Health & Human Services Committee

Tuesday, November 14, 2017
9:00 AM – 11:00 AM
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:	Tuesday, November 14, 2017 09:00 am
End Date and Time:	Tuesday, November 14, 2017 11:00 am
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 23 Recovery Care Services by Renner, Fitzenhagen
HB 35 Patient Safety Culture Surveys by Grant, M.
HB 37 Direct Primary Care Agreements by Burgess, Miller, M.
HB 41 Pregnancy Support and Wellness Services by Toledo

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, November 13, 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., Monday, November 13, 2017.

NOTICE FINALIZED on 11/07/2017 2:13PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 23 Recovery Care Services
SPONSOR(S): Renner
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Royal	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. The bill 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.

The bill 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 on state government.

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

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 442 licensed ASCs in Florida.[2] Of the 308 licensed hospitals in the state, 210 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 in 2015[9]:

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

[1] S. 395.002(3), F.S.
[2] Agency for Health Care Administration, *2018 Agency Legislative Bill Analysis-HB 23*, page 2, October 19, 2017 (on file with Health Innovation Subcommittee staff).
[3] Id.
[4] Agency for Health Care Administration, *Presentation on Ambulatory Surgical Centers- Health Innovation Subcommittee*, slide 10, January 25, 2017 (on staff with Health Innovation Subcommittee 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 Innovation Subcommittee 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 October 30, 2017).
[9] Id.

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;
- 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.

---

[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 October 30, 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.

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;
- 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;

[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 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]

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[35] following an admission.[36]

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

---

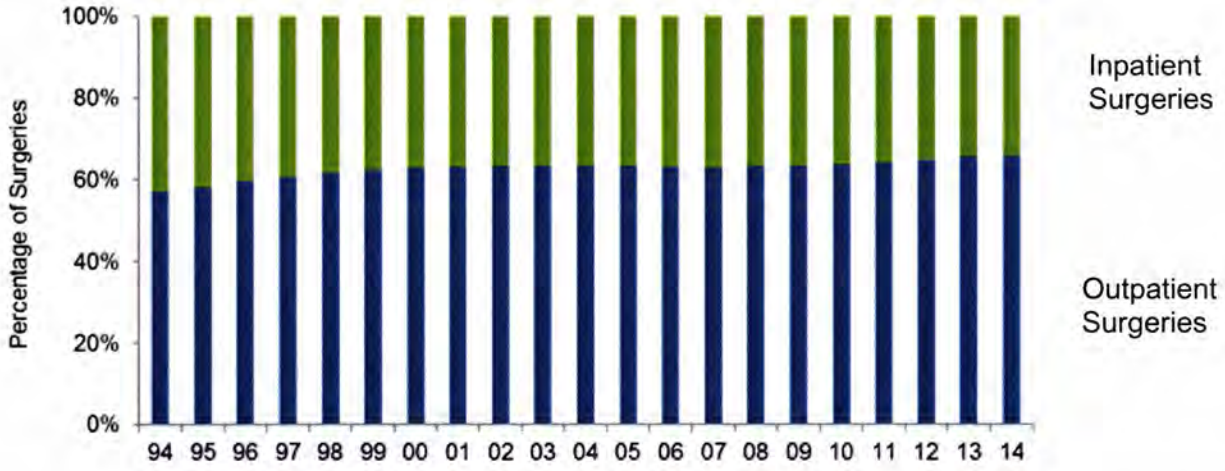
[28] Rule 59A-5.018(2)(a), F.A.C.
[29] Rule 59A-5.004(3), F.A.C.; Agency for Health Care Administration, Ambulatory Surgical Center, *Accrediting Organizations for Ambulatory Surgical Centers,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ambulatory.shtml (last viewed October 30, 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] 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 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.
[36] 42 C.F.R. §416.2

reasonable assurance that the conditions are met.[37] 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.[38] Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.[39] Research shows 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.[40]



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.

---

[37] 42 C.F.R. §416.26(a)(1)
[38] 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).
[39] Munnich E. and Parente S., *Returns to Specialization: Evidence from the Outpatient Surgery Market*, pg. 1 (April 2014), available at https://louisville.edu/faculty/elmunn01/Munnich_Parente_ASC_Quality.pdf (last viewed October 30, 2017); Chart data is from an analysis of the American Hospital Association Annual Survey data from 2014 for community hospitals.
[40] Shapiro, M.D., slide 5, January 25, 2017 (on file with Health Innovation Subcommittee 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).

ASC Cost of Care

Despite the volume of outpatient surgeries today, there is little research on cost savings associated with ASCs.[41] The study that found procedures in ASCs were completed 25 percent faster than the same procedures in hospital-based outpatient facilities also found that ASC efficiency generated a savings of $363-$1,000 per outpatient case.[42]

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.[43] 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.[44] The OIG also found that Medicare beneficiaries realized savings of $2 billion in the form of reduced co-payment obligations in the ASC setting.[45] 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.[46] Beneficiaries, in turn, would save $3 billion.[47]

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.[48] More than $5 billion of the cost reduction accrued to the patient through lower deductible and coinsurance payments.[49] 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.[50]

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.[51]

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.[52] Another

---

[41] Professor Elizabeth L. Munnich, University of Louisville, Louisville, Kentucky, Presentation on Measuring Cost and Quality in Ambulatory Surgical Centers-Health Innovation Subcommittee, slide 2, January 25, 2017 (on file with Health Innovation Subcommittee staff).

[42] Supra, FN 38 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.

[43] 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).

[44] Id. at pg. i.

[45] Id. at pg. ii.

[46] Id.

[47] Id.

[48] 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 October 30, 2017).

[49] Id.

[50] Id.

[51] Supra, FN 41, slide 8.

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.[53] 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.[54]

One study found patient satisfaction with care received at ASCs across the country measured at 92 percent.[55]

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.[56] 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.[57]

RCCs are not eligible for Medicare reimbursement.[58] However, RCCs may receive payments from Medicaid programs.

Three states, Arizona, Connecticut, and Illinois, have specific licenses for RCCs.[59] Other states license RCCs as nursing facilities or hospitals.[60] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[61]

---

[52] Office of Program Policy and Government Accountability, Research Memorandum, *Ambulatory Surgical Centers and Recovery Care Centers*, January 19, 2016 (on file with Health Innovation Subcommittee 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).

[53] Supra, FN 40 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.

[54] Supra, FN 41 at slide 8.

[55] *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.

[56] 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 October 30, 2017).

[57] Id. at pg. 4.

[58] Supra, FN 56.

[59] 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.

[60] 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 October 30, 2017).

[61] Supra FN 56, at pg. 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[62]	Connecticut[63]	Illinois[64]
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

[62] 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).
[63] Conn. Agencies Regs. § 19A-495-571.
[64] 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 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 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.[65]

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

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, 2018.

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.[66]

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 license are anticipated to cover the expense incurred by AHCA in enforcing and regulating the new license.[67]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

---

[65] S. 395.004, F.S.
[66] Supra, FN 2.
[67] Supra, FN 2.

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

A bill to be entitled

An act relating to recovery care services; amending s. 395.001, F.S.; providing legislative intent regarding recovery care centers; amending s. 395.002, F.S.; revising and providing definitions; amending s. 395.003, F.S.; including recovery care centers as facilities licensed under chapter 395, F.S.; creating s. 395.0171, F.S.; providing admission criteria for a recovery care center; requiring emergency care, transfer, and discharge protocols; authorizing the Agency for Health Care Administration to adopt rules; amending s. 395.1055, F.S.; authorizing the agency to establish separate standards for the care and treatment of patients in recovery care centers; amending s. 395.10973, F.S.; directing the agency to enforce special-occupancy provisions of the Florida Building Code applicable to recovery care centers; amending s. 408.802, F.S.; providing applicability of the Health Care Licensing Procedures Act to recovery care centers; amending s. 408.820, F.S.; exempting recovery care centers from specified minimum licensure requirements; amending ss. 385.211, 394.4787, 409.975, and 627.64194, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Section 395.001, Florida Statutes, is amended to read:

395.001 Legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of hospitals, ambulatory surgical centers, recovery care centers, and mobile surgical facilities by providing for licensure of same and for the development, establishment, and enforcement of minimum standards with respect thereto.

Section 2. Subsections (3), (16), and (23) of section 395.002, Florida Statutes, are amended, subsections (25) through (33) are renumbered as subsections (27) through (35), respectively, and new subsections (25) and (26) are added to that section, to read:

395.002 Definitions.—As used in this chapter:

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

or an office maintained for the practice of dentistry may ~~shall~~ not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

(16) "Licensed facility" means a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility licensed in accordance with this chapter.

(23) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital, ambulatory surgical, recovery, or mobile surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07(45), reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds,

and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

(25) "Recovery care center" means a facility the primary purpose of which is to provide recovery care services, in which a patient is admitted and discharged within 72 hours, and which is not part of a hospital.

(26) "Recovery care services" means postsurgical and postdiagnostic medical and general nursing care provided to a patient for whom acute care hospitalization is not required and an uncomplicated recovery is reasonably expected. The term includes postsurgical rehabilitation services. The term does not include intensive care services, coronary care services, or critical care services.

Section 3. Subsection (1) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility in this state.

(b)1. It is unlawful for a person to use or advertise to

the public, in any way or by any medium whatsoever, any facility as a "hospital," "ambulatory surgical center," "recovery care center," or "mobile surgical facility" unless such facility has first secured a license under the provisions of this part.

2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital," "ambulatory surgical center," "recovery care center," or "mobile surgical facility" as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.

Section 4. Section 395.0171, Florida Statutes, is created to read:

395.0171 Recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.—

(1) Admissions to a recovery care center are restricted to patients who need recovery care services.

(2) Each patient must be certified by his or her attending or referring physician or by a physician on staff at the facility as medically stable and not in need of acute care hospitalization before admission.

(3) A patient may be admitted for recovery care services upon discharge from a hospital or an ambulatory surgery center.

A patient may also be admitted postdiagnosis and posttreatment for recovery care services.

(4) A recovery care center must have emergency care and transfer protocols, including transportation arrangements, and referral or admission agreements with at least one hospital.

(5) A recovery care center must have procedures for discharge planning and discharge protocols.

(6) The agency may adopt rules to implement this section.

Section 5. Subsection (10) is renumbered as subsection (11), subsections (2) and (8) of section 395.1055, Florida Statutes, are amended, and a new subsection (10) is added to that section, to read:

395.1055 Rules and enforcement.—

(2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, recovery care centers, mobile surgical facilities, and statutory rural hospitals as defined in s. 395.602.

(8) The agency may not adopt any rule governing the design, construction, erection, alteration, modification, repair, or demolition of any public or private hospital, intermediate residential treatment facility, recovery care center, or ambulatory surgical center. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire

Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern hospitals, intermediate residential treatment facilities, recovery care centers, and ambulatory surgical centers.

(10) The agency shall adopt rules for recovery care centers which include fair and reasonable minimum standards for ensuring that recovery care centers have:

(a) A dietetic department, service, or other similarly titled unit, either on the premises or under contract, which shall be organized, directed, and staffed to ensure the provision of appropriate nutritional care and quality food service.

(b) Procedures to ensure the proper administration of medications. Such procedures shall address the prescribing, ordering, preparing, and dispensing of medications and appropriate monitoring of the effects of such medications on the patient.

(c) A pharmacy, pharmaceutical department, or pharmaceutical service, or similarly titled unit, on the premises or under contract.

Section 6. Subsection (8) of section 395.10973, Florida Statutes, is amended to read:

395.10973 Powers and duties of the agency.—It is the

function of the agency to:

(8) Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate residential treatment facilities, recovery care centers, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

Section 7. Subsection (30) is added to section 408.802, Florida Statutes, to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

(30) Recovery care centers, as provided under part I of chapter 395.

Section 8. Subsection (29) is added to section 408.820, Florida Statutes, to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(29) Recovery care centers, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

Section 9. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

385.211 Refractory and intractable epilepsy treatment and

research at recognized medical centers.—

(2) Notwithstanding chapter 893, medical centers recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(30) ~~395.002(28)~~ that contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 10. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(30) ~~395.002(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 11. Paragraph (b) of subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(30) ~~395.002(28)~~.

4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 12. Paragraphs (b) and (e) of subsection (1) of section 627.64194, Florida Statutes, are amended to read:

627.64194 Coverage requirements for services provided by nonparticipating providers; payment collection limitations.—

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

(b) "Facility" means a licensed facility as defined in s. 395.002(16) and an urgent care center as defined in s. 395.002(32) ~~395.002(30)~~.

(e) "Nonparticipating provider" means a provider who is not a preferred provider as defined in s. 627.6471 or a provider who is not an exclusive provider as defined in s. 627.6472. For purposes of covered emergency services under this section, a

facility licensed under chapter 395 or an urgent care center defined in s. 395.002(32) ~~395.002(30)~~ is a nonparticipating provider if the facility has not contracted with an insurer to provide emergency services to its insureds at a specified rate.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 35 Patient Safety Culture Surveys
SPONSOR(S): Grant
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Crosier	Calamas

SUMMARY ANALYSIS

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, accurate information about the cost and quality of health care is necessary for consumers to make value-based selections.

HB 35 requires the Agency for Health Care Administration (AHCA) to develop patient safety culture surveys to measure aspects of patient safety culture in hospital and ambulatory surgical centers. The surveys shall 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. In designing the survey or surveys, 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.

The bill requires facilities to annually conduct and submit the results of the AHCA-designed culture survey to the Florida Center, and authorizes AHCA to adopt rules to govern 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 for 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, 2018.

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 October 30, 2017, 215 of the 308 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

---

[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.

[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 source include:

- Health insurance claims and other administrative documents;

---

[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 October 27, 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 October 27, 2017).
[18] The World Bank, *Data-United States*, available at http://data.worldbank.org/country/united-states (last viewed October 27, 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 October 27, 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:

---

[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 October 27, 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 October 27, 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, ambulatory surgery center (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 statute 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. As mentioned previously, the duties and obligations were streamlined by HB 1175 in 2016 to eliminate obsolete language, redundant duties, and unnecessary functions. Now, the Florida Center must maintain any data sets in existence before July 1, 2016, unless such data sets duplicate information that is readily available from other credible sources, 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 that allows 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. 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.[36] The survey has since been implemented in hundreds of hospitals across the United States, and in other countries. 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.[37] 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.[38] In 2016, 680 hospitals submitted survey results to the database.[39] 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.[40] 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.

---

[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] 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 October 27, 2017). Besides hospitals, AHRQ developed patient safety culture surveys for hospitals, nursing homes, ambulatory outpatient medical offices, community pharmacies, and ambulatory surgery centers.

[37] Id.

[38] Id.

[39] 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 October 27, 2017).

[40] Id.

- 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.

The survey[41] 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.
- 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 feel free to question the decisions or actions of those with more authority.
  - Staff are 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.

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.[42] In 2014, AHRQ conducted a pilot study on the use of the Patient Safety Culture survey in 59 ASCs.[43] 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.[44] 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.

---

[41] The survey is available at http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/hospital/resources/hospscanform.pdf.
[42] The survey is available at http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/asc/resources/ascsurvey.pdf.
[43] 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 October 27, 2017).
[44] Id. at pg. 1.

University of Texas Safety Attitudes Questionnaire

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[45]. 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.[46]

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.[47] 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.[48]

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.[49] 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.[50]

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.[51] Using the SAQ-ICU version, the study found that lower

---

[45] 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.

[46] 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.

[47] 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.

[48] For each version of the SAQ, item content is the same, with minor modifications to reflect the clinical area.

[49] Makary M., Sexton B. *Patient safety in surgery*. Annals of Surgery 2006; 243:628-35.

[50] Makary, M. *Unaccountable: What Hospitals Won't Tell You and How Transparency Can Revolutionize Health Care* pgs. 90-92 (2012).

[51] Supra, FN 47.

perceptions of management among ICU personnel were significantly associated with higher hospital mortality.[52] 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.[53] 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.[54] Other studies have also found a correlation between positive teamwork attitudes and patient outcomes in ICUs.[55]

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.[56] Another study found a correlation between poor safety climate scores and high burnout rates among NICU nurses.[57] An additional study found that positive teamwork attitudes measured by patient safety culture survey tools are associated with better patient outcomes in pediatric surgery.[58]

Effect of Proposed Changes

HB 35 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. In designing the survey or surveys, 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 to develop the patient safety culture survey.

The bill requires facilities to annually conduct and submit the results of the AHCA-designed culture survey to the Florida Center, and authorizes AHCA to adopt rules to govern 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.

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

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

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.
Section 4: Amends s. 400.991, F.S., relating to licensure requirements; background screenings; prohibitions.

---

[52] Id. at pg. 155.
[53] Id.
[54] Id. at pgs. 155-56.
[55] 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.
[56] Singer S., Lin S. *Relationship of safety climate and safety performance in hospitals.* Health Serv Res 2009;44:399-421.
[57] Profit J., Sharek P. *Burnout in the NICU setting and its relation to safety culture.* BMJ Qual Saf 2014;23:806-813.
[58] 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 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 for an appropriation.
Section 8: Provides an effective date of July 1, 2018.

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, and 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 $352,919 in recurring funds from the Health Care Trust Fund. 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.

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:

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

A bill to be entitled

An act relating to patient safety culture surveys; amending s. 408.05, F.S.; requiring the Agency for Health Care Administration to develop surveys to assess patient safety culture in certain health care facilities; amending s. 408.061, F.S.; revising requirements for the submission of health care data to the agency; amending s. 408.810, F.S.; requiring the submission of patient safety culture survey data as a condition of licensure; amending ss. 400.991, 408.8065, and 408.820, F.S.; conforming cross-references; providing an appropriation; providing an effective date.

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

Section 1. Paragraphs (d) through (i) of subsection (3) of section 408.05, Florida Statutes, are redesignated as paragraphs (e) through (j), respectively, present paragraph (j) is redesignated as paragraph (k) and amended, and a new paragraph (d) is added to that subsection, to read:

408.05 Florida Center for Health Information and Transparency.—

(3) HEALTH INFORMATION TRANSPARENCY.—In order to disseminate and facilitate the availability of comparable and

uniform health information, the agency shall perform the following functions:

(d) Design a patient safety culture survey or surveys to be completed annually by each hospital and ambulatory surgical center licensed under chapter 395. The survey shall be designed 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 perception of facility support for patient safety, and staff opinions on whether the staff member would undergo a health care service or procedure at the facility. The survey shall be anonymous to encourage staff employed by or working in the facility to complete the survey. The agency shall 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 Safety Attitudes Questionnaire developed by the University of Texas, to develop the patient safety culture survey. This paragraph does not apply to licensed facilities operating exclusively as state facilities.

(k) ~~(j)~~ Conduct and make available the results of special health surveys, including facility patient safety culture surveys, health care research, and health care evaluations

conducted or supported under this section. Each year the center shall select and analyze one or more research topics that can be investigated using the data available pursuant to paragraph (c). The selected topics must focus on producing actionable information for improving quality of care and reducing costs. The first topic selected by the center must address preventable hospitalizations.

Section 2. Paragraph (a) of subsection (1) of section 408.061, Florida Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(1) The agency shall require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties and to facilitate transparency in health care pricing data and quality measures. Specifications for data to be collected under this section shall be developed by the agency and applicable contract vendors, with the assistance of technical advisory panels including representatives of affected entities, consumers, purchasers, and such other interested parties as may be determined by the agency.

(a) Data submitted by health care facilities, including the facilities as defined in chapter 395, shall include, but are not limited to: case-mix data, patient admission and discharge

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

information submitted is true and accurate.

Section 3. Subsections (8), (9), and (10) of section 408.810, Florida Statutes, are renumbered as subsections (9), (10), and (11), respectively, and a new subsection (8) is added to that section to read:

408.810 Minimum licensure requirements.—In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license.

(8) Each licensee subject to s. 408.05(3)(d) shall submit facility patient safety culture surveys to the agency in accordance with applicable rules.

Section 4. Paragraph (c) of subsection (4) of section 400.991, Florida Statutes, is amended to read:

400.991 License requirements; background screenings; prohibitions.—

(4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

(c) Proof of financial ability to operate as required under s. 408.810(9) ~~408.810(8)~~. As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least

$500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond.

Section 5. Paragraph (a) of subsection (1) of section 408.8065, Florida Statutes, is amended to read:

408.8065 Additional licensure requirements for home health agencies, home medical equipment providers, and health care clinics.—

(1) An applicant for initial licensure, or initial licensure due to a change of ownership, as a home health agency, home medical equipment provider, or health care clinic shall:

(a) Demonstrate financial ability to operate, as required under s. 408.810(9) ~~408.810(8)~~ and this section. If the applicant's assets, credit, and projected revenues meet or exceed projected liabilities and expenses, and the applicant provides independent evidence that the funds necessary for startup costs, working capital, and contingency financing exist and will be available as needed, the applicant has demonstrated the financial ability to operate.

All documents required under this subsection must be prepared in accordance with generally accepted accounting principles and may be in a compilation form. The financial statements must be signed by a certified public accountant.

Section 6. Section 408.820, Florida Statutes, is amended to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(1) Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.

(2) Birth centers, as provided under chapter 383, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

(3) Abortion clinics, as provided under chapter 390, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

(4) Crisis stabilization units, as provided under parts I and IV of chapter 394, are exempt from s. 408.810(9)-(11) ~~408.810(8)-(10)~~.

(5) Short-term residential treatment facilities, as provided under parts I and IV of chapter 394, are exempt from s. 408.810(9)-(11) ~~408.810(8)-(10)~~.

(6) Residential treatment facilities, as provided under part IV of chapter 394, are exempt from s. 408.810(9)-(11) ~~408.810(8)-(10)~~.

(7) Residential treatment centers for children and adolescents, as provided under part IV of chapter 394, are exempt from s. 408.810(9)-(11) ~~408.810(8)-(10)~~.

(8) Hospitals, as provided under part I of chapter 395,

are exempt from s. 408.810(7), (9), and (10) ~~408.810(7)-(9)~~.

(9) Ambulatory surgical centers, as provided under part I of chapter 395, are exempt from s. 408.810(7), (9), (10), and (11) ~~408.810(7)-(10)~~.

(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

(11) Health care risk managers, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810(4)-(11) ~~408.810(4)-(10)~~, and 408.811.

(12) Nursing homes, as provided under part II of chapter 400, are exempt from ss. 408.810(7) and 408.813(2).

(13) Assisted living facilities, as provided under part I of chapter 429, are exempt from s. 408.810(11) ~~408.810(10)~~.

(14) Home health agencies, as provided under part III of chapter 400, are exempt from s. 408.810(11) ~~408.810(10)~~.

(15) Nurse registries, as provided under part III of chapter 400, are exempt from s. 408.810(6) and (11) ~~(10)~~.

(16) Companion services or homemaker services providers, as provided under part III of chapter 400, are exempt from s. 408.810(6)-(11) ~~408.810(6)-(10)~~.

(17) Adult day care centers, as provided under part III of chapter 429, are exempt from s. 408.810(11) ~~408.810(10)~~.

(18) Adult family-care homes, as provided under part II of chapter 429, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

(19) Homes for special services, as provided under part V of chapter 400, are exempt from s. 408.810(7)-(11) ~~408.810(7)-(10)~~.

(20) Transitional living facilities, as provided under part XI of chapter 400, are exempt from s. 408.810(11) ~~408.810(10)~~.

(21) Prescribed pediatric extended care centers, as provided under part VI of chapter 400, are exempt from s. 408.810(11) ~~408.810(10)~~.

(22) Home medical equipment providers, as provided under part VII of chapter 400, are exempt from s. 408.810(11) ~~408.810(10)~~.

(23) Intermediate care facilities for persons with developmental disabilities, as provided under part VIII of chapter 400, are exempt from s. 408.810(7).

(24) Health care services pools, as provided under part IX of chapter 400, are exempt from s. 408.810(6)-(11) ~~408.810(6)-(10)~~.

(25) Health care clinics, as provided under part X of chapter 400, are exempt from s. 408.810(6), (7), and (11) ~~(10)~~.

(26) Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.

(27) Multiphasic health testing centers, as provided under part II of chapter 483, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.

(28) Organ, tissue, and eye procurement organizations, as provided under part V of chapter 765, are exempt from s. 408.810(5)-(11) ~~408.810(5)-(10)~~.

Section 7. For the 2018-2019 fiscal year, one full-time equivalent position with associated salary rate of 41,106 is authorized, and the sum of $352,919 in recurring funds from the Health Care Trust Fund is appropriated to the Agency for Health Care Administration, for the purpose of implementing the requirements of this act.

Section 8. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 37 Direct Primary Care Agreements
SPONSOR(S): Burgess, Jr. and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 80

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Crosier	Calamas

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.

HB 37 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, 2018.

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 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	372
Third Party Administrators	306
Continuing Care Retirement Communities	73
Discount Medical Plan Organizations	37
Health Maintenance Organizations	36
Fraternal Benefit Societies	37
Prepaid Limited Health Service Organizations/Prepaid Health Clinics	22

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 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

[1] Email correspondence from OIR staff dated August 31, 2017, reflecting the number of entities in the state as of August 21, 2017 (on file with Health and Human Services Committee staff).

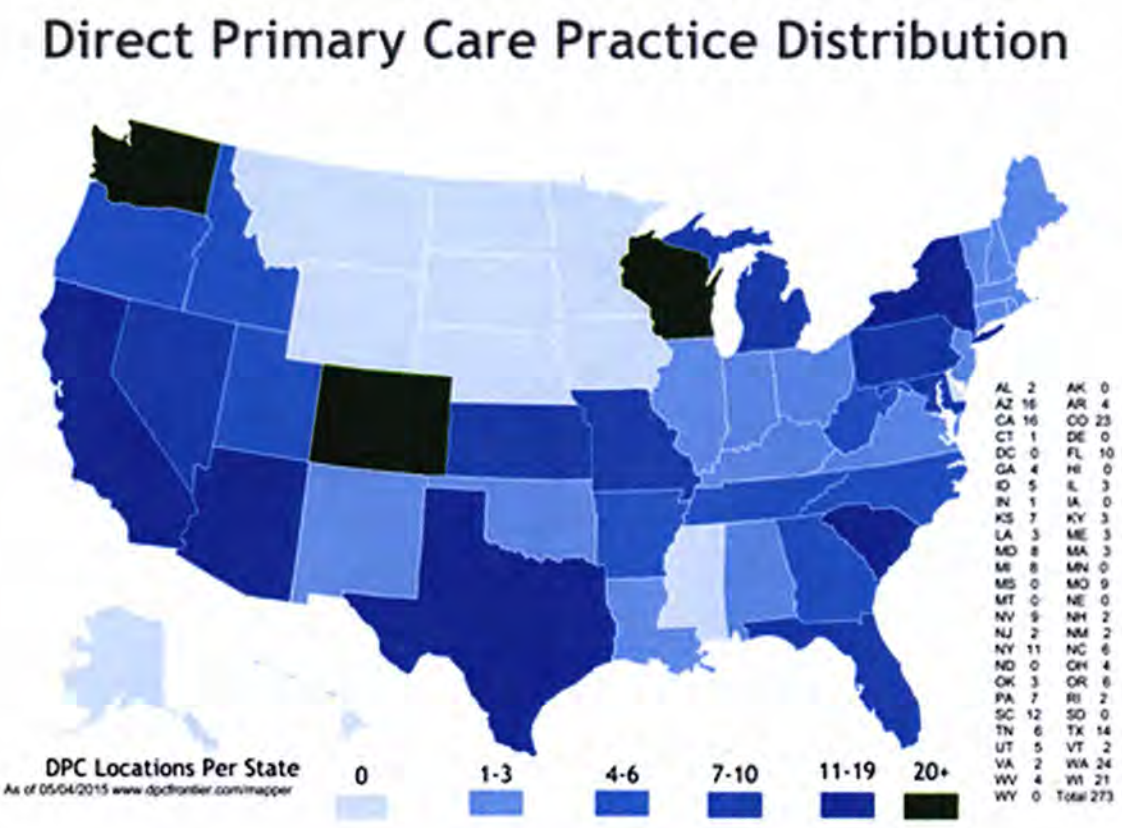
[2] A recent study of 141 DPC practices found the average monthly fee to be $77.38. Philip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med., November-December 2015, Vol. 28 No. 6, pg. 797; approximately two thirds 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 August 31, 2017).

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

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.

Nationwide, there are an estimated 4,400 direct primary care physicians nationwide, up from 756 in 2010[5], in 620 direct primary care practices.[6] The following chart illustrates the concentration of DPC practices in the United States:[7]



[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 August 31, 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 August 31, 2017).
[6] As of August 1, 2017, Direct Primary Care Coalition, available at: http://www.dpcare.org (last viewed August 31, 2017).
[7] Supra, FN 2, Eskew and Klink.

As of June 2016, sixteen states have approved legislation which defines DPC agreements or services as outside the scope of state regulation[8]:

- Washington
- West Virginia
- Oregon
- Utah
- Arizona
- Louisiana
- Michigan
- Mississippi
- Idaho
- Oklahoma
- Kansas
- Missouri
- Texas
- Nebraska
- Tennessee
- Wyoming[9]

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 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)[10] 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.[11] 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.[12] In Colorado and Washington, qualified health plans are offering DPC medical home coverage on each state-based health insurance exchange.[13]

---

[8] Direct Primary Care Coalition, *On the Move in the States with DPC*, available at: http://www.dpcare.org (last viewed August 31, 2017).
[9] 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.
[10] Pub. L. No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).
[11] 42 U.S.C. §1802 (a)(3); 45 C.F.R. §156.245
[12] 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.
[13] 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).

Effect of Proposed Changes

HB 37 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.

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

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, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The Revenue Estimating Conference (REC) has not considered the fiscal impact of HB 37 on the Insurance Premium Tax Group trust fund at this time.

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

A bill to be entitled

An act relating to direct primary care agreements; creating s. 624.27, F.S.; providing definitions; specifying that a direct primary care agreement does not constitute insurance and is not subject to the Florida Insurance Code; specifying that entering into a direct primary care agreement does not constitute the business of insurance and is not subject to the code; providing that a certificate of authority is not required to market, sell, or offer to sell a direct primary care agreement; specifying requirements for a direct primary care agreement; providing an effective date.

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

Section 1. Section 624.27, Florida Statutes, is created to read:

624.27 Direct primary care agreements; exemption from code.—

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

(a) "Direct primary care agreement" means a contract between a primary care provider and a patient, a patient's legal representative, or a patient's employer, which meets the requirements of subsection (4) and does not indemnify for

services provided by a third party.

(b) "Primary care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, or chapter 464, or a primary care group practice, who provides primary care services to patients.

(c) "Primary care services" means the screening, assessment, diagnosis, and treatment of a patient conducted within the competency and training of the primary care provider for the purpose of promoting health or detecting and managing disease or injury.

(2) A direct primary care agreement does not constitute insurance and is not subject to the Florida Insurance Code. The act of entering into a direct primary care agreement does not constitute the business of insurance and is not subject to the Florida Insurance Code.

(3) A primary care provider or an agent of a primary care provider is not required to obtain a certificate of authority or license under the Florida Insurance Code to market, sell, or offer to sell a direct primary care agreement.

(4) For purposes of this section, a direct primary care agreement must:

(a) Be in writing.

(b) Be signed by the primary care provider or an agent of the primary care provider and the patient, the patient's legal representative, or the patient's employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of primary care services that are covered by the monthly fee.

(e) Specify the monthly fee and any fees for primary care services not covered by the monthly fee.

(f) Specify the duration of the agreement and any automatic renewal provisions.

(g) Offer a refund to the patient, the patient's legal representative, or the patient's employer of monthly fees paid in advance if the primary care provider ceases to offer primary care services for any reason.

(h) Contain, in contrasting color and in at least 12-point type, the following statement on the signature page: "This agreement is not health insurance and the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any primary care services covered by the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not workers' compensation insurance and does not replace an

employer's obligations under chapter 440."

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 41 Pregnancy Support and Wellness Services
SPONSOR(S): Toledo
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

The Florida Pregnancy Support Services Program (FPSSP) was established in 2005, to provide supportive counseling and services to pregnant women and their families that promote and encourage childbirth. Under contract with the Department of Health (DOH), Florida Pregnancy Care Network, Inc., manages a network of pregnancy help centers that offer services such as pregnancy testing, counseling, education and training, and referrals to state, community, and medical resources.

The program was created by proviso in 2005, and has received annual appropriations since 2006. The bill codifies the program and defines program requirements.

HB 41 requires DOH to contract with the Florida Pregnancy Care Network, Inc., (FPCN), to provide contract management services for the delivery of pregnancy support services to pregnant women and their families and wellness services to women, regardless of pregnancy. The contract must:

- Require FPCN to establish and manage subcontracts with a sufficient number of providers to ensure the availability of pregnancy support and wellness services for eligible clients;
- Limit the amount of funds that may be used for administration costs;
- Require all paid staff or volunteers of a provider to undergo a background screening if they provide direct services to minors, elderly individuals, or individuals who have a disability;
- Require FPCN to monitor its subcontractors annually, and establish sanctions for noncompliance;
- Require FPCN to only subcontract with providers that solely promote and support childbirth;
- Require informational materials provided to eligible clients be current and accurate, and the reference source of any medical statements made in such materials be made available to eligible clients; and
- Define the contract deliverables, including financial reports and other reports due to DOH.

The bill requires that any services provided under FPSSP be provided in a non-coercive manner, and does not include any religious content.

The bill codifies an existing program funded by $4 million in recurring general revenue funds. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Pregnancy Support Services Program

The Florida Pregnancy Support Services Program (FPSSP) was created in 2005, to encourage women to carry their pregnancies to term, and increase awareness of non-abortion counseling options, such as parenting or adoption.[1] The program, through a network of private pregnancy support centers, provides services to pregnant women (or women who suspect they are pregnant) and their families at no charge, which may continue for 12 months after the birth of the child. Interested women may be connected to a local participating center by accessing a free helpline via telephone, text, or email. The services provided include:

- Free pregnancy testing;
- Abortion education;
- Alternatives to abortion;
- Education and training;
- Counseling; and
- Referrals to state, community, and medical resources.[2]

Currently, the Department of Health (DOH) contracts with the Florida Pregnancy Care Network, Inc. (FPCN), to manage subcontracts with the direct service providers throughout the state that provide the services listed above, as well as an operational call center.[3] The network consists of 61 Florida pregnancy resource organizations representing 105 pregnancy centers.[4]

Under the contract with DOH, a participating provider must:

- Be an established pregnancy organization with a fully functioning pregnancy support program in existence for at least one year;
- Be recognized as tax-exempt under IRS Code 501(c)(3);
- Have a primary mission to promote life-affirming decisions among its clients;
- Provide FPSSP services in a manner that is non-coercive and does not include religious content;
- Offer pregnancy tests and counseling for women who are pregnant or suspect they are pregnant, and seek FPSSP services voluntarily;
- Have a board that hires and oversees a director who implements board policy and manages the organization's operations;
- Maintain a system of financial accountability consistent with generally accepted accounting principles;
- Have board members, directors, employees, and volunteers participate in continuing education, as necessary, in order to effectively perform their duties;
- Not discriminate on the basis of race, creed, color, national origin, age, or marital status;
- Provide services that are confidential, nonjudgmental, and free of charge;
- Make available support information, education, and counseling to women, their partners, and their families to solely promote and support childbirth and to assist them in decisions regarding adoption or parenting; and

---

[1] Florida Pregnancy Care Network, Inc., *Florida Pregnancy Support Services Program (FPSSP), 2016-2017 Compliance Manual*, on file with the Health Quality Subcommittee.
[2] Florida Pregnancy Support Services, *About Us*, available at http://www.floridapregnancysupportservices.com/about-us/ (last visited November, 2017).
[3] *Supra* note 1.
[4] E-mail correspondence with FPCN staff dated October 24, 2017, (on file with the Health and Human Services Committee).

- Must complete FPSSP training.[5]

Under the contract, providers may only be reimbursed for the face-to-face services that they provide to eligible clients. Providers are paid $60 per hour for face-to-face services and are reimbursed $1.50 for each pregnancy test provided to a FPSSP client.[6] Payment is provided monthly through the submission of a properly completed invoice and monthly report.[7] Providers are also responsible for submitting quarterly (including financial reports) and final reports addressing operations for FPSSP during the contract period.

The contract is subject to annual monitoring by DOH to ensure compliance with the contract's provisions. DOH last monitored the program for administrative and programmatic compliance in April 2017, and found the program to be compliant with the terms and conditions of its contract.[8] The Department of Financial Services last reviewed the contract in 2014 for statutory compliance and found no deficiencies with the contract and that DOH's contract management activities were sufficient.[9]

The FPSSP operates a 24-hour toll free number that offers referrals to local pregnancy centers, as well as a text hotline, to which an individual may text the word "choices," for assistance. Assistance is also available by e-mail.[10] In Fiscal Year 2016-2017, the FPSSP served 45,722 clients, provided 143,206 services, and handled 6,064 phone calls to its helpline.[11]

When FPSSP was established, DOH received an initial annual appropriation of $2 million in proviso in the General Appropriations Act to establish and operate the FPSSP.[12] DOH has annually received funding for the operation of the FPSSP in the proviso of the annual appropriations bill. In Fiscal Years 2016-2017 and 2017-2018, the FPSSP received an appropriation of $4 million and was authorized, in proviso, to provide wellness services, including but not limited to, high blood pressure screening, flu vaccines, anemia testing, thyroid screening, cholesterol screening, diabetes screening, assistance with smoking cessation, and tetanus vaccines.[13] Such wellness services may be offered through vouchers or other arrangements that allow the purchase of services from qualified providers.

The FPSSP initiated a pilot project offering wellness services in February 2017, and has since provided wellness services to 2,553 clients, including the performance of on-site testing for sexually transmitted infections (STIs) for 1,959 clients.[14] The program began with 12 providers offering wellness services, but have since added an additional 6 providers, for a total of 18 providers offering wellness services.[15] An additional 12 providers are on a waiting list to offer wellness services to their clients.

Providers Offering Wellness Services Including STI Testing	
A Woman's Choice, Inc.*	Lakeland
A Woman's Place*	Largo

[5] *Id.*
[6] *Id.*
[7] The monthly invoice must include the total reimbursable minutes and the amount requested. In the monthly report, the provider must include the total number of client visits, the number of unduplicated clients served, the number of new clients, the total number of services provided, and how the clients learned of the services.
[8] E-mail correspondence with the Department of Health, dated October 24, 2017.
[9] Department of Financial Services, Bureau of Auditing, "Contract Review Detail by Agency," (July 8, 2015), available at http://www.myfloridacfo.com/aadir/docs/TransparencyReport-7-1-14thru6-30-15.pdf (last visited March 30, 2017). The contract review looks at whether there are clearly established tasks to be performed, whether the tasks to be performed are quantifiable, measurable, and verifiable units of deliverables that must be received and accepted before payment is made, if the contract contains financial consequences if the provider fails to perform in accordance with the contract, whether the contract contains or references statutory provisions related to contracting, and if the agency's contract management activities are sufficient.
[10] *Supra* note 2.
[11] E-mail correspondence with FPCN staff dated October 16, 2017 (on file with the Health and Human Services Committee).
[12] Chapter 2006-25, Laws of Fla., l. 536. These funds are separate from the funds that are generated in the sale of the "Choose Life" license plate. Pursuant to s. 320.08058(29), F.S., funds generated by the license plates are distributed to nongovernmental, not-for-profit agencies within each Florida county which assist pregnant women who are making an adoption plan for their children. The funds are distributed in an amount based on the collection of annual use fees in each county. Agencies that are involved in or associated with abortion activities are specifically prohibited from receiving any fees generated by use of the license plate.
[13] *See* Chapters 2016-66, l. 464, and 2017-70, l. 445, Laws of Fla., respectively.
[14] *Supra* note 11.
[15] E-mail correspondence with FPCN staff dated August 17, 2017 (on file with the Health and Human Services Committee).

Hope Pregnancy Centers, Inc.*	North Lauderdale
Options for Women Pregnancy Help Clinic, Inc.*	Lakeland
Verity Pregnancy and Medical Resource Center	Fort Myers
Providers Offering Wellness Services Excluding STI Testing	
A New Generation of Hernando, Inc.	Springhill
A Woman's Answer Medical Center	Gainesville
Catholic Charities, Inc.*	St. Petersburg
Crisis Pregnancy Center of Gainesville, Inc. d/b/a Sira	Gainesville
Guiding Star Tampa	Lutz
Heartbeat of Miami, Inc.*	Miami
Mary's Pregnancy Resource Center, Inc.*	Fort Lauderdale
Southlake Pregnancy and Family Care Center	Clermont
St. Petersburg Pregnancy Center, Inc.	St. Petersburg
West Pasco Pregnancy Center	New Port Richey
Woman's Care Center of IRC, Inc.	Vero Beach
Providers Offering STI Testing Only	
Sarasota Medical Pregnancy Center, Inc.	Sarasota
Pregnancy Resources	Melbourne

* Provider may offer services at multiple locations.

Effect of Proposed Changes

The bill creates s. 381.96, F.S., to codify the FPSSP in Florida Statutes. The bill establishes eligibility for the program for pregnant women (or women who suspect they are pregnant) who voluntarily seek pregnancy support services and women who voluntarily seek wellness services. The family of a pregnant woman or a woman who suspects she is pregnant is also eligible to receive services. Eligibility for pregnancy support services continues for up to 12 months after the birth of the child.

The bill codifies the services to be provided under the program including pregnancy support services and wellness services. Pregnancy support services, as defined in the bill, are services that promote and encourage childbirth, including direct client services, program awareness activities, and communication activities. Wellness services, as defined by the bill, are services or activities intended to maintain and improve health or prevent illness and injury, including but not limited to flu and tetanus vaccines, anemia testing, assistance with smoking cessation, and screenings for high blood pressure, thyroid functioning, cholesterol, and diabetes.

The bill requires DOH to contract with the Florida FPCN, to provide contract management services for the FPSSP. It requires the FPCN to provide a comprehensive system of care through subcontracts to meet the pregnancy support and wellness needs of eligible clients. The contract with FPCN must:

- Require that FPCN establish and manage subcontracts with a sufficient number of providers to ensure the availability pregnancy support and wellness services for eligible clients;
- Require that 90 percent of contract funds be used on pregnancy support and wellness services for eligible clients;
- Require that FPCN ensures that all paid staff and volunteers of the providers undergo background screenings if they provide direct client services to eligible clients who are minors, elderly, or have a disability;
- Require FPCN to annually monitor the providers for compliance with subcontract provisions and define the actions to be taken for noncompliance;
- Limit the providers with which FPCN may contract to those that solely promote and support childbirth;
- Provide that any informational materials provided to an eligible client by a provider must be current and accurate, with the reference source of any medical statement made available; and

- Define the contract deliverables, including financial reports and other reports due to DOH, timeframes for achieving contractual obligations, and any other requirements that DOH determines necessary, such as staffing and location requirements.

The bill expressly provides that the services provided under the FPSSP be provided in a non-coercive manner and does not include any religious content.

The bill takes effect on July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.96, F.S.; relating to pregnancy support and wellness services.
Section 2: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has no fiscal impact. The bill codifies an existing program funded by $4 million in recurring general revenue funds in the General Appropriations Act each year.

   DOH currently incurs costs related to the oversight of the contractor, which will continue under the bill. Proviso language has limited DOH to $50,000 for agency oversight activities.

   The bill provides that volunteers that provide direct client services to eligible clients who are minors, elderly, or have a disability undergo a background screening. However, this is an existing contractual requirement and should not increase the background screening workload for the Florida Department of Law Enforcement.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Eligible clients continue to receive pregnancy support and wellness services free of charge.

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

A bill to be entitled

An act relating to pregnancy support and wellness services; creating s. 381.96, F.S.; providing definitions; requiring the Department of Health to contract with a not-for-profit statewide alliance of organizations to provide pregnancy support and wellness services through subcontractors; providing duties of the department; providing contract requirements; requiring the contractor to spend a specified percentage of funds on direct client services; requiring the contractor to annually monitor subcontractors; providing for subcontractor background screenings under certain circumstances; specifying the entities eligible for a subcontract; requiring services to be provided in a noncoercive manner and forbidding inclusion of religious content; providing an effective date.

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

Section 1. Section 381.96, Florida Statutes, is created to read:

381.96 Pregnancy support and wellness services.—

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

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

(b) "Eligible client" means a pregnant woman or a woman who suspects she is pregnant, and the family of such woman, who voluntarily seeks pregnancy support services and any woman who voluntarily seeks wellness services.

(c) "Florida Pregnancy Care Network, Inc.," or "network" means the not-for-profit statewide alliance of pregnancy support organizations that provide pregnancy support and wellness services through a comprehensive system of care to women and their families.

(d) "Pregnancy support services" means services that promote and encourage childbirth, including, but not limited to:

1. Direct client services, such as pregnancy testing, counseling, referral, training, and education for pregnant women and their families. A woman and her family shall continue to be eligible to receive direct client services for up to 12 months after the birth of the child.

2. Program awareness activities, including a promotional campaign to educate the public about the pregnancy support services offered by the network and a website that provides information on the location of providers in the user's area and other available community resources.

3. Communication activities, including the operation and maintenance of a hotline or call center with a single statewide toll-free number that is available 24 hours a day for an

eligible client to obtain the location and contact information for a pregnancy center located in the client's area.

(e) "Wellness services" means services or activities intended to maintain and improve health or prevent illness and injury, including, but not limited to, high blood pressure screening, flu vaccines, anemia testing, thyroid screening, cholesterol screening, diabetes screening, assistance with smoking cessation, and tetanus vaccines.

(2) DEPARTMENT DUTIES.—The department shall contract with the network for the management and delivery of pregnancy support and wellness services to eligible clients.

(3) CONTRACT REQUIREMENTS.—The department contract shall specify the contract deliverables, including financial reports and other reports due to the department, timeframes for achieving contractual obligations, and any other requirements the department determines are necessary, such as staffing and location requirements. The contract shall require the network to:

(a) Establish, implement, and monitor a comprehensive system of care through subcontractors to meet the pregnancy support and wellness needs of eligible clients.

(b) Establish and manage subcontracts with a sufficient number of providers to ensure the availability of pregnancy support and wellness services for eligible clients, and maintain and manage the delivery of such services throughout the contract

period.

(c) Spend at least 90 percent of the contract funds on pregnancy support and wellness services.

(d) Offer wellness services through vouchers or other appropriate arrangements that allow the purchase of services from qualified health care providers.

(e) Require a background screening under s. 943.0542 for all paid staff and volunteers of a subcontractor if such staff or volunteers provide direct client services to an eligible client who is a minor or an elderly person or who has a disability.

(f) Annually monitor its subcontractors and specify the sanctions that shall be imposed for noncompliance with the terms of a subcontract.

(g) Subcontract only with providers that exclusively promote and support childbirth.

(h) Ensure that informational materials provided to an eligible client by a provider are current and accurate and cite the reference source of any medical statement included in such materials.

(4) SERVICES.—Services provided pursuant to this section must be provided in noncoercive manner and may not include any religious content.

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

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 41 (2018)

Amendment No.

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	

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Toledo offered the following:

Amendment

Remove lines 56-58 and insert:

screening, anemia testing, thyroid screening, cholesterol screening, diabetes screening, and assistance with smoking cessation.