Health Innovation Subcommittee

Wednesday, February 15, 2017
3:30 PM – 6:00 PM
Reed Hall

Richard Corcoran
Speaker

MaryLynn Magar
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Innovation Subcommittee

Start Date and Time:	Wednesday, February 15, 2017 03:30 pm
End Date and Time:	Wednesday, February 15, 2017 06:00 pm
Location:	Reed Hall (102 HOB)
Duration:	2.50 hrs

Consideration of the following bill(s):

HB 7 Availability of Health Care Services for All Florida Patients by Miller, A.
HB 59 Adult Cardiovascular Services by Pigman
HB 145 Recovery Care Services by Renner, Fitzenhagen
HB 161 Direct Primary Care Agreements by Burgess, Miller, M.
HB 375 Patient Safety Culture Surveys by Grant, M.

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Tuesday, February 14, 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., Tuesday, February 14, 2017.

NOTICE FINALIZED on 02/08/2017 4:04PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7 Availability of Health Care Services for All Florida Patients
SPONSOR(S): Miller, A.
TIED BILLS: **IDEN./SIM. BILLS:** SB 676

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Poche	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The certificate of need (CON) program, administered by the Agency for Health Care Administration (AHCA), requires certain health care facilities to obtain authorization from the state before offering certain new or expanded services. Health care facilities subject to CON review include hospitals, nursing homes, hospices, and intermediate care facilities for the developmentally disabled.

Florida's CON program was established in 1973, and has undergone several changes over the years. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986, but Florida retained its CON program. Nationally, 14 states have no CON requirements for any health care facility or service.

The Florida CON program has three levels of review: full, expedited, and exempt. Expedited review is primarily targeted towards nursing home projects. Projects required to undergo full comparative review include:

- Adding beds in community nursing homes or intermediate care facilities for the developmentally disabled (ICF/DD) by new construction or alteration.
- Building a health care facility, defined as a hospital, long-term care hospital, skilled nursing facility, hospice, or ICF/DD.
- Converting one type of health care facility to another, including the conversion from a general hospital, a specialty hospital, or a long-term care hospital.
- Establishing a hospice or hospice inpatient facility.
- Increasing the number of comprehensive rehabilitation beds.
- Establishing tertiary health services, including inpatient comprehensive rehabilitation services.

The CON program exempts from full CON review the addition of beds to certain existing services, including comprehensive rehabilitation, neonatal intensive care, and psychiatric and substance abuse services.

HB 7 eliminates the entire CON review program in Florida. As a result, any person wishing to build or replace a hospital, skilled nursing facility, hospice, or ICF/DD; establish new nursing home or ICF/DD beds; increase the number of complex medical rehabilitation beds; or establish tertiary services in a hospital, including inpatient complex medical rehabilitation beds need only go through the AHCA licensure process. If an applicant can meet the licensure statutes and regulations, the applicant will be permitted to offer new or additional health care facilities or services to patients in the state without first obtaining a CON from AHCA.

The bill is expected to have a significant negative fiscal impact on AHCA resulting from the loss of CON application and exemption fees. However, the negative fiscal impact will be offset by collecting planning, construction, and licensure fees for new facilities and services and decreased litigation costs associated with challenges to AHCA decisions to award or not award CONs.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Certificate of Need (CON)

CON laws require approval by a state health planning agency before a health care facility may construct or expand, offer a new service, or purchase equipment exceeding a certain cost. CON programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities.[1] Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation.[2] When a hospital or health care service provider cannot meet its obligations, fixed costs must be met through higher charges for the beds that are used or for the number of patients using the service.[3] Larger institutions have higher costs, so CON supporters believe it makes sense to limit facilities to building only enough capacity to meet actual needs.[4]

In addition to cost containment, CON regulation is intended to create a "quid pro quo" in which profitability of covered medical services is increased by restricting competition and, in return, medical providers cross-subsidize specified amounts of indigent care, or medical services to the poor that are unprofitable to the provider.[5] Some states require facilities and providers that obtain a CON to provide a certain amount of indigent care to underinsured or uninsured patients.[6]

Studies have found that CON programs do not meet the goal of limiting costs in health care. A literature review conducted in 2004 by the Federal Trade Commission and the Department of Justice concluded that:

> [O]n balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. Market incumbents can too easily use CON procedures to forestall competitors from entering an incumbent's market. [. . . .] Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns.[7]

Studies are split, however, on whether CON regulation has improved access to care for the underinsured and uninsured. While there is limited research on the subject, some studies have found

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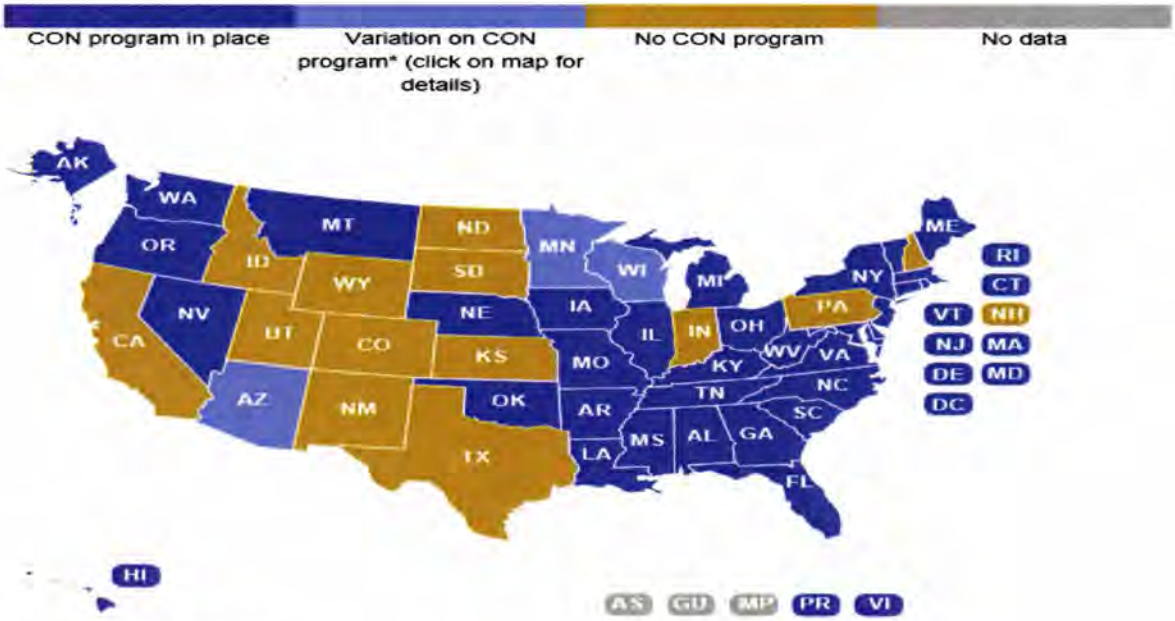
[1] National Conference of State Legislators, *CON-Certificate of Need State Laws,* available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed February 13, 2017).
[2] Id.
[3] Id.
[4] Id.
[5] Thomas Stratmann and Jacob Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* Mercatus Center at George Mason University, July 2014, pg. 2, available at: https://www.mercatus.org/system/files/Stratmann-Certificate-Need.pdf (last viewed February 2, 2017).
[6] For example, see Delaware (Del. Code Ann. tit. 16 § 9303), Georgia (Ga. Code Ann. §111-2-2.40), Rhode Island (R.I. Code R. §6.2.4(B)), and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270).
[7] *Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice*, July 2004, pg. 22, available at: https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice (last viewed February 13, 2017): "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"); Daniel Sherman, Federal Trade Comm'n, *The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis* (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); Monica Noether, Federal Trade Comm'n, *Competition Among Hospitals 82*(1987) (empirical study concluding that CON regulation led to higher prices and expenditures).

that access to care for the underserved populations has increased in states with CON programs,[8] while another has found little, if any, evidence to support such a conclusion.[9] In Florida, the Statewide Medicaid Managed Care (SMMC) program requires all managed care plans to comply with provider network standards to ensure access to care for beneficiaries and imposes significant penalties if access to care is impeded within the program. While Florida maintains a CON program for several types of health care facilities and services, accountability standards within the SMMC program would ensure access to care for Medicaid patients should the CON program be repealed.

According to one study, states with hospital CON regulations have 13 percent fewer hospital beds per 100,000 persons than states without hospital CON regulations.[10] The impact of CON regulations in Florida has been examined as well. A study found that, in Miami-Dade County, CON regulations result in approximately 3,428 fewer hospital beds, between 5 and 10 fewer hospitals offering MRI services, and 18 fewer hospitals offering CT scans.[11]

CON Nationwide

Fourteen states do not have CON requirements for any type of health care facility or service, while three states have a variation on CON requirements.[12] Eight additional states have CON laws for other facilities and services, but do not have CON requirements relating specifically to the addition of hospital beds.[13]



Source: NCSL, August 2016

[8] Tracy Yee, Lucy B. Stark, et al, *Health Care Certificate-of-Need Laws: Policy or Politics?*, Research Brief, National Institute for Health Care Reform, No. 4, May 2011, pg. 6, available at: http://nihcr.org/wp-content/uploads/2015/03/NIHCR_Research_Brief_No._4.pdf (last viewed February 13, 2017) (citing Elana C. Fric-Shamji and Mohammed F. Shamji, *Impact of U.S. Government Regulation on Access to Elective Surgical Care*, Clinical & Investigative Medicine, vol. 31, no. 5 (October 2008) and Ellen S. Campbell and Gary M. Fournier, *Certificate-of-Need Deregulation and Indigent Hospital Care*, Journal of Health Politics, Policy and Law, vol. 18, no. 4 (Winter 1993)).
[9] Christopher J. Conover and Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?*, Journal of Health Politics, Policy and Law, vol. 23, no. 3, pg. 478 (June 1998).
[10] Id.
[11] Christopher Koopman and Thomas Stratman, *Certificate-of-Need Laws: Implications for Florida*, March 2015, pg. 2, available at: https://www.mercatus.org/system/files/Koopman-Certificate-of-NeedFL-MOP.pdf (last viewed February 13, 2017).
[12] New Hampshire was the last state to repeal it's CON program, in 2016. National Conference of State Legislators, *Certificate of Need: State Laws and Programs*, available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed February 13, 2017).
[13] Id.

The states that have repealed their CON program or have a variation on CON requirements, and the dates of repeal, are:

- Arizona (1985 – still retains CON requirements for ambulance service providers);
- California (1987);
- Colorado (1987);
- Idaho (1983);
- Indiana (1996);
- Kansas (1985);
- Minnesota (1984 – still retains several approval processes that function similarly);
- New Hampshire (2016);
- New Mexico (1983);
- North Dakota (1995);
- Pennsylvania (1996);
- South Dakota (1988);
- Texas (1985);
- Utah (1984);
- Wisconsin (2011 – the state maintains an approval process for nursing homes); and
- Wyoming (1989).[14]

On average, states with CON programs regulate 14 different services, devices, and procedures.[15] Florida's CON program currently regulates 11 services or procedures, which is slightly below the national average.[16] Vermont has the most CON laws in place, with more than 30 regulations. Arizona and Ohio have the least number of CON laws.[17]

Florida's CON Program

Overview

Florida's CON program has existed since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act of 1974 ("the Act"), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.[18] Each state was required to have a CON program in compliance with the Act as a condition for obtaining federal funds for health programs. The Act was repealed in 1986.

In Florida, a CON is a written statement issued by AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. The Florida CON program has three levels of review: full, expedited, and exempt.[19] Unless a hospital project is exempt from the CON program, it must undergo a full comparative review. Expedited review is primarily targeted towards nursing home projects.

Projects Subject to Full CON Review

Some hospital projects must to undergo a full comparative CON review, including:

[14] Id.
[15] Id.
[16] Id.
[17] Id.
[18] Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.
[19] S. 408.036, F.S.

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals; and
- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility.[20]

The addition or expansion of certain new or existing hospital services are also required to undergo a full comparative CON review, including:

- Establishing comprehensive medical rehabilitation inpatient services or increasing the number of beds for comprehensive rehabilitation;[21] and
- Establishing tertiary health services.[22]

Section 408.032(17), F.S., requires AHCA to establish by rule a list of all tertiary health services subject to CON review. The list of tertiary health services must be reviewed annually by AHCA to determine if services should be added or deleted.[23] Hospitals must undergo full comparative CON review for the establishment of the following tertiary health services:

- Pediatric cardiac catheterization;
- Pediatric open-heart surgery;
- Neonatal intensive care units;
- Adult open heart surgery; and
- Organ transplantation, including
  - Heart;
  - Kidney;
  - Liver;
  - Bone marrow;
  - Lung; and
  - Pancreas.[24]

Projects Subject to Expedited CON Review

Certain projects are eligible for expedited CON review. Applicants for expedited review are not subject to the application deadlines associated with full comparative review and may submit an application at any time. Projects subject to an expedited review include:

- Transfer of a CON;
- Replacement of a nursing home within the same district;
- Replacement of a nursing home if the proposed site is within a 30-mile radius of the existing nursing home;
- Relocation of a portion of a nursing home's beds to another facility or to establish a new facility in the same district, or a contiguous district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the state does not increase; and

[20] S. 408.036(1)(b), F.S.
[21] S. 408.0361(1)(e), F.S.; Rule 59C-1.039(2)(c), F.A.C. Comprehensive medical rehabilitation inpatient services shape an organized program of intensive care services provided by a coordinated multidisciplinary team to patients with severe physical disabilities, including stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, hip fracture, brain injury, rheumatoid arthritis, neurological disorders, burns and neurological disorders.
[22] S. 408.036(1)(f), F.S.; S. 408.032(17), F.S., defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Besides the specific examples listed above, such services also include medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service.
[23] Rule 59C-1.002(41), F.A.C.
[24] Id.

- Construction of a new community nursing home in a retirement community under certain conditions.[25]

Exemptions from CON Review

Section 408.036(3), F.S., provides exemptions to CON review for certain projects, many involving hospitals, including:

- Adding hospice services or swing beds[26] in a rural hospital, the total of which does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, so long as the conversion of the beds does not involve the construction of new facilities.
- Adding nursing home beds at a skilled nursing facility that is part of a retirement community offering a variety of residential settings and services.[27]
- Building an inmate health care facility by or for the exclusive use of the Department of Corrections.
- Mobile surgical facilities and related health care services provided under contract with the Department of Corrections.
- Adding nursing home beds in a number not exceeding 30 total beds or 25 percent of the number of beds licensed in the facility being replaced in certain circumstances.
- State veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs
- Combining within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict.
- Dividing into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict.
- Adding hospital beds licensed under for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
- Adding nursing home beds licensed in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for adding nursing home beds licensed at a facility that has been designated as a Gold Seal nursing home in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.
- Establishing a level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 15 beds, and if the hospital had a minimum of at least 3,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 5 beds, and is a verified trauma center,[28] and if the applicant has a level II NICU.
- Establishing an adult open heart surgery program in a hospital located within the boundaries of a health service planning district, which:
    - Has experienced an annual net out-migration of at least 600 open heart surgery cases for 3 consecutive years; and
    - Has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.

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[25] S. 408.036(2), F.S.

[26] S. 395.602(2)(g), F.S., defines "swing bed" as a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

[27] S. 408.036(3)(c). F.S. This exemption is limited to a retirement community that had been incorporated in Florida and operating for at least 65 years as of July 1, 1994.

[28] S. 395.4001(14), F.S., defines "trauma center" as a hospital that has been verified by the Department of Health to be in substantial compliance with the requirements in s. 395.4025, F.S., and has been approved to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated as a Level II trauma center pursuant to s. 395.4025(14), F.S.

- For providing percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.
- Adding mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average.
- Replacing a licensed nursing home on the same site, or within 5 miles of the same site if within the same subdistrict, if the number of licensed beds does not increase, except in certain circumstances.
- Consolidating or combining of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning district, by nursing homes with any shared controlled interest within that planning district, if there is no increase in the planning district total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location.
- For beds in state mental health treatment facilities, state mental health forensic facilities and state developmental disabilities centers.
- Establishing a health care facility or project that meets all of the following criteria:
    - The applicant was previously licensed within the past 21 days as a health care facility or provider that is subject to CON;
    - The applicant failed to submit a renewal application and the license expired on or after January 1, 2015;
    - The applicant does not have a license denial or revocation action pending with the agency at the time of the request;
    - The applicant's request is for the same service type, district, service area, and site for which the applicant was previously licensed;
    - The applicant's request, if applicable, includes the same number and type of beds as were previously licensed;
    - The applicant agrees to the same conditions that were previously imposed on the certificate of need or on an exemption related to the applicant's previously licensed health care facility or project; and
    - The applicant applies for initial licensure as required under s. 408.806 within 21 days after the agency approves the exemption request. If the applicant fails to apply in a timely manner, the exemption expires on the 22nd day following the agency's approval of the exemption.

CON Determination of Need and Application and Review Process

A CON is predicated on a determination of need. The future need for services and projects is known as the "fixed need pool"[29], which AHCA publishes for each batching cycle. A batching cycle is a means of grouping of, for comparative review, CON applications submitted for beds, services or programs having a like CON need methodology, or licensing category in the same planning horizon and the same applicable district or subdistrict.[30] Chapter 59C-1, F.A.C., provides need formulas[31] to calculate the

[29] Rule 59C-1.002(19), F.A.C., defines "fixed need pool" as the identified numerical need, as published in the Florida Administrative Register, for new beds or services for the applicable planning horizon established by AHCA in accordance with need methodologies which are in effect by rule at the time of publication of the fixed need pools for the applicable batching cycle.
[30] Rule 59C-1.002(5), F.A.C.
[31] Rule 59C-1.039(5), F.A.C., provides the need formula for comprehensive medical rehabilitation inpatient beds as follows: ((PD/P) x PP / (365 x .85)) – LB – AB = NN where: 1. NN equals the net need for Comprehensive Medical Rehabilitation Inpatient Beds in a District. 2. PD equals the number of inpatient days in Comprehensive Medical Rehabilitation Inpatient Beds in a district for the 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.
3. P equals the estimated population in the district. For applications submitted between January 1 and June 30, P is the population estimate for January of the preceding year; for applications submitted between July 1 and December 31, P is the population estimate for July of the preceding year. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool.
4. PP equals the estimated population in the district for the applicable planning horizon. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool. 5. .85 equals the desired average annual occupancy rate for Comprehensive Medical Rehabilitation Inpatient

fixed need pool for certain services, including NICU services[32], adult and child psychiatric services[33], adult substance abuse services[34], and comprehensive rehabilitation services.[35]

Upon determining that a need exists, AHCA accepts applications for CON based on batching cycles. Section 408.032(5), F.S., establishes the 11 district service areas in Florida, illustrated in the chart below.

The CON review process consists of four batching cycles each year, including two batching cycles each year for each of two project categories: hospital beds and facilities, and other beds and programs.[36] The "hospital beds and facilities" batching cycle includes applicants for new or expanded:

- Hospitals
- Replacement Hospital Facilities
- Neonatal Intensive Care Units Level II and III
- Rehabilitation Beds
- Long Term Care Hospitals
- Inpatient Psychiatric Hospitals
- Inpatient Substance Abuse Hospitals

The "other beds and programs" batching cycle includes:

- Pediatric Open Heart Surgery
- Pediatric Cardiac Catheterization
- Organ Transplantation

Beds in the district. 6. LB equals the district's number of licensed Comprehensive Medical Rehabilitation Inpatient Beds as of the most recent published deadline for Agency initial decisions prior to publication of the Fixed Bed Need Pool.
7. AB equals the district's number of approved Comprehensive Medical Rehabilitation Inpatient Beds.

[32] Rule 59C-1.042(3), F.A.C.
[33] Rule 59C-1.040(4), F.A.C.
[34] Rule 59C-1.041(4), F.A.C.
[35] Rule 59C-1.039(5), F.A.C.
[36] Rule 59C-1.008(1)(g), F.A.C.

- Nursing Home Beds
- Hospice Programs
- Hospice Inpatient Facilities
- ICF/DDs

The following chart illustrates the volume of applications received by AHCA for facilities and services subject to the CON program, and includes the number of exemptions issued, from 2013 to later 2016.[37]

	2013	2014	2015	2016 (partial)
CON Applications Received	32	116	96	53
CON Applications Reviewed	24	25	149	38
CON Exemptions	17	31	49	24

The next chart shows the total number of applications received for certain CON projects and the number of applications approved by AHCA.

Hospital Beds & Facilities Applications for Last 6 Batching Cycles 2014-2016[38]

Proposed Project	*Applications Received*	*Applications Approved*
Comprehensive Medical Rehabilitation Unit	6	1
Acute Care Hospital	20	9
Adult Inpatient Psychiatric Hospital	1	1
Long-Term Care Hospital[39]	0	0
Establish a Replacement Acute Care Hospital	3	3
Establish a Child/Adolescent Psychiatric Hospital	2	2
Total	**32**	**16**

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.[40] A letter of intent must describe the proposal, specify the number of beds sought, and identify the services to be provided and the location of the project.[41] Applications for CON review must be submitted by the specified deadline for the particular batch cycle.[42] AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an

[37] Agency for Health Care Administration, *Certificate of Need (CON) Program-Presentation before the Health Innovation Subcommittee*, January 11, 2017, slide 13 (on file with Health Innovation Subcommittee staff).
[38] Agency Health Care Administration, *CON Decisions & State Agency Action Reports, Hospital Beds and Facilities*, Batching Cycles for August 2016, February 2016, August 2015, February 2015, August 2014, and February 2014, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/decisions.shtml (last viewed February 13, 2017).
[39] A federal moratorium is in place on the construction of any new long-term care acute hospitals.
[40] S. 408.039(2)(a), F.S.
[41] S. 408.039(2)(c), F.S.
[42] Rule 59C-1.008(1)(g), F.A.C.

incomplete application.[43] The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.[44]

Within 60 days of receipt of the completed applications for that batch, AHCA must issue a State Agency Action Report and Notice of Intent to Award a CON for a project in its entirety, to award a CON for identifiable portions of a project, or to deny a CON for a project.[45] AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.[46] If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent to Award the CON become a final order of AHCA.[47]

CON Fees

An applicant for CON review must pay a fee to AHCA when the application is submitted. The minimum CON application filing fee is $10,000.[48] In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however, the total fee may not exceed $50,000.[49] A request for a CON exemption must be accompanied by a $250 fee payable to AHCA.[50]

CON Litigation

Florida law allows competitors to challenge CON decisions. A Notice of Intent to Award a CON may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that the applicant or existing provider will be substantially affected if the CON is awarded.[51] A challenge to a CON decision is heard by an Administrative Law Judge in the Division of Administrative Hearings.[52] AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.[53] A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review[54] within 30 days of receipt of a Final Order.[55]

CON Deregulation

Florida's CON program has been reformed several times over the course of the past 15 years. In 2000, CON review was eliminated for establishing a new home health agency.[56] The number of home health agencies doubled over the ten-year period immediately succeeding the elimination of CON review for establishing a new home health agency. Since 2010, the number of home health agencies has slowly declined.[57]

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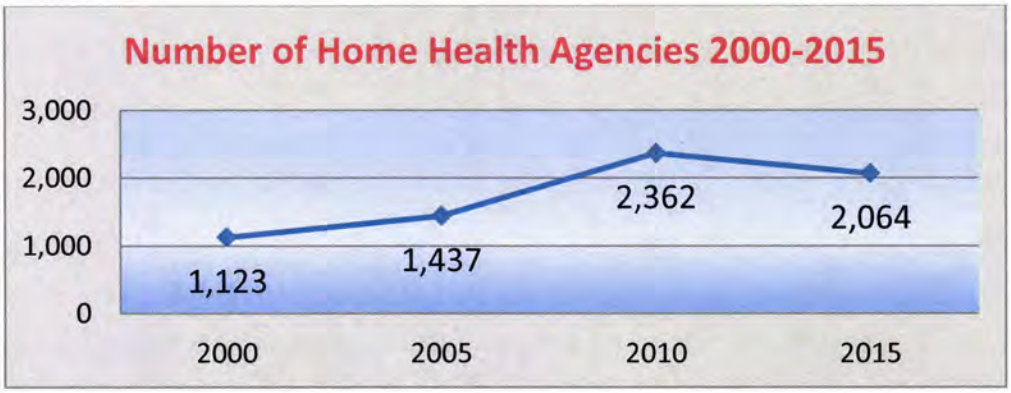
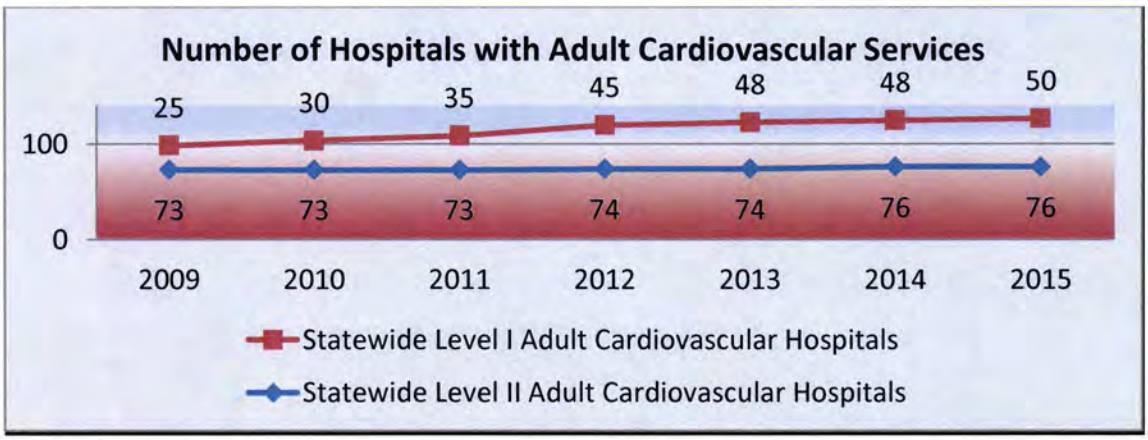
[43] S. 408.039(3)(a), F.S.
[44] Id.
[45] S. 408.039(4)(b), F.S.
[46] S. 408.039(4)(c), F.S.
[47] S. 408.039(4)(d), F.S.
[48] S. 408.038, F.S.
[49] Id.
[50] S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.
[51] S. 408.039(5)(c), F.S.
[52] Id.
[53] S. 408.039(5)(e), F.S.
[54] S. 120.68(1), F.S., a party who is adversely affected by final agency action is entitled to judicial review. A preliminary, procedural, or intermediate order of the agency or of an administrative law judge of the Division of Administrative Hearings is immediately reviewable if review of the final agency decision would not provide an adequate remedy.
[55] S. 408.039(6), F.S.
[56] Ch. 2000-256, Laws of Fla.
[57] Agency for Health Care Administration, *Current Status of Certificate of Need, Effects of Deregulation*, October 20, 2015, pg. 5, available at http://healthandhospitalcommission.com/docs/Oct20Meeting/CONpp102015.pdf (last viewed February 13, 2017).



In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.[58] Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I[59] adult cardiovascular services license has doubled while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased.[60]



In 2007, hospital burn units were also eliminated from the CON program. Instead, licensure standards and other requirements for establishing burn units were relocated to s. 408.0361(2), F.S., and applicable rules.[61]

In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.[62] In addition to the repeal, the legislature imposed limitations on the issuance of CONs for community nursing home beds to limit the growth through July 1, 2017. AHCA may not approve a CON application for new community nursing home beds following the batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2017, equals or exceeds 3,750.[63] AHCA reached the cap of 3,750 beds in February of 2016 and a moratorium on additional beds is in place until June 30, 2017.[64] As a result, AHCA is not currently publishing a fixed

[58] Ch. 2007-214, Laws of Fla.
[59] S. 408.0361, F.S., requires AHCA to adopt rules for the establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery. Rule 59A-3.2085(16) and (17), F.A.C., provides the licensure requirements for Level I and Level II adult cardiovascular services licensure.
[60] Supra, FN 115 at pg. 7.
[61] Rule 59A-3.2085(18), F.A.C.
[62] Ch. 2014-110, Laws of Fla.
[63] S. 408.0436, F.S.
[64] Supra, FN 37 at slide 12.

need pool for additional community nursing home beds;[65]however, beginning with the October 2017 batching cycle AHCA will begin taking applications for additional nursing home beds, assuming that AHCA determines a need for such beds.

CON Reform in Other States

Georgia

The State Commission on the Efficacy of the Certificate of Need Program recommended that CON be maintained and improved after spending 18 months examining the role of CON. The final Commission report, issued in 2006, recommended that Georgia maintain existing CON regulations for hospital beds, adult open heart surgery, and pediatric cardiac catheterization and open heart surgery.[66] The report did not recommend deregulation of any hospital CON project. The CON program for hospital facilities and services remains intact.

Illinois

In 2006, the Legislature passed a law requiring the Commission on Government Forecasting and Accountability (Commission) to "conduct a comprehensive evaluation of the Illinois Health Facilities Planning Act, including a review of the performance of the Illinois Health Facilities Planning Board, to determine if it is meeting the goals and objectives that were originally intended in the law...".[67] The Commission contracted with The Lewin Group to conduct a study on CON, which found that CONs rarely reduce health care costs and, on occasion, increase cost in some states. The study recommended that, while the traditional arguments for CON are empirically weak, based on the preponderance of hard evidence, the CON program should be allowed to sunset. However, the study cautioned that, given the potential for harm to specific critical elements of the health care system, the Legislature should move forward with an abundance of caution.[68]

In 2008, the Legislature decided to study the issue further and passed legislation to create the Task Force on Health Planning Reform (task force).[69] The task force evaluated the current CON program and recommended changes to the structure and function of both the Health Facilities Planning Board and the Department of Public Health in the review of applications to establish, expand, or modify health facilities and related capital expenditures.[70] The task force recommended that the state maintain the CON process and extend the sunset date.[71] Currently, the CON program is scheduled to sunset on December 31, 2019.

Washington State

In 1999, the Joint Legislative Audit Review Committee contracted with the Health Policy Analysis Program of the University of Washington to conduct a legislatively mandated study of the CON program.[72] The study examined the effects of CON, and its possible repeal, on the cost, quality, and availability of health care. The results of the study were based on a literature review, information

[65] *Florida Nursing Home Utilization by District and Subdistrict, July 2015 – June 2016*, available at http://ahca.myflorida.com/mchq/con_fa/Publications/docs/FlNursingUtilization/FloridaNH_UtilizationbyDistrict_Subdistrict-July2015-June2016.pdf (last viewed February 13, 2017).
[66] Commission on the Efficacy of the Certificate of Need Program, *An Analysis and Evaluation of Certificate of Need Regulation in Georgia*, December 29, 2006, available at https://dch.georgia.gov/sites/dch.georgia.gov/files/imported/vgn/images/portal/cit_1210/61/51/72484934FINAL_Georgia_CON_Commission_Report.pdf (last viewed February 13, 2017).
[67] Ill. House Resolution 1497 (2006).
[68] The Lewin Group, *An Evaluation of Illinois' Certificate of Need Program*, Prepared for the State of Illinois Commission on Government Forecasting and Accountability, February 15, 2007, available at http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf (last viewed February 13, 2017).
[69] Ill. Senate Bill 244 (PA 95-0005) of the 95th General Assembly, 2008.
[70] The Illinois Task Force on Health Planning Reform, Final Report, December 31, 2008.
[71] Id.
[72] State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.

gathered from service providers and other experts in Washington, and analyses of states where CON has been completely or partially repealed.[73]

The study concluded that CON has not controlled overall health care spending or hospital costs and found conflicting or limited evidence of the effects of CON on the quality and availability of other health care services or of the effects of repealing CON. The study included three policy options for consideration: reform CON to address its current weaknesses; repeal the program while taking steps to increase monitoring and ensure that relevant goals are being met; or conduct another study to identify more clearly the possible effects of repeal. Washington State decided to keep the CON program.

Virginia

The Virginia General Assembly enacted legislation during the 2015 legislative session requiring the Secretary of Health and Human Resources to convene a workgroup to review the state's Certificate of Public Need (COPN) process.[74]

The law required the workgroup to develop specific recommendations for changes to the COPN process and introduce them during the 2016 Session and highlight any additional changes that may require further study or review.[75] In conducting its review and developing its recommendations, the work group considered data and information about the current COPN process, the impact of such process, and any data or information about similar processes in other states.[76] A final report with recommendations was provided to the General Assembly by December 1, 2015.[77]

In response to a request by the Virginia House of Delegates, the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice (the agencies) submitted a joint statement to the COPN workgroup.[78] The statement explains that the agencies historically have urged states to consider repeal or reform of their CON laws because they can prevent the efficient functioning of health care markets, and thus can harm consumers.[79] As the statement describes, CON laws create barriers to expansion, limit consumer choice, and stifle innovation.[80] Additionally, incumbent providers seeking to thwart or delay entry by new competitors may use CON laws to that end.[81] Finally, the statement asserts that CON laws can deny consumers the benefit of an effective remedy for antitrust violations and can facilitate anticompetitive agreements.[82] For these reasons, the agencies suggested that the workgroup and the General Assembly consider whether Virginia's citizens are well served by its COPN laws and, if not, whether they would benefit from the repeal or retrenchment of those laws.[83]

The workgroup's final report recommended keeping the COPN program, but included several recommendations to improve the program. These recommendations included[84]:

- Revising the process by which the SMFP is reviewed and updated needs to be more timely and rigorous.

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[73] State of Washington Joint Legislative Audit and Review Committee, *Effects of Certificate of Need and its Possible Repeal*, Report 99-1, January 8, 1999, available at http://leg.wa.gov/jlarc/AuditAndStudyReports/Documents/99-1.pdf (last viewed February 13, 2017).
[74] SB 1283, Virginia General Assembly, 2015.
[75] 2015 Va. Acts Chapter 541.
[76] Id.
[77] Id.
[78] *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*, October 26, 2015, available at https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf (last viewed February 13, 2017).
[79] Id. at pg. 2.
[80] Id.
[81] Id.
[82] Id.
[83] Id. at pg. 13.
[84] Virginia Department of Health, Certificate of Public Need Program, *Certificate of Public Need Workgroup – Final Report*, pages 2-7, December 2015, available at https://www.vdh.virginia.gov/Administration/documents/COPN/Final%20Report.pdf.

- Streamlining and making more efficient the process for application submission and review.
- Clarifying and standardizing the manner in which conditions are determined, and the process by which compliance with conditions is enforced.
- Requiring a wide range of program-related information to be made more readily available to the public to increase program transparency.

The workgroup also discussed the extent to which certain medical facilities and projects should continue to remain subject to COPN requirements. The discussions determined an absence of an adequate data-driven, analytical framework to support the development of specific recommendations for the elimination of COPN requirements for certain types of facilities and projects. The workgroup recommended that the General Assembly remove lithotripsy, obstetrical services, magnetic source imaging, nuclear medicine imaging services, and replacement of a medical facility within the same primary service area from the definition of projects subject to the COPN.

North Carolina and South Carolina have also considered legislation to repeal or limit their CON programs in the past year.[85]

Hospital Licensure

Hospitals are regulated by 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.[86] 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.[87]

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.[88]

AHCA must maintain an inventory of hospitals with an emergency department.[89] The inventory must list all services within the capability of each hospital, and such services must appear on the face of the hospital's license. As of February 12, 2017, 218 of the 307 licensed hospitals in the state have an emergency department.[90]

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 per

[85] The North Carolina General Assembly considered two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposed to repeal the CON program in its entirety. House Bill 200 proposed to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The bills were not approved, but the CON repeal may return during the 2017 regular session, which convenes on January 11, 2017. The South Carolina General Assembly considered legislation during the 2016 legislative session to reform the CON program. Currently, South Carolina's CON program requires review for 20 different health care projects and services including hospitals. House Bill 3250 proposed to repeal the CON program effective January 1, 2018, and proposed to reduce CON regulations in the interim by providing several exemptions from CON review. On January 13, 2016, the Senate amended the bill by removing the provision of the bill that sunsets the CON law in 2018. The removal may end up rendering the entire bill meaningless.
[86] S.395.002(12), F.S.
[87] Id.
[88] S. 395.002(28), F.S.
[89] S. 395.1041(2), F.S.
[90] Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals, Emergency Department,* available at http://www.floridahealthfinder.gov, (report generated on February 13, 2017).

hospital or $31.46 per bed, whichever is greater.[91] The inspection fee is $8.00 to $12.00 per bed, but at a minimum $400.00 per facility.[92]

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.[93] 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
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[94]

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

Skilled Nursing Facilities

A nursing home is a facility that provides "24-hour nursing care, personal care, or custodial care for three or more persons . . . who by reason of illness, physical infirmity, or advanced age require [nursing] services" outside of a hospital.[95] Florida nursing homes are regulated under Part II of ch. 400, F.S. AHCA develops rules related to the operation of nursing homes. There are 681 nursing homes in Florida, with 83,411 licensed beds.

Pursuant to s. 408.0436, F.S., there is a moratorium on the addition of new nursing home beds in the state. The moratorium was originally implemented in 2001, extended in 2006, and further extended in 2011. In 2014, facing the expiration of the moratorium in 2016, the Legislature passed, and the Governor signed, HB 287, which lifted the moratorium until AHCA reached the 3,750 bed approval threshold identified in statute. Once the threshold was reached, the moratorium was reinstated. The current moratorium will expire on June 30, 2017.

Intermediate Care Facilities for the Developmentally Disabled (ICF/DDs)

ICF/DDs are an optional Medicaid benefit that enables states to provide comprehensive and individualized health care and rehabilitation services to individuals to promote their functional status and independence.[96] Although it is an optional benefit, all states offer it, often as an alternative to home and community-based services waivers for individuals such level of care.

To be eligible for services from the Agency for Persons with Disabilities, including for placement in a ICF/DD, an applicant must be a Florida resident and have one of the following seven developmental disabilities: autism, cerebral palsy, intellectual disabilities, Down syndrome, Prader-Willi syndrome, Phelan-McDermid syndrome, or spina bifida. Children age 3-5 who are at a high risk of a developmental disability are also eligible for services.

Florida provides the following services in ICF/DDs:

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[91] Rule 59A-3.066(3), F.A.C.
[92] S. 395.0161(3)(a), F.S.
[93] S. 395.1055(2), F.S.
[94] S. 395.1055(1), F.S.
[95] S. 400.021(7), F.S.
[96] U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services, *Intermediate Care Facilities for Individuals with Intellectual Disability (ICF/ID)*, available at https://www.medicaid.gov/medicaid/ltss/institutional/icfid/index.html (last viewed February 13, 2017).

- Activity services
- Dental services
- Dietary services (including therapeutic diet)
- Nursing services
- Pharmacy services
- Physician services
- Rehabilitative care (including physical, speech, occupational and mental health therapies)
- Room/ bed and maintenance services
- Routine personal hygiene items
- Social services[97]

There are 100 ICF/DDs in Florida, with 2,806 licensed treatment beds.[98]

Local Health Councils

Section 408.033, F.S., establishes local health councils as a network of non-profit agencies that conduct regional health planning and implementation activities.[99] Each council's district is designated in Section 408.032, F.S. The Board of Directors of each council is composed of health care providers, purchasers, and nongovernmental consumers. Members serve for two years and are eligible for reappointment. Local health councils develop district health plans containing data, analysis, and recommendations that relate to health care status and needs in the community. The recommendations are designed to improve access to health care, reduce disparities in health status, assist state and local governments in the development of sound and rational health care policies, and advocate on behalf of the underserved.[100]

Local health councils study the impact of various initiatives on the health care system, provide assistance to the public and private sectors, and create and disseminate materials designed to increase their communities and understanding of health care issues.[101]

There are 11 local health councils in the state, as follows:

- Region 1 – Pensacola
- Region 2 – Tallahassee
- Region 3 – Gainesville/Ocala
- Region 4 – Jacksonville
- Region 5 – St. Petersburg
- Region 6 – Tampa
- Region 7 – Orlando
- Region 8 – Sarasota/Ft. Myers
- Region 9 – West Palm Beach
- Region 10 – Ft. Lauderdale
- Region 11 – Miami

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[97] Agency for Health Care Administration, *Florida Medicaid's Covered Services and HCBS Waivers-Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) Services*, available at http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/bhfu/Intermediate_Care.shtml (last viewed February 13, 2017).
[98] Agency for Health Care Administration, Florida Health Finder, *Intermediate Care Facilities for the Developmentally Disabled* (report generated on February 13, 2107).
[99] Florida Department of Health, *Florida's Local Health Councils*, available at http://www.floridahealth.gov/%5C/provider-and-partner-resources/health-councils/index.html (last viewed February 13, 2017).
[100] Id.
[101] Id.

Adult Cardiovascular Care

Adult cardiovascular services (ACS) were previously regulated through the Certificate-of-Need (CON)[102] program. In 2007, CON review was eliminated for adult cardiac catheterization and adult open-heart surgery services[103] and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program;[104] however, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[105]

Section 408.0361, F.S., establishes two levels of hospital program licensure for ACS:

- Level I: The program is authorized to perform adult percutaneous cardiac intervention (PCI) without onsite cardiac surgery.
- Level II: The program is authorized to perform PCI with onsite cardiac surgery.[106]

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms,[107] for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow.[108] It also includes the selective catheterization of the coronary ostia[109] with injection of contrast medium into the coronary arteries.[110]

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform diagnostic procedures[111] only; the license does not allow for the performance of therapeutic procedures.[112] Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.[113]

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[102] The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. In addition, the CON program requires a facility to demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program, it must undergo a full comparative review or an expedited review.

[103] Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.

[104] Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla.

[105] S. 408.0361(2), F.S.

[106] S. 408.0361(3)(a), F.S.

[107] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

[108] Rule 59A-3.2085(13)(b)1., F.A.C.

[109] A coronary ostia is either of the two openings in the aortic sinuses, the pouches behind each of the three leaflets of the aortic valve, that mark the origins of the left and right coronary arteries.

[110] Rule 59A-3.2085(13)(b)1., F.A.C.

[111] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.

[112] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administering of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.
S. 408.0361(1)(b), F.S.

[113] S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214 available at http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000 (last viewed February 13, 2017). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

As of December 1, 2016, there are 22 general acute care hospitals with an adult diagnostic cardiac catheterization program in Florida.[114]

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open heart surgery capability.[115] For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease[116] and a formalized, written transfer agreement with a hospital that has a Level II program.[117]

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[118] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[119] Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.[120]
Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
    - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
    - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
    - Be skilled in all aspects of interventional cardiology equipment; and
    - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[121]

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[114] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last viewed February 13, 2017).
[115] Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.
[116] Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."
[117] S. 408.0361(3)(b), F.S.
[118] Rule 59A-3.2085(16)(a)5., F.A.C.
[119] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)*, available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last viewed February 13, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.
[120] Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

As of December 1, 2016, there are 54 general acute care hospitals with a Level I ACS program in Florida.[122]

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, but have on-site open heart surgery capability.[123] For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.[124]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons, which includes standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[125] Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the American College of Cardiology-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[126] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[127]

As of December 1, 2016, there are 77 general acute care hospitals[128] with a Level II ACS program in Florida.[129]

Rural Hospitals

A rural hospital is an acute care hospital that has 100 or fewer licensed beds and an emergency room which is:[130]

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[121] Rule 59A-3.2085(16)(b), F.A.C.
[122] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last viewed February 13, 2017).
[123] Rule 59A-3.2085(17)(a), F.A.C.
[124] S. 408.0361(3)(c), F.S.
[125] Rule 59A-3.2085(16)(a)5., F.A.C.
[126] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.
[127] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf?sfvrsn=2 (last viewed February 13, 2017).
[128] 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of 2016 SB 1518*, Jan. 12, 2016 (on file with Health Innovation Subcommittee staff).
[129] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last viewed February 13, 2017).
[130] S. 395.602(2)(e), F.S.

- The sole provider within a county with a population density of up to 100 persons per square mile;[131]
- At least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;[132]
- Supported by a tax district or subdistrict the boundaries of which encompass a population of up to 100 persons per square mile;[133]
- Classified as a sole community hospital under 42 C.F.R. s. 412.92 with up to 175 licensed beds;[134]
- Serving an area that has a population of up to 100 persons per square mile;[135] or
- A hospital designated as a critical access hospital, as defined in s. 408.07.[136]

Rural hospitals provide emergency department services, inpatient care, outpatient care, long-term care, and care coordination services for a population of people who do not live in an urban setting.[137] Rural hospitals have specific challenges that hospitals in more urban areas may not experience:

- Rural residents are older, poorer, and more likely to have chronic diseases than urban residents.
- Rural hospitals are typically smaller than urban hospitals.
- Rural hospitals provide a higher percentage of care in outpatient settings and are more likely to offer home health care, skilled nursing care, and assisted living services; all of which have lower Medicare margins than inpatient care.
- Rural hospitals rely more heavily on reimbursement from public programs whose payments fall short of costs.[138]

As of February 13, 2017, there are 13 facilities in the state designated as rural hospitals.[139] Most of those facilities have 25 beds or less, but Northwest Florida Medical Center in Chipley has 59 beds and Shands Starke Regional Medical Center has 49 beds.

Hospice

Hospice care is a continuum of palliative and supportive care for a terminally ill patient and his or her family members.[140] Hospice care is provided by a hospice team which includes physicians, nurses, medical social workers, spiritual/pastoral counselors, home health aides, therapists, bereavement counselors, and specially trained volunteers.[141] Hospices can be for-profit or non-profit and provide four levels of care:

- **Routine care** provides the patient with hospice services at home or in a home-like setting. The patient's family provides the primary care with the assistance of the hospice team.

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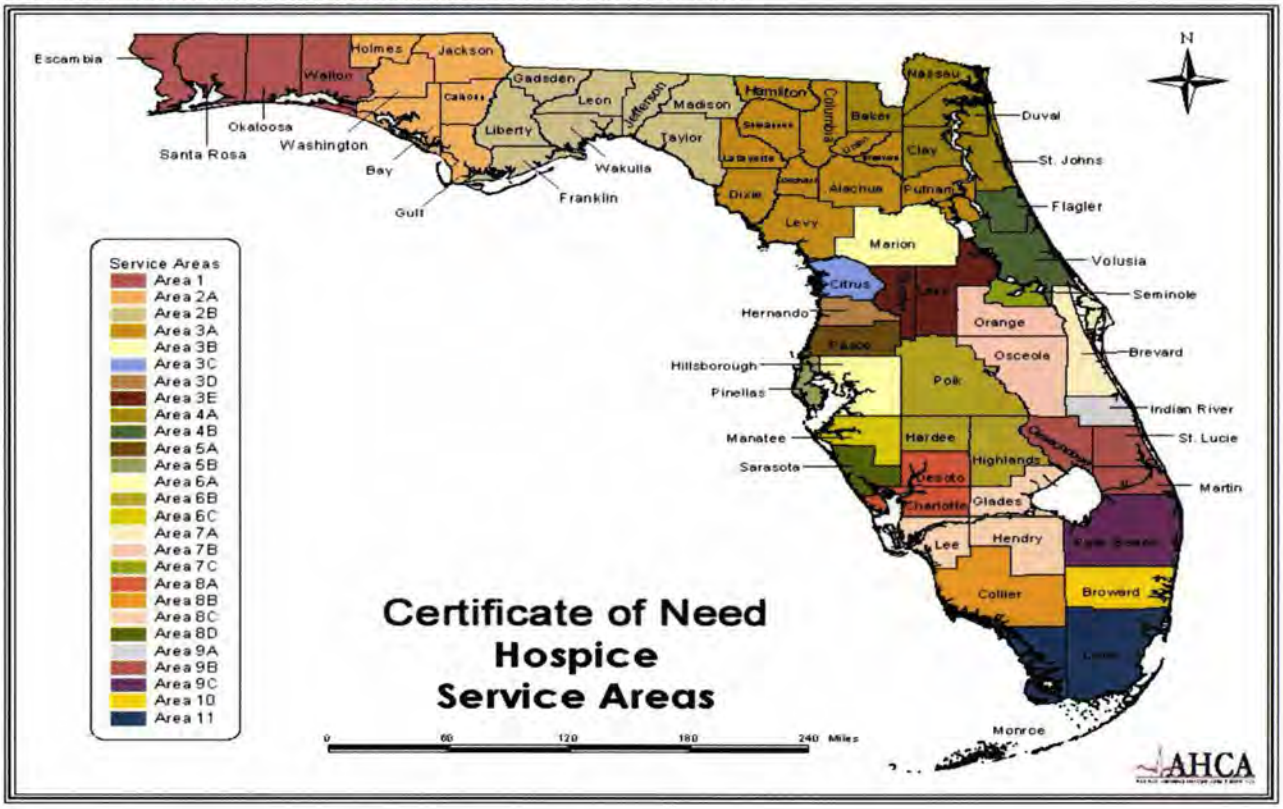
[131] S. 395.602(2)(e)1., F.S.
[132] S. 395.602(2)(e)2., F.S.
[133] S. 395.602(2)(e)3., F.S.
[134] S. 395.602(2)(e)4., F.S.
[135] S. 395.602(2)(e)5., F.S. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency.
[136] S. 395.602(2)(e)6., F.S.
[137] Rural Health Information Hub, *Rural Hospitals*, available at https://www.ruralhealthinfo.org/topics/hospitals (last viewed February 13, 2017).
[138] Id.
[139] Agency for Health Care Administration, Florida Health Finder, Facility/Provider Locator-Rural Hospital
[140] Fla. Admin. Code R. 59C-1.0355. S. 400.601(10), F.S., defines "terminally ill" as a patient with a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course.
[141] Florida Hospice and Palliative Care Association, *About Hospice*, available at http://www.floridahospices.org/hospice-palliative-care/about-hospice/, (last visited February 13, 2107).

- **Continuous care** provides the patient with skilled nursing services in his or her home during a crisis.
- **Inpatient care** is provided in a healthcare facility for symptoms of a crisis that cannot be managed in the patient's home. Inpatient care is provided on a temporary basis as determined by the patient's physician and the hospice team.
- **Respite care** is provided in a healthcare facility and is primarily to provide the patient's family members and caretakers with a period of relief.[142]

Hospices in Florida

As of February 12, 2017, there are 45 licensed hospice providers in the state, across 27 service areas. The chart below illustrates the location of each service area.[143]



In six of the 27 hospice service areas, there is only one hospice provider that is either licensed or approved to serve that area. The six areas include:

- Area 3D, consisting of Hernando County
- Area 6C, consisting of Manatee County
- Area 8A, consisting of Charlotte and DeSoto Counties
- Area 8C, consisting of Glades, Hendry, and Lee Counties
- Area 8D, consisting of Sarasota County
- Area 9A, consisting of Indian River County.

In the most recent need projections for hospice programs published in October 2016, AHCA found a net need for one new hospice provider in subdistrict 3A, consisting of Alachua, Bradford, Columbia,

[142] Id.
[143] Agency for Health Care Administration, *Service Area Maps, Hospices*, available at http://ahca.myflorida.com/MCHQ/CON_FA/maps/images/hospice.jpg (last viewed February 13, 2017).

Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties, which has two licensed hospice providers, and a net need for one new hospice provider in subdistrict 3E, consisting of Lake and Sumter Counties, which also has two licensed hospice providers.[144]

Continuing Care Retirement Communities (CCRCs)

A CCRC is a residential alternative for older adults, usually age 65 and older, that provides flexible housing options, a coordinated system of services and amenities, and a lifetime continuum of care that addresses the varying health and wellness needs of residents as they grow older.[145] The foundation of the CCRC model is based on enabling residents to move within the community if their health care needs change and they require supervision.[146] The services provided by the CCRC are purchased by the resident are governed by contract, or resident service agreement. Entry fees can range from $20,000 to more than $1 million, depending on the geographic location of the CCC, features of the living space, size of the living unit, additional services and amenities selected, whether one or two individuals receive services, and the type of service contract.[147] There are 44 CCRCs in Florida.[148]

The typical accommodations and services include:

- Independent living units – a cottage, townhouse, cluster home, or apartment; the resident is generally healthy and requires little, or no, assistance with activities of daily living.
- Assisted living – a studio or one-bedroom apartment designed for frail individuals who can still maintain a level of independence but need some assistance with activities of daily living.
- Nursing – nursing services are offered on-site or nearby the CCC to provide constant care for recovery from a short-term injury or illness, treatment of a chronic condition, or higher levels of services.
- Memory-care support – offers dedicated cognitive support care with the goal of maximizing function, maintaining dignity, preserving sense of self, and optimizing independence.[149]

CCRCs have the ability to add "sheltered" nursing home beds outside the fixed need pool and moratorium established for community nursing home beds. Providers that have sheltered beds pay a biennial licensure fee of $100.50 per bed for all of their beds where providers with community beds pay $112.50 per bed. Sheltered beds were established through s. 651.118, F.S., and are for the exclusive use of life care contract holders. Sheltered beds can be granted through expedited review on a one to four ratio (one sheltered bed for every four residences) to the CCRC.

Effect of Proposed Changes

CON Program

The bill eliminates the CON program and makes necessary conforming changes throughout the Florida Statutes. Hospitals, nursing homes, hospices, and intermediate care facilities for the developmentally disabled will be able to expand facilities, number of beds, and types of services without seeking prior authorization from the state. Each entity will still be required to complete the licensure process through AHCA.

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[144] Agency for Health Care Administration, *Florida Need Projections for Hospice Programs-Background Information for Use in Conjunction with the October 2016 Batching Cycle for the January 2018 Hospice Planning Horizon,* October 2016, at p. 12, http://ahca.myflorida.com/MCHQ/CON_FA/Publications/docs/FlNeedProjections/October2016_HospiceNeedProjections.pdf (last visited February 13, 2017).

[145] Continuing Care Retirement Community Task Force, Leading Age, American Seniors Housing Association, *Today's Continuing Care Retirement Community*, at page 2 (Jane E. Zarem ed. 2010).

[146] Id.

[147] Id., at page 9.

[148] Office of Insurance Regulation, *Fast Facts-December 2016*, page 6 (on file with Health Innovation Subcommittee staff).

[149] Supra, FN 1, at 4.

The bill also makes a conforming change to s. 395.1055, F.S., to ensure that AHCA has rulemaking authority, after the repeal of the CON review requirements for hospitals, to maintain quality requirements for tertiary services that may be offered by a hospital. Current CON rules for tertiary services, such as comprehensive medical rehabilitation, neonatal intensive care services, organ transplantation, and pediatric cardiac catheterization, include quality standards for those programs.[150] The bill deletes s. 408.032, F.S., which includes the definition of "tertiary health service." This eliminates authority for CON rules, including quality standards. The conforming change transfers rulemaking authority for the quality standards from the CON law to the hospital licensure law. The change eliminates any implication or interpretation that AHCA loses rulemaking authority to impose and maintain licensure requirements for tertiary health services as a result of the repeal of the CON review requirements for hospitals.

Though experts in the CON field dispute many issues when it comes to whether or not to repeal the CON program, the bill makes clear that the barrier to market entry will be removed and certain providers will see growth. The repeal of the CON program in Florida will allow for the growth of hospitals, nursing homes, hospices, tertiary hospital services, and other beds and services, increasing access to care and services for patients. Repeal of the CON in Florida will permit providers to enter the market without the approval of the state, and there will no longer be CON application fees between $10,000 and $50,000 that may discourage smaller providers from seeking a license.

Inactive Licenses

Current law permits a health care provider subject to the CON program to apply for and receive an inactive license if the provider expects to be temporarily unable to provide services, but expects to resume services within 12 months. The bill removes the reference to the CON program to conform to the changes made by the bill.

The bill allows a hospital, nursing home, intermediate care facility for the developmentally disabled, or ambulatory surgical center to obtain an inactive license due to the temporary inability to provide services due to construction or renovation. The facility must expect to provide services again within 12 months. However, in order to receive the inactive license, AHCA must review and approve the construction or renovation plans.

Adult Cardiovascular Care

The bill moves quality standards and requirements currently in s. 408.0361, F.S., which is repealed by the bill, to the hospital licensure provisions in s. 395.1055, F.S. These quality standards and requirements impact adult cardiovascular care services and hospital burn units.

The bill also requires each provider of pediatric cardiac catheterization, pediatric open heart surgery, neonatal intensive care, comprehensive medical rehabilitation, and pediatric and adult organ transplant services to comply with rules adopted by the AHCA that establish licensure standards governing each program.

Rural Hospitals

The bill deletes several obsolete definitions associated with rural hospitals. The definitions for "emergency care hospital", "essential access community hospital", and "rural primary care hospital" are deleted in the bill because those terms are no longer used to refer to such facilities. Instead, these facilities are referred to as Critical Access Hospitals. Also, the bill deletes the definition of "inactive rural hospital bed." AHCA keeps count of inactive hospital beds for the purpose of determining the fixed

[150] The current CON rules which include quality standards, in addition to the CON market-entry requirements, are 59C-1.039, F.A.C. (comprehensive medical rehabilitation); 59C-1.042, F.A.C. (neonatal intensive care services); 59C-1.044, F.A.C. (organ transplantation); 59C-1.032, F.A.C. (pediatric cardiac catheterization); 59C-1.033, F.A.C. (adult and pediatric open heart surgery programs); and 59A-3.2085(16)-(17), F.A.C. (adult cardiovascular services).

need for additional beds in the CON program. Since the bill repeals the CON program entirely, AHCA will no longer keep the hospital bed inventory, and the definition is no longer necessary.

Hospice

The bill requires that any hospice initially licensed on or after July 1, 2017, must be a freestanding hospice facility and be accredited by a national accreditation organization recognized by CMS. The provision will likely limit the overexpansion of hospices across the state after CON repeal.

The bill makes several conforming changes to reflect the repeal of the CON program.

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

B. SECTION DIRECTORY:

Section 1: Repeals s. 154.245, F.S., relating to Agency for Health Care Administration certificate of need required as a condition to bond validation and project construction.
Section 2: Amends s. 159.27, F.S., relating to definitions.
Section 3: Amends s. 186.503, F.S., relating to definitions relating to Florida Regional Planning Council Act.
Section 4: Amends s. 189.08, F.S., relating to special district public facilities report.
Section 5: Amends s. 220.1845, F.S., relating to contaminated site rehabilitation tax credit.
Section 6: Amends s. 376.30781, F.S., relating to tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.
Section 7: Amends s. 376.86, F.S., relating to Brownfield Areas Loan Guarantee Program.
Section 8: Creates s. 381.4066, F.S., relating to local and state health planning.
Section 9: Amends s. 383.216, F.S., relating to community-based prenatal and infant health care.
Section 10: Amends s. 395.0191, F.S., relating to staff membership and clinical privileges.
Section 11: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 12: Amends s. 395.1065, F.S., relating to criminal and administrative penalties; moratorium.
Section 13: Amends s. 395.602, F.S., relating to rural hospitals.
Section 14: Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.
Section 15: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
Section 16: Repeals s. 395.604, F.S., relating to other rural hospital programs.
Section 17: Repeals s. 395.605, F.S., relating to emergency care hospitals.
Section 18: Amends s. 400.071, F.S., relating to application for license for nursing homes.
Section 19: Amends s. 400.606, F.S., relating to license; application; renewal; conditional license or permit; certificate of need.
Section 20: Amends s. 400.6085, F.S., relating to contractual services.
Section 21: Repeals s. 408.031, F.S., relating to short title.
Section 22: Repeals s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act.
Section 23: Repeals s. 408.033, F.S., relating to local and state health planning.
Section 24: Repeals s. 408.034, F.S., relating to duties and responsibilities of agency; rules.
Section 25: Repeals s. 408.035, F.S., relating to review criteria.
Section 26: Repeals s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 27: Repeals s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 28: Repeals s. 408.037, F.S., relating to application content.
Section 29: Repeals s. 408.038, F.S., relating to fees.
Section 30: Repeals s. 408.039, F.S., relating to review process.
Section 31: Repeals s. 408.040, F.S., relating to conditions and monitoring.
Section 32: Repeals s. 408.041, F.S., relating to certificate of need; penalties.
Section 33: Repeals s. 408.042, F.S., relating to limitation on transfer.

Section 34: Repeals s. 408.043, F.S., relating to special provisions.
Section 35: Repeals s. 408.0436, F.S., relating to limitation on nursing home certificates of need.
Section 36: Repeals s. 408.044, F.S., relating to injunction.
Section 37: Repeals s. 408.045, F.S., relating to certificate of need; competitive sealed proposals.
Section 38: Repeals s. 408.0455, F.S., relating to rules; pending proceedings.
Section 39: Amends s. 408.07, F.S., relating to definitions.
Section 40: Amends s. 408.806, F.S., relating to license application process.
Section 41: Amends s. 408.808, F.S., relating to license categories.
Section 42: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 43: Amends s. 408.820, F.S., relating to exemptions.
Section 44: Amends s. 409.9116, F.S., relating to disproportionate share/financial assistance program for rural hospitals.
Section 45: Amends s. 641.60, F.S., relating to Statewide Managed Care Ombudsman Committee.
Section 46: Repeals s. 651.118, F.S., relating to Agency for Health Care Administration; certificates of need; sheltered beds; community beds.
Section 47: Amends s. 1009.65, F.S., relating to Medical Education Reimbursement and Loan Repayment Program.
Section 48: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will experience a reduction in revenue resulting from the loss of CON application and exemption fees following repeal of the program. The reduction may be mitigated by a reduction in workload and by an increase in fees collected for licensure. The annual loss of CON fees is estimated at $1,740,000, based on the average CON fees collected over the past 10 years:

Fiscal Year	CON Fees
06/07	$1,931,599.77
07/08	$1,479,441.58
08/09	$729,795.81
09/10	$779,289.87
10/11	$1,335,547.75
11/12	$916,199.02
12/13	$1,482,784.00
13/14	$1,307,016.50
14/15	$5,455,836.90
15/16	$2,004,250.59

The portion of CON fees paid by provider type varies widely from year to year. In 2015-16 the array was approximately:

Provider	Portion of CON Fees	Amount of CON Fees
Nursing Homes	59%	$1,174,268
Hospitals	33%	$662,268
Hospices	8%	$151,328
ICF/DDs	1%	$16,386

AHCA expects an increase in initial and biennial licensure fees for each category of facility and services which is no longer subject to the CON program. Although an exact figure on growth is difficult to know, AHCA anticipates the following growth projections:

- Hospital beds –
  - 600 per year, or 10 additional construction projects.
- Nursing homes –
  - Year 2- 15 120-bed homes – 1,800 beds
  - Year 3- 15 120-bed homes – 1,800 beds
  - Existing facilities- 13 60-bed wings – 780 beds
- Hospices –
  - Year 1- 10 new facilities
  - Year 2- 20 new facilities
  - Year 3- 20 new facilities

Each new or additional project will submit fees and other costs in order to meet planning, construction, and operating requirements. AHCA estimates, over the first two to three years following the repeal of the CON, to earn revenue based on bed fees, construction fees, and other costs to offset the loss of CON fees.

2. Expenditures:

AHCA may experience increased workload resulting from an increase in licensure applications. The expenditure associated with any increase in workload is indeterminate yet likely insignificant. The increased workload will likely be offset by the reduced workload resulting from the repeal of the CON program review process. Staff currently in the CON program will be transitioned to assist with rule development and additional licensure responsibilities. Additional staff will be needed in the Office of Plans and Construction, the Bureau of Field Operations, and the General Counsel's Office. Licensure fee and federal participation revenues paid to the Health Care Trust will be sufficient to support the additional positions required. Additional budget authority will be necessary for the FTEs.

AHCA will likely see a significant amount of savings in litigation expenses from defending its decision to award or deny CONs. Legal costs associated with CON will also be eliminated. There have been seven CON cases, which led to hearings, in each of the last two years. Such trials can involve multiple litigants and last weeks or months, depending upon the case. Each case that goes to formal hearing costs AHCA roughly $25,000.00 to $35,000.00 for costs such as court reporter fees, deposition transcripts, DOAH fees, and appellate costs. The estimated annual legal cost savings from CON repeal are estimated at $210,000. Agency legal costs also include attorneys. The legal staff will be shifted to handle licensure legal activity with expected new provider growth as a result of CON repeal.

The additional costs associated with the review and approval of construction or renovation plans submitted by a facility seeking an inactive license is unknown, but likely to be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals, nursing homes, hospices, and ICF/DDs will experience a significant, positive fiscal impact resulting from the elimination of CON fees, which range from $10,000 to $50,000, should such facilities seek to establish new facilities or beds. The facilities will also avoid the costs of litigating the award of, or failure to award, a CON by the AHCA.

By removing the CON review program, established providers are likely to realize increased competition for patients.

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 rulemaking authority necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The current title of the bill, "Availability of Health Care Services for All Florida Patients", does not encompass the complete impact of the bill on many areas of the health care industry. Primarily, the bill eliminates the entire CON program in Florida. Therefore, it is recommended that the title of the bill be changed to, "Certificate of Need", in order to reflect the purpose of the bill.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the availability of health care services for all Florida patients; creating s. 381.4066, F.S.; establishing local health councils; providing for appointment of members; providing powers and duties; designating health service planning districts; providing for funding; requiring the Agency for Health Care Administration to establish rules relating to imposition of fees and financial accountability; providing duties of the agency for planning and data maintenance; requiring the Department of Health to contract with local health councils for certain services; amending s. 395.1055, F.S.; requiring the agency to adopt rules establishing licensure standards for adult cardiovascular services providers; requiring providers to comply with certain national standards; amending s. 395.602, F.S.; deleting definitions; amending s. 395.603, F.S.; deleting provisions relating to deactivation and reactivation of general hospitals beds in certain rural hospitals; repealing s. 154.245, F.S., relating to issuance of certificate of need by the Agency for Health Care Administration as a condition to bond validation and project construction; repealing s. 395.6025, F.S., relating to rural hospital replacement

facilities; repealing s. 395.604, F.S., relating to other rural hospital programs; repealing s. 395.605, F.S., relating to emergency care hospitals; repealing s. 408.031, F.S., relating to the Health Facility and Services Development Act; repealing s. 408.032, F.S., relating to definitions; repealing s. 408.033, F.S., relating to local and state health planning; repealing s. 408.034, F.S., relating to duties and responsibilities of the agency; repealing s. 408.035, F.S., relating to review criteria; repealing s. 408.036, F.S., relating to projects subject to review; repealing s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure; repealing s. 408.037, F.S., relating to application content; repealing s. 408.038, F.S., relating to fees; repealing s. 408.039, F.S., relating to the review process for certificates of need; repealing s. 408.040, F.S., relating to conditions imposed on and monitoring of certificates of need; repealing s. 408.041, F.S., relating to penalties for failure to obtain certificate of need when required; repealing s. 408.042, F.S., relating to limitation on transfer; repealing s. 408.043, F.S., relating to special provisions; repealing s. 408.0436, F.S., relating to limitation on nursing home certificates of need;

repealing s. 408.044, F.S., relating to injunction; repealing s. 408.045, F.S., relating to competitive sealed certificate of need proposals; repealing s. 408.0455, F.S., relating to rules and pending proceedings; repealing s. 651.118, F.S., relating to issuance of certificates of need by the Agency for Health Care Administration for nursing home beds; amending ss. 159.27, 186.503, 189.08, 220.1845, 376.30781, 376.86, 383.216, 395.0191, 395.1065, 400.071, 400.606, 400.6085, 408.07, 408.806, 408.808, 408.810, 408.820, 409.9116, 641.60, and 1009.65, F.S.; conforming references and cross-references; providing an effective date.

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

Section 1. Section 154.245, Florida Statutes, is repealed.

Section 2. Subsection (16) of section 159.27, Florida Statutes, is amended to read:

159.27 Definitions.—The following words and terms, unless the context clearly indicates a different meaning, shall have the following meanings:

(16) "Health care facility" means property operated in the private sector, whether operated for profit or not, used for or useful in connection with the diagnosis, treatment, therapy,

rehabilitation, housing, or care of or for aged, sick, ill, injured, infirm, impaired, disabled, or handicapped persons, without discrimination among such persons due to race, religion, or national origin; or for the prevention, detection, and control of disease, including, without limitation thereto, hospital, clinic, emergency, outpatient, and intermediate care, including, but not limited to, facilities for the elderly such as assisted living facilities, facilities defined in s. 154.205(8), day care and share-a-home facilities, nursing homes, and the following related property when used for or in connection with the foregoing: laboratory; research; pharmacy; laundry; health personnel training and lodging; patient, guest, and health personnel food service facilities; and offices and office buildings for persons engaged in health care professions or services~~; provided, if required by ss. 400.601-400.611 and ss. 408.031-408.045, a certificate of need therefor is obtained prior to the issuance of the bonds~~.

Section 3. Subsection (7) of section 186.503, Florida Statutes, is amended to read:

186.503 Definitions relating to Florida Regional Planning Council Act.—As used in this act, the term:

(7) "Local health council" means an ~~a regional~~ agency established pursuant to s. 381.4066 ~~408.033.~~

Section 4. Subsection (3) of section 189.08, Florida Statutes, is amended to read:

189.08 Special district public facilities report.—

~~(3) A special district proposing to build, improve, or expand a public facility which requires a certificate of need pursuant to chapter 408 shall elect to notify the appropriate local general-purpose government of its plans either in its 7-year plan or at the time the letter of intent is filed with the Agency for Health Care Administration pursuant to s. 408.039.~~

Section 5. Paragraph (k) of subsection (2) of section 220.1845, Florida Statutes, is amended to read:

220.1845 Contaminated site rehabilitation tax credit.—

(2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.—

(k) In order to encourage the construction and operation of a new health care facility as defined in ~~s. 408.032 or~~ s. 408.07, or a health care provider as defined in s. 408.07 or s. 408.7056, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed $500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 6. Paragraph (f) of subsection (3) of section

376.30781, Florida Statutes, is amended to read:

376.30781 Tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.—

(3)

(f) In order to encourage the construction and operation of a new health care facility or a health care provider, as defined in ~~s. 408.032,~~ s. 408.07~~,~~ or s. 408.7056, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed $500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 7. Subsection (1) of section 376.86, Florida Statutes, is amended to read:

376.86 Brownfield Areas Loan Guarantee Program.—

(1) The Brownfield Areas Loan Guarantee Council is created to review and approve or deny, by a majority vote of its membership, the situations and circumstances for participation

in partnerships by agreements with local governments, financial institutions, and others associated with the redevelopment of brownfield areas pursuant to the Brownfields Redevelopment Act for a limited state guaranty of up to 5 years of loan guarantees or loan loss reserves issued pursuant to law. The limited state loan guaranty applies only to 50 percent of the primary lenders loans for redevelopment projects in brownfield areas. If the redevelopment project is for affordable housing, as defined in s. 420.0004, in a brownfield area, the limited state loan guaranty applies to 75 percent of the primary lender's loan. If the redevelopment project includes the construction and operation of a new health care facility or a health care provider, as defined in ~~s. 408.032,~~ s. 408.07~~,~~ or s. 408.7056, on a brownfield site and the applicant has obtained documentation in accordance with s. 376.30781 indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider, the limited state loan guaranty applies to 75 percent of the primary lender's loan. A limited state guaranty of private loans or a loan loss reserve is authorized for lenders licensed to operate in the state upon a determination by the council that such an arrangement would be in the public interest and the likelihood of the success of the loan is great.

Section 8. Section 381.4066, Florida Statutes, is created to read:

381.4066 Local and state health planning.—

(1) LOCAL HEALTH COUNCILS.—

(a) Local health councils are hereby established as public or private nonprofit agencies serving the counties of a health service planning district. The members of each council shall be appointed in an equitable manner by the county commissions having jurisdiction in the respective district. Each council shall be composed of a number of persons equal to one and one half times the number of counties which compose the district or 12 members, whichever is greater. Each county in a district shall be entitled to at least one member on the council. The balance of the membership of the council shall be allocated among the counties of the district on the basis of population rounded to the nearest whole number, except that in a district composed of only two counties, each county shall have at least four members. The appointees shall be representatives of health care providers, health care purchasers, and nongovernmental health care consumers, not excluding elected government officials. The members of the consumer group shall include a representative number of persons over 60 years of age. A majority of council members shall consist of health care purchasers and health care consumers. The local health council shall provide each county commission a schedule for appointing

council members to ensure that council membership complies with the requirements of this paragraph. The members of the council shall elect a chair. Members shall serve for terms of 2 years and may be eligible for reappointment.

(b) Health service planning districts are composed of the following counties:

District 1.—Escambia, Santa Rosa, Okaloosa, and Walton Counties.

District 2.—Holmes, Washington, Bay, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, and Taylor Counties.

District 3.—Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, and Lake Counties.

District 4.—Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia Counties.

District 5.—Pasco and Pinellas Counties.

District 6.—Hillsborough, Manatee, Polk, Hardee, and Highlands Counties.

District 7.—Seminole, Orange, Osceola, and Brevard Counties.

District 8.—Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier Counties.

District 9.—Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach Counties.

District 10.—Broward County.

District 11.—Miami-Dade and Monroe Counties.

(c) Each local health council may:

1. Develop a district area health plan that permits each local health council to develop strategies and set priorities for implementation based on its unique local health needs.

2. Advise the Agency for Health Care Administration on health care issues and resource allocations.

3. Promote public awareness of community health needs, emphasizing health promotion and cost-effective health service selection.

4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of medically indigent persons, and assist the Agency for Health Care Administration and other state agencies in carrying out data collection activities that relate to the functions in this subsection.

5. Advise and assist any regional planning councils within each district that have elected to address health issues in their strategic regional policy plans with the development of the health element of the plans to address the health goals and policies in the State Comprehensive Plan.

6. Advise and assist local governments within each district on the development of an optional health plan element of the comprehensive plan provided in chapter 163, to ensure

compatibility with the health goals and policies in the State Comprehensive Plan and district health plan. To facilitate the implementation of this section, the local health council shall annually provide the local governments in its service area, upon request, with:

a. A copy and appropriate updates of the district health plan.

b. A report of hospital and nursing home utilization statistics for facilities within the local government jurisdiction.

7. Monitor and evaluate the adequacy, appropriateness, and effectiveness, within the district, of local, state, federal, and private funds distributed to meet the needs of the medically indigent and other underserved population groups.

8. In conjunction with the Department of Health, plan for the provision of services at the local level for persons infected with the human immunodeficiency virus.

9. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.

(d) Each local health council shall enter into a memorandum of agreement with each regional planning council in its district that elects to address health issues in its strategic regional policy plan. In addition, each local health

council shall enter into a memorandum of agreement with each local government that includes an optional health element in its comprehensive plan. Each memorandum of agreement must specify the manner in which each local government, regional planning council, and local health council will coordinate its activities to ensure a unified approach to health planning and implementation efforts.

(e) Local health councils may employ personnel or contract for staffing services with persons who possess appropriate qualifications to carry out the councils' purposes. Such personnel are not state employees.

(f) Personnel of the local health councils shall provide an annual orientation to council members about council member responsibilities.

(g) Each local health council may accept and receive, in furtherance of its health planning functions, funds, grants, and services from governmental agencies and from private or civic sources to perform studies related to local health planning in exchange for such funds, grants, or services. Each council shall, no later than January 30 of each year, render to the Department of Health an accounting of the receipt and disbursement of such funds received.

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care

facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories, except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to part III of chapter 641, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and prorated for the licensure period.

(b)1. A hospital licensed under chapter 395, a nursing home licensed under chapter 400, and an assisted living facility licensed under chapter 429 shall be assessed an annual fee based on number of beds.

2. All other facilities and organizations listed in paragraph (a) shall each be assessed an annual fee of $150.

3. Facilities operated by the Department of Children and Families, the Department of Health, or the Department of Corrections and any hospital that meets the definition of rural hospital pursuant to s. 395.602 are exempt from the assessment required in this subsection.

(c) The agency shall, by rule, establish:

1. Fees for hospitals and nursing homes based on an assessment of $2 per bed. However, no such facility shall be assessed more than a total of $500 under this subsection.

2. Fees for assisted living facilities based on an assessment of $1 per bed. However, no such facility shall be assessed more than a total of $150 under this subsection.

3. An annual fee of $150 for all other facilities and organizations listed in paragraph (a).

(d) The agency shall, by rule, establish a facility billing and collection process for the billing and collection of the health facility fees authorized by this subsection.

(e) A health facility which is assessed a fee under this subsection is subject to a fine of $100 per day for each day in which the facility is late in submitting its annual fee up to the maximum of the annual fee owed by the facility. A facility that refuses to pay the fee or fine is subject to the forfeiture of its license.

(f) The agency shall deposit all health care facility assessments that are assessed under this subsection in the Health Care Trust Fund and shall transfer such funds to the Department of Health for funding of the local health councils.

(3) DUTIES AND RESPONSIBILITIES OF THE AGENCY FOR HEALTH CARE ADMINISTRATION.—

(a) The agency is responsible for the coordinated planning of health care services in the state.

(b) The agency shall develop and maintain a comprehensive health care database. The agency or its contractor is authorized to require the submission of information from health facilities, health service providers, and licensed health professionals which is determined by the agency, through rule, to be necessary for meeting the agency's responsibilities as established in this section.

(c) The Department of Health shall contract with the local health councils for the services specified in subsection (1). All contract funds shall be distributed according to an allocation plan developed by the department. The department may withhold funds from a local health council or cancel its contract with a local health council that does not meet performance standards agreed upon by the department and local health councils.

Section 9. Subsection (1) of section 383.216, Florida Statutes, is amended to read:

383.216 Community-based prenatal and infant health care.—

(1) The Department of Health shall cooperate with localities which wish to establish prenatal and infant health care coalitions, and shall acknowledge and incorporate, if appropriate, existing community children's services organizations, pursuant to this section within the resources

allocated. The purpose of this program is to establish a partnership among the private sector, the public sector, state government, local government, community alliances, and maternal and child health care providers, for the provision of coordinated community-based prenatal and infant health care. The prenatal and infant health care coalitions must work in a coordinated, nonduplicative manner with local health planning councils established pursuant to s. 381.4066 ~~408.033.~~

Section 10. Subsection (10) of section 395.0191, Florida Statutes, is amended to read:

395.0191 Staff membership and clinical privileges.—

~~(10) Nothing herein shall be construed by the agency as requiring an applicant for a certificate of need to establish proof of discrimination in the granting of or denial of hospital staff membership or clinical privileges as a precondition to obtaining such certificate of need under the provisions of s. 408.043.~~

Section 11. Paragraph (f) of subsection (1) of section 395.1055, Florida Statutes, is amended, and subsections (10) through (13) are added to that section, to read:

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

~~(f) All hospitals submit such data as necessary to conduct certificate-of-need reviews required under part I of chapter 408. Such data shall include, but shall not be limited to, patient origin data, hospital utilization data, type of service reporting, and facility staffing data. The agency may not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals.~~

(10) Each provider of adult diagnostic cardiac catheterization services shall comply with most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories and rules adopted by the agency that establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules shall ensure that such programs:

(a) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(b) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(c) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(d) Demonstrate a plan to provide services to Medicaid and charity care patients.

(11) Each provider of adult cardiovascular services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards.

(12) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels:

1. A Level I program that authorizes the performance of adult percutaneous cardiac intervention without onsite cardiac surgery.

2. A Level II program that authorizes the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis

of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient

selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(g) For a hospital licensed for Level I or Level II adult cardiovascular services, participation in clinical outcome reporting systems operated by the American College of Cardiology and the Society of Thoracic Surgeons.

(13) Each provider of pediatric cardiac catheterization, pediatric open heart surgery, neonatal intensive care, comprehensive medical rehabilitation, and pediatric and adult organ transplant services shall comply with rules adopted by the agency that establish licensure standards governing the operation of such programs. The rules shall ensure that such programs:

(a) Comply with established applicable practice guidelines.

(b) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(c) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(d) Demonstrate a plan to provide services to Medicaid and

charity care patients.

Section 12. Subsection (5) of section 395.1065, Florida Statutes, is amended to read:

395.1065 Criminal and administrative penalties; moratorium.—

(5) The agency shall impose a fine of $500 for each instance of the facility's failure to provide the information required by rules adopted pursuant to s. 395.1055(1)(g) ~~395.1055(1)(h)~~.

Section 13. Subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

(2) DEFINITIONS.—As used in this part, the term:

~~(a) "Emergency care hospital" means a medical facility which provides:~~

~~1. Emergency medical treatment; and~~

~~2. Inpatient care to ill or injured persons prior to their transportation to another hospital or provides inpatient medical care to persons needing care for a period of up to 96 hours. The 96-hour limitation on inpatient care does not apply to respite, skilled nursing, hospice, or other nonacute care patients.~~

~~(b) "Essential access community hospital" means any facility which:~~

~~1. Has at least 100 beds;~~

~~2. Is located more than 35 miles from any other essential~~

~~access community hospital, rural referral center, or urban hospital meeting criteria for classification as a regional referral center;~~

~~3. Is part of a network that includes rural primary care hospitals;~~

~~4. Provides emergency and medical backup services to rural primary care hospitals in its rural health network;~~

~~5. Extends staff privileges to rural primary care hospital physicians in its network; and~~

~~6. Accepts patients transferred from rural primary care hospitals in its network.~~

~~(c) "Inactive rural hospital bed" means a licensed acute care hospital bed, as defined in s. 395.002(13), that is inactive in that it cannot be occupied by acute care inpatients.~~

(a) ~~(d)~~ "Rural area health education center" means an area health education center (AHEC), as authorized by Pub. L. No. 94-484, which provides services in a county with a population density of no greater than 100 persons per square mile.

(b) ~~(e)~~ "Rural hospital" means an acute care hospital licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:

1. The sole provider within a county with a population density of up to 100 persons per square mile;

2. An acute care hospital, in a county with a population density of up to 100 persons per square mile, which is at least

30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;

3. A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;

4. A hospital classified as a sole community hospital under 42 C.F.R. s. 412.92 which has up to 175 licensed beds;

5. A hospital with a service area that has a population of up to 100 persons per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency; or

6. A hospital designated as a critical access hospital, as defined in s. 408.07.

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room. An acute care hospital that has not

previously been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation, to the agency. A hospital that was licensed as a rural hospital during the 2010-2011 or 2011-2012 fiscal year shall continue to be a rural hospital from the date of designation through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room.

~~(f) "Rural primary care hospital" means any facility meeting the criteria in paragraph (e) or s. 395.605 which provides:~~

~~1. Twenty-four-hour emergency medical care;~~

~~2. Temporary inpatient care for periods of 72 hours or less to patients requiring stabilization before discharge or transfer to another hospital. The 72-hour limitation does not apply to respite, skilled nursing, hospice, or other nonacute care patients; and~~

~~3. Has no more than six licensed acute care inpatient beds.~~

(c) ~~(g)~~ "Swing-bed" means a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

Section 14. Section 395.6025, Florida Statutes, is repealed.

Section 15. Section 395.603, Florida Statutes, is amended to read:

395.603 Deactivation of general hospital beds; rural hospital impact statement.—

~~(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with inactive beds shall provide 24-hour emergency medical care by staffing an emergency room. Providers with inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate-of-need purposes, for~~

~~10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.~~

~~(2)~~ In formulating and implementing policies and rules that may have significant impact on the ability of rural hospitals to continue to provide health care services in rural communities, the agency, the department, or the respective regulatory board adopting policies or rules regarding the licensure or certification of health care professionals shall provide a rural hospital impact statement. The rural hospital impact statement shall assess the proposed action in light of the following questions:

(1) ~~(a)~~ Do the health personnel affected by the proposed action currently practice in rural hospitals or are they likely to in the near future?

(2) ~~(b)~~ What are the current numbers of the affected health personnel in this state, their geographic distribution, and the number practicing in rural hospitals?

(3) ~~(c)~~ What are the functions presently performed by the affected health personnel, and are such functions presently performed in rural hospitals?

(4) ~~(d)~~ What impact will the proposed action have on the

ability of rural hospitals to recruit the affected personnel to practice in their facilities?

(5) ~~(e)~~ What impact will the proposed action have on the limited financial resources of rural hospitals through increased salaries and benefits necessary to recruit or retain such health personnel?

(6) ~~(f)~~ Is there a less stringent requirement which could apply to practice in rural hospitals?

(7) ~~(g)~~ Will this action create staffing shortages, which could result in a loss to the public of health care services in rural hospitals or result in closure of any rural hospitals?

Section 16. Section 395.604, Florida Statutes, is repealed.

Section 17. Section 395.605, Florida Statutes, is repealed.

Section 18. Subsection (3) of section 400.071, Florida Statutes, is amended to read:

400.071 Application for license.—

~~(3) It is the intent of the Legislature that, in reviewing a certificate-of-need application to add beds to an existing nursing home facility, preference be given to the application of a licensee who has been awarded a Gold Seal as provided for in s. 400.235, if the applicant otherwise meets the review criteria specified in s. 408.035.~~

Section 19. Subsections (3), (4), and (5) of section

400.606, Florida Statutes, are amended to read:

400.606 License; application; renewal; conditional license or permit; certificate of need.—

(3) Any hospice initially licensed on or after July 1, 2017, must be accredited by a national accreditation organization that is recognized by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by the state. Such accreditation must be maintained as a requirement of licensure. ~~The agency shall not issue a license to a hospice that fails to receive a certificate of need under the provisions of part I of chapter 408. A licensed hospice is a health care facility as that term is used in s. 408.039(5) and is entitled to initiate or intervene in an administrative hearing~~.

(4) A hospice initially licensed on or after July 1, 2017, must establish and maintain a freestanding hospice facility that is engaged in providing inpatient and related services and that is not otherwise licensed as a health care facility ~~shall obtain a certificate of need~~. However, a freestanding hospice facility that has six or fewer beds is not required to comply with institutional standards such as, but not limited to, standards requiring sprinkler systems, emergency electrical systems, or special lavatory devices.

~~(5) The agency may deny a license to an applicant that fails to meet any condition for the provision of hospice care or~~

~~services imposed by the agency on a certificate of need by final agency action, unless the applicant can demonstrate that good cause exists for the applicant's failure to meet such condition.~~

Section 20. Paragraph (b) of subsection (2) of section 400.6085, Florida Statutes, is amended to read:

400.6085 Contractual services.—A hospice may contract out for some elements of its services. However, the core services, as set forth in s. 400.609(1), with the exception of physician services, shall be provided directly by the hospice. Any contract entered into between a hospice and a health care facility or service provider must specify that the hospice retains the responsibility for planning, coordinating, and prescribing hospice care and services for the hospice patient and family. A hospice that contracts for any hospice service is prohibited from charging fees for services provided directly by the hospice care team that duplicate contractual services provided to the patient and family.

(2) With respect to contractual arrangements for inpatient hospice care:

~~(b) Hospices contracting for inpatient care beds shall not be required to obtain an additional certificate of need for the number of such designated beds. Such beds shall remain licensed to the health care facility and be subject to the appropriate inspections.~~

Section 21. Section 408.031, Florida Statutes, is

repealed.

Section 22. Section 408.032, Florida Statutes, is repealed.

Section 23. Section 408.033, Florida Statutes, is repealed.

Section 24. Section 408.034, Florida Statutes, is repealed.

Section 25. Section 408.035, Florida Statutes, is repealed.

Section 26. Section 408.036, Florida Statutes, is repealed.

Section 27. Section 408.0361, Florida Statutes, is repealed.

Section 28. Section 408.037, Florida Statutes, is repealed.

Section 29. Section 408.038, Florida Statutes, is repealed.

Section 30. Section 408.039, Florida Statutes, is repealed.

Section 31. Section 408.040, Florida Statutes, is repealed.

Section 32. Section 408.041, Florida Statutes, is repealed.

Section 33. Section 408.042, Florida Statutes, is repealed.

Section 34. Section 408.043, Florida Statutes, is repealed.

Section 35. Section 408.0436, Florida Statutes, is repealed.

Section 36. Section 408.044, Florida Statutes, is repealed.

Section 37. Section 408.045, Florida Statutes, is repealed.

Section 38. Section 408.0455, Florida Statutes, is repealed.

Section 39. Section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.—As used in this chapter, ~~with the exception of ss. 408.031-408.045,~~ the term:

(1) "Accepted" means that the agency has found that a report or data submitted by a health care facility or a health care provider contains all schedules and data required by the agency and has been prepared in the format specified by the agency, and otherwise conforms to applicable rule or Florida Hospital Uniform Reporting System manual requirements regarding reports in effect at the time such report was submitted, and the data are mathematically reasonable and accurate.

(2) "Adjusted admission" means the sum of acute and intensive care admissions divided by the ratio of inpatient revenues generated from acute, intensive, ambulatory, and

ancillary patient services to gross revenues. If a hospital reports only subacute admissions, then "adjusted admission" means the sum of subacute admissions divided by the ratio of total inpatient revenues to gross revenues.

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

(4) "Alcohol or chemical dependency treatment center" means an organization licensed under chapter 397.

(5) "Ambulatory care center" means an organization which employs or contracts with licensed health care professionals to provide diagnosis or treatment services predominantly on a walk-in basis and the organization holds itself out as providing care on a walk-in basis. Such an organization is not an ambulatory care center if it is wholly owned and operated by five or fewer health care providers.

(6) "Ambulatory surgical center" means a facility licensed as an ambulatory surgical center under chapter 395.

(7) "Audited actual data" means information contained within financial statements examined by an independent, Florida-licensed, certified public accountant in accordance with generally accepted auditing standards, but does not include data within a financial statement about which the certified public accountant does not express an opinion or issues a disclaimer.

(8) "Birth center" means an organization licensed under s. 383.305.

(9) "Cardiac catheterization laboratory" means a freestanding facility that employs or contracts with licensed health care professionals to provide diagnostic or therapeutic services for cardiac conditions such as cardiac catheterization or balloon angioplasty.

(10) "Case mix" means a calculated index for each health care facility or health care provider, based on patient data, reflecting the relative costliness of the mix of cases to that facility or provider compared to a state or national mix of cases.

(11) "Clinical laboratory" means a facility licensed under s. 483.091, excluding: any hospital laboratory defined under s. 483.041(6); any clinical laboratory operated by the state or a political subdivision of the state; any blood or tissue bank where the majority of revenues are received from the sale of blood or tissue and where blood, plasma, or tissue is procured from volunteer donors and donated, processed, stored, or distributed on a nonprofit basis; and any clinical laboratory which is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that same group practice.

(12) "Comprehensive rehabilitative hospital" or "rehabilitative hospital" means a hospital licensed by the

agency as a specialty hospital as defined in s. 395.002; provided that the hospital provides a program of comprehensive medical rehabilitative services and is designed, equipped, organized, and operated solely to deliver comprehensive medical rehabilitative services, and further provided that all licensed beds in the hospital are classified as "comprehensive rehabilitative beds" pursuant to s. 395.003(4), and are not classified as "general beds."

(13) "Consumer" means any person other than a person who administers health activities, is a member of the governing body of a health care facility, provides health services, has a fiduciary interest in a health facility or other health agency or its affiliated entities, or has a material financial interest in the rendering of health services.

(14) "Continuing care facility" means a facility licensed under chapter 651.

(15) "Critical access hospital" means a hospital that meets the definition of "critical access hospital" in s. 1861(mm)(1) of the Social Security Act and that is certified by the Secretary of Health and Human Services as a critical access hospital.

(16) "Cross-subsidization" means that the revenues from one type of hospital service are sufficiently higher than the costs of providing such service as to offset some of the costs of providing another type of service in the hospital. Cross-

subsidization results from the lack of a direct relationship between charges and the costs of providing a particular hospital service or type of service.

(17) "Deductions from gross revenue" or "deductions from revenue" means reductions from gross revenue resulting from inability to collect payment of charges. For hospitals, such reductions include contractual adjustments; uncompensated care; administrative, courtesy, and policy discounts and adjustments; and other such revenue deductions, but also includes the offset of restricted donations and grants for indigent care.

(18) "Diagnostic-imaging center" means a freestanding outpatient facility that provides specialized services for the diagnosis of a disease by examination and also provides radiological services. Such a facility is not a diagnostic-imaging center if it is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice and no diagnostic-imaging work is performed at such facility for patients referred by any health care provider who is not a member of that same group practice.

(19) "FHURS" means the Florida Hospital Uniform Reporting System developed by the agency.

(20) "Freestanding" means that a health facility bills and receives revenue which is not directly subject to the hospital assessment for the Public Medical Assistance Trust Fund as

described in s. 395.701.

(21) "Freestanding radiation therapy center" means a facility where treatment is provided through the use of radiation therapy machines that are registered under s. 404.22 and the provisions of the Florida Administrative Code implementing s. 404.22. Such a facility is not a freestanding radiation therapy center if it is wholly owned and operated by physicians licensed pursuant to chapter 458 or chapter 459 who practice within the specialty of diagnostic or therapeutic radiology.

(22) "GRAA" means gross revenue per adjusted admission.

(23) "Gross revenue" means the sum of daily hospital service charges, ambulatory service charges, ancillary service charges, and other operating revenue. Gross revenues do not include contributions, donations, legacies, or bequests made to a hospital without restriction by the donors.

(24) "Health care facility" means an ambulatory surgical center, a hospice, a nursing home, a hospital, a diagnostic-imaging center, a freestanding or hospital-based therapy center, a clinical laboratory, a home health agency, a cardiac catheterization laboratory, a medical equipment supplier, an alcohol or chemical dependency treatment center, a physical rehabilitation center, a lithotripsy center, an ambulatory care center, a birth center, or a nursing home component licensed under chapter 400 within a continuing care facility licensed

under chapter 651.

(25) "Health care provider" means a health care professional licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 463, chapter 464, chapter 465, chapter 466, part I, part III, part IV, part V, or part X of chapter 468, chapter 483, chapter 484, chapter 486, chapter 490, or chapter 491.

(26) "Health care purchaser" means an employer in the state, other than a health care facility, health insurer, or health care provider, who provides health care coverage for her or his employees.

(27) "Health insurer" means any insurance company authorized to transact health insurance in the state, any insurance company authorized to transact health insurance or casualty insurance in the state that is offering a minimum premium plan or stop-loss coverage for any person or entity providing health care benefits, any self-insurance plan as defined in s. 624.031, any health maintenance organization authorized to transact business in the state pursuant to part I of chapter 641, any prepaid health clinic authorized to transact business in the state pursuant to part II of chapter 641, any multiple-employer welfare arrangement authorized to transact business in the state pursuant to ss. 624.436-624.45, or any fraternal benefit society providing health benefits to its members as authorized pursuant to chapter 632.

(28) "Home health agency" means an organization licensed under part III of chapter 400.

(29) "Hospice" means an organization licensed under part IV of chapter 400.

(30) "Hospital" means a health care institution licensed by the Agency for Health Care Administration as a hospital under chapter 395.

(31) "Lithotripsy center" means a freestanding facility that employs or contracts with licensed health care professionals to provide diagnosis or treatment services using electro-hydraulic shock waves.

(32) "Local health council" means the agency defined in s. 381.4066 ~~408.033.~~

(33) "Market basket index" means the Florida hospital input price index (FHIPI), which is a statewide market basket index used to measure inflation in hospital input prices weighted for the Florida-specific experience which uses multistate regional and state-specific price measures, when available. The index shall be constructed in the same manner as the index employed by the Secretary of the United States Department of Health and Human Services for determining the inflation in hospital input prices for purposes of Medicare reimbursement.

(34) "Medical equipment supplier" means an organization that provides medical equipment and supplies used by health care

providers and health care facilities in the diagnosis or treatment of disease.

(35) "Net revenue" means gross revenue minus deductions from revenue.

(36) "New hospital" means a hospital in its initial year of operation as a licensed hospital and does not include any facility which has been in existence as a licensed hospital, regardless of changes in ownership, for over 1 calendar year.

(37) "Nursing home" means a facility licensed under s. 400.062 or, for resident level and financial data collection purposes only, any institution licensed under chapter 395 and which has a Medicare or Medicaid certified distinct part used for skilled nursing home care, but does not include a facility licensed under chapter 651.

(38) "Operating expenses" means total expenses excluding income taxes.

(39) "Other operating revenue" means all revenue generated from hospital operations other than revenue directly associated with patient care.

(40) "Physical rehabilitation center" means an organization that employs or contracts with health care professionals licensed under part I or part III of chapter 468 or chapter 486 to provide speech, occupational, or physical therapy services on an outpatient or ambulatory basis.

(41) "Prospective payment arrangement" means a financial

agreement negotiated between a hospital and an insurer, health maintenance organization, preferred provider organization, or other third-party payor which contains, at a minimum, the elements provided for in s. 408.50.

(42) "Rate of return" means the financial indicators used to determine or demonstrate reasonableness of the financial requirements of a hospital. Such indicators shall include, but not be limited to: return on assets, return on equity, total margin, and debt service coverage.

(43) "Rural hospital" means an acute care hospital licensed under chapter 395, having 100 or fewer licensed beds and an emergency room, and which is:

(a) The sole provider within a county with a population density of no greater than 100 persons per square mile;

(b) An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from another acute care hospital within the same county;

(c) A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer per square mile;

(d) A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this paragraph, the term "service area" means the fewest number of

zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the Agency for Health Care Administration; or

(e) A critical access hospital.

Population densities used in this subsection must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2015, if the hospital continues to have 100 or fewer licensed beds and an emergency room. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this subsection shall be granted such designation upon application, including supporting documentation, to the Agency for Health Care Administration.

(44) "Special study" means a nonrecurring data-gathering and analysis effort designed to aid the agency in meeting its responsibilities pursuant to this chapter.

(45) "Teaching hospital" means any Florida hospital officially affiliated with an accredited Florida medical school which exhibits activity in the area of graduate medical education as reflected by at least seven different graduate

medical education programs accredited by the Accreditation Council for Graduate Medical Education or the Council on Postdoctoral Training of the American Osteopathic Association and the presence of 100 or more full-time equivalent resident physicians. The Director of the Agency for Health Care Administration shall be responsible for determining which hospitals meet this definition.

Section 40. Subsection (6) of section 408.806, Florida Statutes, is amended to read:

408.806 License application process.—

(6) ~~The agency may not issue an initial license to a health care provider subject to the certificate-of-need provisions in part I of this chapter if the licensee has not been issued a certificate of need or certificate-of-need exemption, when applicable.~~ Failure to apply for the renewal of a license prior to the expiration date renders the license void.

Section 41. Subsection (3) of section 408.808, Florida Statutes, is amended to read:

408.808 License categories.—

(3) INACTIVE LICENSE.—An inactive license may be issued to a hospital, nursing home, intermediate care facility for the developmentally disabled, or ambulatory surgical center ~~health care provider subject to the certificate-of-need provisions in part I of this chapter~~ when the provider is currently licensed, does not have a provisional license, and will be temporarily

unable to provide services due to construction or renovation but is reasonably expected to resume services within 12 months. Before an inactive license will be issued, the licensee must have plans approved by the agency. Such designation may be made for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional months upon demonstration by the licensee of the provider's progress toward reopening. ~~However, if after 20 months in an inactive license status, a statutory rural hospital, as defined in s. 395.602, has demonstrated progress toward reopening, but may not be able to reopen prior to the inactive license expiration date, the inactive designation may be renewed again by the agency for up to 12 additional months.~~ For purposes of such a second renewal, ~~if construction or renovation is required, the licensee must have had plans approved by the agency and~~ construction must have already commenced and ~~pursuant to s. 408.032(4); however, if construction or renovation is not required,~~ the licensee must provide proof of having made an enforceable capital expenditure greater than 25 percent of the total costs associated with the construction or renovation ~~hiring of staff and the purchase of equipment and supplies needed to operate the facility upon opening~~. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted to the agency and must include a written justification for the inactive license with the beginning and ending dates of

inactivity specified, a plan for the transfer of any clients to other providers, and the appropriate licensure fees. The agency may not accept a request that is submitted after initiating closure, after any suspension of service, or after notifying clients of closure or suspension of service, unless the action is a result of a disaster at the licensed premises. For the purposes of this section, the term "disaster" means a sudden emergency occurrence beyond the control of the licensee, whether natural, technological, or manmade, which renders the provider inoperable at the premises. Upon agency approval, the provider shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive license period is the date the provider ceases operations. The end of the inactive license period shall become the license expiration date. All licensure fees must be current, must be paid in full, and may be prorated. Reactivation of an inactive license requires the approval of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part, authorizing statutes, and applicable rules.

Section 42. Subsection (10) of section 408.810, Florida Statutes, is amended 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.

~~(10) The agency may not issue a license to a health care provider subject to the certificate-of-need provisions in part I of this chapter if the health care provider has not been issued a certificate of need or an exemption. Upon initial licensure of any such provider, the authorization contained in the certificate of need shall be considered fully implemented and merged into the license and shall have no force and effect upon termination of the license for any reason.~~

Section 43. 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)-(9) ~~408.810(5)-(10)~~.

(2) Birth centers, as provided under chapter 383, are exempt from s. 408.810(7)-(9) ~~408.810(7)-(10)~~.

(3) Abortion clinics, as provided under chapter 390, are exempt from s. 408.810(7)-(9) ~~408.810(7)-(10)~~.

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

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

(8) Hospitals, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(9).

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

(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(9) ~~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)-(9) ~~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(10).~~

~~(14) Home health agencies, as provided under part III of~~

~~chapter 400, are exempt from s. 408.810(10).~~

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

(14)~~(16)~~ Companion services or homemaker services providers, as provided under part III of chapter 400, are exempt from s. 408.810(6)-(9) ~~408.810(6)-(10)~~.

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

(15)~~(18)~~ Adult family-care homes, as provided under part II of chapter 429, are exempt from s. 408.810(7)-(9) ~~408.810(7)-(10)~~.

(16)~~(19)~~ Homes for special services, as provided under part V of chapter 400, are exempt from s. 408.810(7)-(9) ~~408.810(7)-(10)~~.

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

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

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

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

(18)~~(24)~~ Health care services pools, as provided under

part IX of chapter 400, are exempt from s. 408.810(6)-(9) ~~408.810(6)-(10)~~.

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

(20)~~(26)~~ Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(9) ~~408.810(5)-(10)~~.

(21)~~(27)~~ Multiphasic health testing centers, as provided under part II of chapter 483, are exempt from s. 408.810(5)-(9) ~~408.810(5)-(10)~~.

(22)~~(28)~~ Organ, tissue, and eye procurement organizations, as provided under part V of chapter 765, are exempt from s. 408.810(5)-(9) ~~408.810(5)-(10)~~.

Section 44. Subsection (6) of section 409.9116, Florida Statutes, is amended to read:

409.9116 Disproportionate share/financial assistance program for rural hospitals.—In addition to the payments made under s. 409.911, the Agency for Health Care Administration shall administer a federally matched disproportionate share program and a state-funded financial assistance program for statutory rural hospitals. The agency shall make disproportionate share payments to statutory rural hospitals that qualify for such payments and financial assistance payments to statutory rural hospitals that do not qualify for disproportionate share payments. The disproportionate share

program payments shall be limited by and conform with federal requirements. Funds shall be distributed quarterly in each fiscal year for which an appropriation is made. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(6) This section applies only to hospitals that were defined as statutory rural hospitals, or their successor-in-interest hospital, prior to January 1, 2001. Any additional hospital that is defined as a statutory rural hospital, or its successor-in-interest hospital, on or after January 1, 2001, is not eligible for programs under this section unless additional funds are appropriated each fiscal year specifically to the rural hospital disproportionate share and financial assistance programs in an amount necessary to prevent any hospital, or its successor-in-interest hospital, eligible for the programs prior to January 1, 2001, from incurring a reduction in payments because of the eligibility of an additional hospital to participate in the programs. A hospital, or its successor-in-interest hospital, which received funds pursuant to this section before January 1, 2001, and which qualifies under s. 395.602(2)(b) ~~395.602(2)(c)~~, shall be included in the programs under this section and is not required to seek additional appropriations under this subsection.

Section 45. Paragraph (c) of subsection (1) of section 641.60, Florida Statutes, is amended to read:

641.60 Statewide Managed Care Ombudsman Committee.—

(1) As used in ss. 641.60-641.75:

(c) "District" means one of the health service planning districts as defined in s. 381.4066 ~~408.032~~.

Section 46. Section 651.118, Florida Statutes, is repealed.

Section 47. Paragraph (b) of subsection (2) of section 1009.65, Florida Statutes, is amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(b) All payments shall be contingent on continued proof of primary care practice in an area defined in s. 395.602(2)(b) ~~395.602(2)(c)~~, or an underserved area designated by the Department of Health, provided the practitioner accepts Medicaid reimbursement if eligible for such reimbursement. Correctional facilities, state hospitals, and other state institutions that employ medical personnel shall be designated by the Department of Health as underserved locations. Locations with high incidences of infant mortality, high morbidity, or low Medicaid participation by health care professionals may be designated as

underserved.

Section 48. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7 (2017)

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 Innovation Subcommittee

Representative Miller, A. offered the following:

Amendment (with title amendment)

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

Remove lines 2-3 and insert:

An act relating to certificate of need; creating s.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 59 Adult Cardiovascular Services
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 58

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Langston	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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

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

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

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

HB 59 authorizes hospitals with Level I ACS programs to meet the prerequisite 500 hours of training required for nursing and technical catheterization laboratory staff, if, throughout the training period, the program:

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

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Percutaneous Cardiac Intervention (PCI)

Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.[1] PCI uses a catheter to insert a stent in the heart to reopen blood vessels that have been narrowed by plaque build-up, a condition known as atherosclerosis.[2] The catheter is threaded through blood vessels into the heart where the coronary artery is narrowed.[3] Once in place, a balloon tip covered with a stent is inflated to compress the plaque and expand the stent.[4] When the plaque is compressed and the stent is in place, the balloon is deflated and withdrawn, leaving the stent to hold the artery open.[5]

Hospital Licensure

The Agency for Health Care Administration (AHCA) regulates hospitals under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[6] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, and other definitive medical treatment.[7]

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

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[8]

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

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

Regulation of Adult Cardiovascular Services

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

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

Adult Diagnostic Cardiac Catheterization Program

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

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

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[9] The CON regulatory process under chapter 408, F.S., requires specified health care services and facilities to be approved by AHCA before they are made available to the public. In addition, the CON program requires a facility to demonstrate a need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Section 408.036, F.S., specifies which health care projects are subject to review and provides three levels of review: full, expedited and exempt. Unless a hospital project is exempt from the CON program under s. 408.036(3), F.S., it must undergo a full comparative review or an expedited review.

[10] Ch. 2007-214, Laws of Fla. CON review remains in effect for pediatric cardiac catheterization and pediatric open-heart surgery. Rule 59C-1.002(41), F.A.C.

[11] Existing providers and any provider with a notice of intent to grant a CON or a final order of the agency granting a CON for ACS or burn units were considered grandfathered and received a license for their programs effective July 1, 2004. The grandfathered license was effective for three years or until July 1, 2008, whichever was longer. S. 408.0361(2), F.S.; s. 2, ch. 2004-382, Laws of Fla.

[12] S. 408.0361(2), F.S.

[13] S. 408.0361(3)(a), F.S.

[14] An arteriogram is an imaging test that uses x-rays and a contrast dye to see inside the arteries of the heart.

[15] Rule 59A-3.2085(13)(b)1., F.A.C.

[16] A coronary ostia is either of the two openings in the aortic sinuses – the pouches behind each of the three leaflets of the aortic valve – that mark the origins of the left and right coronary arteries.

[17] Rule 59A-3.2085(13)(b)1., F.A.C.

[18] Diagnostic procedures include left heart catheterization with coronary angiography and left ventriculography; right heart catheterization; hemodynamic monitoring line insertion; aortogram; emergency temporary pacemaker insertion; myocardial biopsy; diagnostic trans-septal procedures; intra-coronary ultrasound (CVIS); fluoroscopy; and hemodynamic stress testing. Rule 59A-3.2085(13)(b)4., F.A.C.

[19] Examples of therapeutic procedures are PCI or stent insertion, intended to treat an identified condition or the administration of intra-coronary drugs, such as thrombolytic agents. Rule 59A-3.2085(13)(b)3., F.A.C.

[20] S. 408.0361(1)(b), F.S.

[21] S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214, available at http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaeff7461&t=633921658057830000

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

Level I ACS Programs

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

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

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

Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.

(last visited February 7, 2017). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

[22] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last visited February 7, 2017).

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

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

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

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

[27] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)* available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last visited February 7, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

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

- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
    - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
    - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
    - Be skilled in all aspects of interventional cardiology equipment; and
    - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[29]

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

Level II ACS Programs

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

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

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons, which includes standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[33] Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the ACC-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[34] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[35]

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[29] Rule 59A-3.2085(16)(b), F.A.C.
[30] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last visited February 7, 2017).
[31] Rule 59A-3.2085(17)(a), F.A.C.
[32] S. 408.0361(3)(c), F.S.
[33] Rule 59A-3.2085(16)(a)5., F.A.C.
[34] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.
[35] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf (last visited February 7, 2017).

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

PCI Best Practices

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

Effect of the Bill

Training for Nursing and Technical Staff

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

The bill authorizes a hospital with a Level I ACS program to provide the prerequisite 500 hours of training required for nursing and technical staff to work in the cardiac interventional laboratory, if, throughout the training period, the ACS program:

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

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

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

[37] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last visited February 7, 2017).

[38] Gregory J. Dehmer, et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup,* Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., Mar. 17, 2014.

[39] Id.

[40] Id.

[41] Id. The Expert Consensus document cites data from a 2010-2011 National Cardiovascular Data Registry showing that half (49%) of reporting facilities performed fewer than 400 PCIs annually and of these, 65% of the facilities without on-site surgery backup had an annual case volume of less than 200 PCIs.

[42] Supra, note 38.

B. SECTION DIRECTORY:

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to adult cardiovascular services; amending s. 408.0361, F.S.; expanding rulemaking criteria for the Agency for Health Care Administration for licensure of hospitals performing percutaneous cardiac intervention procedures; providing an effective date.

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

Section 1. Paragraph (b) of subsection (3) of section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.—

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a

hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have demonstrated experience in handling acutely ill patients requiring intervention based on the staff member's previous experience in dedicated cardiac interventional laboratories or surgical centers. If a staff member's previous experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open-heart-surgery program, the staff member's previous experience qualifies only if, at the time the staff member acquired his or her experience, the dedicated cardiac interventional laboratory:

1. Had an annual volume of 500 or more percutaneous cardiac intervention procedures;

2. Achieved a demonstrated success rate of 95 percent or greater for percutaneous cardiac intervention procedures;

3. Experienced a complication rate of less than 5 percent for percutaneous cardiac intervention procedures; and

4. Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Poche	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

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, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Ambulatory Surgical Centers (ASCs)

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

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

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

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

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

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

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[1] S. 395.002(3), F.S.
[2] Agency for Health Care Administration, *All Florida Ambulatory (Outpatient) Surgery Centers Results*, available at http://www.floridahealthfinder.gov/CompareCare/ListFacilities.aspx (last viewed February 5, 2017).
[3] Agency for Health Care Administration, *2017 Agency Legislative Bill Analysis-HB 145*, page 2, January 4, 2017 (on file with Health Innovation Subcommittee staff).
[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 February 5, 2017).
[9] Id.

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

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

ASC Licensure

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

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

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

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

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

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;

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

- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

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

Staff and Personnel Rules

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

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

Infection Control Rules

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

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

Emergency Management Plan Rules

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

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

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

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

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

Accreditation

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

AHCA is also required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements.[33] However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[34]

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

Federal Requirements

Medicare

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

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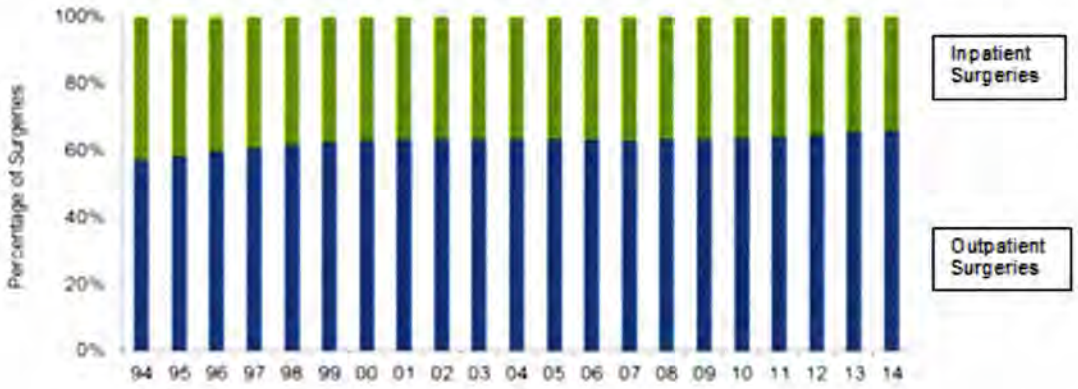
[28] Rule 59A-5.018(2)(a), F.A.C.
[29] Rule 59A-5.004(3), F.A.C.; Agency for Health Care Administration, Ambulatory Surgical Center, *Accrediting Organizations for Ambulatory Surgical Centers,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ambulatory.shtml (last viewed February 5, 2017).
[30] Rule 59A-5.004(1) and (2), F.A.C.
[31] Rule 59A-5.004(3), F.A.C.
[32] Rule 59A-5.004(5), F.A.C.
[33] Rule 59A-5.004(1), F.S., and s. 395.0161, F.S.
[34] S. 395.0161(2), F.S.
[35] Supra, FN 3.
[36] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 137, 04-01-15), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf (last viewed February 5, 2017); Exceeding the 24-hour time frame is expected to be a rare occurrence and each rare occurrence is expected to be

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

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

ASC Cost of Care and Quality Outcomes

There has been tremendous growth in the outpatient surgery segment of health care in the U.S., facilitated by advances in technology. From 1981 through 2005, the number of outpatient surgeries increased ten-fold.[39] Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.[40] 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.[41]



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

[37] 42 C.F.R. §416.2

[38] 42 C.F.R. §416.26(a)(1)

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

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

[41] Professor Elizabeth L. Munnich, University of Louisville, Louisville, Kentucky, *Presentation on Measuring Cost and Quality in Ambulatory Surgical Centers-Health Innovation Subcommittee*, slide 5, January 25, 2017 (on file with Health 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).

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.

ASC Cost of Care

Despite the volume of outpatient surgeries today, there is little research on cost savings associated with ASCs.[42] 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.[43]

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.[44] 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.[45] The OIG also found that Medicare beneficiaries realized savings of $2 billion in the form of reduced co-payment obligations in the ASC setting.[46] 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.[47] Beneficiaries, in turn, would save $3 billion.[48]

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.[49] More than $5 billion of the cost reduction accrued to the patient through lower deductible and coinsurance payments.[50] 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.[51]

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.

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[42] Supra, FN 41 at slide 2.
[43] Supra, FN 39 at pg. 767; The savings calculation is based on the estimated charges for operating room time, set at $29 to $80 per minute, not including surgeon and anesthesia provider fees. Macario A. *What does one minute of operating room time cost?* J Clin Anesth. 2010;22(4):233–6.
[44] 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).
[45] Id. at pg. i.
[46] Id. at pg. ii.
[47] Id.
[48] Id.
[49] Healthcare Bluebook and HealthSmart, *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, page 7 (June 2016), available at http://www.ascassociation.org/asca/communities/community-home/librarydocuments/viewdocument?DocumentKey=61197e80-d852-4004-860a-2424968b005b (last viewed February 7, 2017).
[50] Id.
[51] Id.

- Medicare saved an additional $42.6 million on colonoscopies performed in ASCs.[52]

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.[53] Another study showed that patients who underwent a high volume procedure in an ASC were less likely than those treated in a hospital-based outpatient department to visit an ER or be admitted to the hospital following surgery.[54] 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.[55]

One study found patient satisfaction with care received at ASCs across the country measured at 92 percent.[56]

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.[57] 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.[58]

RCCs are not eligible for Medicare reimbursement.[59] However, RCCs may receive payments from Medicaid programs.

Three states, Arizona, Connecticut, and Illinois, have specific licenses for RCCs.[60] Other states license RCCs as nursing facilities or hospitals.[61] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[62]

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

[53] 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).

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

[55] Supra, FN 41 at slide 8.

[56] *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.

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

[58] Id. at pg. 4.

[59] Supra, FN 57.

[60] 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.

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

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

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[63]	Connecticut[64]	Illinois[65]
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

[63] 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).
[64] Conn. Agencies Regs. § 19A-495-571.
[65] 210 Ill. Comp. Stat. Ann. 3/35; Ill. Admin. Code tit. 77, §§ 210.2500 & 210.2800.

Effect of Proposed Changes

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

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

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

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

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

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

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

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

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

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

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

The license fee for a RCC will be set by rule by AHCA and must be at least $1,500.[66]

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

B. SECTION DIRECTORY:

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. Applicants for licensure as a RCC will be subject to the Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews, an application fee of at least $1,500, and a licensure inspection fee of $400.[67]

2. Expenditures:

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

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

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

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

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

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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. Subsections (2) and (8) of section 395.1055, Florida Statutes, are amended, and 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, 2017.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Poche	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

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

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, or the patient's legal representative;
- Allow either party to terminate the agreement by written notice followed by, at least, a 30 day waiting period;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of services that are covered by the monthly fee;
- Specify the monthly fee and any fees for services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Provide for a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason;
- State that the agreement is not health insurance and that the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement for any primary care services covered by the agreement; and
- 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.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Office of Insurance Regulation

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

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

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

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

Direct Primary Care

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

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

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

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

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

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

The following chart illustrates the concentration of DPC practices in the United States:[5]

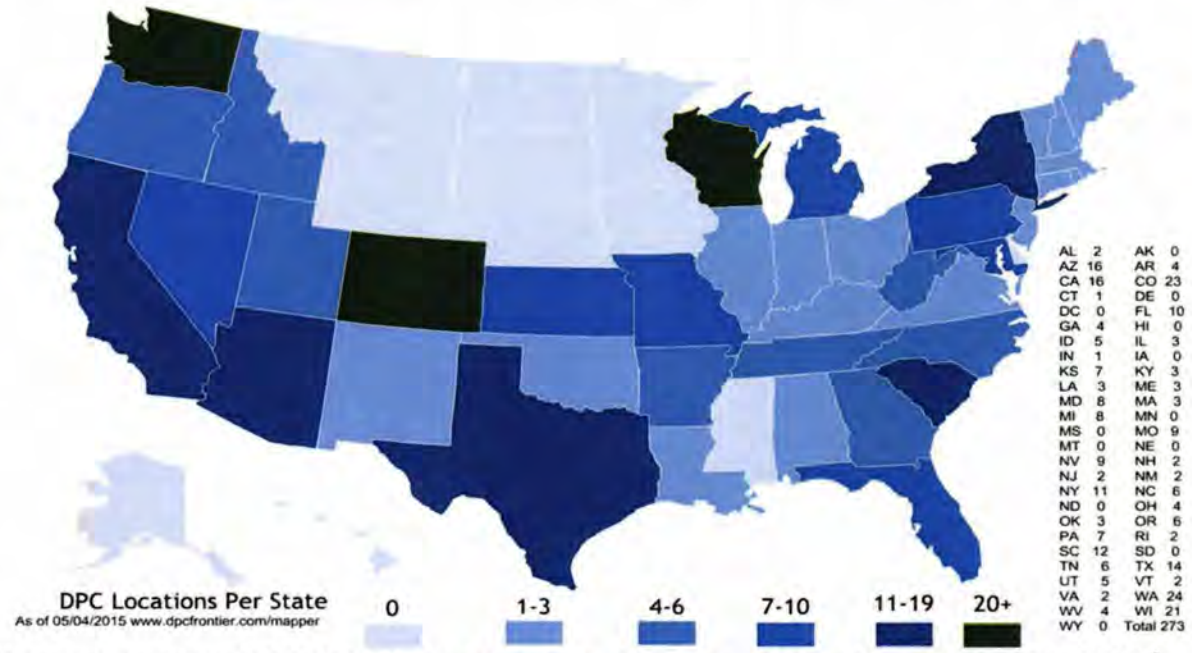
[2] A recent study of 141 DPC practices found the average monthly fee to be $77.38. Philip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med., November-December 2015, Vol. 28 No. 6, pg. 797; approximately two thirds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

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

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

[5] See supra, FN 2, Eskew and Klink.

Direct Primary Care Practice Distribution



There are an estimated 4,400 direct primary care physicians nationwide, up from 756 in 2010.[6]

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

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

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

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

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

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)[8] 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.[9] 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.[10] In Colorado and Washington, qualified health plans are offering DPC medical home coverage on each state-based health insurance exchange.[11]

Effect of Proposed Changes

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

The bill requires a direct primary care agreement to:

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, the patient's legal representative, or an employer;
- Allow either party to terminate the agreement by written notice followed by, at least, a 30 day waiting period;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of services that are covered by the monthly fee;
- Specify the monthly fee and any fees for services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Provide for a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason;
- State that the agreement is not health insurance and that the primary care provider will not bill the patient's health insurance policy or plan for services covered under the agreement; and
- 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.

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

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[8] Pub. L. No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).
[9] 42 U.S.C. §1802 (a)(3); 45 C.F.R. §156.245
[10] 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.
[11] 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 Innovation Subcommittee staff).

B. SECTION DIRECTORY:

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

On March 20th and December 4th, 2015, the Revenue Estimating Conference (REC) adopted an estimate of the impact of previous versions of this bill, which had similar or identical language to HB 161. The REC estimated the prior bills to have either no impact or a negative, indeterminate impact to General Revenue, reflecting uncertainty about whether DPC agreements might be subject to regulation by OIR and thereby subject to insurance premium tax under s. 624.509, F.S.

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, the patient's legal representative, or an 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, that provides medical services to patients which are commonly provided without referral from another health care provider.

(c) "Primary care service" 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, including chapter 636. 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, including chapter 636.

(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, including chapter 636, 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 an 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 an 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 statements on the signature page:

1. 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.

2. 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.

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

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 161 (2017)

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 Innovation Subcommittee

Representative Burgess offered the following:

Amendment

Between lines 78 and 79, insert:

3. This agreement is not workers' compensation insurance and may not replace the employer's obligations under chapter 440, Florida Statutes.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 375 Patient Safety Culture Surveys
SPONSOR(S): Grant
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Poche	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

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 375 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 appears to have a negative, fiscal impact on state government that may be mitigated by staffing and informational technology options available to AHCA.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Facility Regulation

Hospitals

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

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

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

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

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

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

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

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

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

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

Ambulatory Surgical Centers (ASCs)

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

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

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

- Governing body bylaws, rules and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- The comprehensive Emergency Management Plan.[13]

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

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

Health Care Price and Quality Transparency

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

[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;

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[16] National Committee for Quality Assurance, *The Essential Guide to Health Quality*, page 6, available at http://www.ncqa.org/Portals/0/Publications/Resource/%20Library/NCQA_Primer_web.pdf (last viewed February 13, 2017).
[17] The Henry J. Kaiser Foundation, Peterson-Kaiser Health System Tracker, *Health Spending Explorer-U.S. Health Expenditures 1960-2014*, available at http://www.healthsystemtracker.org/interactive/health-spending-explorer/?display=U.S.%2520%2524%2520Billions&service=Hospitals%252CPhysicians%2520%2526%2520Clinics%252CPrescriptions%2520Drug (last viewed February 13, 2017).
[18] The World Bank, *Data-United States*, available at http://data.worldbank.org/country/united-states (last viewed February 13, 2017).
[19] Supra, FN 55.
[20] McGlynn, E.A., Asch, S.M., et al., *The quality of health care delivered to adults in the United States*, New England Journal of Medicine, 348(26): 2635-45, June 2, 2003.
[21] James, J., *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, Journal of Patient Safety, 9(3): 122-128 (September 2013).
[22] Centers for Disease Control, *Healthcare-associated infections (HAI), Data and Statistics-HAI Prevalence Survey*, available at http://www.cdc.gov/HAI/surveillance/index.html (last viewed February 13, 2017).
[23] U.S. Government Accountability Office, *Health Care Transparency-Actions Needed to Improve Cost and Quality Information for Consumers*, October 2014, pgs. 6-7 (citing quality measure categories established by the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse, available at http://qualitymeasures.ahrq.gov/tutorial/varieties.aspx).

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

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

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

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

Florida Center for Health Information and Transparency

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

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

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

The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, 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 which allow easy access to information on hospitals, ambulatory surgery centers, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. The website also provides tools to researchers and professionals to allow specialized data queries, but requires users to have some knowledge of medical coding and terminology. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator, hospital and ambulatory surgery centers performance data, data on mortality, complication, and infection rates for hospitals, and a facility/provider locator. AHCA is frequently improving the functionality of the website by adding more information and search capabilities.

Patient Safety Culture Surveys[35]

Patient safety culture can be defined as the set of values, beliefs, and norms about what is important, how to behave, and what attitudes are appropriate when it comes to patient safety in a workgroup or organization. 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.

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[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 February 13, 2017). Besides hospitals, AHRQ developed patient safety culture surveys for hospitals, nursing homes, ambulatory outpatient medical offices, community pharmacies, and ambulatory surgery centers.

[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 February 13, 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.

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[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 February 13, 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

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[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).

hospital mortality and length of stay.[51] Using the SAQ-ICU version, the study found that lower 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 375 requires AHCA to develop hospital and ASC patient safety culture surveys to measure aspects of patient safety culture, including frequency of adverse events, quality of handoffs and transitions, comfort in reporting a potential problem or error, the level of teamwork within hospital units and the facility as a whole, staff compliance with patient safety regulations and guidelines, staff's perception of facility support for patient safety, and staff's opinions on whether or not they would undergo a health care service or procedure at the facility. 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, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.05, F.S., relating to Florida Center for Health Information and Transparency.

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[51] Supra, FN 47.
[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 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.
Section 5: Amends s. 408.8065, F.S., relating to additional licensure requirements for home health agencies, home medical providers, and health care clinics.
Section 6: Amends s. 408.820, F.S., relating to exemptions.
Section 7: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

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

2. Expenditures:

AHCA has previously estimated the cost to implement the patient safety culture survey, including the cost of a contracted research organization to collect, analyze, and report survey findings and the cost of one additional staff to manage the contract and survey process, to be $500,000, based on an historical rate of $28 per completed survey charged by a contracted research organization for other surveys, multiplied by an estimated sample size of 17,857 surveys completed by staff from all licensed facilities.[59] AHCA intends to encourage online survey completion, which would reduce this estimate.[60] AHCA is examining the cost of developing, distributing, and processing the surveys without a contractor.[61]

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

[59] Agency for Health Care Administration, *2106 Agency Bill Analysis-HB 1175,* January 11, 2016, page 7 (on file with Health Innovation Subcommittee staff).
[60] Email correspondence between AHCA staff and Select Committee staff on January 18, 2016 (on file with Health Innovation Subcommittee staff).
[61] Telephone conference between AHCA staff and Health Innovation Subcommittee staff on February 13, 2017.

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:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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 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. This act shall take effect July 1, 2017.