Select Committee on Affordable Healthcare Access

Thursday, November 19, 2015
4:00 PM – 6:00 PM
Morris Hall

Steve Crisafulli
Speaker

Jose Oliva
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Select Committee on Affordable Healthcare Access

Start Date and Time: Thursday, November 19, 2015 04:00 pm

End Date and Time: Thursday, November 19, 2015 06:00 pm

Location: Morris Hall (17 HOB)

Duration: 2.00 hrs

Consideration of the following bill(s):

HB 37 Direct Primary Care by Costello
HB 85 Recovery Care Services by Fitzenhagen
HB 437 Certificates of Need for Hospitals by Sprowls

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Wednesday, November 18, 2015.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, November 18, 2015.

NOTICE FINALIZED on 11/12/2015 3:32PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 37 Direct Primary Care
SPONSOR(S): Costello
TIED BILLS: **IDEN./SIM. BILLS:** SB 132

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access		Poche	Calamas
2) Finance & Tax Committee			
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.

HB 37 provides that a direct primary care agreement (agreement) and the act of entering into such an agreement are not insurance and not subject to regulation under the Florida Insurance Code (Code), including chapter 636, F.S. The bill also exempts a primary care provider, which includes a primary care group practice, or his or her agent, from any certification or licensure requirements in the Code for marketing, selling, or offering to sell an agreement. An agreement must:

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, or the patient's legal representative;
- Allow either party to terminate the agreement by written notice followed by a waiting period;
- 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 may have a negative indeterminate impact on state General Revenue, which may be offset by a positive indeterminate impact on state General Revenue resulting from the bill.

The bill provides an effective date of July 1, 2016.

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	442
Third Party Administrators	299
Continuing Care Retirement Communities	63
Discount Medical Plan Organizations	42
Health Maintenance Organizations	35
Fraternal Benefit Societies	36
Prepaid Limited Health Service Organizations/Prepaid Health Clinics	27

Direct Primary Care

Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the primary care provider-patient relationship. Through a contractual agreement, a patient pays a monthly fee, usually between $50 and $100 per individual,[2] to the primary care provider for defined primary care services. Theses primary care services may include:

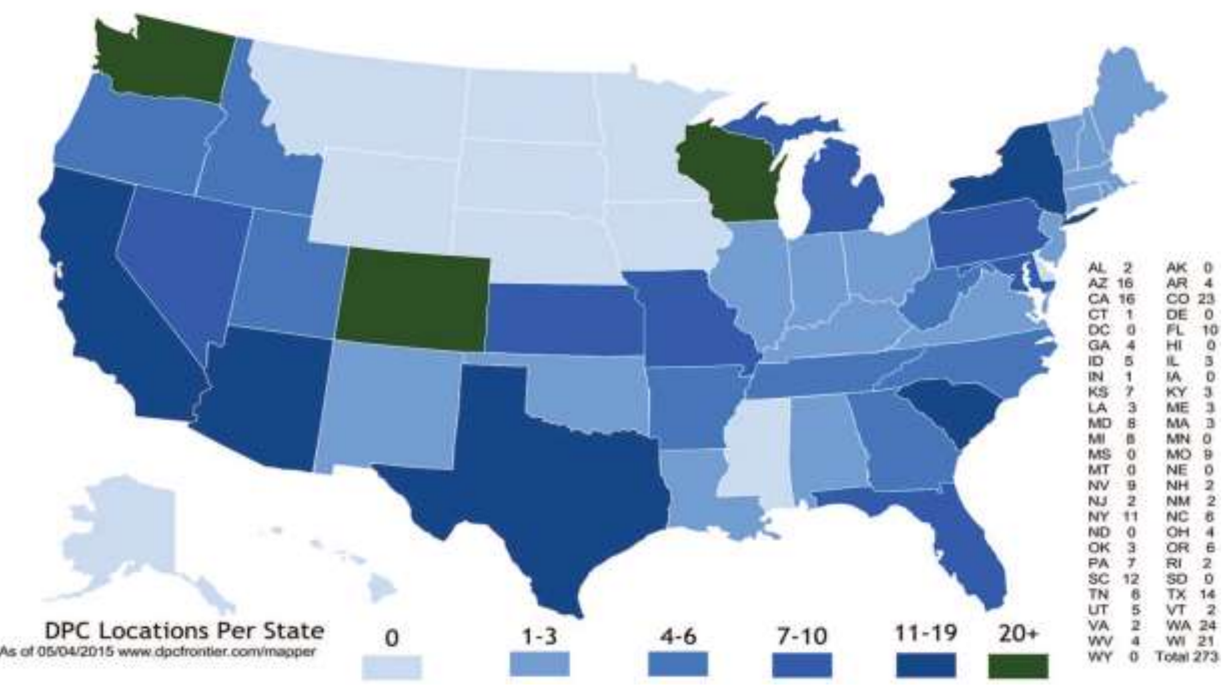
[1] Email correspondence from OIR staff dated November 12, 2015 (on file with Select Committee staff).
[2] A recent study of 141 DPC practices found the average monthly fee to be $77.38. Philip M. Eskew and Kathleen Klink, Direct Primary Care: Practice Distribution and Cost Across the Nation, Journal of the Amer. Bd. of Family Med., November-December 2015, Vol. 28

- 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 utilize all services under the agreement at no extra charge. Some DPC practices also include routine preventative services, like lab 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]



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 November 11, 2015).

[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 November 11, 2015).

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

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

As of July 2015, thirteen 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

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 are 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

The bill 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:

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[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 November 11, 2015).
[7] Direct Primary Care Coalition, *On the Move in the States with DPC*, available at: http://www.dpcare.org (last viewed November 11, 2015).
[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)
[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 Select Committee staff).

- 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 a waiting period;
- 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.[12]

The bill provides an effective date of July 1, 2016.

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, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have a negative indeterminate impact on state General Revenue based on a reduction in the collection of insurance premium tax for persons who may drop health coverage under a traditional health insurance policy or plan in favor of a direct primary care agreement, which is not subject to the insurance premium tax.

   The bill may have a positive indeterminate impact on state General Revenue based on an increase in the collection of insurance premium tax for previously uninsured persons who may enter into a direct primary care agreement and pair it with a high deductible health plan, which is subject to the insurance premium tax, to meet the requirements of the Patient Protection and Affordable Care Act.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[12] Pending any federal rules to the contrary, pairing a direct primary care contract with a high deductible health plan to provide wrap-around coverage would meet the minimum essential coverage requirements. This option is likely to be less expensive than a traditional insurance product. See 42 U.S.C. 18021(a)(3).

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

1 A bill to be entitled
2 An act relating to direct primary care; creating s.
3 624.27, F.S.; providing definitions; specifying that a
4 direct primary care agreement does not constitute
5 insurance and is not subject to the Florida Insurance
6 Code, including chapter 636, F.S., relating to prepaid
7 limited health service organizations and discount
8 medical plan organizations; specifying that entering
9 into a direct primary care agreement does not
10 constitute the business of insurance and is not
11 subject to the code; providing that a certificate of
12 authority is not required to market, sell, or offer to
13 sell a direct primary care agreement; specifying
14 criteria for a direct primary care agreement;
15 providing an effective date.
16
17 Be It Enacted by the Legislature of the State of Florida:
18
19 Section 1. Section 624.27, Florida Statutes, is created to
20 read:
21 624.27 Application of code as to direct primary care
22 agreements.—
23 (1) As used in this section, the term:
24 (a) "Direct primary care agreement" means a contract
25 between a primary care provider and a patient, the patient's
26 legal representative, or an employer, which meets the criteria

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

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

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

53 (b) Be signed by the primary care provider or an agent of
54 the primary care provider and the patient, the patient's legal
55 representative, or an employer.
56 (c) Allow a party to terminate the agreement by written
57 notice to the other party after a period specified in the
58 agreement.
59 (d) Describe the scope of primary care services that are
60 covered by the monthly fee.
61 (e) Specify the monthly fee and any fees for primary care
62 services not covered by the monthly fee.
63 (f) Specify the duration of the agreement and any
64 automatic renewal provisions.
65 (g) Offer a refund to the patient of monthly fees paid in
66 advance if the primary care provider ceases to offer primary
67 care services for any reason.
68 (h) State that the agreement is not health insurance and
69 that the primary care provider will not file any claims against
70 the patient's health insurance policy or plan for reimbursement
71 for any primary care services covered by the agreement.
72 (i) State that the agreement does not qualify as minimum
73 essential coverage to satisfy the individual shared
74 responsibility provision of the Patient Protection and
75 Affordable Care Act pursuant to 26 U.S.C. s. 5000A.
76 Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 85 Recovery Care Services
SPONSOR(S): Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 212

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access		Guzzo	Calamas
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Pursuant to s. 395.002, 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, 2016.

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 429 ASCs in Florida.[2]

In 2014, there were 2,933,087 visits to ASCs in Florida.[3] Visits occur at hospital-based outpatient facilities or freestanding ASCs. Hospital-based outpatient facilities accounted for 46 percent and freestanding ASCs accounted for 54 percent of the total number of visits. Of the $33.8 billion in total charges for ambulatory procedures in 2014, hospital-based outpatient facilities accounted for 77 percent of the charges, while freestanding ASCs accounted for 23 percent.[4] The average charge at the hospital-based facilities ($19,140) was larger than the average charge at the freestanding ASCs ($5,018).[5] Two procedures, colonoscopy and gastrointestinal endoscopy, are consistently in the top 10 procedures performed by both facility types.[6] In 2014, the average charge for a colonoscopy by site was $6,694 for hospital-based outpatient facilities and $2,391 for freestanding ASCs.[7] The average charge for gastrointestinal endoscopy by site was $9,537 for hospital-based outpatient facilities and $2,269 for freestanding ASCs.[8] This data was not adjusted for acuity, so it may reflect higher acuity levels in hospital patients.

In 2014, the charges for visits to freestanding ASCs and hospital-based outpatient facilities were paid mainly by commercial Insurance and Medicare. Commercial insurance paid for 40 percent of charges ($13.6 billion), while Medicare paid for 30 percent of charges ($10.1 billion).[9] The next three top payer groups (Medicare Managed Care, Medicaid, and Medicaid Managed Care) accounted for a combined 21.6 percent ($7.3 billion) of charges.[10]

ASC Licensure

ASCs are licensed and regulated by the Agency for Health Care Administration (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;

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[1] S. 395.002(3), F.S.
[2] AHCA Agency Bill Analysis, dated September 18, 2015, pg. 3 (on file with Select Committee on Affordable Healthcare Access staff).
[3] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Facility Type and Average Charges,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed on November 12, 2015).
[4] Id.
[5] Id.
[6] 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 November 12, 2015).
[7] Id.
[8] Id.
[9] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Patient, Primary Payer, and Average Charges* http://www.floridahealthfinder/gov/QueryTool/QTResults.aspx (last viewed on November 10, 2015).
[10] Id.
[11] SS. 395.001-1065, F.S., and Part II, Chapter 408, F.S.

- 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 hospitals and 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 hospitals and ASCs must include minimum standards for ensuring that:

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

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

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.[16] In providing these services, ACSs are required to have certain professional staff available, including:

- A registered nurse to serve as operating room circulating nurse;[17]
- 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;[18] and
- A Registered professional nurse in the recovery area during the patient's recovery period.[19]

Infection Control Rules

ASCs are required to establish an infection control program, which must include written policies and procedures reflecting the scope of the program.[20] The written policies and procedures must be reviewed at least every two years by the infection control program members.[21] The infection control program must include:

[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.
[16] Rule 59A-5.0085, F.A.C.
[17] Rule 59A-5.0085(3)(c), F.A.C.
[18] Rule 59A-5.0085(2)(b), F.A.C.
[19] Rule 59A-5.0085(3)(d), F.A.C.
[20] Rule 59A-5.011(1), F.A.C.
[21] Rule 59A-5.011(2), F.A.C.

- Surveillance, prevention, and control of infection among patients and personnel;[22]
- A system for identifying, reporting, evaluating and maintaining records of infections;[23]
- Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the ASC;[24] and
- Development and coordination of training programs in infection control for all personnel.[25]

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency.[26] The ASC must review the plan and update it annually.[27]

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission for Health Care Organizations, the Accreditation Association for Ambulatory Health Care, and the American Osteopathic Association Healthcare Facilities Accreditation Program.[28] AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs.[29] AHCA must accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements.[30] AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.[31]

AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements.[32] 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.[33]

In 2014, 373 licensed ASCs in Florida were accredited by a national accrediting organization.[34]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical

[22] Rule 59A-5.011(1)(a), F.A.C.
[23] Rule 59A-5.011(1)(b), F.A.C.
[24] Rule 59A-5.011(1)(c), F.A.C.
[25] Rule 59A-5.011(1)(d), F.A.C.
[26] Rule 59A-5.018(1), F.A.C.
[27] Id.
[28] Rule 59A-5.004(3), F.A.C., and AHCA 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 November 13, 2015).
[29] Rule 59A-5.004(1) and (2), F.A.C.
[30] Rule 59A-5.004(3), F.A.C.
[31] Rule 59A-5.004(5), F.A.C.
[32] Rule 59A-5.004(1), F.S., and s. 395.0161, F.S.
[33] S. 395.0161(2), F.S.
[34] Agency for Health Care Administration, *Ambulatory Surgical Center Regulatory Overview,* March 2015 (on file with Select Committee on Affordable Healthcare Access staff).

services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[35] following an admission.[36]

CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met.[37] All of the CMS conditions for coverage requirements are included in Chapter 59A-5, F.A.C., and apply to all ASCs in Florida. 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.

<u>Recovery Care Centers</u>

Recovery care centers (RCCs) are entities that provide short-term nursing care, support, and pain control for patients that do not require acute hospitalization.[38] 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 ASCs following surgery, which allows ASCs to perform more complex procedures.[39]

RCCs are not eligible for Medicare reimbursement.[40] However, RCCs may receive payments from Medicaid programs. One 1999 survey noted that RCCs received payment in the following breakdown: 41% from managed care plans, 29% from self-pay, 16% from indemnity plans, and 9% from workers' compensation.[41]

Three states, Arizona, Connecticut, and Illinois, have specific licenses for "recovery care centers."[42] Other states license RCCs as nursing facilities or hospitals.[43] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[44]

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[35] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 99, 01-31-14) exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

[36] 42 C.F.R. §416.2

[37] 42 C.F.R. §416.26(1)

[38] Medicare Payment Advisory Comm'n, Report to the Congress: Medicare Payment for Post-Surgical Recovery Care Centers, (2000).

[39] Id. at 4.

[40] See Medicare Payment Advisory Comm'n, Supra FN 20.

[41] Medicare Payment Advisory Comm'n, Supra FN 20, at 6 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

[42] Ariz. Rev. Stat. Ann.§§ 36-448.51-36-448.55; Conn. Conn. Agencies Regs § 19A-495-571; 210 Ill. Comp. Stat. Ann. 3/35.

[43] Sandra Lee Breisch, *Profits in Short Stays*, Am. Acad. of Orthopaedic Surgeons Bulletin (June, 1999), available at http://www2.aaos.org/bulletin/jun99/asc.htm

[44] Medicare Payment Advisory Comm'n, supra FN 20, at 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[45]	Connecticut[46]	Illinois[47]
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 recovery care center.	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

[45] 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).
[46] Conn. Agencies Regs. § 19A-495-571.
[47] 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. Federal 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. The bill adds RCCs to the list of facilities subject to the provisions of Chapter 395, Part I. An applicant for RCC licensure must follow the general licensing procedures in Chapter 408, Part II. Additionally, the applicant will be subject to the license, inspection, safety, facility and other requirements of Chapter 395, Part I.

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

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

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

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to an RCC. A patient may receive recovery care services in an 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.[48]

The bill provides an effective date of July 1, 2016.

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. 395.301, F.S., related to itemized patient bill; form and content prescribed by the agency.
Section 8: Amends s. 408.802, F.S., related to applicability.
Section 9: Amends s. 408.820, F.S., related to exemptions.
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: Provides an effective date of July 1, 2016.

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. AHCA estimates that five entities may apply for licensure. Applicants for licensure as a RCC will be subject to a 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.[49]

2. Expenditures:

   The creation of the RCC license will require AHCA to regulate these facilities in accordance with Chapters 395 and 408, F.S., and any rules adopted by AHCA. The fees associated with the new license are anticipated to cover the expenses incurred by AHCA in enforcement and regulation of the new license. No additional staff will be required as existing regulatory staff is sufficient to absorb the workload associated with up to 10 licenses.[50]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[48] Section 395.004, F.S.
[49] AHCA Agency Bill Analysis, dated September 18, 2015, pg. 3 (on file with Select Committee on Affordable Healthcare Access staff).
[50] Id.

2. Expenditures:

   None.

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 merely because the recovery time will be longer than the ASC limit would allow.

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

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to recovery care services; amending s.
3 395.001, F.S.; providing legislative intent regarding
4 recovery care centers; amending s. 395.002, F.S.;
5 revising and providing definitions; amending s.
6 395.003, F.S.; including recovery care centers as
7 facilities licensed under chapter 395, F.S.; creating
8 s. 395.0171, F.S.; providing admission criteria for a
9 recovery care center; requiring emergency care,
10 transfer, and discharge protocols; authorizing the
11 Agency for Health Care Administration to adopt rules;
12 amending s. 395.1055, F.S.; authorizing the agency to
13 establish separate standards for the care and
14 treatment of patients in recovery care centers;
15 amending s. 395.10973, F.S.; directing the agency to
16 enforce special-occupancy provisions of the Florida
17 Building Code applicable to recovery care centers;
18 amending s. 395.301, F.S.; providing for format and
19 content of a patient bill from a recovery care center;
20 amending s. 408.802, F.S.; providing applicability of
21 the Health Care Licensing Procedures Act to recovery
22 care centers; amending s. 408.820, F.S.; exempting
23 recovery care centers from specified minimum licensure
24 requirements; amending ss. 394.4787 and 409.975, F.S.;
25 conforming cross-references; providing an effective
26 date.

27

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

29

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

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

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

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

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

157 centers, and ambulatory surgical centers.
158 (10) The agency shall adopt rules for recovery care
159 centers which include fair and reasonable minimum standards for
160 ensuring that recovery care centers have:
161 (a) A dietetic department, service, or other similarly
162 titled unit, either on the premises or under contract, which
163 shall be organized, directed, and staffed to ensure the
164 provision of appropriate nutritional care and quality food
165 service.
166 (b) Procedures to ensure the proper administration of
167 medications. Such procedures shall address the prescribing,
168 ordering, preparing, and dispensing of medications and
169 appropriate monitoring of the effects of such medications on the
170 patient.
171 (c) A pharmacy, pharmaceutical department, or
172 pharmaceutical service, or similarly titled unit, on the
173 premises or under contract.
174 Section 6. Subsection (8) of section 395.10973, Florida
175 Statutes, is amended to read:
176 395.10973 Powers and duties of the agency.—It is the
177 function of the agency to:
178 (8) Enforce the special-occupancy provisions of the
179 Florida Building Code which apply to hospitals, intermediate
180 residential treatment facilities, recovery care centers, and
181 ambulatory surgical centers in conducting any inspection
182 authorized by this chapter and part II of chapter 408.

183 Section 7. Subsection (3) of section 395.301, Florida
184 Statutes, is amended to read:
185 395.301 Itemized patient bill; form and content prescribed
186 by the agency; patient admission status notification.—
187 (3) On each itemized statement submitted pursuant to
188 subsection (1) there shall appear the words "A FOR-PROFIT (or
189 NOT-FOR-PROFIT or PUBLIC) HOSPITAL (or AMBULATORY SURGICAL
190 CENTER or RECOVERY CARE CENTER) LICENSED BY THE STATE OF
191 FLORIDA" or substantially similar words sufficient to identify
192 clearly and plainly the ownership status of the licensed
193 facility. Each itemized statement must prominently display the
194 phone number of the medical facility's patient liaison who is
195 responsible for expediting the resolution of any billing dispute
196 between the patient, or his or her representative, and the
197 billing department.
198 Section 8. Subsection (30) is added to section 408.802,
199 Florida Statutes, to read:
200 408.802 Applicability.—The provisions of this part apply
201 to the provision of services that require licensure as defined
202 in this part and to the following entities licensed, registered,
203 or certified by the agency, as described in chapters 112, 383,
204 390, 394, 395, 400, 429, 440, 483, and 765:
205 (30) Recovery care centers, as provided under part I of
206 chapter 395.
207 Section 9. Subsection (29) is added to section 408.820,
208 Florida Statutes, to read:

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209 408.820 Exemptions.—Except as prescribed in authorizing
210 statutes, the following exemptions shall apply to specified
211 requirements of this part:
212 (29) Recovery care centers, as provided under part I of
213 chapter 395, are exempt from s. 408.810(7)-(10).
214 Section 10. Subsection (7) of section 394.4787, Florida
215 Statutes, is amended to read:
216 394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788,
217 and 394.4789.—As used in this section and ss. 394.4786,
218 394.4788, and 394.4789:
219 (7) "Specialty psychiatric hospital" means a hospital
220 licensed by the agency pursuant to s. 395.002(30) ~~395.002(28)~~
221 and part II of chapter 408 as a specialty psychiatric hospital.
222 Section 11. Paragraph (b) of subsection (1) of section
223 409.975, Florida Statutes, is amended to read:
224 409.975 Managed care plan accountability.—In addition to
225 the requirements of s. 409.967, plans and providers
226 participating in the managed medical assistance program shall
227 comply with the requirements of this section.
228 (1) PROVIDER NETWORKS.—Managed care plans must develop and
229 maintain provider networks that meet the medical needs of their
230 enrollees in accordance with standards established pursuant to
231 s. 409.967(2)(c). Except as provided in this section, managed
232 care plans may limit the providers in their networks based on
233 credentials, quality indicators, and price.
234 (b) Certain providers are statewide resources and

235 essential providers for all managed care plans in all regions.
236 All managed care plans must include these essential providers in
237 their networks. Statewide essential providers include:
238 1. Faculty plans of Florida medical schools.
239 2. Regional perinatal intensive care centers as defined in
240 s. 383.16(2).
241 3. Hospitals licensed as specialty children's hospitals as
242 defined in s. 395.002(30) ~~395.002(28)~~.
243 4. Accredited and integrated systems serving medically
244 complex children that are comprised of separately licensed, but
245 commonly owned, health care providers delivering at least the
246 following services: medical group home, in-home and outpatient
247 nursing care and therapies, pharmacy services, durable medical
248 equipment, and Prescribed Pediatric Extended Care.
249
250 Managed care plans that have not contracted with all statewide
251 essential providers in all regions as of the first date of
252 recipient enrollment must continue to negotiate in good faith.
253 Payments to physicians on the faculty of nonparticipating
254 Florida medical schools shall be made at the applicable Medicaid
255 rate. Payments for services rendered by regional perinatal
256 intensive care centers shall be made at the applicable Medicaid
257 rate as of the first day of the contract between the agency and
258 the plan. Payments to nonparticipating specialty children's
259 hospitals shall equal the highest rate established by contract
260 between that provider and any other Medicaid managed care plan.

261 Section 12. This act shall take effect July 1, 2016.

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 437 Certificates of Need for Hospitals
SPONSOR(S): Sprowls
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access		Guzzo	Calamas
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, 22 states do not require CON review to add hospital beds. Of those states, 14 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:

- Construction of a new hospital;
- Replacement of a hospital if the proposed project site is more than one mile from the hospital being replaced;
- Conversion from one type of hospital to another, including the conversion between a general hospital, specialty hospital, or a long-term care hospital; and
- Establishment of tertiary health services and 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.

An applicant for CON review must submit a fee with the application. The minimum CON application filing fee is $10,000. 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. The fee for a CON exemption is $250.

HB 437 eliminates CON review requirements for hospitals and hospital services and makes necessary conforming changes throughout part I of chapter 408, F.S. The bill also removes the CON review requirement for increasing the number of comprehensive rehabilitation beds in a facility that offers comprehensive rehabilitation services.

The bill makes a conforming change to s. 395.1055, F.S., to ensure that AHCA has rulemaking authority, after the repeal of the CON review process for hospitals, to maintain licensure requirements and quality standards for tertiary health services offered by a hospital.

The bill is expected to have a significant negative fiscal impact on AHCA resulting from the loss of CON application and exemption fees for hospital services.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

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 November 13, 2015, 219 of the 306 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
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[9]

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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 (report generated on November 13, 2015).
[6] Rule 59A-3.006(3), F.A.C.
[7] S. 395.0161(3)(a), F.S.
[8] S. 395.1055(2), F.S.
[9] S. 395.1055(1), F.S.

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

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.[10] Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, for example, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation.[11] 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.[12] Larger institutions have higher costs, so CON supporters say it makes sense to limit facilities to building only enough capacity to meet actual needs.[13]

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.[14] Some states require facilities and providers that obtain a CON to provide a certain amount of indigent care to underinsured or uninsured patients.[15]

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.[16]

Studies are split, however, on whether CON regulation has improved access to care for the underinsured and uninsured.[17] While there is limited research on the subject, some studies have found

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[10] 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 November 13, 2015).
[11] Id.
[12] Id.
[13] Id.
[14] 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: http://mercatus.org/publication/do-certificate-need-laws-increase-indigent-care (last viewed November 13, 2015).
[15] For example, 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) require CON applicants to comply with such provisions.
[16] "Improving Health Care: A Does of Competition: A Report by the Federal Trade Commission and the Department of Justice," July 2004, available at: https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice (last viewed November 13, 2015): "[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).
[17] Supra, FN 10 at pg. 18.

that access to care for the underserved populations has increased in states with CON programs,[18] while another has found little, if any, evidence to support such a conclusion.[19] 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.[20] 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.[21]

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.[22] 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, including hospices. The Florida CON program has three levels of review: full, expedited and exempt.[23] 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 are required to undergo a full comparative CON review, including:

- 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.[24]

The addition of certain new or expansion of certain 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;[25] and

[18] 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://www.nihcr.org/index.php?download=119ncfl17 (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)).
[19] 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).
[20] Id.
[21] Christopher Koopman and Thomas Stratman, "Certificate-of-Need Laws: Implications for Florida," March 2015, pg. 2, available at: http://mercatus.org/sites/default/files/Koopman-Certficate-of-NeedFL-MOP.pdf. (last viewed November 13, 2015).
[22] Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.
[23] S. 408.036, F.S.
[24] S. 408.036(1)(b), F.S.

- Establishing tertiary health services.[26]

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.[27]

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.[28]

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.[29]

[25] S. 408.0361(1)(e), F.S.
[26] S. 408.036(1)(f), F.S., and s. 408.032(17), F.S., which 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. Examples of tertiary health services include pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and 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.
[27] Rule 59C-1.039(2)(c), F.A.C.
[28] Rule 59C-1.002(41), F.A.C.
[29] Rule 59C-1.002(41), F.A.C.

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
- Construction of a new community nursing home in a retirement community under certain conditions.[30]

Exemptions from CON Review

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

- Adding swing beds[31] 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, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities.
- Adding hospital beds licensed under chapter 395, F.S., for comprehensive rehabilitation, the total of which may not exceed 10 total beds or 10 percent of the licensed capacity, 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,[32] 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.
- For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.

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

[31] 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.

[32] 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.

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”[33], 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.[34] Chapter 59C-1, F.A.C., provides need formulas[35] to calculate the fixed need pool for certain services, including NICU services[36], adult and child psychiatric services[37], adult substance abuse services[38], and comprehensive rehabilitation services.[39]

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.

Certificate of Need Service Areas

[33] 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.
[34] Rule 59C-1.002(5), F.A.C.
[35] 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 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.
[36] Rule 59C-1.042(3), F.A.C.
[37] Rule 59C-1.040(4), F.A.C.
[38] Rule 59C-1.041(4), F.A.C.
[39] Rule 59C-1.039(5), F.A.C.

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.[40] The "hospital beds and facilities" batching cycle includes applicants for new or expanded:

- Comprehensive medical rehabilitation beds;
- Adult psychiatric beds;
- Child and adolescent psychiatric beds;
- Adult substance abuse beds;
- NICU level II beds; and
- NICU level III beds.[41]

The "other beds and programs" batching cycle includes:

- Nursing home beds;
- Hospice beds;
- Pediatric open heart surgery;
- Pediatric cardiac catheterization services; and
- Organ transplantation services.[42]

Hospital Beds & Facilities Applications for Last 4 Batching Cycles 2013-2015[43]

Proposed Project	*Applications Received*	*Applications Approved*
Establish a Comprehensive Medical Rehabilitation Unit	9	1
Establish an Acute Care Hospital	4	3
Establish an Adult Inpatient Psychiatric Hospital	4	3
Establish a Long-Term Care Hospital	2	2
Establish a Replacement Acute Care Hospital	2	2
Establish a Child/Adolescent Psychiatric Hospital	1	1
Total	**22**	**12**

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.[44] 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.[45]

Applications for CON review must be submitted by the specified deadline for the particular batch cycle.[46] AHCA must review the application within 15 days of the filing deadline and, if necessary,

[40] Rule 59C-1.008(1)(g), F.A.C.
[41] Rule 59C-1.008(1), F.A.C.
[42] Id.
[43] AHCA, CON Decisions & State Agency Action Reports, Hospital Beds and Facilities, February 2015 batching cycle, August 2014 batching cycle, February 2014 batching cycle, and August 2013 batching cycle, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/decisions.shtml (last viewed November 13, 2015). Pursuant to s. 408.036, F.S., and rule 59C-1.004(1), F.A.C., requests for an expedited review or exemption may be made at any time and are not subject to batching requirements.
[44] S. 408.039(2)(a), F.S.
[45] S. 408.039(2)(c), F.S.

request additional information for an incomplete application.[47] The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.[48]

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.[49] AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.[50] 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.[51]

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.[52] 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.[53] A request for a CON exemption must be accompanied by a $250 fee payable to AHCA.[54]

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 challenge will be substantially affected if the CON is awarded.[55] A challenge to a CON decision is heard by an Administrative Law Judge under the Division of Administrative Hearings.[56] AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.[57] A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review[58] within 30 days of receipt of a Final Order.[59]

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.[60] 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.[61]

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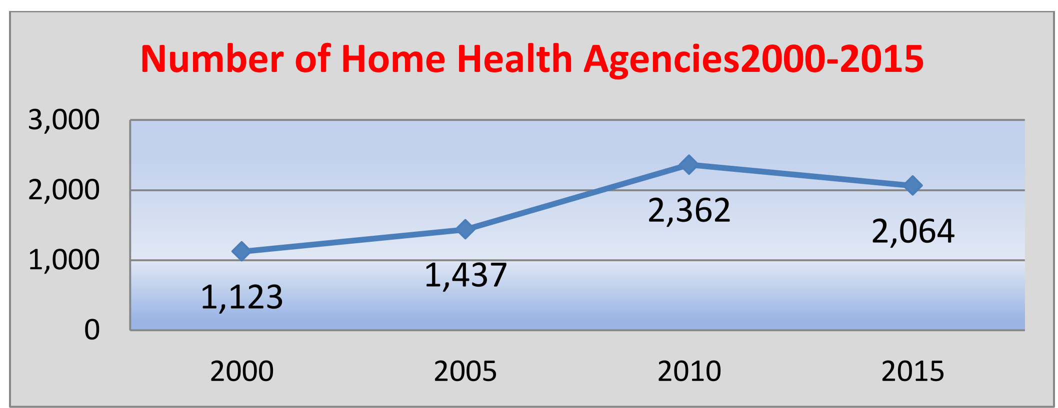
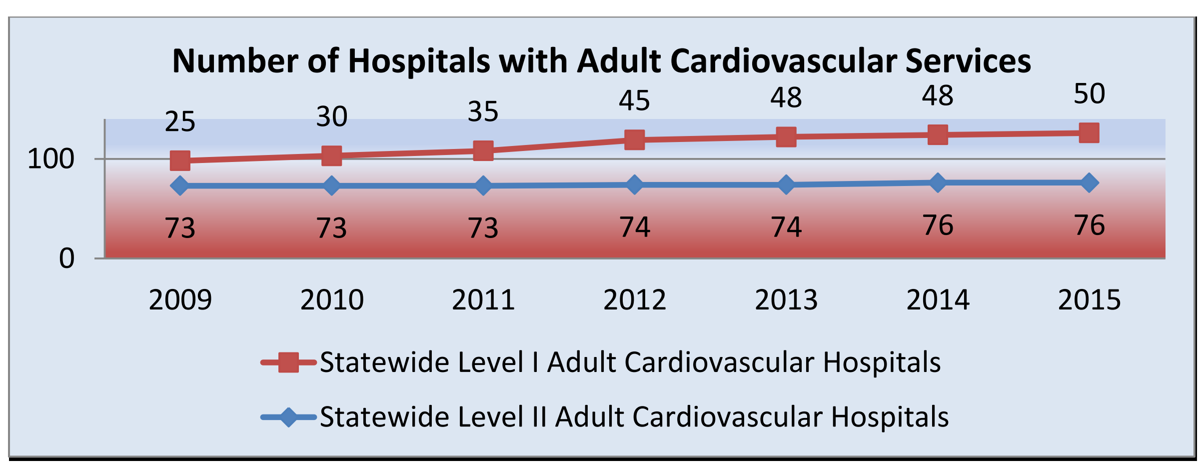
[46] Rule 59C-1.008(1)(g), F.A.C.
[47] S. 408.039(3)(a), F.S.
[48] Id.
[49] S. 408.039(4)(b), F.S.
[50] S. 408.039(4)(c), F.S.
[51] S. 408.039(4)(d), F.S.
[52] S. 408.038, F.S.
[53] Id.
[54] S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.
[55] S. 408.039(5)(c), F.S.
[56] Id.
[57] S. 408.039(5)(e), F.S.
[58] 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.
[59] S. 408.039(6), F.S.
[60] Ch. 2000-256, Laws of Fla.
[61] AHCA, Current Status of Certificate of Need, Effects of Deregulation, October 20, 2015, available at http://healthandhospitalcommission.com/Meetings.shtml (last viewed November 13, 2015).



In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.[62] Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I[63] adult cardiovascular services license has doubled while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased.[64]



In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.[65] 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.[66] As of October, 2015, 3,373 nursing home beds have been approved since the moratorium has been lifted.[67]

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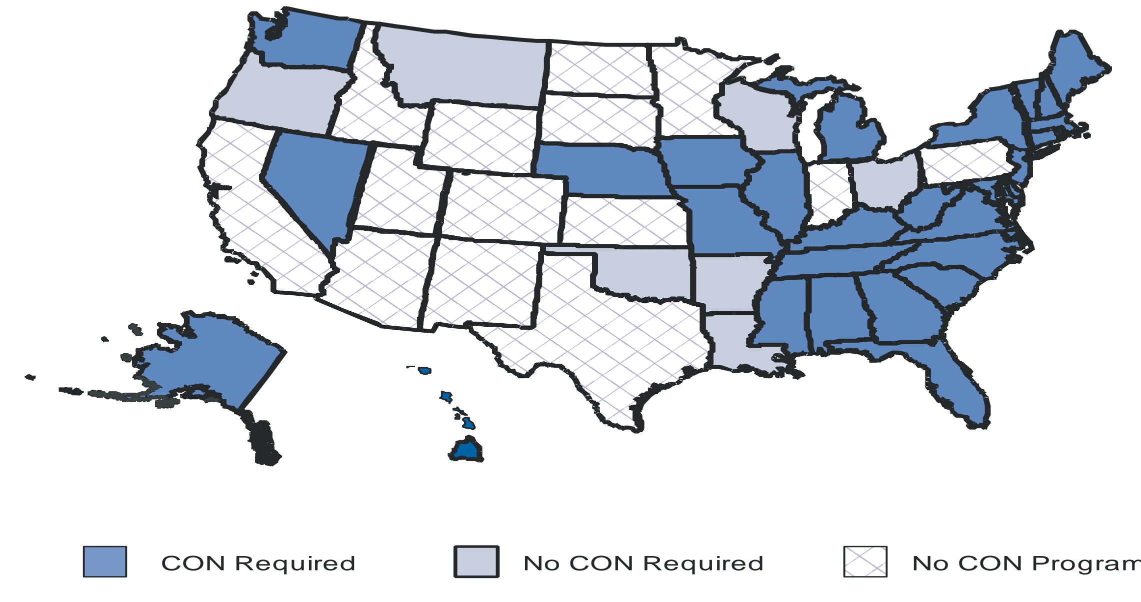
[62] Ch. 2007-214, Laws of Fla.
[63] S. 408.0361, F.S., requires AHCA to adopt rules for the establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing 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.
[64] Supra, FN 62 at pg. 7.
[65] Ch. 2014-110, Laws of Fla.
[66] S. 408.0436, F.S.
[67] AHCA, Nursing Home Licensure and Regulation, Presentation to the Health Innovation Subcommittee, October 6, 2015, (on file with Select Committee on Affordable Healthcare Access staff).

Nursing Home CON Applications Since July 2014[68]					
	Oct. 2014[69]	April 2015[70]	Expedited Reviews	Exemptions	Total
Bed Need Published	3,115	657			3,772
Notices of Intent Filed	179	28			207
Applications Submitted	87	19			106
Approved Beds	2,447	381	240	305	3,373
Denied Beds	5,827	519			6,346
New Facilities	22	2	2		26
Additions to Existing Facilities	12	8			20

<u>CON Nationwide</u>

Fourteen states do not have CON requirements for any type of health care facility or service.[71] 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.[72]



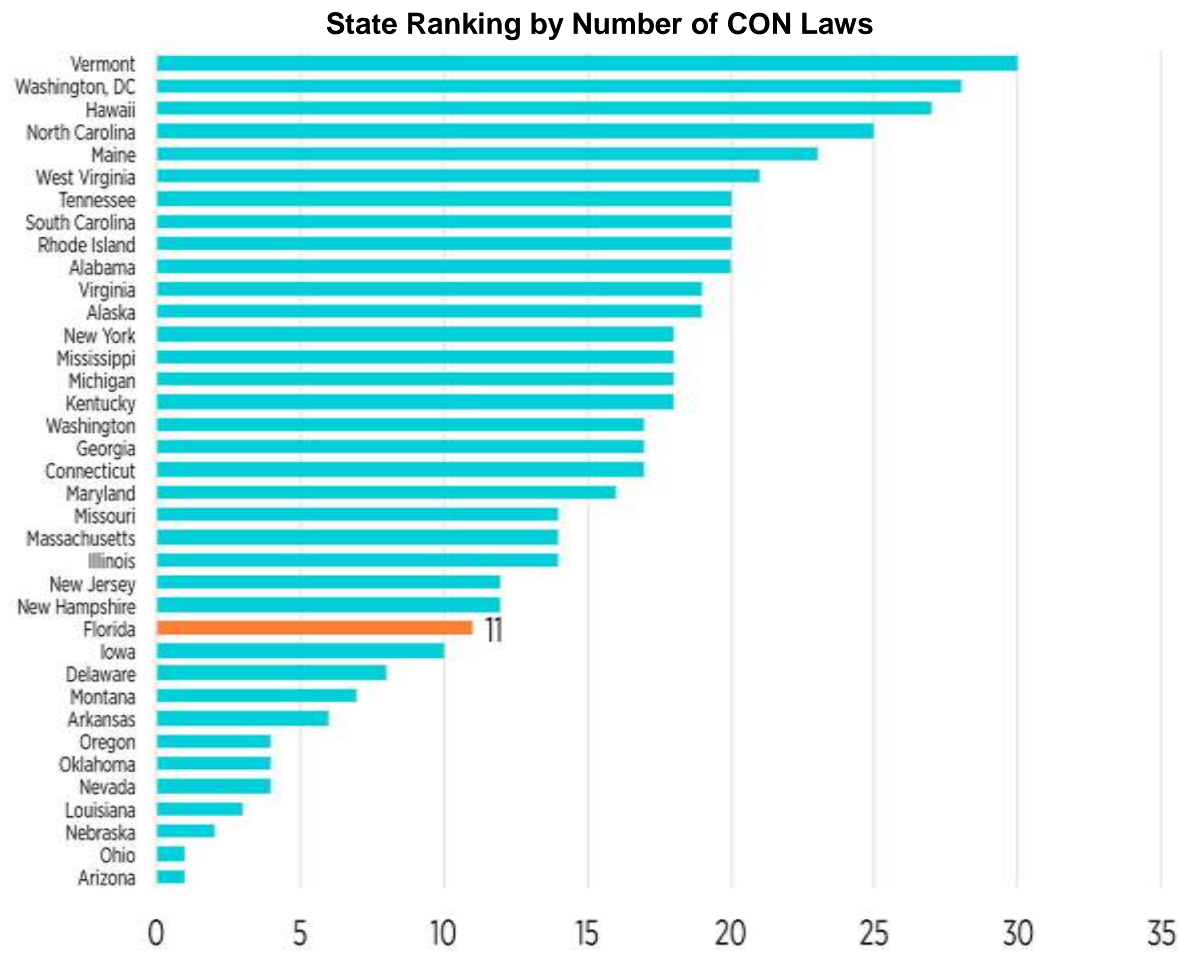
[68] Id.
[69] The decision date for this batching cycle was February 20, 2015.
[70] The decision date for this batching cycle was August 21, 2015.
[71] National Conference of State Legislators, Certificate of Need: State Laws and Programs, available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed November 13, 2015).
[72] Id.

The states that have repealed their CON program, and the dates of repeal, are:

- Arizona (1985 – still retains CON requirements for ambulance service providers);
- California (1987);
- Idaho (1983);
- Indiana (1996);
- Kansas (1985);
- Minnesota (1985);
- New Mexico (1983);
- North Dakota (1995);
- Pennsylvania (1996);
- South Dakota (1988);
- Texas (1985);
- Utah (1984);
- Wisconsin (2011); and
- Wyoming (1989).[73]

On average, states with CON programs regulate 14 different services, devices, and procedures.[74] Florida's CON program currently regulates 11, which is slightly below the national average.[75] Vermont has the most CON laws in place. Arizona has the least number of CON laws.[76]

State Ranking by Number of CON Laws



[73] Id.
[74] Supra, FN 18 at pg. 3.
[75] Id.
[76] Id.

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.[77] 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 (Commission) on Government Forecasting and Accountability 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…".[78] 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.[79]

In 2008, the Legislature decided to study the issue further and passed legislation to create the Task Force on Health Planning Reform (task force).[80] 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.[81] The task force recommended that the state maintain the CON process and extend the sunset date.[82] 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.[83] The study examined the effects of CON, and its possible repeal, on the cost, quality, and availability health care. The results of the study were based on a literature review, information gathered from service providers and other experts in Washington, and analyses of states where CON has been completely or partially repealed.[84]

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

[77] Supra, FN 71 at pgs. 62 and 82.
[78] Ill. House Resolution 1497 (2006).
[79] 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 November 13, 2015).
[80] Ill. Senate Bill 244 (PA 95-0005) of the 95th General Assembly, 2008
[81] The Illinois Task Force on Health Planning Reform, Final Report, December 31, 2008.
[82] Id.
[83] State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.
[84] 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://www.leg.wa.gov/JLARC/AuditAndStudyReports/1999/Documents/99-1.pdf (last viewed October 27, 2015).

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 adopted 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.[85]

The workgroup is required to develop specific recommendations for changes to the COPN process to be introduced during the 2016 Session of the General Assembly and any additional changes that may require further study or review.[86] In conducting its review and developing its recommendations, the work group must consider data and information about the current COPN process, the impact of such process, and any data or information about similar processes in other states.[87] A final report with recommendations must be provided to the General Assembly by December 1, 2015.[88]

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.[89] 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.[90] As the statement describes, CON laws create barriers to expansion, limit consumer choice, and stifle innovation.[91] Additionally, incumbent providers seeking to thwart or delay entry by new competitors may use CON laws to that end.[92] Finally, the statement asserts that CON laws can deny consumers the benefit of an effective remedy for antitrust violations and can facilitate anticompetitive agreements.[93] 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.[94]

Currently, both North Carolina and South Carolina are considering legislation to repeal or limit their CON programs.[95]

Effect of Proposed Changes

The bill eliminates CON review requirements for hospitals and hospital services and makes necessary conforming changes throughout part I of chapter 408, F.S. The bill also removes the CON review requirement for increasing the number of comprehensive rehabilitation beds in a facility that offers

[85] SB 1283, Virginia General Assembly, 2015.
[86] 2015 Va. Acts Chapter 541.
[87] Id.
[88] Id.
[89] 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 http://www.vdh.state.va.us/Administration/documents/COPN/Federal%20Trade%20Commission%20and%20Department%20of%20Justice.pdf (last viewed November 12, 2015).
[90] Supra, FN 87 at pg. 2.
[91] Id.
[92] Id.
[93] Id.
[94] Supra, FN 87 at pg. 13.
[95] The North Carolina General Assembly is considering two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposes to repeal the CON program in its entirety. House Bill 200 proposes to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The legislative session begins in April. The South Carolina General Assembly is also considering 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 proposes to repeal the CON program effective January 1, 2018, and proposes to reduce CON regulations in the interim by providing several exemptions from CON review. The legislative session begins in January.

comprehensive rehabilitation services. Hospitals will be able to expand the number of beds and the types of services without seeking prior authorization from the state. Similarly, facilities that offer comprehensive rehabilitation services will be able to increase the number of beds to meet demand without first seeking prior authorization from the state.

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.[96] The bill deletes the definition of "tertiary health service" in s. 408.032, F.S., to repeal the CON review requirement for a hospital to establish such services. 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.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act.
Section 2: Amends s. 408.034, F.S., relating to duties and responsibilities of the agency; rules.
Section 3: Amends s. 408.035, F.S., relating to review criteria.
Section 4: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 5: Amends s. 408.037, F.S., relating to application content.
Section 6: Amends s. 408.039, F.S, relating to review process.
Section 7: Amends s. 408.043, F.S., relating to special provisions.
Section 8: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 9: Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.
Section 10: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
Section 11: Amends s. 395.604, F.S., relating to other rural hospital programs.
Section 12: Amends s. 395.605, F.S., relating to emergency care hospitals.
Section 13: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 14: Provides an effective date of July 1, 2016.

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 for hospital services which may be mitigated by a reduction in workload. Fees collected in 2014 resulted in revenue of approximately $650,000.[97] An indeterminate amount of the reduction in revenue will be negated by an increase in fees collected for hospital licensure.

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[96] 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).
[97] AHCA, Agency Bill Analysis of HB 31A, p. 5, May 21, 2015 (on file with the Select Committee on Affordable Healthcare Access staff).

2. Expenditures:

AHCA may experience increased workload resulting from an increase in hospital 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 review process for hospitals.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals will experience a significant positive fiscal impact resulting from the elimination of CON fees, which range from $10,000 to $50,000.

By removing the CON review program for hospitals, the hospital industry is likely to realize increased competition in services offered by hospitals.

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:

No additional rulemaking authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to certificates of need for hospitals;
3 amending s. 408.032, F.S.; revising definitions;
4 amending s. 408.034, F.S.; revising duties and
5 responsibilities of the Agency for Health Care
6 Administration in the exercise of its authority to
7 issue licenses to health care facilities and health
8 service providers; amending s. 408.035, F.S.; revising
9 review criteria for applications for certificate-of-
10 need determinations for health care facilities and
11 health services; excluding general hospitals from such
12 review; amending s. 408.036, F.S.; revising health-
13 care-related projects subject to review for a
14 certificate of need and exemptions therefrom; amending
15 s. 408.037, F.S.; revising content requirements with
16 respect to an application for a certificate of need;
17 amending s. 408.039, F.S.; revising the review process
18 for certificates of need; amending s. 408.043, F.S.;
19 revising special provisions to eliminate provisions
20 relating to osteopathic acute care hospitals; amending
21 s. 395.1055, F.S.; revising the agency's rulemaking
22 authority with respect to minimum standards for
23 hospitals; requiring hospitals that provide certain
24 services to meet specified licensure requirements;
25 deleting requirements for submitting data by hospitals
26 for certificate-of-need reviews, to conform to changes

27 made by the act; repealing s. 395.6025, F.S., relating
28 to rural hospital replacement facilities; amending ss.
29 395.603, 395.604, and 395.605, F.S.; conforming
30 references; amending s. 408.0361, F.S.; deleting
31 outdated licensure provisions for cardiovascular
32 services and burn units; providing an effective date.
33
34 Be It Enacted by the Legislature of the State of Florida:
35
36 Section 1. Subsections (8) through (17) of section
37 408.032, Florida Statutes, are amended to read:
38 408.032 Definitions relating to Health Facility and
39 Services Development Act.—As used in ss. 408.031-408.045, the
40 term:
41 (8) "Health care facility" means a ~~hospital, long-term~~
42 ~~care hospital,~~ skilled nursing facility, hospice, or
43 intermediate care facility for the developmentally disabled. A
44 facility relying solely on spiritual means through prayer for
45 healing is not included as a health care facility.
46 ~~(9) "Health services" means inpatient diagnostic,~~
47 ~~curative, or comprehensive medical rehabilitative services and~~
48 ~~includes mental health services. Obstetric services are not~~
49 ~~health services for purposes of ss. 408.031-408.045.~~
50 (9) ~~(10)~~ "Hospice" or "hospice program" means a hospice as
51 defined in part IV of chapter 400.
52 ~~(11) "Hospital" means a health care facility licensed~~

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53 ~~under chapter 395.~~
54 (10) ~~(12)~~ "Intermediate care facility for the
55 developmentally disabled" means a residential facility licensed
56 under part VIII of chapter 400.
57 ~~(13) "Long-term care hospital" means a hospital licensed~~
58 ~~under chapter 395 which meets the requirements of 42 C.F.R. s.~~
59 ~~412.23(e) and seeks exclusion from the acute care Medicare~~
60 ~~prospective payment system for inpatient hospital services.~~
61 ~~(14) "Mental health services" means inpatient services~~
62 ~~provided in a hospital licensed under chapter 395 and listed on~~
63 ~~the hospital license as psychiatric beds for adults; psychiatric~~
64 ~~beds for children and adolescents; intensive residential~~
65 ~~treatment beds for children and adolescents; substance abuse~~
66 ~~beds for adults; or substance abuse beds for children and~~
67 ~~adolescents.~~
68 (11) ~~(15)~~ "Nursing home geographically underserved area"
69 means:
70 (a) A county in which there is no existing or approved
71 nursing home;
72 (b) An area with a radius of at least 20 miles in which
73 there is no existing or approved nursing home; or
74 (c) An area with a radius of at least 20 miles in which
75 all existing nursing homes have maintained at least a 95 percent
76 occupancy rate for the most recent 6 months or a 90 percent
77 occupancy rate for the most recent 12 months.
78 (12) ~~(16)~~ "Skilled nursing facility" means an institution,

79 or a distinct part of an institution, which is primarily engaged
80 in providing, to inpatients, skilled nursing care and related
81 services for patients who require medical or nursing care, or
82 rehabilitation services for the rehabilitation of injured,
83 disabled, or sick persons.
84 ~~(17) "Tertiary health service" means a health service~~
85 ~~which, due to its high level of intensity, complexity,~~
86 ~~specialized or limited applicability, and cost, should be~~
87 ~~limited to, and concentrated in, a limited number of hospitals~~
88 ~~to ensure the quality, availability, and cost-effectiveness of~~
89 ~~such service. Examples of such service include, but are not~~
90 ~~limited to, pediatric cardiac catheterization, pediatric open-~~
91 ~~heart surgery, organ transplantation, neonatal intensive care~~
92 ~~units, comprehensive rehabilitation, and medical or surgical~~
93 ~~services which are experimental or developmental in nature to~~
94 ~~the extent that the provision of such services is not yet~~
95 ~~contemplated within the commonly accepted course of diagnosis or~~
96 ~~treatment for the condition addressed by a given service. The~~
97 ~~agency shall establish by rule a list of all tertiary health~~
98 ~~services.~~
99 Section 2. Subsection (2) of section 408.034, Florida
100 Statutes, is amended to read:
101 408.034 Duties and responsibilities of agency; rules.—
102 (2) In the exercise of its authority to issue licenses to
103 health care facilities and health service providers, as provided
104 under chapter ~~chapters~~ 393 ~~and 395~~ and parts II, IV, and VIII of

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105 chapter 400, the agency may not issue a license to any health
106 care facility or health service provider that fails to receive a
107 certificate of need or an exemption for the licensed facility or
108 service.
109 Section 3. Section 408.035, Florida Statutes, is amended
110 to read:
111 408.035 Review criteria.—
112 ~~(1)~~ The agency shall determine the reviewability of
113 applications and shall review applications for certificate-of-
114 need determinations for health care facilities and health
115 services in context with the following criteria~~, except for~~
116 ~~general hospitals as defined in s. 395.002~~:
117 (1)~~(a)~~ The need for the health care facilities and health
118 services being proposed.
119 (2)~~(b)~~ The availability, quality of care, accessibility,
120 and extent of utilization of existing health care facilities and
121 health services in the service district of the applicant.
122 (3)~~(c)~~ The ability of the applicant to provide quality of
123 care and the applicant's record of providing quality of care.
124 (4)~~(d)~~ The availability of resources, including health
125 personnel, management personnel, and funds for capital and
126 operating expenditures, for project accomplishment and
127 operation.
128 (5)~~(e)~~ The extent to which the proposed services will
129 enhance access to health care for residents of the service
130 district.

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131 <u>(6)</u>~~(f)~~ The immediate and long-term financial feasibility
132 of the proposal.
133 <u>(7)</u>~~(g)~~ The extent to which the proposal will foster
134 competition that promotes quality and cost-effectiveness.
135 <u>(8)</u>~~(h)~~ The costs and methods of the proposed construction,
136 including the costs and methods of energy provision and the
137 availability of alternative, less costly, or more effective
138 methods of construction.
139 <u>(9)</u>~~(i)~~ The applicant's past and proposed provision of
140 health care services to Medicaid patients and the medically
141 indigent.
142 <u>(10)</u>~~(j)~~ The applicant's designation as a Gold Seal Program
143 nursing facility pursuant to s. 400.235, when the applicant is
144 requesting additional nursing home beds at that facility.
145 ~~(2) For a general hospital, the agency shall consider only~~
146 ~~the criteria specified in paragraph (1)(a), paragraph (1)(b),~~
147 ~~except for quality of care in paragraph (1)(b), and paragraphs~~
148 ~~(1)(e), (g), and (i).~~
149 Section 4. Section 408.036, Florida Statutes, is amended
150 to read:
151 408.036 Projects subject to review; exemptions.—
152 (1) APPLICABILITY.—Unless exempt under subsection (3), all
153 health-care-related projects, as described in <u>this subsection</u>
154 ~~paragraphs (a)-(f)~~, are subject to review and must file an
155 application for a certificate of need with the agency. The
156 agency is exclusively responsible for determining whether a

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157 health-care-related project is subject to review under ss.
158 408.031-408.045.
159 (a) The addition of beds in community nursing homes or
160 intermediate care facilities for the developmentally disabled by
161 new construction or alteration.
162 (b) The new construction or establishment of additional
163 health care facilities, including a replacement health care
164 facility when the proposed project site is not located on the
165 same site as or within 1 mile of the existing health care
166 facility, if the number of beds in each licensed bed category
167 will not increase.
168 (c) The conversion from one type of health care facility
169 to another~~, including the conversion from a general hospital, a~~
170 ~~specialty hospital, or a long-term care hospital~~.
171 (d) The establishment of a hospice or hospice inpatient
172 facility, except as provided in s. 408.043.
173 ~~(e) An increase in the number of beds for comprehensive~~
174 ~~rehabilitation.~~
175 ~~(f) The establishment of tertiary health services,~~
176 ~~including inpatient comprehensive rehabilitation services.~~
177 (2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt
178 pursuant to subsection (3), the following projects are subject
179 to expedited review:
180 (a) Transfer of a certificate of need~~, except that when an~~
181 ~~existing hospital is acquired by a purchaser, all certificates~~
182 ~~of need issued to the hospital which are not yet operational~~

183 ~~shall be acquired by the purchaser without need for a transfer~~.
184 (b) Replacement of a nursing home, if the proposed project
185 site is within a 30-mile radius of the replaced nursing home. If
186 the proposed project site is outside the subdistrict where the
187 replaced nursing home is located, the prior 6-month occupancy
188 rate for licensed community nursing homes in the proposed
189 subdistrict must be at least 85 percent in accordance with the
190 agency's most recently published inventory.
191 (c) Replacement of a nursing home within the same
192 district, if the proposed project site is outside a 30-mile
193 radius of the replaced nursing home but within the same
194 subdistrict or a geographically contiguous subdistrict. If the
195 proposed project site is in the geographically contiguous
196 subdistrict, the prior 6-month occupancy rate for licensed
197 community nursing homes for that subdistrict must be at least 85
198 percent in accordance with the agency's most recently published
199 inventory.
200 (d) Relocation of a portion of a nursing home's licensed
201 beds to another facility or to establish a new facility within
202 the same district or within a geographically contiguous
203 district, if the relocation is within a 30-mile radius of the
204 existing facility and the total number of nursing home beds in
205 the state does not increase.
206 (e) New construction of a community nursing home in a
207 retirement community as further provided in this paragraph.
208 1. Expedited review under this paragraph is available if

209 all of the following criteria are met:
210 a. The residential use area of the retirement community is
211 deed-restricted as housing for older persons as defined in s.
212 760.29(4)(b).
213 b. The retirement community is located in a county in
214 which 25 percent or more of its population is age 65 and older.
215 c. The retirement community is located in a county that
216 has a rate of no more than 16.1 beds per 1,000 persons age 65
217 years or older. The rate shall be determined by using the
218 current number of licensed and approved community nursing home
219 beds in the county per the agency's most recent published
220 inventory.
221 d. The retirement community has a population of at least
222 8,000 residents within the county, based on a population data
223 source accepted by the agency.
224 e. The number of proposed community nursing home beds in
225 an application does not exceed the projected bed need after
226 applying the rate of 16.1 beds per 1,000 persons aged 65 years
227 and older projected for the county 3 years into the future using
228 the estimates adopted by the agency reduced by the agency's most
229 recently published inventory of licensed and approved community
230 nursing home beds in the county.
231 2. No more than 120 community nursing home beds shall be
232 approved for a qualified retirement community under each request
233 for expedited review. Subsequent requests for expedited review
234 under this process may not be made until 2 years after

235 construction of the facility has commenced or 1 year after the
236 beds approved through the initial request are licensed,
237 whichever occurs first.
238 3. The total number of community nursing home beds which
239 may be approved for any single deed-restricted community
240 pursuant to this paragraph may not exceed 240, regardless of
241 whether the retirement community is located in more than one
242 qualifying county.
243 4. Each nursing home facility approved under this
244 paragraph must be dually certified for participation in the
245 Medicare and Medicaid programs.
246 5. Each nursing home facility approved under this
247 paragraph must be at least 1 mile, as measured over publicly
248 owned roadways, from an existing approved and licensed community
249 nursing home.
250 6. A retirement community requesting expedited review
251 under this paragraph shall submit a written request to the
252 agency for expedited review. The request must include the number
253 of beds to be added and provide evidence of compliance with the
254 criteria specified in subparagraph 1.
255 7. After verifying that the retirement community meets the
256 criteria for expedited review specified in subparagraph 1., the
257 agency shall publicly notice in the Florida Administrative
258 Register that a request for an expedited review has been
259 submitted by a qualifying retirement community and that the
260 qualifying retirement community intends to make land available

261 for the construction and operation of a community nursing home.
262 The agency's notice must identify where potential applicants can
263 obtain information describing the sales price of, or terms of
264 the land lease for, the property on which the project will be
265 located and the requirements established by the retirement
266 community. The agency notice must also specify the deadline for
267 submission of the certificate-of-need application, which may not
268 be earlier than the 91st day or later than the 125th day after
269 the date the notice appears in the Florida Administrative
270 Register.
271 8. The qualified retirement community shall make land
272 available to applicants it deems to have met its requirements
273 for the construction and operation of a community nursing home
274 but may sell or lease the land only to the applicant that is
275 issued a certificate of need by the agency under this paragraph.
276 a. A certificate-of-need application submitted under this
277 paragraph must identify the intended site for the project within
278 the retirement community and the anticipated costs for the
279 project based on that site. The application must also include
280 written evidence that the retirement community has determined
281 that both the provider submitting the application and the
282 project satisfy its requirements for the project.
283 b. If the retirement community determines that more than
284 one provider satisfies its requirements for the project, it may
285 notify the agency of the provider it prefers.
286 9. The agency shall review each submitted application. If

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287 multiple applications are submitted for a project published
288 pursuant to subparagraph 7., the agency shall review the
289 competing applications.
290
291 The agency shall develop rules to implement the expedited review
292 process, including time schedule, application content that may
293 be reduced from the full requirements of s. 408.037(1), and
294 application processing.
295 (3) EXEMPTIONS.—Upon request, the following projects are
296 subject to exemption from the provisions of subsection (1):
297 (a) For hospice services ~~or for swing beds in a rural~~
298 ~~hospital, as defined in s. 395.602, in a number that does not~~
299 ~~exceed one-half of its licensed beds~~.
300 ~~(b) For the conversion of licensed acute care hospital~~
301 ~~beds to Medicare and Medicaid certified skilled nursing beds in~~
302 ~~a rural hospital, as defined in s. 395.602, so long as the~~
303 ~~conversion of the beds does not involve the construction of new~~
304 ~~facilities. The total number of skilled nursing beds, including~~
305 ~~swing beds, may not exceed one-half of the total number of~~
306 ~~licensed beds in the rural hospital as of July 1, 1993.~~
307 ~~Certified skilled nursing beds designated under this paragraph,~~
308 ~~excluding swing beds, shall be included in the community nursing~~
309 ~~home bed inventory. A rural hospital that subsequently~~
310 ~~decertifies any acute care beds exempted under this paragraph~~
311 ~~shall notify the agency of the decertification, and the agency~~
312 ~~shall adjust the community nursing home bed inventory~~

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313 ~~accordingly.~~
314 (b) ~~(c)~~ For the addition of nursing home beds at a skilled
315 nursing facility that is part of a retirement community that
316 provides a variety of residential settings and supportive
317 services and that has been incorporated and operated in this
318 state for at least 65 years on or before July 1, 1994. All
319 nursing home beds must not be available to the public but must
320 be for the exclusive use of the community residents.
321 (c) ~~(d)~~ For an inmate health care facility built by or for
322 the exclusive use of the Department of Corrections as provided
323 in chapter 945. This exemption expires when such facility is
324 converted to other uses.
325 (d) ~~(e)~~ For mobile surgical facilities and related health
326 care services provided under contract with the Department of
327 Corrections or a private correctional facility operating
328 pursuant to chapter 957.
329 (e) ~~(f)~~ For the addition of nursing home beds licensed
330 under chapter 400 in a number not exceeding 30 total beds or 25
331 percent of the number of beds licensed in the facility being
332 replaced under paragraph (2)(b), paragraph (2)(c), or paragraph
333 (j) ~~(p)~~, whichever is less.
334 (f) ~~(g)~~ For state veterans' nursing homes operated by or on
335 behalf of the Florida Department of Veterans' Affairs in
336 accordance with part II of chapter 296 for which at least 50
337 percent of the construction cost is federally funded and for
338 which the Federal Government pays a per diem rate not to exceed

339 one-half of the cost of the veterans' care in such state nursing
340 homes. These beds shall not be included in the nursing home bed
341 inventory.
342 (g) ~~(h)~~ For combination within one nursing home facility of
343 the beds or services authorized by two or more certificates of
344 need issued in the same planning subdistrict. An exemption
345 granted under this paragraph shall extend the validity period of
346 the certificates of need to be consolidated by the length of the
347 period beginning upon submission of the exemption request and
348 ending with issuance of the exemption. The longest validity
349 period among the certificates shall be applicable to each of the
350 combined certificates.
351 (h) ~~(i)~~ For division into two or more nursing home
352 facilities of beds or services authorized by one certificate of
353 need issued in the same planning subdistrict. An exemption
354 granted under this paragraph shall extend the validity period of
355 the certificate of need to be divided by the length of the
356 period beginning upon submission of the exemption request and
357 ending with issuance of the exemption.
358 ~~(j) For the addition of hospital beds licensed under~~
359 ~~chapter 395 for comprehensive rehabilitation in a number that~~
360 ~~may not exceed 10 total beds or 10 percent of the licensed~~
361 ~~capacity, whichever is greater.~~
362 ~~1. In addition to any other documentation otherwise~~
363 ~~required by the agency, a request for exemption submitted under~~
364 ~~this paragraph must:~~

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365 ~~a. Certify that the prior 12-month average occupancy rate~~
366 ~~for the licensed beds being expanded meets or exceeds 80~~
367 ~~percent.~~
368 ~~b. Certify that the beds have been licensed and~~
369 ~~operational for at least 12 months.~~
370 ~~2. The timeframes and monitoring process specified in s.~~
371 ~~408.040(2)(a)-(c) apply to any exemption issued under this~~
372 ~~paragraph.~~
373 ~~3. The agency shall count beds authorized under this~~
374 ~~paragraph as approved beds in the published inventory of~~
375 ~~hospital beds until the beds are licensed.~~
376 <u>(i)</u>~~(k)~~ For the addition of nursing home beds licensed
377 under chapter 400 in a number not exceeding 10 total beds or 10
378 percent of the number of beds licensed in the facility being
379 expanded, whichever is greater; or, for the addition of nursing
380 home beds licensed under chapter 400 at a facility that has been
381 designated as a Gold Seal nursing home under s. 400.235 in a
382 number not exceeding 20 total beds or 10 percent of the number
383 of licensed beds in the facility being expanded, whichever is
384 greater.
385 1. In addition to any other documentation required by the
386 agency, a request for exemption submitted under this paragraph
387 must certify that:
388 a. The facility has not had any class I or class II
389 deficiencies within the 30 months preceding the request.
390 b. The prior 12-month average occupancy rate for the

391 nursing home beds at the facility meets or exceeds 94 percent.
392 c. Any beds authorized for the facility under this
393 paragraph before the date of the current request for an
394 exemption have been licensed and operational for at least 12
395 months.
396 2. The timeframes and monitoring process specified in s.
397 408.040(2)(a)-(c) apply to any exemption issued under this
398 paragraph.
399 3. The agency shall count beds authorized under this
400 paragraph as approved beds in the published inventory of nursing
401 home beds until the beds are licensed.
402 ~~(l) For the establishment of:~~
403 ~~1. A Level II neonatal intensive care unit with at least~~
404 ~~10 beds, upon documentation to the agency that the applicant~~
405 ~~hospital had a minimum of 1,500 births during the previous 12~~
406 ~~months;~~
407 ~~2. A Level III neonatal intensive care unit with at least~~
408 ~~15 beds, upon documentation to the agency that the applicant~~
409 ~~hospital has a Level II neonatal intensive care unit of at least~~
410 ~~10 beds and had a minimum of 3,500 births during the previous 12~~
411 ~~months; or~~
412 ~~3. A Level III neonatal intensive care unit with at least~~
413 ~~5 beds, upon documentation to the agency that the applicant~~
414 ~~hospital is a verified trauma center pursuant to s.~~
415 ~~395.4001(14), and has a Level II neonatal intensive care unit,~~
416

417 ~~if the applicant demonstrates that it meets the requirements for~~
418 ~~quality of care, nurse staffing, physician staffing, physical~~
419 ~~plant, equipment, emergency transportation, and data reporting~~
420 ~~found in agency certificate-of-need rules for Level II and Level~~
421 ~~III neonatal intensive care units and if the applicant commits~~
422 ~~to the provision of services to Medicaid and charity patients at~~
423 ~~a level equal to or greater than the district average. Such a~~
424 ~~commitment is subject to s. 408.040.~~
425 ~~(m)1. For the provision of adult open-heart services in a~~
426 ~~hospital located within the boundaries of a health service~~
427 ~~planning district, as defined in s. 408.032(5), which has~~
428 ~~experienced an annual net out-migration of at least 600 open-~~
429 ~~heart-surgery cases for 3 consecutive years according to the~~
430 ~~most recent data reported to the agency, and the district's~~
431 ~~population per licensed and operational open-heart programs~~
432 ~~exceeds the state average of population per licensed and~~
433 ~~operational open-heart programs by at least 25 percent. All~~
434 ~~hospitals within a health service planning district which meet~~
435 ~~the criteria reference in sub-subparagraphs 2.a.-h. shall be~~
436 ~~eligible for this exemption on July 1, 2004, and shall receive~~
437 ~~the exemption upon filing for it and subject to the following:~~
438 ~~a. A hospital that has received a notice of intent to~~
439 ~~grant a certificate of need or a final order of the agency~~
440 ~~granting a certificate of need for the establishment of an open-~~
441 ~~heart-surgery program is entitled to receive a letter of~~
442 ~~exemption for the establishment of an adult open-heart-surgery~~

443 ~~program upon filing a request for exemption and complying with~~
444 ~~the criteria enumerated in sub-subparagraphs 2.a.-h., and is~~
445 ~~entitled to immediately commence operation of the program.~~
446 ~~b. An otherwise eligible hospital that has not received a~~
447 ~~notice of intent to grant a certificate of need or a final order~~
448 ~~of the agency granting a certificate of need for the~~
449 ~~establishment of an open-heart-surgery program is entitled to~~
450 ~~immediately receive a letter of exemption for the establishment~~
451 ~~of an adult open-heart-surgery program upon filing a request for~~
452 ~~exemption and complying with the criteria enumerated in sub-~~
453 ~~subparagraphs 2.a.-h., but is not entitled to commence operation~~
454 ~~of its program until December 31, 2006.~~
455 ~~2. A hospital shall be exempt from the certificate-of-need~~
456 ~~review for the establishment of an open-heart-surgery program~~
457 ~~when the application for exemption submitted under this~~
458 ~~paragraph complies with the following criteria:~~
459 ~~a. The applicant must certify that it will meet and~~
460 ~~continuously maintain the minimum licensure requirements adopted~~
461 ~~by the agency governing adult open-heart programs, including the~~
462 ~~most current guidelines of the American College of Cardiology~~
463 ~~and American Heart Association Guidelines for Adult Open Heart~~
464 ~~Programs.~~
465 ~~b. The applicant must certify that it will maintain~~
466 ~~sufficient appropriate equipment and health personnel to ensure~~
467 ~~quality and safety.~~
468 ~~c. The applicant must certify that it will maintain~~

469 ~~appropriate times of operation and protocols to ensure~~
470 ~~availability and appropriate referrals in the event of~~
471 ~~emergencies.~~
472 ~~d. The applicant can demonstrate that it has discharged at~~
473 ~~least 300 inpatients with a principal diagnosis of ischemic~~
474 ~~heart disease for the most recent 12-month period as reported to~~
475 ~~the agency.~~
476 ~~e. The applicant is a general acute care hospital that is~~
477 ~~in operation for 3 years or more.~~
478 ~~f. The applicant is performing more than 300 diagnostic~~
479 ~~cardiac catheterization procedures per year, combined inpatient~~
480 ~~and outpatient.~~
481 ~~g. The applicant's payor mix at a minimum reflects the~~
482 ~~community average for Medicaid, charity care, and self-pay~~
483 ~~patients or the applicant must certify that it will provide a~~
484 ~~minimum of 5 percent of Medicaid, charity care, and self-pay to~~
485 ~~open-heart-surgery patients.~~
486 ~~h. If the applicant fails to meet the established criteria~~
487 ~~for open-heart programs or fails to reach 300 surgeries per year~~
488 ~~by the end of its third year of operation, it must show cause~~
489 ~~why its exemption should not be revoked.~~
490 ~~3. By December 31, 2004, and annually thereafter, the~~
491 ~~agency shall submit a report to the Legislature providing~~
492 ~~information concerning the number of requests for exemption it~~
493 ~~has received under this paragraph during the calendar year and~~
494 ~~the number of exemptions it has granted or denied during the~~

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495 ~~calendar year.~~
496 ~~(n) For the provision of percutaneous coronary~~
497 ~~intervention for patients presenting with emergency myocardial~~
498 ~~infarctions in a hospital without an approved adult open-heart-~~
499 ~~surgery program. In addition to any other documentation required~~
500 ~~by the agency, a request for an exemption submitted under this~~
501 ~~paragraph must comply with the following:~~
502 ~~1. The applicant must certify that it will meet and~~
503 ~~continuously maintain the requirements adopted by the agency for~~
504 ~~the provision of these services. These licensure requirements~~
505 ~~shall be adopted by rule and must be consistent with the~~
506 ~~guidelines published by the American College of Cardiology and~~
507 ~~the American Heart Association for the provision of percutaneous~~
508 ~~coronary interventions in hospitals without adult open-heart~~
509 ~~services. At a minimum, the rules must require the following:~~
510 ~~a. Cardiologists must be experienced interventionalists~~
511 ~~who have performed a minimum of 75 interventions within the~~
512 ~~previous 12 months.~~
513 ~~b. The hospital must provide a minimum of 36 emergency~~
514 ~~interventions annually in order to continue to provide the~~
515 ~~service.~~
516 ~~c. The hospital must offer sufficient physician, nursing,~~
517 ~~and laboratory staff to provide the services 24 hours a day, 7~~
518 ~~days a week.~~
519 ~~d. Nursing and technical staff must have demonstrated~~
520 ~~experience in handling acutely ill patients requiring~~

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521 ~~intervention based on previous experience in dedicated~~
522 ~~interventional laboratories or surgical centers.~~
523 ~~e. Cardiac care nursing staff must be adept in hemodynamic~~
524 ~~monitoring and Intra-aortic Balloon Pump (IABP) management.~~
525 ~~f. Formalized written transfer agreements must be~~
526 ~~developed with a hospital with an adult open-heart-surgery~~
527 ~~program, and written transport protocols must be in place to~~
528 ~~ensure safe and efficient transfer of a patient within 60~~
529 ~~minutes. Transfer and transport agreements must be reviewed and~~
530 ~~tested, with appropriate documentation maintained at least every~~
531 ~~3 months. However, a hospital located more than 100 road miles~~
532 ~~from the closest Level II adult cardiovascular services program~~
533 ~~does not need to meet the 60-minute transfer time protocol if~~
534 ~~the hospital demonstrates that it has a formalized, written~~
535 ~~transfer agreement with a hospital that has a Level II program.~~
536 ~~The agreement must include written transport protocols that~~
537 ~~ensure the safe and efficient transfer of a patient, taking into~~
538 ~~consideration the patient's clinical and physical~~
539 ~~characteristics, road and weather conditions, and viability of~~
540 ~~ground and air ambulance service to transfer the patient.~~
541 ~~g. Hospitals implementing the service must first undertake~~
542 ~~a training program of 3 to 6 months' duration, which includes~~
543 ~~establishing standards and testing logistics, creating quality~~
544 ~~assessment and error management practices, and formalizing~~
545 ~~patient-selection criteria.~~
546 ~~2. The applicant must certify that it will use at all~~

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547 ~~times the patient-selection criteria for the performance of~~
548 ~~primary angioplasty at hospitals without adult open-heart-~~
549 ~~surgery programs issued by the American College of Cardiology~~
550 ~~and the American Heart Association. At a minimum, these criteria~~
551 ~~would provide for the following:~~
552 ~~a. Avoidance of interventions in hemodynamically stable~~
553 ~~patients who have identified symptoms or medical histories.~~
554 ~~b. Transfer of patients who have a history of coronary~~
555 ~~disease and clinical presentation of hemodynamic instability.~~
556 ~~3. The applicant must agree to submit a quarterly report~~
557 ~~to the agency detailing patient characteristics, treatment, and~~
558 ~~outcomes for all patients receiving emergency percutaneous~~
559 ~~coronary interventions pursuant to this paragraph. This report~~
560 ~~must be submitted within 15 days after the close of each~~
561 ~~calendar quarter.~~
562 ~~4. The exemption provided by this paragraph does not apply~~
563 ~~unless the agency determines that the hospital has taken all~~
564 ~~necessary steps to be in compliance with all requirements of~~
565 ~~this paragraph, including the training program required under~~
566 ~~sub-subparagraph 1.g.~~
567 ~~5. Failure of the hospital to continuously comply with the~~
568 ~~requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2.~~
569 ~~and 3. will result in the immediate expiration of this~~
570 ~~exemption.~~
571 ~~6. Failure of the hospital to meet the volume requirements~~
572 ~~of sub-subparagraphs 1.a. and b. within 18 months after the~~

573 ~~program begins offering the service will result in the immediate~~
574 ~~expiration of the exemption.~~
575
576 ~~If the exemption for this service expires under subparagraph 5.~~
577 ~~or subparagraph 6., the agency may not grant another exemption~~
578 ~~for this service to the same hospital for 2 years and then only~~
579 ~~upon a showing that the hospital will remain in compliance with~~
580 ~~the requirements of this paragraph through a demonstration of~~
581 ~~corrections to the deficiencies that caused expiration of the~~
582 ~~exemption. Compliance with the requirements of this paragraph~~
583 ~~includes compliance with the rules adopted pursuant to this~~
584 ~~paragraph.~~
585 ~~(o) For the addition of mental health services or beds if~~
586 ~~the applicant commits to providing services to Medicaid or~~
587 ~~charity care patients at a level equal to or greater than the~~
588 ~~district average. Such a commitment is subject to s. 408.040.~~
589 (j) ~~(p)~~ For replacement of a licensed nursing home on the
590 same site, or within 5 miles of the same site if within the same
591 subdistrict, if the number of licensed beds does not increase
592 except as permitted under paragraph (e) ~~(f)~~.
593 (k) ~~(q)~~ For consolidation or combination of licensed
594 nursing homes or transfer of beds between licensed nursing homes
595 within the same planning district, by nursing homes with any
596 shared controlled interest within that planning district, if
597 there is no increase in the planning district total number of
598 nursing home beds and the site of the relocation is not more

599 than 30 miles from the original location.
600 (l) ~~(r)~~ For beds in state mental health treatment
601 facilities defined in s. 394.455 and state mental health
602 forensic facilities operated under chapter 916.
603 (m) ~~(s)~~ For beds in state developmental disabilities
604 centers as defined in s. 393.063.
605 (n) ~~(t)~~ For the establishment of a health care facility or
606 project that meets all of the following criteria:
607 1. The applicant was previously licensed within the past
608 21 days as a health care facility or provider that is subject to
609 subsection (1).
610 2. The applicant failed to submit a renewal application
611 and the license expired on or after January 1, 2015.
612 3. The applicant does not have a license denial or
613 revocation action pending with the agency at the time of the
614 request.
615 4. The applicant's request is for the same service type,
616 district, service area, and site for which the applicant was
617 previously licensed.
618 5. The applicant's request, if applicable, includes the
619 same number and type of beds as were previously licensed.
620 6. The applicant agrees to the same conditions that were
621 previously imposed on the certificate of need or on an exemption
622 related to the applicant's previously licensed health care
623 facility or project.
624 7. The applicant applies for initial licensure as required

625 under s. 408.806 within 21 days after the agency approves the
626 exemption request. If the applicant fails to apply in a timely
627 manner, the exemption expires on the 22nd day following the
628 agency's approval of the exemption.
629
630 Notwithstanding subparagraph 1., an applicant whose license
631 expired between January 1, 2015, and the effective date of this
632 act may apply for an exemption within 30 days of this act
633 becoming law.
634 (4) REQUESTS FOR EXEMPTION.—A request for exemption under
635 subsection (3) may be made at any time and is not subject to the
636 batching requirements of this section. The request shall be
637 supported by such documentation as the agency requires by rule.
638 The agency shall assess a fee of $250 for each request for
639 exemption submitted under subsection (3).
640 (5) NOTIFICATION.—Health care facilities and providers
641 must provide to the agency notification of~~:~~
642 ~~(a)~~ replacement of a health care facility when the
643 proposed project site is located in the same district and on the
644 existing site or within a 1-mile radius of the replaced health
645 care facility, if the number and type of beds do not increase.
646 ~~(b) The termination of a health care service, upon 30~~
647 ~~days' written notice to the agency.~~
648 ~~(c) The addition or delicensure of beds.~~
649
650 Notification under this subsection may be made by electronic,

651 facsimile, or written means at any time before the described
652 action has been taken.
653 Section 5. Section 408.037, Florida Statutes, is amended
654 to read:
655 408.037 Application content.—
656 (1) ~~Except as provided in subsection (2) for a general~~
657 ~~hospital,~~ An application for a certificate of need must contain:
658 (a) A detailed description of the proposed project and
659 statement of its purpose and need in relation to the district
660 health plan.
661 (b) A statement of the financial resources needed by and
662 available to the applicant to accomplish the proposed project.
663 This statement must include:
664 1. A complete listing of all capital projects, including
665 new health facility development projects and health facility
666 acquisitions applied for, pending, approved, or underway in any
667 state at the time of application, regardless of whether or not
668 that state has a certificate-of-need program or a capital
669 expenditure review program pursuant to s. 1122 of the Social
670 Security Act. The agency may, by rule, require less-detailed
671 information from major health care providers. This listing must
672 include the applicant's actual or proposed financial commitment
673 to those projects and an assessment of their impact on the
674 applicant's ability to provide the proposed project.
675 2. A detailed listing of the needed capital expenditures,
676 including sources of funds.

677 3. A detailed financial projection, including a statement
678 of the projected revenue and expenses for the first 2 years of
679 operation after completion of the proposed project. This
680 statement must include a detailed evaluation of the impact of
681 the proposed project on the cost of other services provided by
682 the applicant.
683 (c) An audited financial statement of the applicant or the
684 applicant's parent corporation if audited financial statements
685 of the applicant do not exist. In an application submitted by an
686 existing health care facility, health maintenance organization,
687 or hospice, financial condition documentation must include, but
688 need not be limited to, a balance sheet and a profit-and-loss
689 statement of the 2 previous fiscal years' operation.
690 ~~(2) An application for a certificate of need for a general~~
691 ~~hospital must contain a detailed description of the proposed~~
692 ~~general hospital project and a statement of its purpose and the~~
693 ~~needs it will meet. The proposed project's location, as well as~~
694 ~~its primary and secondary service areas, must be identified by~~
695 ~~zip code. Primary service area is defined as the zip codes from~~
696 ~~which the applicant projects that it will draw 75 percent of its~~
697 ~~discharges. Secondary service area is defined as the zip codes~~
698 ~~from which the applicant projects that it will draw its~~
699 ~~remaining discharges. If, subsequent to issuance of a final~~
700 ~~order approving the certificate of need, the proposed location~~
701 ~~of the general hospital changes or the primary service area~~
702 ~~materially changes, the agency shall revoke the certificate of~~

703 ~~need. However, if the agency determines that such changes are~~
704 ~~deemed to enhance access to hospital services in the service~~
705 ~~district, the agency may permit such changes to occur. A party~~
706 ~~participating in the administrative hearing regarding the~~
707 ~~issuance of the certificate of need for a general hospital has~~
708 ~~standing to participate in any subsequent proceeding regarding~~
709 ~~the revocation of the certificate of need for a hospital for~~
710 ~~which the location has changed or for which the primary service~~
711 ~~area has materially changed. In addition, the application for~~
712 ~~the certificate of need for a general hospital must include a~~
713 ~~statement of intent that, if approved by final order of the~~
714 ~~agency, the applicant shall within 120 days after issuance of~~
715 ~~the final order or, if there is an appeal of the final order,~~
716 ~~within 120 days after the issuance of the court's mandate on~~
717 ~~appeal, furnish satisfactory proof of the applicant's financial~~
718 ~~ability to operate. The agency shall establish documentation~~
719 ~~requirements, to be completed by each applicant, which show~~
720 ~~anticipated provider revenues and expenditures, the basis for~~
721 ~~financing the anticipated cash-flow requirements of the~~
722 ~~provider, and an applicant's access to contingency financing. A~~
723 ~~party participating in the administrative hearing regarding the~~
724 ~~issuance of the certificate of need for a general hospital may~~
725 ~~provide written comments concerning the adequacy of the~~
726 ~~financial information provided, but such party does not have~~
727 ~~standing to participate in an administrative proceeding~~
728 ~~regarding proof of the applicant's financial ability to operate.~~

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729 ~~The agency may require a licensee to provide proof of financial~~
730 ~~ability to operate at any time if there is evidence of financial~~
731 ~~instability, including, but not limited to, unpaid expenses~~
732 ~~necessary for the basic operations of the provider.~~
733 (2)~~(3)~~ The applicant must certify that it will license and
734 operate the health care facility. For an existing health care
735 facility, the applicant must be the licenseholder of the
736 facility.
737 Section 6. Paragraphs (c) and (d) of subsection (3),
738 paragraphs (b) and (c) of subsection (5), and paragraph (d) of
739 subsection (6) of section 408.039, Florida Statutes, are amended
740 to read:
741 408.039 Review process.—The review process for
742 certificates of need shall be as follows:
743 (3) APPLICATION PROCESSING.—
744 ~~(c) Except for competing applicants, in order to be~~
745 ~~eligible to challenge the agency decision on a general hospital~~
746 ~~application under review pursuant to paragraph (5)(c), existing~~
747 ~~hospitals must submit a detailed written statement of opposition~~
748 ~~to the agency and to the applicant. The detailed written~~
749 ~~statement must be received by the agency and the applicant~~
750 ~~within 21 days after the general hospital application is deemed~~
751 ~~complete and made available to the public.~~
752 ~~(d) In those cases where a written statement of opposition~~
753 ~~has been timely filed regarding a certificate of need~~
754 ~~application for a general hospital, the applicant for the~~

755 ~~general hospital may submit a written response to the agency.~~
756 ~~Such response must be received by the agency within 10 days of~~
757 ~~the written statement due date.~~
758 (5) ADMINISTRATIVE HEARINGS.—
759 (b) Hearings shall be held in Tallahassee unless the
760 administrative law judge determines that changing the location
761 will facilitate the proceedings. The agency shall assign
762 proceedings requiring hearings to the Division of Administrative
763 Hearings of the Department of Management Services within 10 days
764 after the time has expired for requesting a hearing. Except upon
765 unanimous consent of the parties or upon the granting by the
766 administrative law judge of a motion of continuance, hearings
767 shall commence within 60 days after the administrative law judge
768 has been assigned. ~~For an application for a general hospital,~~
769 ~~administrative hearings shall commence within 6 months after the~~
770 ~~administrative law judge has been assigned, and a continuance~~
771 ~~may not be granted absent a finding of extraordinary~~
772 ~~circumstances by the administrative law judge.~~ All parties,
773 except the agency, shall bear their own expense of preparing a
774 transcript. In any application for a certificate of need which
775 is referred to the Division of Administrative Hearings for
776 hearing, the administrative law judge shall complete and submit
777 to the parties a recommended order as provided in ss. 120.569
778 and 120.57. The recommended order shall be issued within 30 days
779 after the receipt of the proposed recommended orders or the
780 deadline for submission of such proposed recommended orders,

781 whichever is earlier. The division shall adopt procedures for
782 administrative hearings which shall maximize the use of
783 stipulated facts and shall provide for the admission of prepared
784 testimony.
785 (c) In administrative proceedings challenging the issuance
786 or denial of a certificate of need, only applicants considered
787 by the agency in the same batching cycle are entitled to a
788 comparative hearing on their applications. Existing health care
789 facilities may initiate or intervene in an administrative
790 hearing upon a showing that an established program will be
791 substantially affected by the issuance of any certificate of
792 need, whether reviewed under s. 408.036(1) or (2), to a
793 competing proposed facility or program within the same district.
794 ~~With respect to an application for a general hospital, competing~~
795 ~~applicants and only those existing hospitals that submitted a~~
796 ~~detailed written statement of opposition to an application as~~
797 ~~provided in this paragraph may initiate or intervene in an~~
798 ~~administrative hearing. Such challenges to a general hospital~~
799 ~~application shall be limited in scope to the issues raised in~~
800 ~~the detailed written statement of opposition that was provided~~
801 ~~to the agency. The administrative law judge may, upon a motion~~
802 ~~showing good cause, expand the scope of the issues to be heard~~
803 ~~at the hearing. Such motion shall include substantial and~~
804 ~~detailed facts and reasons for failure to include such issues in~~
805 ~~the original written statement of opposition.~~
806 (6) JUDICIAL REVIEW.—

807 ~~(d) The party appealing a final order that grants a~~
808 ~~general hospital certificate of need shall pay the appellee's~~
809 ~~attorney's fees and costs, in an amount up to $1 million, from~~
810 ~~the beginning of the original administrative action if the~~
811 ~~appealing party loses the appeal, subject to the following~~
812 ~~limitations and requirements:~~
813 ~~1. The party appealing a final order must post a bond in~~
814 ~~the amount of $1 million in order to maintain the appeal.~~
815 ~~2. Except as provided under s. 120.595(5), in no event~~
816 ~~shall the agency be held liable for any other party's attorney's~~
817 ~~fees or costs.~~
818 Section 7. Subsection (1) of section 408.043, Florida
819 Statutes, is amended to read:
820 408.043 Special provisions.—
821 ~~(1) OSTEOPATHIC ACUTE CARE HOSPITALS.—When an application~~
822 ~~is made for a certificate of need to construct or to expand an~~
823 ~~osteopathic acute care hospital, the need for such hospital~~
824 ~~shall be determined on the basis of the need for and~~
825 ~~availability of osteopathic services and osteopathic acute care~~
826 ~~hospitals in the district. When a prior certificate of need to~~
827 ~~establish an osteopathic acute care hospital has been issued in~~
828 ~~a district, and the facility is no longer used for that purpose,~~
829 ~~the agency may continue to count such facility and beds as an~~
830 ~~existing osteopathic facility in any subsequent application for~~
831 ~~construction of an osteopathic acute care hospital.~~
832 Section 8. Paragraph (f) of subsection (1) of section

833 395.1055, Florida Statutes, is amended to read:
834 395.1055 Rules and enforcement.—
835 (1) The agency shall adopt rules pursuant to ss.
836 120.536(1) and 120.54 to implement the provisions of this part,
837 which shall include reasonable and fair minimum standards for
838 ensuring that:
839 (f) All hospitals providing pediatric cardiac
840 catheterization, pediatric open-heart surgery, organ
841 transplantation, neonatal intensive care services, psychiatric
842 services, or comprehensive medical rehabilitation meet the
843 minimum licensure requirements adopted by the agency. Such
844 licensure requirements shall include quality of care, nurse
845 staffing, physician staffing, physical plant, equipment,
846 emergency transportation, and data reporting standards submit
847 such data as necessary to conduct certificate-of-need reviews
848 required under part I of chapter 408. Such data shall include,
849 but shall not be limited to, patient origin data, hospital
850 utilization data, type of service reporting, and facility
851 staffing data. The agency may not collect data that identifies
852 or could disclose the identity of individual patients. The
853 agency shall utilize existing uniform statewide data sources
854 when available and shall minimize reporting costs to hospitals.
855 Section 9. Section 395.6025, Florida Statutes, is
856 repealed.
857 Section 10. Subsection (1) of section 395.603, Florida
858 Statutes, is amended to read:

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859 395.603 Deactivation of general hospital beds; rural
860 hospital impact statement.—
861 (1) The agency shall establish, by rule, a process by
862 which a rural hospital, as defined in s. 395.602, that seeks
863 licensure as a rural primary care hospital or as an emergency
864 care hospital, or becomes a certified rural health clinic as
865 defined in Pub. L. No. 95-210, or becomes a primary care program
866 such as a county health department, community health center, or
867 other similar outpatient program that provides preventive and
868 curative services, may deactivate general hospital beds. Rural
869 primary care hospitals and emergency care hospitals shall
870 maintain the number of actively licensed general hospital beds
871 necessary for the facility to be certified for Medicare
872 reimbursement. Hospitals that discontinue inpatient care to
873 become rural health care clinics or primary care programs shall
874 deactivate all licensed general hospital beds. All hospitals,
875 clinics, and programs with inactive beds shall provide 24-hour
876 emergency medical care by staffing an emergency room. Providers
877 with inactive beds shall be subject to the criteria in s.
878 395.1041. The agency shall specify in rule requirements for
879 making 24-hour emergency care available. ~~Inactive general~~
880 ~~hospital beds shall be included in the acute care bed inventory,~~
881 ~~maintained by the agency for certificate-of-need purposes, for~~
882 ~~10 years from the date of deactivation of the beds. After 10~~
883 ~~years have elapsed, inactive beds shall be excluded from the~~
884 ~~inventory.~~ The agency shall, at the request of the licensee,

885 reactivate the inactive general beds upon a showing by the
886 licensee that licensure requirements for the inactive general
887 beds are met.
888 Section 11. Subsection (1) of section 395.604, Florida
889 Statutes, is amended to read:
890 395.604 Other rural hospital programs.—
891 (1) The agency may license rural primary care hospitals
892 subject to federal approval for participation in the Medicare
893 and Medicaid programs. Rural primary care hospitals shall be
894 treated in the same manner as emergency care hospitals and rural
895 hospitals with respect to ss. 395.605(2)-(7)(a) ~~395.605(2)-~~
896 ~~(8)(a)~~, 408.033(2)(b)3., and 408.038.
897 Section 12. Subsection (5) of section 395.605, Florida
898 Statutes, is amended to read:
899 395.605 Emergency care hospitals.—
900 ~~(5) Rural hospitals that make application under the~~
901 ~~certificate-of-need program to be licensed as emergency care~~
902 ~~hospitals shall receive expedited review as defined in s.~~
903 ~~408.032. Emergency care hospitals seeking relicensure as acute~~
904 ~~care general hospitals shall also receive expedited review.~~
905 Section 13. Subsections (2) and (4) of section 408.0361,
906 Florida Statutes, are amended to read:
907 408.0361 Cardiovascular services and burn unit licensure.—
908 (2) Each provider of adult cardiovascular services or
909 operator of a burn unit shall comply with rules adopted by the
910 agency that establish licensure standards that govern the

911 provision of adult cardiovascular services or the operation of a
912 burn unit. Such rules shall consider, at a minimum, staffing,
913 equipment, physical plant, operating protocols, the provision of
914 services to Medicaid and charity care patients, accreditation,
915 licensure period and fees, and enforcement of minimum standards.
916 ~~The certificate-of-need rules for adult cardiovascular services~~
917 ~~and burn units in effect on June 30, 2004, are authorized~~
918 ~~pursuant to this subsection and shall remain in effect and shall~~
919 ~~be enforceable by the agency until the licensure rules are~~
920 ~~adopted.~~ Existing providers and any provider with a notice of
921 intent to grant a certificate of need or a final order of the
922 agency granting a certificate of need for adult cardiovascular
923 services or burn units shall be considered grandfathered and
924 receive a license for their programs effective on the effective
925 date of this act. The grandfathered licensure shall be for at
926 least 3 years or until July 1, 2008, whichever is longer, but
927 shall be required to meet licensure standards applicable to
928 existing programs for every subsequent licensure period.
929 ~~(4) In order to ensure continuity of available services,~~
930 ~~the holder of a certificate of need for a newly licensed~~
931 ~~hospital that meets the requirements of this subsection may~~
932 ~~apply for and shall be granted Level I program status regardless~~
933 ~~of whether rules relating to Level I programs have been adopted.~~
934 ~~To qualify for a Level I program under this subsection, a~~
935 ~~hospital seeking a Level I program must be a newly licensed~~
936 ~~hospital established pursuant to a certificate of need in a~~

937 ~~physical location previously licensed and operated as a~~
938 ~~hospital, the former hospital must have provided a minimum of~~
939 ~~300 adult inpatient and outpatient diagnostic cardiac~~
940 ~~catheterizations for the most recent 12-month period as reported~~
941 ~~to the agency, and the newly licensed hospital must have a~~
942 ~~formalized, written transfer agreement with a hospital that has~~
943 ~~a Level II program, including written transport protocols to~~
944 ~~ensure safe and efficient transfer of a patient within 60~~
945 ~~minutes. A hospital meeting the requirements of this subsection~~
946 ~~may apply for certification of Level I program status before~~
947 ~~taking possession of the physical location of the former~~
948 ~~hospital, and the effective date of Level I program status shall~~
949 ~~be concurrent with the effective date of the newly issued~~
950 ~~hospital license.~~
951 Section 14. This act shall take effect July 1, 2016.

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