various conforming changes to reflect the provisions of the bill.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.05, F.S., relating to Florida Center for Health Information and Transparency.
Section 2: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 3: Amends s. 408.810, F.S., relating to minimum licensure requirements.

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[53] Id. at pg. 155.
[54] Id.
[55] Id. at pgs. 155-56.
[56] Baggs J, Schmitt M, Mushlin A, Mitchell P, Eldredge D, Oakes D, Hutson AD: *Association between nurse-physician collaboration and patient outcomes in three intensive care units.* Crit Care Med 1999; 27:1991–8; Shortell S, Zimmerman J, Rousseau D, Gillies R, Wagner D, Draper E, Knaus W, Duffy J: *The performance of intensive care units: Does good management make a difference?* Med Care 1994; 32:508–25; Knaus W, Draper E, Zimmerman J: *An evaluation of outcome from intensive care in major medical centers.* Ann Intern Med 1986; 10:410–8.
[57] Singer S., Lin S. *Relationship of safety climate and safety performance in hospitals*. Health Serv Res 2009;44:399-421.
[58] Profit J., Sharek P. *Burnout in the NICU setting and its relation to safety culture.* BMJ Qual Saf 2014;23:806-813.
[59] de Leval M, Carthey J, Wright D, Farewell V, Reason J: *Human factors and cardiac surgery: A multicenter study.* J Thorac Cardiovasc Surg 2000;119:661–72.

Section 4: Amends s. 400.991, F.S., relating to licensure requirements; background screenings; prohibitions.
Section 5: Amends s. 408.8065, F.S., relating to additional licensure requirements for home health agencies, home medical providers, and health care clinics.
Section 6: Amends s. 408.820, F.S., relating to exemptions.
Section 7: Provides an appropriation.
Section 8: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   AHCA may realize an increase in revenue by imposing fines on hospitals and ASCs that fail to submit patient safety culture survey results. The amount of fines that may be collected under the bill is indeterminate, but will offset costs of investigations and administrative actions.

2. Expenditures:

   The cost to implement the patient safety culture survey, including the cost to collect, analyze, and report survey findings is estimated to be $300,000 in recurring funds from the Health Care Trust Fund. AHCA intends to encourage online survey completion, which would reduce this estimate.[60] AHCA is examining the cost of developing, distributing, and processing the surveys without a contractor.[61] Additionally, the cost of one full-time equivalent (FTE) staff to manage the survey process is estimated to be $52,919 in recurring costs from the Health Care Trust Fund, with associated salary rate of 41,106.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care consumers will have access to patient safety culture survey results from hospitals and ASCs. Consumers may use the information contained in the results, such as whether or not physicians and nurses feel comfortable in receiving treatment in the facilities where they work, to make informed decisions about where they receive health care services. Hospitals and ASCs with poor survey results may realize a reduction in patient volume, while hospitals and ASCs with positive survey results may realize an increase in patient volume.

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[60] Email correspondence between AHCA staff and Select Committee staff on January 18, 2016 (on file with Health and Human Services Committee staff).
[61] Telephone conference between AHCA staff and Health Innovation Subcommittee staff on February 13, 2017.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   None. The bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable. AHCA has sufficient existing rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 7, 2017, the Health Care Appropriations Subcommittee adopted an amendment that provides an appropriation in the sum of $352,919 in recurring funds from the Health Care Trust Fund and one full-time equivalent (FTE) position with associated salary rate for the purpose of carrying out this act.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.

1 A bill to be entitled
2 An act relating to patient safety culture surveys;
3 amending s. 408.05, F.S.; requiring the Agency for
4 Health Care Administration to develop surveys to
5 assess patient safety culture in certain health care
6 facilities; amending s. 408.061, F.S.; revising
7 requirements for the submission of health care data to
8 the agency; amending s. 408.810, F.S.; requiring the
9 submission of patient safety culture survey data as a
10 condition of licensure; amending ss. 400.991,
11 408.8065, and 408.820, F.S.; conforming cross-
12 references; providing an appropriation; providing an
13 effective date.
14
15 Be It Enacted by the Legislature of the State of Florida:
16
17 Section 1. Paragraphs (d) through (i) of subsection (3) of
18 section 408.05, Florida Statutes, are redesignated as paragraphs
19 (e) through (j), respectively, present paragraph (j) is
20 redesignated as paragraph (k) and amended, and a new paragraph
21 (d) is added to that subsection, to read:
22 408.05 Florida Center for Health Information and
23 Transparency.—
24 (3) HEALTH INFORMATION TRANSPARENCY.—In order to
25 disseminate and facilitate the availability of comparable and

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

26 uniform health information, the agency shall perform the
27 following functions:
28 (d) Design a patient safety culture survey or surveys to
29 be completed annually by each hospital and ambulatory surgical
30 center licensed under chapter 395. The survey shall be designed
31 to measure aspects of patient safety culture, including
32 frequency of adverse events, quality of handoffs and
33 transitions, comfort in reporting a potential problem or error,
34 the level of teamwork within hospital units and the facility as
35 a whole, staff compliance with patient safety regulations and
36 guidelines, staff perception of facility support for patient
37 safety, and staff opinions on whether the staff member would
38 undergo a health care service or procedure at the facility. The
39 survey shall be anonymous to encourage staff employed by or
40 working in the facility to complete the survey. The agency shall
41 review and analyze nationally recognized patient safety culture
42 survey products, including, but not limited to, the patient
43 safety surveys developed by the federal Agency for Healthcare
44 Research and Quality and the Safety Attitudes Questionnaire
45 developed by the University of Texas, to develop the patient
46 safety culture survey. This paragraph does not apply to licensed
47 facilities operating exclusively as state facilities.
48 (k)~~(j)~~ Conduct and make available the results of special
49 health surveys, including facility patient safety culture
50 surveys, health care research, and health care evaluations

51 conducted or supported under this section. Each year the center
52 shall select and analyze one or more research topics that can be
53 investigated using the data available pursuant to paragraph (c).
54 The selected topics must focus on producing actionable
55 information for improving quality of care and reducing costs.
56 The first topic selected by the center must address preventable
57 hospitalizations.
58 Section 2. Paragraph (a) of subsection (1) of section
59 408.061, Florida Statutes, is amended to read:
60 408.061 Data collection; uniform systems of financial
61 reporting; information relating to physician charges;
62 confidential information; immunity.—
63 (1) The agency shall require the submission by health care
64 facilities, health care providers, and health insurers of data
65 necessary to carry out the agency's duties and to facilitate
66 transparency in health care pricing data and quality measures.
67 Specifications for data to be collected under this section shall
68 be developed by the agency and applicable contract vendors, with
69 the assistance of technical advisory panels including
70 representatives of affected entities, consumers, purchasers, and
71 such other interested parties as may be determined by the
72 agency.
73 (a) Data submitted by health care facilities, including
74 the facilities as defined in chapter 395, shall include, but are
75 not limited to: case-mix data, patient admission and discharge

76 data, hospital emergency department data which shall include the
77 number of patients treated in the emergency department of a
78 licensed hospital reported by patient acuity level, data on
79 hospital-acquired infections as specified by rule, data on
80 complications as specified by rule, data on readmissions as
81 specified by rule, with patient and provider-specific
82 identifiers included, actual charge data by diagnostic groups or
83 other bundled groupings as specified by rule, facility patient
84 safety culture surveys, financial data, accounting data,
85 operating expenses, expenses incurred for rendering services to
86 patients who cannot or do not pay, interest charges,
87 depreciation expenses based on the expected useful life of the
88 property and equipment involved, and demographic data. The
89 agency shall adopt nationally recognized risk adjustment
90 methodologies or software consistent with the standards of the
91 Agency for Healthcare Research and Quality and as selected by
92 the agency for all data submitted as required by this section.
93 Data may be obtained from documents such as, but not limited to:
94 leases, contracts, debt instruments, itemized patient statements
95 or bills, medical record abstracts, and related diagnostic
96 information. Reported data elements shall be reported
97 electronically in accordance with rule 59E-7.012, Florida
98 Administrative Code. Data submitted shall be certified by the
99 chief executive officer or an appropriate and duly authorized
100 representative or employee of the licensed facility that the

101 information submitted is true and accurate.
102 Section 3. Subsections (8), (9), and (10) of section
103 408.810, Florida Statutes, are renumbered as subsections (9),
104 (10), and (11), respectively, and a new subsection (8) is added
105 to that section to read:
106 408.810 Minimum licensure requirements.—In addition to the
107 licensure requirements specified in this part, authorizing
108 statutes, and applicable rules, each applicant and licensee must
109 comply with the requirements of this section in order to obtain
110 and maintain a license.
111 (8) Each licensee subject to s. 408.05(3)(d) shall submit
112 facility patient safety culture surveys to the agency in
113 accordance with applicable rules.
114 Section 4. Paragraph (c) of subsection (4) of section
115 400.991, Florida Statutes, is amended to read:
116 400.991 License requirements; background screenings;
117 prohibitions.—
118 (4) In addition to the requirements of part II of chapter
119 408, the applicant must file with the application satisfactory
120 proof that the clinic is in compliance with this part and
121 applicable rules, including:
122 (c) Proof of financial ability to operate as required
123 under s. 408.810(9) ~~408.810(8)~~. As an alternative to submitting
124 proof of financial ability to operate as required under s.
125 408.810(8), the applicant may file a surety bond of at least

126 $500,000 which guarantees that the clinic will act in full
127 conformity with all legal requirements for operating a clinic,
128 payable to the agency. The agency may adopt rules to specify
129 related requirements for such surety bond.
130 Section 5. Paragraph (a) of subsection (1) of section
131 408.8065, Florida Statutes, is amended to read:
132 408.8065 Additional licensure requirements for home health
133 agencies, home medical equipment providers, and health care
134 clinics.—
135 (1) An applicant for initial licensure, or initial
136 licensure due to a change of ownership, as a home health agency,
137 home medical equipment provider, or health care clinic shall:
138 (a) Demonstrate financial ability to operate, as required
139 under s. 408.810(9) ~~408.810(8)~~ and this section. If the
140 applicant's assets, credit, and projected revenues meet or
141 exceed projected liabilities and expenses, and the applicant
142 provides independent evidence that the funds necessary for
143 startup costs, working capital, and contingency financing exist
144 and will be available as needed, the applicant has demonstrated
145 the financial ability to operate.
146
147 All documents required under this subsection must be prepared in
148 accordance with generally accepted accounting principles and may
149 be in a compilation form. The financial statements must be
150 signed by a certified public accountant.

151 Section 6. Section 408.820, Florida Statutes, is amended
152 to read:
153 408.820 Exemptions.—Except as prescribed in authorizing
154 statutes, the following exemptions shall apply to specified
155 requirements of this part:
156 (1) Laboratories authorized to perform testing under the
157 Drug-Free Workplace Act, as provided under ss. 112.0455 and
158 440.102, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.
159 (2) Birth centers, as provided under chapter 383, are
160 exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.
161 (3) Abortion clinics, as provided under chapter 390, are
162 exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.
163 (4) Crisis stabilization units, as provided under parts I
164 and IV of chapter 394, are exempt from s. 408.810(9)-(11)
165 ~~408.810(8)-(10)~~.
166 (5) Short-term residential treatment facilities, as
167 provided under parts I and IV of chapter 394, are exempt from s.
168 408.810(9)-(11) ~~408.810(8)-(10)~~.
169 (6) Residential treatment facilities, as provided under
170 part IV of chapter 394, are exempt from s. 408.810(9)-(11)
171 ~~408.810(8)-(10)~~.
172 (7) Residential treatment centers for children and
173 adolescents, as provided under part IV of chapter 394, are
174 exempt from s. 408.810(9)-(11) ~~408.810(8)-(10)~~.
175 (8) Hospitals, as provided under part I of chapter 395,

176 are exempt from s. 408.810(7), (9), and (10) ~~408.810(7)-(9)~~.
177 (9) Ambulatory surgical centers, as provided under part I
178 of chapter 395, are exempt from s. 408.810(7), (9), (10), and
179 (11) ~~408.810(7)-(10)~~.
180 (10) Mobile surgical facilities, as provided under part I
181 of chapter 395, are exempt from s. 408.810(7)-(11) ~~408.810(7)-~~
182 ~~(10)~~.
183 (11) Health care risk managers, as provided under part I
184 of chapter 395, are exempt from ss. 408.806(7), 408.810(4)-(11)
185 ~~408.810(4)-(10)~~, and 408.811.
186 (12) Nursing homes, as provided under part II of chapter
187 400, are exempt from ss. 408.810(7) and 408.813(2).
188 (13) Assisted living facilities, as provided under part I
189 of chapter 429, are exempt from s. 408.810(11) ~~408.810(10)~~.
190 (14) Home health agencies, as provided under part III of
191 chapter 400, are exempt from s. 408.810(11) ~~408.810(10)~~.
192 (15) Nurse registries, as provided under part III of
193 chapter 400, are exempt from s. 408.810(6) and (11) ~~(10)~~.
194 (16) Companion services or homemaker services providers,
195 as provided under part III of chapter 400, are exempt from s.
196 408.810(6)-(11) ~~408.810(6)-(10)~~.
197 (17) Adult day care centers, as provided under part III of
198 chapter 429, are exempt from s. 408.810(11) ~~408.810(10)~~.
199 (18) Adult family-care homes, as provided under part II of
200 chapter 429, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

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201 (19) Homes for special services, as provided under part V
202 of chapter 400, are exempt from s. 408.810(7)-(11) ~~408.810(7)-~~
203 ~~(10)~~.
204 (20) Transitional living facilities, as provided under
205 part XI of chapter 400, are exempt from s. 408.810(11)
206 ~~408.810(10)~~.
207 (21) Prescribed pediatric extended care centers, as
208 provided under part VI of chapter 400, are exempt from s.
209 408.810(11) ~~408.810(10)~~.
210 (22) Home medical equipment providers, as provided under
211 part VII of chapter 400, are exempt from s. 408.810(11)
212 ~~408.810(10)~~.
213 (23) Intermediate care facilities for persons with
214 developmental disabilities, as provided under part VIII of
215 chapter 400, are exempt from s. 408.810(7).
216 (24) Health care services pools, as provided under part IX
217 of chapter 400, are exempt from s. 408.810(6)-(11) ~~408.810(6)-~~
218 ~~(10)~~.
219 (25) Health care clinics, as provided under part X of
220 chapter 400, are exempt from s. 408.810(6), (7), and (11) ~~(10)~~.
221 (26) Clinical laboratories, as provided under part I of
222 chapter 483, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.
223 (27) Multiphasic health testing centers, as provided under
224 part II of chapter 483, are exempt from s. 408.810(5)-(11)
225 ~~408.810(5)-(10)~~.

226 (28) Organ, tissue, and eye procurement organizations, as
227 provided under part V of chapter 765, are exempt from s.
228 408.810(5)-(11) ~~408.810(5)-(10)~~.
229 Section 7. For the 2017-2018 fiscal year, one full-time
230 equivalent position with associated salary rate of 41,106 is
231 authorized, and the sum of $352,919 in recurring funds from the
232 Health Care Trust Fund is appropriated to the Agency for Health
233 Care Administration, for the purpose of implementing the
234 requirements of this act.
235 Section 8. This act shall take effect July 1, 2017.

HB 589

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 589 Prescription Drug Price Transparency
SPONSOR(S): Yarborough
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N	Langston	Poche
2) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Spending on prescription drugs has risen sharply in the United States over the past few years. From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent, to an average cost of $44 per brand name prescription drug. Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.

In Florida, consumers can research prescription drug prices at www.MyFloridaRx.com (MyFloridaRx). MyFloridaRx is a joint effort between the Office of the Attorney General (AG) and the Agency for Health Care Administration (AHCA). The website lists the usual and customary prices charged by pharmacies for 150 of the most commonly prescribed brand name drugs and associated generic equivalents.

MyFloridaRx shows price data for retail pharmacies dispensing at least one of the top 150 prescription drugs dispensed to a Medicaid beneficiary. The statute requires participating pharmacies to provide AHCA their prices quarterly, including the usual and customary retail price for a 30-day supply of the prescription drug at a standard dose. Once AHCA receives the data, it is submitted to the AG's office, which maintains the website and updates it monthly.

When a consumer queries MyFloridaRx, search results provide the pharmacy name, address and phone number, the prescription drug name and strength, the most commonly dispensed quantity, and price. These results can be sorted by pharmacy name, zip code, drug name, drug quantity, or price.

HB 589 doubles the number of prescription drugs that must be posted to MyFloridaRx, from 150 to 300. Additionally, the bill codifies the current practice by which prescription drug pricing information is reported to AHCA, from quarterly to monthly. As a result, patients who query MyFloridaRx will have access to pricing information for more prescription drugs.

The bill removes obsolete language referencing deadlines for implementation that have already passed.

The bill does not have a fiscal impact on state or local government.

The bill provides an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

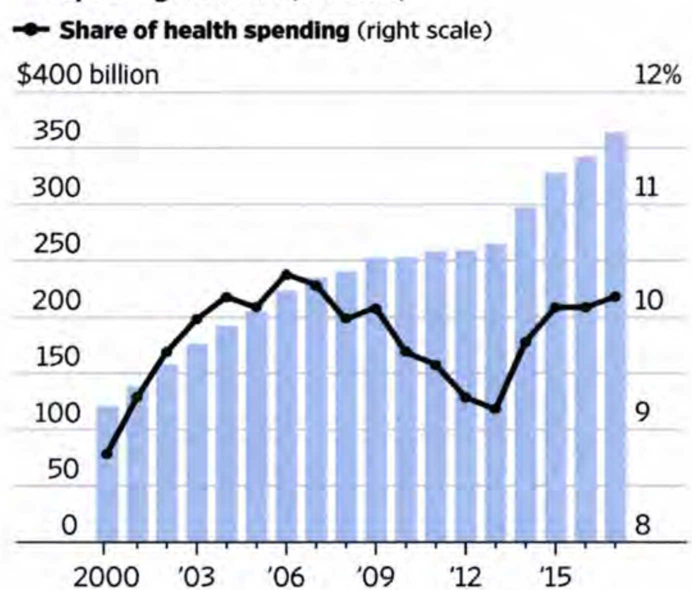
A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drug Cost and Pricing

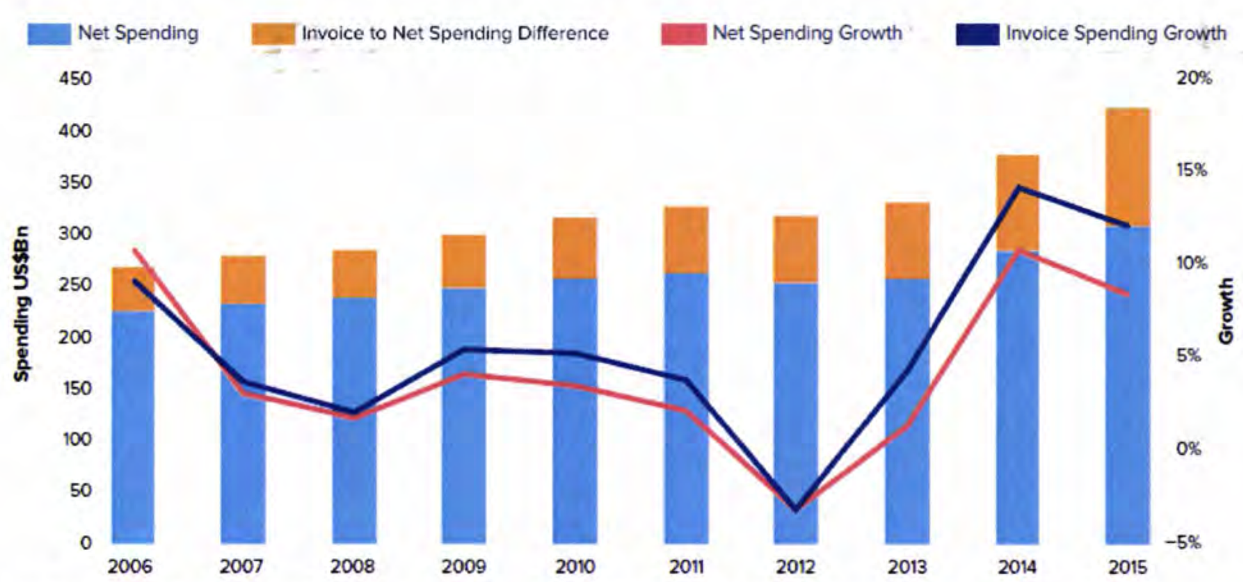
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5] Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Prescription Drug Spending as a Share of Health Spending 2000-2017[7]

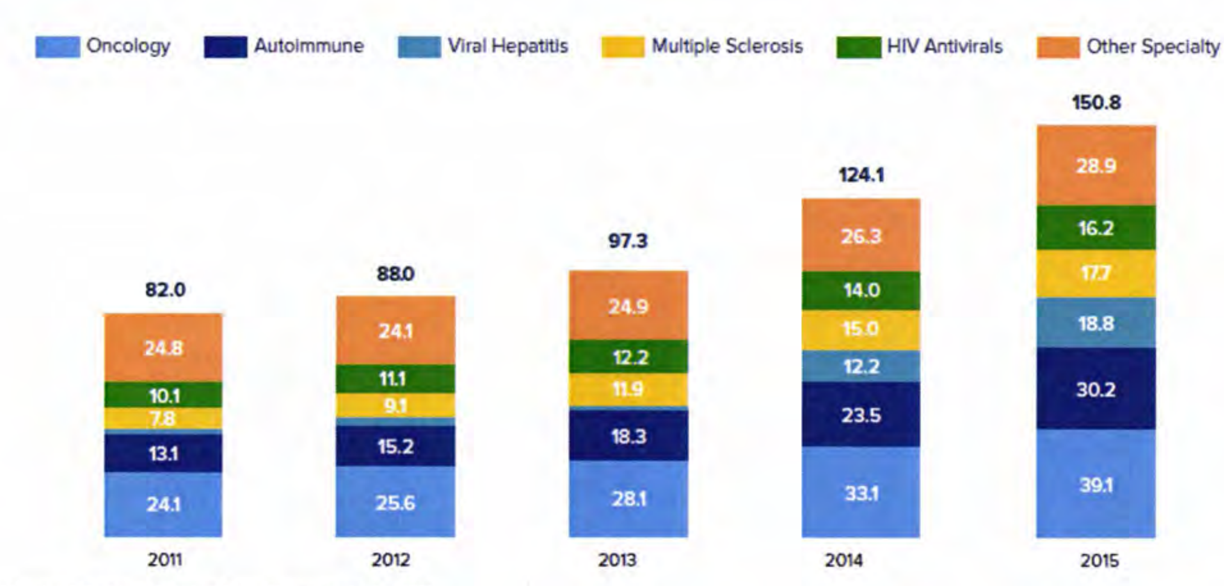


[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited March 13, 2017).
[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited March 10, 2017).
[3] 2017 Segal Health Plan Cost Trend Survey, *available at*, https://www.segalco.com/media/2716/me-trend-survey-2017.pdf (last visited March 13, 2017)
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 2017)
[5] *Supra*, note 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2017).
[7] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?*, THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited March 13, 2017).

Total U.S. Spending on Prescription Drugs, 2015[8]



Total U.S. Spending on Specialty Prescription Drugs, 2015[9]



[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020 (last visited March 13, 2017).
[9] Id.

Pharmaceutical companies take into account a number of factors, including the market for the particular prescription drug, the cost of comparative treatments, cost of research and development, the price of the manufacturing and ingredients, and maximization of profits when deciding to set drug price.[10] The costs associated with developing a new prescription drug can be very high. A recent analysis by the Tufts Center for the Study of Drug Development of the average cost to develop and gain marketing approval for a new prescription drug estimated the cost at $2.558 billion, and noted that when post-approval research and development activities were included, the cost rose to $2.870 billion.[11] The following factors increased costs of prescription drug development:

- Increased clinical trial complexity;
- Larger clinical trial sizes;
- Higher input costs from the medical sector;
- Changes in protocol design to include efforts to gather health technology assessment information; and
- Testing on comparator drugs to accommodate payer demands for comparative effectiveness data.[12]

Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name prescription drug prices that have been increasing in recent years at rates far beyond the consumer price index.[13] Prescription drug sales are larger than the gross domestic product of 15 countries, combined.[14] Additionally, per capita spending on prescription drugs in the United States is more than double that of 19 other industrialized nations and accounts for an estimated 17 percent of overall personal health care services.[15] Depending upon the health issue being treated, the price can be far higher; for example, of the ten prescription drugs costing more than $30,000 for a 30 day supply, half are used to treat Hepatitis C.[16]

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[10] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Special Committee On Aging, United States Senate (Dec. 2016), *available at*, https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf (last visited February 17, 2017).

[11] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs*, Journal of Health Economics, Volume 47, pp. 20-33 (May 2016).

[12] Id.

[13] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,* JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.

[14] Kathlyn Stone, The Most Expensive Prescription Drugs in the World, THE BALANCE, Aug. 9, 2016, https://www.thebalance.com/the-8-most-expensive-prescription-drugs-in-the-world-2663232 (last visited February 17, 2017).

[15] *Supra*, note 13

[16] Beth Braverman, *The 20 Most Expensive Prescription Drugs in America,* THE FISCAL TIMES, Oct. 17, 2016, http://www.thefiscaltimes.com/Media/Slideshow/2016/10/17/10-Most-Expensive-Prescription-Drugs-America (last visited March 10, 2017).

20 Most Expensive Drugs in the United States[17]

Drug Name	Cost for 30 day supply	Condition	Manufacturer
1. Sovaldi	$75,600	Hepatitis C	Gilead Sciences, Inc.
2. Harvoni	$74,000	Hepatitis C	Gilead Sciences, Inc.
3. Cinryze	$72,100	Hereditary Angioedema	Shire
4. HP Acthar	$51,600	Systemic Lupus Erythematosus	Mallinckrodt[18]
5. Daklinza	$50,700	Hepatitis C	Bristol-Myers Squibb Company
6. Olysio	$41,800	Hepatitis C	Janssen Therapeutics
7. Orkambi	$41,200	Cystic Fibrosis	Vertex Pharmaceuticals
8. Cuprime	$39,800[19]	Wilson's Disease	Valient
9. Firazyr	$35,800	Hereditary Angioedema	Shite
10. Viekira Pak	$34,600	Hepatitis C	AbbVie
11. Kalydeco	$29,700	Cystic Fibrosis	Vertex Pharmaceuticals
12. Syprine	$29,300	Wilson's Disease	Valeant Pharmaceuticals
13. Cosentyx	$29,300	Plaque Psoriasis, Psoriatic Arthritis	Novartis Pharmaceuticals
14. Daraprim	$26,000	Toxoplasmosis	Turing Pharmaceuticals
15. Kynamro	$25,300	High Cholesterol	Kastle Therapeutics
16. Pomalyst	$15,800	Multiple Myeloma	Celgene Corporation
17. Zytiga	$15,400	Prostate Cancer	Janssen Biotech
18. Jakafi	$13,200	Myelofibrosis, Polycythemia Vera	Incyte
19. Copaxone	$12,300	Multiple Sclerosis	Teva Neuroscience
20. Tecfidera	$10,400	Multiple Sclerosis	Biogen

Prescription Drug Price Transparency in Florida

MyFloridaRx

MyFloridaRx is a joint effort between the Office of the Attorney General (AG) and the Agency for Health Care Administration (AHCA) that lists the usual and customary prices of 150 of the most commonly prescribed brand name drugs and associated generic equivalents.[20] Prescription drug prices are reported for a 30-day supply at a standard dose.[21] The data must be reported for each prescription drug by pharmacy and by metropolitan statistical area or region and updated quarterly.[22] AHCA receives the data and submits it to the AG's office; AG staff maintains the website and updates it monthly.[23]

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[17] Id.

[18] Under the initial manufacturer, Questcor, the price increased to more than $28,000 a vial from $40 in the decade leading up to when it was acquired by Mallinckrodt. Andrew Pollack and Chad Bray, *Mallinckrodt Pharmaceuticals to Buy Questcor for $5.6 Billion*, THE NEW YORK TIMES, Apr. 7, 2014, https://dealbook.nytimes.com/2014/04/07/mallinckrodt-to-buy-californias-questcor-for-5-6-billion/?_r=0 (last visited March 13, 2017).

[19] According to statistics released by the Senate Special Committee on Aging, the drug's price rose by a staggering 5,786% in a little more than five years following the company's acquisition of Aton Pharma in 2010. The price of Cuprimine over the past ten years has risen from $93 to $26,188.64, with a 300% increase in the month of July 2015 alone. Zachary Brennan, *Senate Committee Offers Inside Look at the Rise and Fall of Valeant Pharmaceuticals*, REGULATORY AFFAIRS PROFESSIONAL SOCIETY, May 9, 2016, http://raps.org/Regulatory-Focus/News/2016/05/09/24897/Senate-Committee-Offers-Inside-Look-at-the-Rise-and-Fall-of-Valeant-Pharmaceuticals/#sthash.LfFt9C1R.dpuf (last visited March 13, 2017).

[20] S. 408.062(1)(h), F.S., requires AHCA to report data on the retail prices charged by pharmacies for the 100 most frequently prescribed medicines.

[21] S. 408.062(1)(h), F.S.

[22] Id.

[23] Presentation by Molly McKinstry, Agency for Health Care Administration, and Cindy Rutledge, Office of the Attorney General, *MyFloridaRx: Prescription Drug Pricing Website*, presentation to the Health Innovation Subcommittee, Feb. 8, 2017, slide 3. (On file with Health Innovation Subcommittee staff).

MyFloridaRX allows consumers to search available prescription drugs by selecting a county, selecting one or all cities within that county, and then selecting the drug.[24] The results provide the pharmacy name, address and phone number, the prescription drug name and strength, the most commonly dispensed quantity, and price. Results can be sorted by pharmacy name, zip code, prescription drug name, quantity, or price.[25] Depending on the selected prescription drug, it may be available at a number of pharmacies, or just a few, and the price may vary greatly or not at all.

Example Prescription Drug Price Comparison[26]
ProAir HFA 90mcg Inhaler

City (County)	Lowest Price	Highest Price	*% Diff*
Monticello (Jefferson County)	**$69.99**	**$70.99**	***1.4%***
Niceville (Okaloosa County)	**$63.74**	**$70.99**	***11.4%***
Okeechobee (Okeechobee County)	**$64.05**	**$349.25**	***445.3%***
Belle Glade (Palm Beach County)	**$69.99**	**$74.14**	***5.9%***
West Palm Beach (Palm Beach County)	**$59.98**	**$74.99**	***25.0%***
Jacksonville (Duval County)	**$62.25**	**$108.10**	***73.7%***

MyFloridaRx shows only retail pharmacies dispensing at least one prescription drug to a Medicaid beneficiary. Therefore, the retail pharmacies appearing on the website are those that dispensed at least one of the top 150 posted prescription drugs to someone using Medicaid assistance to purchase that medication.[27] Participating pharmacies provide the state with all pricing levels, including the "usual and customary" retail price.[28]

Usual and Customary Price

AHCA is required to reimburse Medicaid providers in accordance with state and federal law.[29] Medicaid reimbursement methodologies differ based upon what type of services or goods are being provided; however, these methodologies often include a prohibition against reimbursement in excess of the provider's "usual and customary" rate for the service or good. Typically, the reimbursement is the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee, whichever is less.[30]

In order to receive payment from AHCA, a provider must certify that the service or good has been completely furnished to the Medicaid recipient and that the amount billed does not exceed the provider's usual and customary charge.[31] The term "usual and customary" is not defined in Florida law,[32] but in the context of prescription drugs, it is understood to mean the average charge to all other customers in any quarter for the same prescription drug, quantity, and strength.[33] This price, however, is self-reported and may vary from the price charged at the time a medication is dispensed.[34]

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[24] *Rx Drug Price Finder*, MYFLORIDARX, http://myfloridarx.com/rx.nsf/finder (last visited March 13, 2017).
[25] Id.
[26] *Supra*, note 23, slide 10.
[27] *Frequently Asked Questions - FAQs*, MYFLORIDARX, http://www.myfloridarx.com/RX.nsf/pages/FAQs (last visited March 13, 2017).
[28] Id.
[29] S. 409.908, F.S. Requirements for reimbursement are established according to methodologies set forth in AHCA's administrative rules and in policy manuals and handbooks incorporated by reference.
[30] Id; see also ss. 409.912(8)(a), F.S.; 409.9128(5), F.S.; and 409.967, F.S.; 42 C.F.R. 447.512; Florida Medicaid Provider General Handbook, as incorporated in Rule 59G-5.020, F.A.C.; and Florida Medicaid Prescribed Drug Services Handbook, as incorporated in Rule 59G-4.250, F.A.C.
[31] Id.
[32] Usual and customary is identified as a payment methodology in chapters 394, 400, 409, 440, 627, 641, and 817; however, the term is not defined.
[33] *Supra*, note 23, slide 3.
[34] Id.

National Trends in Prescription Drug Price Transparency Laws

Policymakers at the state and federal levels are working to improve prescription drug price transparency. The Unites States Congress has recognized that prescription drug price transparency could provide useful information to address the issue.[35] Similarly, a workgroup of the National Academy for State Health Policy suggests that promoting greater transparency in prescription drug pricing and payment may help to address rising prescription drug costs.[36] In an effort to increase price transparency, the workgroup recommended pricing documentation for select high-priced drugs, justification for price increases above a specific threshold, and disclosures of price discounts and rebates.[37]

Federal Trends

During the 114th Congress in 2016, proposed federal legislation required prescription drug manufacturers to justify certain price increases in a report to the Department of Health and Human Services (HHS). The Fair Accountability and Innovative Research Drug Pricing Act of 2016 (the FAIR Act)[38] required manufacturers to notify HHS and submit a transparency and justification report 30 days before a price increase of more than 10 percent during a 12-month period was implemented. Manufacturers also had to justify each price increase that took place during the year.[39] The FAIR Act imposed a $100,000 daily penalty on manufacturers that failed to submit a report.[40]

Other proposed legislation created an interagency drug price review board to collect data on drug and device prices and manufacturing costs and, if necessary, take enforcement action against manufacturers that charge consumers excessive prices.[41] The Prescription Drug and Medical Device Price Review Board Act of 2016 (the Act) created a board to review reports of each manufacturer of prescription drugs or medical devices sold in the United States and prescribe a formula for determining whether the average manufacturer price for a drug or device over an annual quarter is an excessive price.[42] The Act imposed civil penalties and reduced patent terms for manufacturers found to be charging excessive prices for prescription drugs or devices.[43]

Neither of these legislative proposals became law. However, the current Congress has proposed similar legislation. In January 2017, the Lower Drug Costs through Competition Act was filed in the House of Representatives.[44] The bill amends the Federal Food, Drug, and Cosmetic Act by revising review and approval provisions of certain generic drug applications or supplements to generic drug applications for certain drugs.[45] The House Energy and Commerce Committee is expected to take up this legislation as part of its effort to increase transparency around the backlog of generic drug applications and promote increased generic drug development to address high prescription drug prices.[46]

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[35] *Supra*, note 1.
[36] *States and the Rising Cost of Pharmaceuticals: A Call to Action*, NATIONAL ACADEMY FOR STATE HEALTH POLICY WORK GROUP, Oct. 2016, *available at,* http://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf (last visited March 13, 2017).
[37] Id.
[38] Fair Accountability and Innovative Research Drug Pricing Act of 2016, S. 3335 114th Cong. (Sept. 15, 2016), *available at,* https://www.congress.gov/114/bills/s3335/BILLS-114s3335is.pdf (last visited February 17, 2017).
[39] Id.
[40] Id.
[41] Prescription Drug and Medical Device Price Review Board Act of 2016, H.R. 6501 114th Cong. (Dec. 8, 2016), *available at*, https://www.congress.gov/bill/114th-congress/house-bill/6501/text (last visited March 13, 2017).
[42] Id.
[43] Id.
[44] Lower Drug Costs through Competition Act, H.R. 749 114th Cong. (Jan. 30, 2017), available at, https://www.congress.gov/bill/115th-congress/house-bill/749/text (last visited March 13, 2017).
[45] Id.
[46] *U.S. House panel to take up bill to spur generic drug development*, REUTERS, Feb. 2, 2017, http://www.reuters.com/article/us-usa-congress-genericdrugs-idUSKBN15H21B (Last visited March 13, 2017).

State Trends

State legislation proposing prescription drug manufacturer transparency and pricing requirements was filed in at least 16 states[47] during the 2015–2016 legislative sessions.[48] Common elements included imposing annual reporting requirements on manufacturers of higher-cost drugs,[49] imposing a cap on prices determined to be excessive, and establishing drug review boards or programs to review drug prices.[50]

In 2016, Vermont passed a law requiring the Attorney General to identify and report on up to 15 state-purchased prescription drugs on which the state spends a significant amount and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or 15 percent or more over the past 12 months.[51] The law requires drug manufacturers to provide a justification for the increase in the wholesale acquisition cost of the drug and provides fines for failure to do so of up to $10,000. The law also requires insurers to provide information about the State Health Benefit Exchange plan's drug formularies. The first report was published on December 1, 2016,[52] and identified ten drugs[53] subject to the new law.[54] In the report, manufacturers identified a number of factors they consider in making pricing decisions, including the economic value to patients given the effectiveness of the drug compared to other drugs in the same class, investments made in creating the drug, including in research and development, and the risks associated with manufacturing the drug.[55]

A ballot initiative in California, the California Drug Price Relief Act, (Proposition 61), which appeared on the 2016 ballot, proposed to cap the amount that any state agency could pay for prescription drugs at

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[47] Legislation was introduced in California, Colorado, Louisiana, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Vermont, Virginia, Washington and West Virginia.

[48] National Conference of State Legislatures, Richard Cauchi, *2015-2016 State Legislation to Require Prescription Drug Cost and Price Transparency*, Nov. 7, 2016, https://comm.ncsl.org/productfiles/83403539/2015-16_Leg_Cost_Trans_PresDrugs.pdf (last visited March 13, 2017).

[49] Id.; *see, e.g.,* S 7686, New York State Senate, https://www.nysenate.gov/legislation/bills/2015/s7686/amendment/original (last visited March 13, 2017); and SB 1010, California Senate, February 11, 2016, https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB1010 (last visited March 10, 2017). New York SB 7686, which sought to require drug manufacturers to file a an annual report on costs for prescription drugs with a price of $1,000 or more for a 30 day supply or an increased prices within a 3-month period of 3 times the consumer price index. The report required detailed statistics on fifteen segments of actual costs including research, clinical trials, production, marketing, direct-to-consumer advertising, and prescriber education, and required the state to make that information available online. Similarly, California SB 1010 would have required health plans to report detailed information on prescription drug costs, such as the most prescribed and most costly medicines, to the Department of Managed Health Care and Department of Insurance, which would then compile specified reported information into a consumer-friendly report addressing the overall impact of drug costs on health care premiums. Under SB 1010, drug manufacturers would have had to notify specified state purchasers, health plans, and health insurers, at least 60 days prior to the planned effective date, if the wholesale acquisition cost of a prescription drug was increasing by more than 10% during any 12-month period or if a prescription drug was being introduced to market that has a wholesale acquisition cost $10,000 or more annually or per course of treatment, and justify that cost.

[50] *See, e.g.,* A 762, New Jersey Assembly, Nov. 16, 2015, available at http://www.njleg.state.nj.us/2014/Bills/A5000/4722_I1.PDF (last visited March 13, 2017). New Jersey A. 762 sought to establish the Prescription Drug Review Commission that would develop a list of prescription drugs for which there was substantial public interest in understanding the development of pricing for the drugs and require the manufacturer of the drug to report on total costs for the drug, research and development costs, marketing cost, price for the drug in other countries, and the net typical price charged to pharmacy benefit managers.

[51] 18 V.S.A. s. 4631a.

[52] *Report of Attorney General to the Legislature Regarding Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635*, Vermont Attorney General's Office, Dec. 1, 2016, *available at,* http://ago.vermont.gov/assets/files/Consumer/AGO%20Report%20-%20Pharma%20Cost%20Transparency.pdf (last visited March 13, 2017).

[53] *Drug List Per Act 165*, Vermont Attorney General's Office, *available at* http://ago.vermont.gov/assets/files/Consumer/Drug%20List%20Per%20Act%20165.pdf (last visited March 13, 2017).

[54] *Supra*, note 52.

[55] Id.

the cost paid by the U.S. Department of Veterans Affairs.[56] The initiative was rejected with 54 percent of voters opposed to the initiative.[57] There is a similar ballot initiative slated for the November 2017 general election in Ohio.[58]

Effect of the Bill

Current law requires MyFloridaRx to list the top 100 most frequently prescribed drugs, although the website provides the top 150 most frequently prescribed drugs. HB 589 doubles the number of prescription drugs to be listed on the website to 300. Additionally, the bill codifies the current practice of monthly reporting of prescription drug pricing information to AHCA.

Consumers who query MyFloridaRx will have access to more pricing information for more prescription drugs as a result of the bill. Better-informed consumers can find and purchase lower-priced prescription drugs, thereby changing market demand and likely lowering overall prices. As retail pharmacies realize what their competitors are charging for the same prescription drug, prices will likely stabilize at the median price.

The bill also removes obsolete language referencing deadlines for implementing s. 408.062(1)(h), Fla. Stat., which have already passed.

The bill provides an effective date of upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.062, F.S., relating to research, analyses, studies, and reports.
Section 2: Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[56] *California Proposition 61, Drug Price Standards (2016),* BALLOTPEDIA, https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_(2016) (last visited March 13, 2017)
[57] *California Proposition 61 – Drug Price Standards Initiative – Results: Rejected*, THE NEW YORK TIMES, Dec. 13, 2016, http://www.nytimes.com/elections/results/california-ballot-measure-61-state-agency-drug-prices (last visited March 13, 2017).
[58] The measure is nearly identical to Proposition 61. *Drug price reduction campaign will return to Ohio in 2017,* THE COLUMBUS DISPATCH, Aug. 16, 2016, http://www.dispatch.com/content/stories/local/2016/08/16/drug-price-reduction-campaign-will-return-to-ohio-in-2017.html (last visited March 13, 2017).

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Consumers will have access to the usual and customary retail prices for 300 of the most frequently dispensed prescription drugs, which will help them make informed financial decisions on prescription drug purchases.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to prescription drug price
3 transparency; amending s. 408.062, F.S.; requiring the
4 Agency for Health Care Administration to collect data
5 on the retail prices charged by pharmacies for the 300
6 most frequently prescribed medicines; requiring the
7 agency to update its website monthly; providing an
8 effective date.
9
10 Be It Enacted by the Legislature of the State of Florida:
11
12 Section 1. Paragraph (h) of subsection (1) of section
13 408.062, Florida Statutes, is amended to read:
14 408.062 Research, analyses, studies, and reports.—
15 (1) The agency shall conduct research, analyses, and
16 studies relating to health care costs and access to and quality
17 of health care services as access and quality are affected by
18 changes in health care costs. Such research, analyses, and
19 studies shall include, but not be limited to:
20 (h) The collection of a statistically valid sample of data
21 on the retail prices charged by pharmacies for the <u>300</u> ~~100~~ most
22 frequently prescribed medicines from any pharmacy licensed by
23 this state ~~as a special study authorized by the Legislature to~~
24 ~~be performed by the agency quarterly~~. If the drug is available
25 generically, price data shall be reported for the generic drug

26 and price data of a brand-named drug for which the generic drug
27 is the equivalent shall be reported. The agency shall make
28 available on its Internet website for each pharmacy~~, no later~~
29 ~~than October 1, 2006,~~ drug prices for a 30-day supply at a
30 standard dose. The data collected shall be reported for each
31 drug by pharmacy and by metropolitan statistical area or region
32 and updated monthly ~~quarterly~~.
33 Section 2. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7009 PCB HQS 17-02 Ratification of Rules of the Board of Medicine
SPONSOR(S): Health Quality Subcommittee, Massullo, MD
TIED BILLS: **IDEN./SIM. BILLS:** SB 7012

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	13 Y, 0 N	Siples	McElroy
1) Health & Human Services Committee		Siples	Calamas
2) Rules & Policy Committee			

SUMMARY ANALYSIS

HB 7009 ratifies an adopted rule amendment to Rule 64B8-9.009, F.A.C., so that the adopted rule amendment may go into effect.

Under ch. 120, F.S., the Administrative Procedures Act, the formal rulemaking process begins by an agency giving notice of the proposed rule. The notice is published by the Department of State in the Florida Administrative Register and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

Rule 64B8-9.009, F.A.C., establishes the standard of care for various levels of office surgeries. In 2016, the Board of Medicine adopted an amendment to this rule as it applies to Level I office surgeries. Specifically, the rule amendment requires physician offices in which Level I office surgery procedures are performed to maintain the availability of two drugs, Flumazenil and Naloxone, when performing such procedures.

The SERC developed for the adopted rule amendment to Rule 64B8-9.009, F.A.C., shows that the amendment will create an adverse economic effect of $1,759.429.28, over the first 5 years the rule is in effect. Section 120.54(3), F.S., requires that any rule having an adverse economic impact exceeding $1 million over the first 5 years it is in effect must be ratified by the Legislature before it may go in effect.

The bill may have a negative fiscal impact on an individual physician office that performs Level I surgeries of $85.96. The total number of physician offices that may be impacted is 20,468. The bill has no fiscal impact on state or local governments.

The scope of the bill is limited to this rulemaking procedure and does not adopt the substance of the rule into statute.

The bill is effective upon coming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Rulemaking Authority and Legislative Ratification

Rulemaking authority is delegated by the Legislature[1] through statute and authorizes an agency to "adopt, develop, establish, or otherwise create"[2] a rule.[3] To adopt a rule an agency must have a general or specific grant of authority from the Legislature to implement a specific law through rulemaking.[4] The grant of rulemaking authority itself need not be detailed.[5] The specific statute being interpreted or implemented through rulemaking must provide specific standards and guidelines to preclude the administrative agency from exercising unbridled discretion in creating policy or applying the law.[6]

The formal rulemaking process begins by an agency giving notice of the proposed rule.[7] The notice is published by the Department of State in the Florida Administrative Register[8] and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

A SERC must be prepared if the proposed rule will have a negative impact on small business or if the proposed rule is likely to directly or indirectly increase the total regulatory costs by more than $200,000, within one year of the rule's implementation.[9] The SERC must include an economic analysis projecting a proposed rule's adverse effect on specified aspects of the state's economy or increase in regulatory costs.[10] The SERC must analyze a rule's potential impact over the 5 year period from when the rule goes into effect. The economic analysis should show whether the rule, directly or indirectly is:

- Likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment;[11]
- Likely to have an adverse impact on business competitiveness,[12] productivity, or innovation;[13]
- Likely to increase regulatory costs, including any transactional costs.[14]

A rule may be adopted but cannot go into effect if the analysis shows the projected impact of the proposed rule in any one of these areas will exceed $1 million in the aggregate for the 5 year period.[15]

[1] *Southwest Florida Water Management District v. Save the Manatee Club, Inc.*, 773 So. 2d 594 (Fla. 1st DCA 2000).
[2] Section 120.52(17), F.S.
[3] A rule is an agency statement of general applicability interpreting, implementing, or prescribing law or policy, including the procedure and practice requirements of an agency as well as certain types of forms. *See* s. 120.52(16), F.S., and *Florida Department of Financial Services v. Capital Collateral Regional Counsel-Middle Region,* 969 So. 2d 527, 530 (Fla. 1st DCA 2007).
[4] Section 120.52(8), F.S., and s. 120.536(1), F.S.
[5] *Save the Manatee Club, Inc., supra* note 1 at 599.
[6] *Sloban v. Florida Board of Pharmacy,*982 So. 2d 26, 29-30 (Fla. 1st DCA 2008); *Board of Trustees of the Internal Improvement Trust Fund v. Day Cruise Association, Inc.,* 794 So. 2d 696, 704 (Fla. 1st DCA 2001).
[7] Section 120.54(3)(a)1, F.S..
[8] Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.
[9] Section 120.54(1)(b), F.S.
[10] Section 120.541(2)(a), F.S.
[11] Section 120.541(2)(a)1., F.S.
[12] Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.
[13] Section 120.541(2)(a) 2., F.S.
[14] Section 120.541(2)(a) 3., F.S.
[15] Section 120.541(3), F.S.

The law distinguishes between a rule being "adopted" and becoming enforceable or "effective."[16] A rule must be filed for adoption before it may go into effect[17] and cannot be filed for adoption until completion of the rulemaking process.[18] A rule projected to have a specific economic impact exceeding $1 million in the aggregate over 5 years[19] must be ratified by the Legislature before it may go into effect.[20]

Rule 64B8-9.009, F.A.C.

Chapter 458, F.S., provides rulemaking authority for the licensure and regulation of the practice of medicine to the Department of Health (DOH) and the Florida Board of Medicine (Board). The Board has authority to establish, by rule, standards of practice and standards of care for particular settings.[21] Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[22]

In Rule 64B8-9.009, F.A.C., the Board sets forth the standards of care that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390 or 395, F.S.[23] Prior to performing any surgery, the physician must evaluate the risk of anesthesia and of the surgical procedure to be performed. The physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[24]

There are several levels of office surgeries that are governed by the rule, which sets forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery. Level I involves the most minor of surgeries, which require minimal sedation or local or topical anesthesia, and have a remote the chance of complications requiring hospitalization.[25] Level II office surgeries involve moderate sedation and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[26] Level III office surgeries are the most complex and require deep sedation or general anesthesia; the physician performing the surgery must have staff privileges to perform the same procedure in a hospital as that being performed in the office setting.[27]

A Level I office surgery includes the following:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas, repair of a laceration, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia;
- Liposuction involving removal of less than 4,000cc supernatant fat;[28]
- Incision and drainage of superficial abscesses, limited endoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple factures or small joint dislocations;
- Procedures that do not require pre-operative medication other than minimal pre-operative tranquilization of the patient; and the anesthesia used is local, topical, or none; or

[16] Section 120.54(3)(e)6. Before a rule becomes enforceable, thus "effective," the agency first must complete the rulemaking process and file the rule for adoption with the Department of State.
[17] Section 120.54(3)(e)6., F.S.
[18] Section 120.54(3)(e), F.S.
[19] Section 120.541(2)(a), F.S.
[20] Section 120.541(3), F.S.
[21] Section 458.331(v), F.S.
[22] *Id.*
[23] Rule 64B8-9.009(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.
[24] Rule 64B8-9.009(2), F.A.C.
[25] Rule 64B8-9.009(3), F.A.C.
[26] Rule 64B8-9.009(4), F.A.C.
[27] Rule 64B8-9.009(6), F.A.C.
[28] Liposuction may be performed with other separate procedures in a Level II or Level III office setting, but additional restrictions apply. *See* Rule 64B8-9.009(2), F.A.C.

- Procedures in which the chances of complication requiring hospitalization are remote.[29]

The Board rule for Level I office surgeries requires the surgeon to have training on regional anesthetic drugs and hold a current certification in advanced cardiac life support. Additionally, there must be an assistant present during the surgery who is certified in basic life support.[30] The rule also requires that the physician's office have available intravenous supplies, oxygen, oral airways, and a positive pressure ventilation device. The office must also have certain quantities of medication including atropine, diphenhydramine, epinephrine, and hydrocortisone.

Proposed Rule Amendment to Rule 64B8-9.009, F.A.C.

The proposed rule amendment requires physician offices that perform Level I office surgeries to obtain and have available two additional medications. The rule requires Flumazenil, if a benzodiazepine is administered, and Naloxone, if an opiate is administered. Flumazenil is used to reverse the effects of benzodiazepine-induced sedation,[31] and Naloxone is used to reverse the effects of opiate-induced sedation.[32] Both drugs are antagonists that may be used to block or reverse the effects of the sedation drug given during the surgical procedure if there is a case of excessive sedation.

The estimated cost to each physician office performing Level I office surgeries is $29.98 for the required quantity of Flumazenil and $55.98 for the required quantity of Naloxone.[33] The board estimates 20,468 physician offices may be affected by the rule change. This creates an adverse economic impact of $1,759,429.28 over the first 5 years the bill is in effect.[34]

Effect of Proposed Change

The bill ratifies Rule 64B8-9.009, FA.C., solely to meet the condition for effectiveness imposed by s. 120.541(3), F.S., and expressly limits ratification to the effectiveness of the rule. The bill directs that the act shall not be codified in the Florida Statutes, but only noted in the historical comments to the rule by the Department of State.

The bill is effective upon becoming law.

B. SECTION DIRECTORY:

Section 1: Ratifies Rule 64B8-9.009, F.A.C.,
Section 2: Provides that the act goes into effect upon becoming law.

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[29] Rule 64B8-9.009(3), F.A.C.
[30] *Id.* The rule specifically exempts physician performing certain 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 procedures from meeting this requirement.
[31] Scott R Votey et al., *Flumazenil: A New Benzodiazepine Antagonist*, 20 Annals of Emergency Medicine 181-188 (1991), *available at* http://www.annemergmed.com/article/S0196-0644(05)81219-3/pdf (last visited February 12, 2017). Benzodiazepine may include such drugs as Xanax®, Ativan®, or Valium®.
[32] U.S. National Library of Medicine, Medline Plus, "Naloxone Injection," (last rev. February 15, 2016), *available at* https://medlineplus.gov/druginfo/meds/a612022.html (last visited February 12, 2017).
[33] Board of Medicine, "Statement of Estimated Regulatory Costs for Proposed Amendments to Rule 64B8-9.009, F.A.C.," on file with the Health Quality Subcommittee.
[34] *Id.* These medications have a shelf-life that equals or exceeds 5 years.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill is not anticipated to have an adverse impact on the cost to DOH in implementing or enforcing the proposed rule.[35]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The individual cost for each physician office performing Level I office surgeries, as defined by the rule, will increase by $85.96. DOH estimates that there are approximately 20,468 physician offices that would be impacted by the rule.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill meets the final statutory requirement for the board to exercise its rulemaking authority concerning the standards of care for office surgery. No additional rulemaking authority is required.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[35] *Supra* note 33.

1 A bill to be entitled
2 An act relating to ratification of rules of the Board
3 of Medicine; ratifying rules related to the standard
4 of care for office surgery, for the sole and exclusive
5 purpose of satisfying any condition on effectiveness
6 pursuant to s. 120.541(3), F.S., which requires
7 ratification of any rule meeting any specified
8 thresholds for likely adverse impact or increase in
9 regulatory costs; providing applicability; providing
10 an effective date.
11
12 Be It Enacted by the Legislature of the State of Florida:
13
14 Section 1. (1) The following rule is ratified for the
15 sole and exclusive purpose of satisfying any condition on the
16 effectiveness imposed under s. 120.541(3), Florida Statutes:
17 Rule 64B8-9.009, Florida Administrative Code, titled "Standard
18 of Care for Office Surgery" as filed for adoption with the
19 Department of State pursuant to the certification package dated
20 June 15, 2016.
21 (2) This act serves no other purpose and shall not be
22 codified in the Florida Statutes. After this act becomes law,
23 its enactment and effective dates shall be noted in the Florida
24 Administrative Code, the Florida Administrative Register, or
25 both, as appropriate. This act does not alter rulemaking

26 authority delegated by prior law, does not constitute
27 legislative preemption of or exception to any provision of law
28 governing adoption or enforcement of the rule cited, and is
29 intended to preserve the status of any cited rule as a rule
30 under chapter 120, Florida Statutes. This act does not cure any
31 rulemaking defect or preempt any challenge based on lack of
32 authority or a violation of the legal requirements governing the
33 adoption of any rule cited.
34 Section 2. This act shall take effect upon becoming a law.

HB 7041

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7041 PCB OTA 17-02 Pub. Rec. and Meetings/Peer Review Panel/James & Esther King Biomedical Research Program & William G. "Bill" Bankhead, Jr., & David Coley Cancer Research Program

SPONSOR(S): Oversight, Transparency & Administration Subcommittee, Combee

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Oversight, Transparency & Administration Subcommittee	14 Y, 0 N	Toliver	Harrington
1) Health & Human Services Committee		Siples	Calamas
2) Government Accountability Committee			

SUMMARY ANALYSIS

The Open Government Sunset Review Act requires the Legislature to review each public record and each public meeting exemption five years after enactment. If the Legislature does not reenact the exemption, it automatically repeals on October 2nd of the fifth year after enactment.

The James and Esther King Biomedical Research Program was created to provide an annual and perpetual source of funding to support research initiatives that address the healthcare problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease. The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program was created to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process. Both programs award competitive grants and fellowships for biomedical research. The grants are awarded based on criteria and standards developed by the Biomedical Research Advisory Council and are reviewed by independent peer review panels.

Current law provides that when the peer review panels convene to evaluate grant or fellowship applications submitted to the James and Esther King Biomedical Research Program or to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, the portion of the meeting in which applications for biomedical research grants are discussed, is exempt from public meeting requirements. In addition, any records generated relating to research grant applications or the review of those applications, except final recommendations, are confidential and exempt from public record requirements. Information held confidential and exempt may be disclosed with the express written consent of the individual to whom the information pertains or the individuals legal guardian or by court order.

The bill reenacts the public meeting and public record exemptions, which will repeal on October 2, 2017, if this bill does not become law.

The bill does not appear to have a fiscal impact on state or local governments.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Open Government Sunset Review Act

The Open Government Sunset Review Act (Act)[1] sets forth a legislative review process for newly created or substantially amended public record or public meeting exemptions. It requires an automatic repeal of the exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.[2]

The Act provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. In addition, it may be no broader than is necessary to meet one of the following purposes:

- Allow the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protect sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protect trade or business secrets.[3]

If, and only if, in reenacting an exemption that will repeal, the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required.[4] If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created[5] then a public necessity statement and a two-thirds vote for passage are not required.

James and Esther King and Bankhead-Coley Research Programs

The James and Esther King Biomedical Research Program (King Program) is established within the Florida Department of Health (DOH) and is funded by the proceeds of the Lawton Chiles Endowment Fund, cigarette surcharge, and the General Revenue Fund.[6] The purpose of the King Program is to provide an annual and perpetual source of funding in order to support research initiatives that address the healthcare problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease.[7] The funds appropriated to the King Program are to be used to award research grants and fellowships.[8]

The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) is established within DOH and is funded by an annual appropriation from the General Revenue Fund.[9] The purpose of the Bankhead-Coley Program is to advance progress towards cures for cancer and cancer-related illnesses through grants awarded through a peer-reviewed process.[10]

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[1] Section 119.15, F.S.
[2] Section 119.15(3), F.S.
[3] Section 119.15(6)(b), F.S.
[4] Section 24(c), Art. I, FLA. CONST.
[5] An example of an exception to a public record exemption would be allowing another agency access to confidential and exempt records.
[6] Section 215.5602(1) and (12), F.S.
[7] Section 215.5602(1), F.S.
[8] Section 215.5602(2), F.S.
[9] Sections 381.922(5) and 215.5602(12), F.S.
[10] Section 381.922(1), F.S.

Research grants and fellowships are awarded based on criteria and standards developed by the Biomedical Research Advisory Council (Council),[11] an entity created within DOH.[12] Each grant or fellowship application is evaluated by a peer review panel to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit.[13] The peer review panel reviews the content of each proposal and establishes a scientific priority score.[14] The score must be considered in the review process by the Council[15] which then makes recommendations to the State Surgeon General as to what grants or fellowships should be awarded.[16] The Council and peer review panels are directed to establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest.[17]

Public Record and Public Meeting Exemptions under Review

In 2012, the Legislature created a public meeting exemption for portions of meetings of peer review panels under the King and Bankhead-Coley Programs.[18] The Legislature also created a public records exemption that provides that any research grant applications provided to the panel[19] or any records generated by the panel relating to the review of those applications, except final recommendations,[20] are confidential and exempt[21] from public record requirements. The information may only be disclosed with the express written consent of the individual to whom the information pertains or the individuals legal guardian or by court order.[22]

The 2012 public necessity statement for the exemptions provides that:[23]

> The research grant applications contain information of a confidential nature, including ideas and processes, the disclosure of which could injure the affected researcher. Maintaining confidentiality is a hallmark of scientific peer review when awarding grants, is practiced by the National Science Foundation and the National Institutes of Health, and allows for candid exchanges between reviewers critiquing proposals. The Legislature further finds that closing access to meetings of scientific peer review panels in which biomedical research applications are discussed serves a public good by ensuring that decisions are based upon merit without bias or undue influence. Further, the Legislature finds that records generated during meetings of the peer review panels related to the review of applications for biomedical research grants must be protected for the same reasons that justify the closing of such meetings.

Pursuant to the Open Government Sunset Review Act, the exemptions will repeal on October 2, 2017, unless reenacted by the Legislature.[24]

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[11] Section 215.5602(4)(f), F.S.

[12] Section 215.5602(3), F.S.

[13] Sections 215.5602(6) and 381.922(3)(b), F.S.

[14] Sections 215.5602(6) and 381.922(3)(b), F.S

[15] Sections 215.5602(6) and 381.922(3)(b), F.S.

[16] Section 215.5602(5)(b) and 381.922(3)(a), F.S.

[17] Sections 215.5602(7) and 381.922(3)(c), F.S.

[18] Sections 215.56021(1) and 318.92201(1), F.S.; *see also* ch. 2012-15, L.O.F.

[19] Sections 215.56021(3) and 318.92201(3), F.S.

[20] Sections 215.56021(2) and 381.92201(2), F.S.

[21] There is a difference between records the Legislature designates exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. (*See WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48, 53 (Fla. 5th DCA 2004), review denied 892 So.2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So.2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So.2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released, by the custodian of public records, to anyone other than the persons or entities specifically designated in the statutory exemption. (*See* Attorney General Opinion 85-62, August 1, 1985).

[22] Sections 215.56021(4) and 381.92201(4), F.S.

[23] Chapter 2012-15, L.O.F.

During the 2016 interim, subcommittee staff sent DOH a questionnaire as part of its review under the Open Government Sunset Review Act. DOH recommended reenactment of the exemptions as is, noting that "[g]rant applications contain novel research ideas, can be considered intellectual property, and should not be made available."[25] The department also explained that "[p]eer review exemptions for meetings and records are supported by the Biomedical Research Advisory Council and the Alzheimer's Disease Research Grant Advisory Board."[26]

Effect of the Bill

The bill removes the repeal date thereby reenacting the public meeting exemption for portions of a meeting of a peer review panel in which applications for biomedical research grants are discussed. The bill also reenacts the public record exemptions for research grant applications provided to a peer review panel and any records generated by the panel relating to the review of those applications, except final recommendations.

In 2012, the public meeting and public record exemptions were cross published in two different statutes. The bill repeals the duplicative provision from law. As such, the repeal of the duplicative provision does not have a substantive effect.[27]

B. SECTION DIRECTORY:

Section 1 repeals a duplicative statute.

Section 2 amends s. 381.92201, F.S., to save from repeal the public meeting and public record exemptions for peer review panels under the King and Bankhead-Coley Programs.

Section 3 provides an effective date of October 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

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[24] Sections 215.56021(5) and 381.92201(5), F.S.

[25] Open Government Sunset Review of ss. 215.56021 and 381.92201, F.S., relating to Peer Review Panels, questionnaire by House and Senate Staff, August 10, 2016, at question 11 (on file with the Oversight, Transparency & Administration Subcommittee).

[26] *Id.* at question 12.

[27] DOH confirmed in the questionnaire that one section of law would be sufficient to cover both the King and Bankhead-Coley Programs as both "statutory provisions are the same." *Id.* at question 9.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

1 A bill to be entitled
2 An act relating to a review under the Open Government
3 Sunset Review Act; repealing s. 215.56021, F.S., which
4 provides an exemption from public records and public
5 meeting requirements for certain records generated by,
6 and meetings of, a peer review panel under the James
7 and Esther King Biomedical Research Program and the
8 William G. "Bill" Bankhead, Jr., and David Coley
9 Cancer Research Program; amending s. 381.92201, F.S.,
10 which provides an exemption from public records and
11 public meeting requirements for certain records
12 generated by, and meetings of, a peer review panel
13 under the James and Esther King Biomedical Research
14 Program and the William G. "Bill" Bankhead, Jr., and
15 David Coley Cancer Research Program; removing the
16 scheduled repeal of the exemption; providing an
17 effective date.
18
19 Be It Enacted by the Legislature of the State of Florida:
20
21 Section 1. Section 215.56021, Florida Statutes, is
22 repealed.
23 Section 2. Subsection (5) of section 381.92201, Florida
24 Statutes, is amended to read:
25 381.92201 Exemptions from public records and public

26 meetings requirements; peer review panels.—
27 ~~(5) Subsections (1), (2), (3), and (4) are subject to the~~
28 ~~Open Government Sunset Review Act in accordance with s. 119.15~~
29 ~~and shall stand repealed on October 2, 2017, unless reviewed and~~
30 ~~saved from repeal through reenactment by the Legislature.~~
31 Section 3. This act shall take effect October 1, 2017.