

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7 Certificate of Need
SPONSOR(S): Health Innovation Subcommittee, Miller, A.
TIED BILLS: **IDEN./SIM. BILLS:** SB 676

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 5 N, As CS	Poche	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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

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 The federal health planning legislation was repealed in 1986, but Florida retained its CON program.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

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

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

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

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

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

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0007a.HIS

DATE: 2/16/2017

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Certificate of Need (CON)

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

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

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

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

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

¹ National Conference of State Legislators, *CON-Certificate of Need State Laws*, available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last viewed February 13, 2017).

² Id.

³ Id.

⁴ Id.

⁵ Thomas Stratmann and Jacob Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* Mercatus Center at George Mason University, July 2014, pg. 2, available at: <https://www.mercatus.org/system/files/Stratmann-Certificate-Need.pdf> (last viewed February 2, 2017).

⁶ For example, see Delaware (Del. Code Ann. tit. 16 § 9303), Georgia (Ga. Code Ann. §111-2-2.40), Rhode Island (R.I. Code R. §6.2.4(B)), and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270).

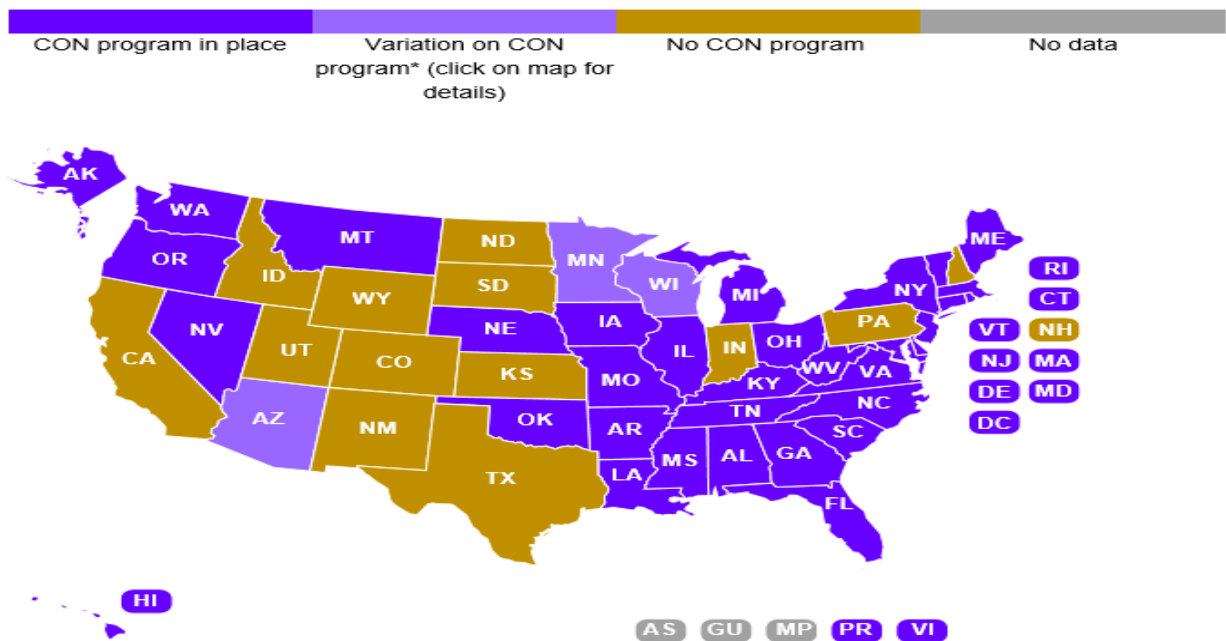
⁷ *Improving Health Care: A Dose of Competition: A Report by the Federal Trade Commission and the Department of Justice*, July 2004, pg. 22, available at: <https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice> (last viewed February 13, 2017): "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"; Daniel Sherman, Federal Trade Comm'n, *The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis* (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); Monica Noether, Federal Trade Comm'n, *Competition Among Hospitals 82*(1987) (empirical study concluding that CON regulation led to higher prices and expenditures).

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

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

CON Nationwide

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



Source: NCSL, August 2016

⁸ Tracy Yee, Lucy B. Stark, et al, *Health Care Certificate-of-Need Laws: Policy or Politics?*, Research Brief, National Institute for Health Care Reform, No. 4, May 2011, pg. 6, available at: http://nihcr.org/wp-content/uploads/2015/03/NIHCR_Research_Brief_No._4.pdf (last viewed February 13, 2017) (citing Elana C. Fric-Shamji and Mohammed F. Shamji, *Impact of U.S. Government Regulation on Access to Elective Surgical Care*, *Clinical & Investigative Medicine*, vol. 31, no. 5 (October 2008) and Ellen S. Campbell and Gary M. Fournier, *Certificate-of-Need Deregulation and Indigent Hospital Care*, *Journal of Health Politics, Policy and Law*, vol. 18, no. 4 (Winter 1993)).

⁹ Christopher J. Conover and Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?*, *Journal of Health Politics, Policy and Law*, vol. 23, no. 3, pg. 478 (June 1998).

¹⁰ Id.
¹¹ Christopher Koopman and Thomas Stratman, *Certificate-of-Need Laws: Implications for Florida*, March 2015, pg. 2, available at: <https://www.mercatus.org/system/files/Koopman-Certificate-of-NeedFL-MOP.pdf> (last viewed February 13, 2017).

¹² New Hampshire was the last state to repeal its CON program, in 2016. National Conference of State Legislators, *Certificate of Need: State Laws and Programs*, available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last viewed February 13, 2017).

¹³ Id.

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

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

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

Florida's CON Program

Overview

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

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

Projects Subject to Full CON Review

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

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals; and

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁸ Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.

¹⁹ S. 408.036, F.S.

- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility.²⁰

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

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

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

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

Projects Subject to Expedited CON Review

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

- Transfer of a CON;
- Replacement of a nursing home within the same district;
- Replacement of a nursing home if the proposed site is within a 30-mile radius of the existing nursing home;
- Relocation of a portion of a nursing home's beds to another facility or to establish a new facility in the same district, or a contiguous district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the state does not increase; and
- Construction of a new community nursing home in a retirement community under certain conditions.²⁵

²⁰ S. 408.036(1)(b), F.S.

²¹ S. 408.0361(1)(e), F.S.; Rule 59C-1.039(2)(c), F.A.C. Comprehensive medical rehabilitation inpatient services shape an organized program of intensive care services provided by a coordinated multidisciplinary team to patients with severe physical disabilities, including stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, hip fracture, brain injury, rheumatoid arthritis, neurological disorders, burns and neurological disorders.

²² S. 408.036(1)(f), F.S.; S. 408.032(17), F.S., defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Besides the specific examples listed above, such services also include medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service.

²³ Rule 59C-1.002(41), F.A.C.

²⁴ Id.

²⁵ S. 408.036(2), F.S.

Exemptions from CON Review

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

- Adding hospice services or swing beds²⁶ in a rural hospital, the total of which does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, so long as the conversion of the beds does not involve the construction of new facilities.
- Adding nursing home beds at a skilled nursing facility that is part of a retirement community offering a variety of residential settings and services.²⁷
- Building an inmate health care facility by or for the exclusive use of the Department of Corrections.
- Mobile surgical facilities and related health care services provided under contract with the Department of Corrections.
- Adding nursing home beds in a number not exceeding 30 total beds or 25 percent of the number of beds licensed in the facility being replaced in certain circumstances.
- State veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs
- Combining within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict.
- Dividing into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict.
- Adding hospital beds licensed under for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
- Adding nursing home beds licensed in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for adding nursing home beds licensed at a facility that has been designated as a Gold Seal nursing home in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.
- Establishing a level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 15 beds, and if the hospital had a minimum of at least 3,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 5 beds, and is a verified trauma center,²⁸ and if the applicant has a level II NICU.
- Establishing an adult open heart surgery program in a hospital located within the boundaries of a health service planning district, which:
 - Has experienced an annual net out-migration of at least 600 open heart surgery cases for 3 consecutive years; and
 - Has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.
- For providing percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.
- Adding mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average.

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

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

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

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

CON Determination of Need and Application and Review Process

A CON is predicated on a determination of need. The future need for services and projects is known as the "fixed need pool"²⁹, which AHCA publishes for each batching cycle. A batching cycle is a means of grouping of, for comparative review, CON applications submitted for beds, services or programs having a like CON need methodology, or licensing category in the same planning horizon and the same applicable district or subdistrict.³⁰ Chapter 59C-1, F.A.C., provides need formulas³¹ to calculate the fixed need pool for certain services, including NICU services³², adult and child psychiatric services³³, adult substance abuse services³⁴, and comprehensive rehabilitation services.³⁵

²⁹ Rule 59C-1.002(19), F.A.C., defines "fixed need pool" as the identified numerical need, as published in the Florida Administrative Register, for new beds or services for the applicable planning horizon established by AHCA in accordance with need methodologies which are in effect by rule at the time of publication of the fixed need pools for the applicable batching cycle.

³⁰ Rule 59C-1.002(5), F.A.C.

³¹ Rule 59C-1.039(5), F.A.C., provides the need formula for comprehensive medical rehabilitation inpatient beds as follows: $((PD/P) \times PP / (365 \times .85)) - LB - AB = NN$ 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.

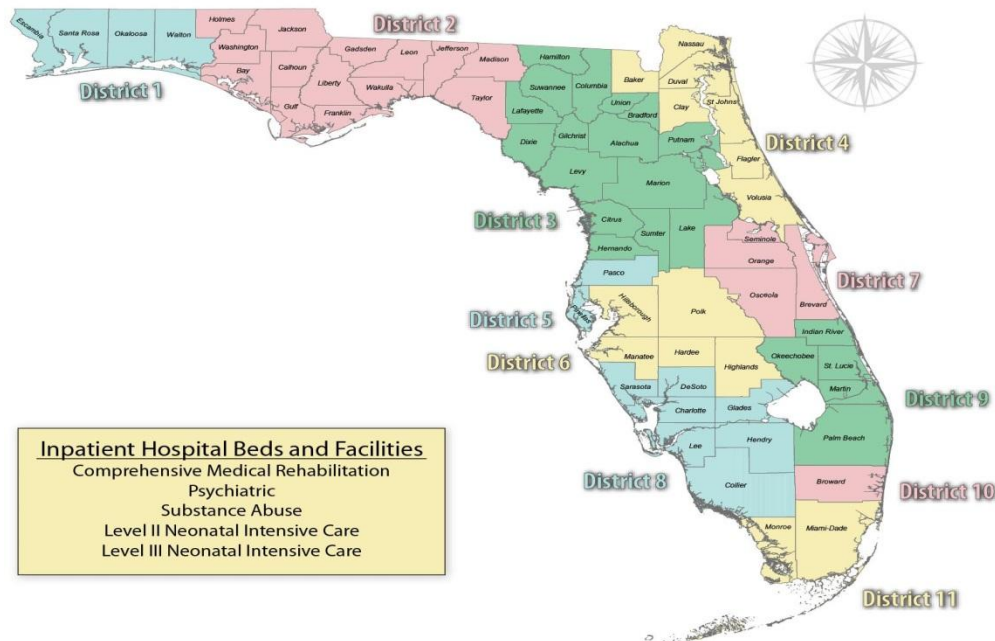
³² Rule 59C-1.042(3), F.A.C.

³³ Rule 59C-1.040(4), F.A.C.

³⁴ Rule 59C-1.041(4), F.A.C.

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



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.³⁵ The “hospital beds and facilities” batching cycle includes applicants for new or expanded:

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

The “other beds and programs” batching cycle includes:

- Pediatric Open Heart Surgery
- Pediatric Cardiac Catheterization
- Organ Transplantation
- Nursing Home Beds
- Hospice Programs
- Hospice Inpatient Facilities
- ICF/DDs

The following chart illustrates the volume of applications received by AHCA for facilities and services subject to the CON program, and includes the number of exemptions issued, from 2013 to later 2016.³⁷

³⁵ Rule 59C-1.039(5), F.A.C.

³⁶ Rule 59C-1.008(1)(g), F.A.C.

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

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

Hospital Beds & Facilities Applications for Last 6 Batching Cycles 2014-2016³⁸

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

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.⁴⁰ A letter of intent must describe the proposal, specify the number of beds sought, and identify the services to be provided and the location of the project.⁴¹ Applications for CON review must be submitted by the specified deadline for the particular batch cycle.⁴² AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.⁴³ The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.⁴⁴

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

³⁷ Agency for Health Care Administration, *Certificate of Need (CON) Program-Presentation before the Health Innovation Subcommittee*, January 11, 2017, slide 13 (on file with Health Innovation Subcommittee staff).

³⁸ Agency Health Care Administration, *CON Decisions & State Agency Action Reports, Hospital Beds and Facilities, Batching Cycles for August 2016, February 2016, August 2015, February 2015, August 2014, and February 2014*, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/decisions.shtml (last viewed February 13, 2017).

³⁹ A federal moratorium is in place on the construction of any new long-term care acute hospitals.

⁴⁰ S. 408.039(2)(a), F.S.

⁴¹ S. 408.039(2)(c), F.S.

⁴² Rule 59C-1.008(1)(g), F.A.C.

⁴³ S. 408.039(3)(a), F.S.

⁴⁴ Id.

⁴⁵ S. 408.039(4)(b), F.S.

⁴⁶ S. 408.039(4)(c), F.S.

21 days of the publication, the State Agency Action Report and the Notice of Intent to Award the CON become a final order of AHCA.⁴⁷

CON Fees

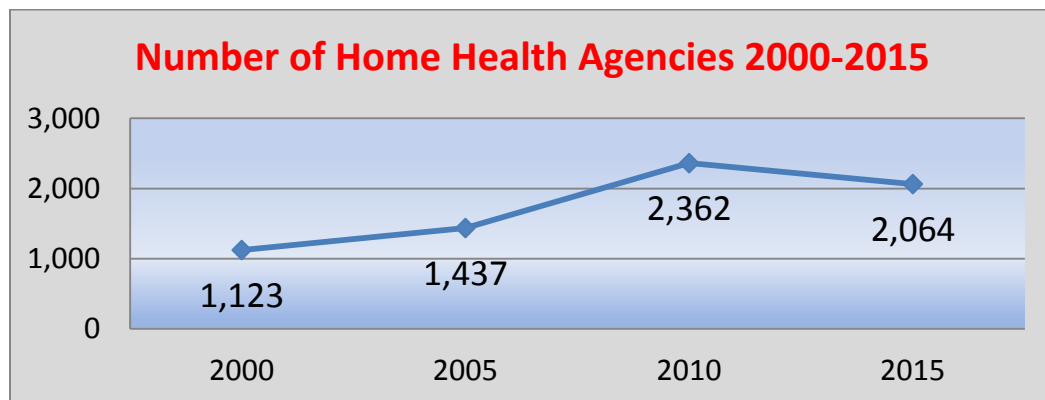
An applicant for CON review must pay a fee to AHCA when the application is submitted. The minimum CON application filing fee is \$10,000.⁴⁸ In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however, the total fee may not exceed \$50,000.⁴⁹ A request for a CON exemption must be accompanied by a \$250 fee payable to AHCA.⁵⁰

CON Litigation

Florida law allows competitors to challenge CON decisions. A Notice of Intent to Award a CON may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that the applicant or existing provider will be substantially affected if the CON is awarded.⁵¹ A challenge to a CON decision is heard by an Administrative Law Judge in the Division of Administrative Hearings.⁵² AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.⁵³ A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review⁵⁴ within 30 days of receipt of a Final Order.⁵⁵

CON Deregulation

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



⁴⁷ S. 408.039(4)(d), F.S.

⁴⁸ S. 408.038, F.S.

⁴⁹ Id.

⁵⁰ S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.

⁵¹ S. 408.039(5)(c), F.S.

⁵² Id.

⁵³ S. 408.039(5)(e), F.S.

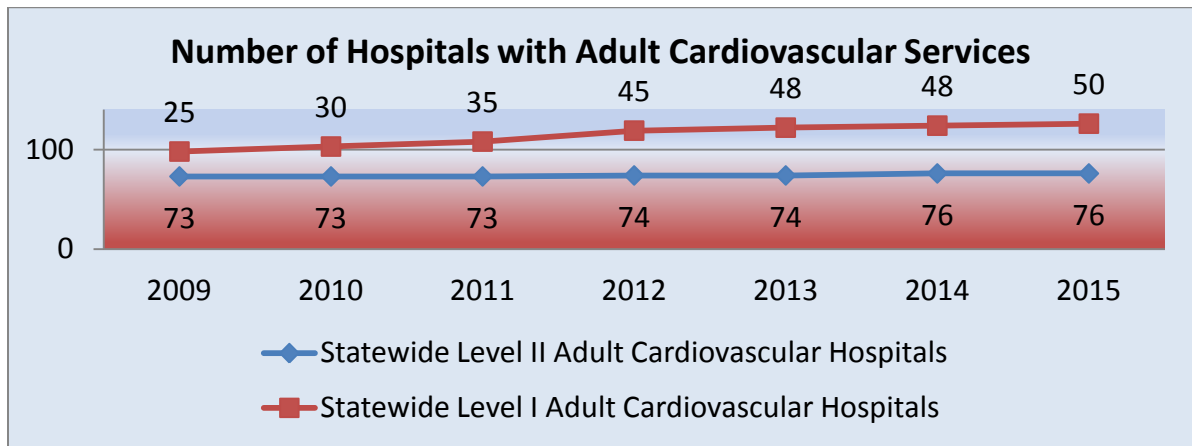
⁵⁴ S. 120.68(1), F.S., a party who is adversely affected by final agency action is entitled to judicial review. A preliminary, procedural, or intermediate order of the agency or of an administrative law judge of the Division of Administrative Hearings is immediately reviewable if review of the final agency decision would not provide an adequate remedy.

⁵⁵ S. 408.039(6), F.S.

⁵⁶ Ch. 2000-256, Laws of Fla.

⁵⁷ Agency for Health Care Administration, *Current Status of Certificate of Need, Effects of Deregulation*, October 20, 2015, pg. 5, available at <http://healthandhospitalcommission.com/docs/Oct20Meeting/CONpp102015.pdf> (last viewed February 13, 2017).

In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.⁵⁸ Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I⁵⁹ adult cardiovascular services license has doubled while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased.⁶⁰



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

In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.⁶² In addition to the repeal, the legislature imposed limitations on the issuance of CONs for community nursing home beds to limit the growth through July 1, 2017. AHCA may not approve a CON application for new community nursing home beds following the batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2017, equals or exceeds 3,750.⁶³ AHCA reached the cap of 3,750 beds in February of 2016 and a moratorium on additional beds is in place until June 30, 2017.⁶⁴ As a result, AHCA is not currently publishing a fixed need pool for additional community nursing home beds;⁶⁵ however, beginning with the October 2017 batching cycle AHCA will begin taking applications for additional nursing home beds, assuming that AHCA determines a need for such beds.

CON Reform in Other States

Georgia

The State Commission on the Efficacy of the Certificate of Need Program recommended that CON be maintained and improved after spending 18 months examining the role of CON. The final Commission report, issued in 2006, recommended that Georgia maintain existing CON regulations for hospital beds, adult open heart surgery, and pediatric cardiac catheterization and open heart surgery.⁶⁶ The report did

⁵⁸ Ch. 2007-214, Laws of Fla.

⁵⁹ S. 408.0361, F.S., requires AHCA to adopt rules for the establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery. Rule 59A-3.2085(16) and (17), F.A.C., provides the licensure requirements for Level I and Level II adult cardiovascular services licensure.

⁶⁰ Supra, FN 115 at pg. 7.

⁶¹ Rule 59A-3.2085(18), F.A.C.

⁶² Ch. 2014-110, Laws of Fla.

⁶³ S. 408.0436, F.S.

⁶⁴ Supra, FN 37 at slide 12.

⁶⁵ *Florida Nursing Home Utilization by District and Subdistrict, July 2015 – June 2016*, available at http://ahca.myflorida.com/mchq/con_fa/Publications/docs/FINursingUtilization/FloridaNH_UtilizationbyDistrict_Subdistrict-July2015-June2016.pdf (last viewed February 13, 2017).

⁶⁶ Commission on the Efficacy of the Certificate of Need Program, *An Analysis and Evaluation of Certificate of Need Regulation in Georgia*, December 29, 2006, available at https://dch.georgia.gov/sites/dch.georgia.gov/files/imported/vgn/images/portal/cit_1210/61/51/72484934FINAL_Georgia_CON_Commission_Report.pdf (last viewed February 13, 2017).

not recommend deregulation of any hospital CON project. The CON program for hospital facilities and services remains intact.

Illinois

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

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

Washington State

In 1999, the Joint Legislative Audit Review Committee contracted with the Health Policy Analysis Program of the University of Washington to conduct a legislatively mandated study of the CON program.⁷² The study examined the effects of CON, and its possible repeal, on the cost, quality, and availability of health care. The results of the study were based on a literature review, information gathered from service providers and other experts in Washington, and analyses of states where CON has been completely or partially repealed.⁷³

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

Virginia

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

⁶⁷ Ill. House Resolution 1497 (2006).

⁶⁸ The Lewin Group, *An Evaluation of Illinois’ Certificate of Need Program*, Prepared for the State of Illinois Commission on Government Forecasting and Accountability, February 15, 2007, available at <http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf> (last viewed February 13, 2017).

⁶⁹ Ill. Senate Bill 244 (PA 95-0005) of the 95th General Assembly, 2008.

⁷⁰ The Illinois Task Force on Health Planning Reform, Final Report, December 31, 2008.

⁷¹ Id.

⁷² State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.

⁷³ State of Washington Joint Legislative Audit and Review Committee, *Effects of Certificate of Need and its Possible Repeal*, Report 99-1, January 8, 1999, available at <http://leg.wa.gov/jlarc/AuditAndStudyReports/Documents/99-1.pdf> (last viewed February 13, 2017).

⁷⁴ SB 1283, Virginia General Assembly, 2015.

The law required the workgroup to develop specific recommendations for changes to the COPN process and introduce them during the 2016 Session and highlight any additional changes that may require further study or review.⁷⁵ In conducting its review and developing its recommendations, the work group considered data and information about the current COPN process, the impact of such process, and any data or information about similar processes in other states.⁷⁶ A final report with recommendations was provided to the General Assembly by December 1, 2015.⁷⁷

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

The workgroup's final report recommended keeping the COPN program, but included several recommendations to improve the program. These recommendations included⁸⁴:

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

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

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

⁷⁵ 2015 Va. Acts Chapter 541.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*, October 26, 2015, available at

https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf (last viewed February 13, 2017).

⁷⁹ *Id.* at pg. 2.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.* at pg. 13.

⁸⁴ Virginia Department of Health, Certificate of Public Need Program, *Certificate of Public Need Workgroup – Final Report*, pages 2-7, December 2015, available at <https://www.vdh.virginia.gov/Administration/documents/COPN/Final%20Report.pdf>.

⁸⁵ The North Carolina General Assembly considered two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposed to repeal the CON program in its entirety. House Bill 200 proposed to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The bills were not approved, but the CON repeal may return during the 2017 regular session, which convenes on January 11, 2017. The South Carolina General Assembly considered legislation during the 2016 legislative session to reform the CON program. Currently, South Carolina's CON program requires review for 20 different health care projects and services including hospitals. House Bill 3250 proposed to repeal

Hospital Licensure

Hospitals are regulated by AHCA under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.⁸⁶ Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment.⁸⁷

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

- A range of medical services restricted to a defined age or gender group;
- A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- Intensive residential treatment programs for children and adolescents.⁸⁸

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

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is \$1,565.13 per hospital or \$31.46 per bed, whichever is greater.⁹¹ The inspection fee is \$8.00 to \$12.00 per bed, but at a minimum \$400.00 per facility.⁹²

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.⁹³ The rules for general and specialty hospitals must include minimum standards to ensure:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.⁹⁴

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

Skilled Nursing Facilities

the CON program effective January 1, 2018, and proposed to reduce CON regulations in the interim by providing several exemptions from CON review. On January 13, 2016, the Senate amended the bill by removing the provision of the bill that sunsets the CON law in 2018. The removal may end up rendering the entire bill meaningless.

⁸⁶ S.395.002(12), F.S.

⁸⁷ Id.

⁸⁸ S. 395.002(28), F.S.

⁸⁹ S. 395.1041(2), F.S.

⁹⁰ Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals, Emergency Department*, available at <http://www.floridahealthfinder.gov>, (report generated on February 13, 2017).

⁹¹ Rule 59A-3.066(3), F.A.C.

⁹² S. 395.0161(3)(a), F.S.

⁹³ S. 395.1055(2), F.S.

⁹⁴ S. 395.1055(1), F.S.

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

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

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

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

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

Florida provides the following services in ICF/DDs:

- Activity services
- Dental services
- Dietary services (including therapeutic diet)
- Nursing services
- Pharmacy services
- Physician services
- Rehabilitative care (including physical, speech, occupational and mental health therapies)
- Room/ bed and maintenance services
- Routine personal hygiene items
- Social services⁹⁷

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

Local Health Councils

Section 408.033, F.S., establishes local health councils as a network of non-profit agencies that conduct regional health planning and implementation activities.⁹⁹ Each council's district is designated in Section 408.032, F.S. The Board of Directors of each council is composed of health care providers, purchasers, and nongovernmental consumers. Members serve for two years and are eligible for

⁹⁵ S. 400.021(7), F.S.

⁹⁶ U.S. Department of Health and Human Services, Centers for Medicaid and Medicare Services, *Intermediate Care Facilities for Individuals with Intellectual Disability (ICF/ID)*, available at <https://www.medicaid.gov/medicaid/ltss/institutional/icfid/index.html> (last viewed February 13, 2017).

⁹⁷ Agency for Health Care Administration, *Florida Medicaid's Covered Services and HCBS Waivers-Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) Services*, available at http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Policy/behavioral_health_coverage/bhfu/Intermediate_Care.shtml (last viewed February 13, 2017).

⁹⁸ Agency for Health Care Administration, Florida Health Finder, *Intermediate Care Facilities for the Developmentally Disabled* (report generated on February 13, 2107).

⁹⁹ Florida Department of Health, *Florida's Local Health Councils*, available at <http://www.floridahealth.gov/%5C/provider-and-partner-resources/health-councils/index.html> (last viewed February 13, 2017).

reappointment. Local health councils develop district health plans containing data, analysis, and recommendations that relate to health care status and needs in the community. The recommendations are designed to improve access to health care, reduce disparities in health status, assist state and local governments in the development of sound and rational health care policies, and advocate on behalf of the underserved.¹⁰⁰

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

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

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

¹⁰⁰ Id.

¹⁰¹ Id.

Adult Cardiovascular Care

Adult cardiovascular services (ACS) were previously regulated through the Certificate-of-Need (CON)¹⁰² program. In 2007, CON review was eliminated for adult cardiac catheterization and adult open-heart surgery services¹⁰³ and regulation was accomplished through the licensure process. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program;¹⁰⁴ however, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.¹⁰⁵

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

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

Adult Diagnostic Cardiac Catheterization Program

Diagnostic cardiac catheterization is a procedure requiring the passage of a catheter into one or more chambers of the heart, with or without coronary arteriograms,¹⁰⁷ for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow.¹⁰⁸ It also includes the selective catheterization of the coronary ostia¹⁰⁹ with injection of contrast medium into the coronary arteries.¹¹⁰

AHCA regulates the operation of adult inpatient diagnostic cardiac catheterization programs through licensure. This license permits the program to perform diagnostic procedures¹¹¹ only; the license does not allow for the performance of therapeutic procedures.¹¹² Providers of diagnostic cardiac catheterization services comply with the most recent guidelines of the American College of Cardiology and American Heart Association for cardiac catheterization and cardiac catheterization laboratories.¹¹³

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

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

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

¹⁰⁵ S. 408.0361(2), F.S.

¹⁰⁶ S. 408.0361(3)(a), F.S.

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

¹⁰⁸ Rule 59A-3.2085(13)(b)1., F.A.C.

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

¹¹⁰ Rule 59A-3.2085(13)(b)1., F.A.C.

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

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

¹¹³ S. 408.0361(1)(a), F.S.; Rule 59A-3.2085(13)(g), F.A.C., requires compliance with the guidelines found in the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCAI Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214 available at <http://www.scai.org/asset.axd?id=d4338c24-9beb-4f5a-8f14-a4edaef7461&t=633921658057830000> (last viewed February 13, 2017). These guidelines address, among other things, clinical proficiency, patient outcomes, equipment maintenance and management, quality improvement program development, and minimum caseload volumes for cardiac catheterization laboratories as well as patient preparations, procedural issues, performance issues, and post procedural issues for the performance of cardiac catheterization.

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

Level I ACS Programs

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

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease¹¹⁶ and a formalized, written transfer agreement with a hospital that has a Level II program.¹¹⁷

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services¹¹⁸ and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.¹¹⁹ Additionally, they must comply with the reporting requirements of the American College of Cardiology-National Cardiovascular Data Registry.¹²⁰

Level I ACS programs must meet the following staffing requirements:

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

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

¹¹⁴ Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last viewed February 13, 2017).

¹¹⁵ Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.

¹¹⁶ Heart condition caused by narrowed heart arteries. This is also called “coronary artery disease” and “coronary heart disease.”

¹¹⁷ S. 408.0361(3)(b), F.S.

¹¹⁸ Rule 59A-3.2085(16)(a)5., F.A.C.

¹¹⁹ Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)*, available at <http://circ.ahajournals.org/content/113/1/156.full.pdf+html> (last viewed February 13, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.

¹²⁰ Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

¹²¹ Rule 59A-3.2085(16)(b), F.A.C.

Level II ACS Programs

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

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

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

As of December 1, 2016, there are 77 general acute care hospitals¹²⁸ with a Level II ACS program in Florida.¹²⁹

Rural Hospitals

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

- The sole provider within a county with a population density of up to 100 persons per square mile;¹³¹
- At least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;¹³²
- Supported by a tax district or subdistrict the boundaries of which encompass a population of up to 100 persons per square mile;¹³³

¹²² Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_I_ACS_Listing.pdf (last viewed February 13, 2017).

¹²³ Rule 59A-3.2085(17)(a), F.A.C.

¹²⁴ S. 408.0361(3)(c), F.S.

¹²⁵ Rule 59A-3.2085(16)(a)5., F.A.C.

¹²⁶ Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.

¹²⁷ Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf?sfvrsn=2 (last viewed February 13, 2017).

¹²⁸ 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of 2016 SB 1518*, Jan. 12, 2016 (on file with Health Innovation Subcommittee staff).

¹²⁹ Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Level_II_ACS_Listing.pdf (last viewed February 13, 2017).

¹³⁰ S. 395.602(2)(e), F.S.

¹³¹ S. 395.602(2)(e)1., F.S.

¹³² S. 395.602(2)(e)2., F.S.

- Classified as a sole community hospital under 42 C.F.R. s. 412.92 with up to 175 licensed beds,¹³⁴
- Serving an area that has a population of up to 100 persons per square mile,¹³⁵ or
- A hospital designated as a critical access hospital, as defined in s. 408.07.¹³⁶

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

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

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

Hospice

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

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

¹³³ S. 395.602(2)(e)3., F.S.

¹³⁴ S. 395.602(2)(e)4., F.S.

¹³⁵ S. 395.602(2)(e)5., F.S. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency.

¹³⁶ S. 395.602(2)(e)6., F.S.

¹³⁷ Rural Health Information Hub, *Rural Hospitals*, available at <https://www.ruralhealthinfo.org/topics/hospitals> (last viewed February 13, 2017).

¹³⁸ Id.

¹³⁹ Agency for Health Care Administration, Florida Health Finder, Facility/Provider Locator-Rural Hospital

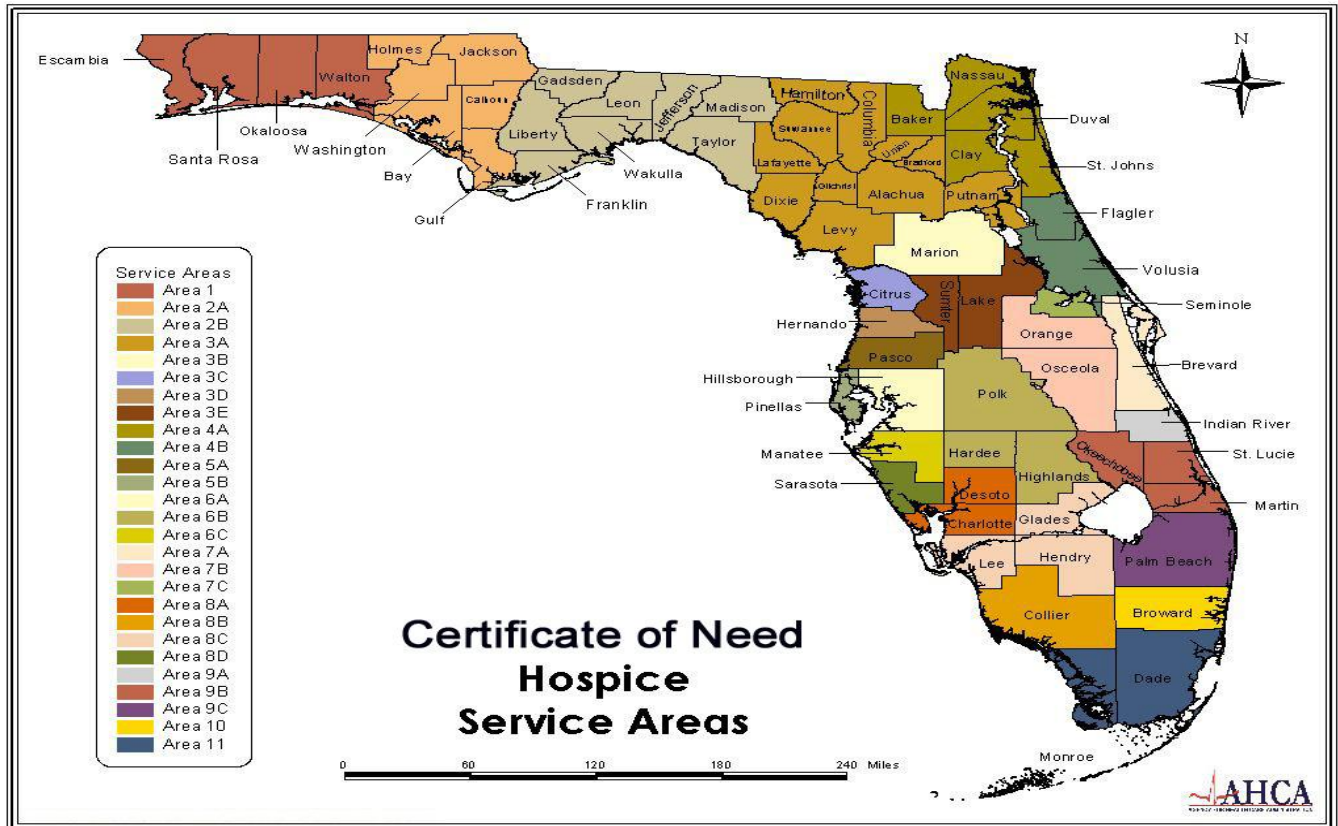
¹⁴⁰ Fla. Admin. Code R. 59C-1.0355. S. 400.601(10), F.S., defines "terminally ill" as a patient with a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course.

¹⁴¹ Florida Hospice and Palliative Care Association, *About Hospice*, available at <http://www.floridahospices.org/hospice-palliative-care/about-hospice/>, (last visited February 13, 2107).

¹⁴² Id.

Hospices in Florida

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



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

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

In the most recent need projections for hospice programs published in October 2016, AHCA found a net need for one new hospice provider in subdistrict 3A, consisting of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties, which has two licensed hospice providers, and a net need for one new hospice provider in subdistrict 3E, consisting of Lake and Sumter Counties, which also has two licensed hospice providers.¹⁴⁴

Continuing Care Retirement Communities (CCRCs)

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

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

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

The typical accommodations and services include:

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

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

Effect of Proposed Changes

CON Program

CS/HB 7 eliminates the entire CON program and makes necessary conforming changes throughout the Florida Statutes. Hospitals, nursing homes, hospices, and ICF/DDs will be able to establish and expand facilities, the number of beds, and types of services without seeking prior authorization from the state. Each entity will still be required to complete the AHCA licensure process.

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

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

¹⁴⁶ Id.

¹⁴⁷ Id., at page 9.

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

¹⁴⁹ Supra, FN 1, at 4.

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

maintain licensure requirements for tertiary health services as a result of the repeal of the CON review requirements for hospitals.

Though experts in the CON field dispute many issues when it comes to whether or not to repeal the CON program, the bill makes clear that the barrier to market entry will be removed and certain providers will see growth. The repeal of the CON program in Florida will allow for the growth of hospitals, nursing homes, hospices, tertiary hospital services, and other beds and services, increasing access to care and services for patients. Repeal of the CON in Florida will permit providers to enter the market without the approval of the state, and will eliminate CON application fees between \$10,000 and \$50,000 that may discourage smaller providers from seeking a license.

Inactive Licenses

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

The bill allows a hospital, nursing home, ICF/DD, or ambulatory surgical center to obtain an inactive license due to a temporary inability to provide services cause by construction or renovation. The facility must expect to provide services again within 12 months. However, in order to receive the inactive license, AHCA must review and approve the facility's construction or renovation plans.

Adult Cardiovascular Care

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

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

Rural Hospitals

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

Hospice

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

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

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

B. SECTION DIRECTORY:

- Section 1:** Repeals s. 154.245, F.S., relating to Agency for Health Care Administration certificate of need required as a condition to bond validation and project construction.
- Section 2:** Amends s. 159.27, F.S., relating to definitions.
- Section 3:** Amends s. 186.503, F.S., relating to definitions relating to Florida Regional Planning Council Act.
- Section 4:** Amends s. 189.08, F.S., relating to special district public facilities report.
- Section 5:** Amends s. 220.1845, F.S., relating to contaminated site rehabilitation tax credit.
- Section 6:** Amends s. 376.30781, F.S., relating to tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.
- Section 7:** Amends s. 376.86, F.S., relating to Brownfield Areas Loan Guarantee Program.
- Section 8:** Creates s. 381.4066, F.S., relating to local and state health planning.
- Section 9:** Amends s. 383.216, F.S., relating to community-based prenatal and infant health care.
- Section 10:** Amends s. 395.0191, F.S., relating to staff membership and clinical privileges.
- Section 11:** Amends s. 395.1055, F.S., relating to rules and enforcement.
- Section 12:** Amends s. 395.1065, F.S., relating to criminal and administrative penalties; moratorium.
- Section 13:** Amends s. 395.602, F.S., relating to rural hospitals.
- Section 14:** Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.
- Section 15:** Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
- Section 16:** Repeals s. 395.604, F.S., relating to other rural hospital programs.
- Section 17:** Repeals s. 395.605, F.S., relating to emergency care hospitals.
- Section 18:** Amends s. 400.071, F.S., relating to application for license for nursing homes.
- Section 19:** Amends s. 400.606, F.S., relating to license; application; renewal; conditional license or permit; certificate of need.
- Section 20:** Amends s. 400.6085, F.S., relating to contractual services.
- Section 21:** Repeals s. 408.031, F.S., relating to short title.
- Section 22:** Repeals s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act.
- Section 23:** Repeals s. 408.033, F.S., relating to local and state health planning.
- Section 24:** Repeals s. 408.034, F.S., relating to duties and responsibilities of agency; rules.
- Section 25:** Repeals s. 408.035, F.S., relating to review criteria.
- Section 26:** Repeals s. 408.036, F.S., relating to projects subject to review; exemptions.
- Section 27:** Repeals s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
- Section 28:** Repeals s. 408.037, F.S., relating to application content.
- Section 29:** Repeals s. 408.038, F.S., relating to fees.
- Section 30:** Repeals s. 408.039, F.S., relating to review process.
- Section 31:** Repeals s. 408.040, F.S., relating to conditions and monitoring.
- Section 32:** Repeals s. 408.041, F.S., relating to certificate of need; penalties.
- Section 33:** Repeals s. 408.042, F.S., relating to limitation on transfer.
- Section 34:** Repeals s. 408.043, F.S., relating to special provisions.
- Section 35:** Repeals s. 408.0436, F.S., relating to limitation on nursing home certificates of need.
- Section 36:** Repeals s. 408.044, F.S., relating to injunction.
- Section 37:** Repeals s. 408.045, F.S., relating to certificate of need; competitive sealed proposals.
- Section 38:** Repeals s. 408.0455, F.S., relating to rules; pending proceedings.
- Section 39:** Amends s. 408.07, F.S., relating to definitions.
- Section 40:** Amends s. 408.806, F.S., relating to license application process.
- Section 41:** Amends s. 408.808, F.S., relating to license categories.
- Section 42:** Amends s. 408.810, F.S., relating to minimum licensure requirements.
- Section 43:** Amends s. 408.820, F.S., relating to exemptions.
- Section 44:** Amends s. 409.9116, F.S., relating to disproportionate share/financial assistance program for rural hospitals.
- Section 45:** Amends s. 641.60, F.S., relating to Statewide Managed Care Ombudsman Committee.
- Section 46:** Repeals s. 651.118, F.S., relating to Agency for Health Care Administration; certificates of need; sheltered beds; community beds.

Section 47: Amends s. 1009.65, F.S., relating to Medical Education Reimbursement and Loan Repayment Program.

Section 48: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

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

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

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

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

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

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

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

2. Expenditures:

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

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

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

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rulemaking authority necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 15, 2017, the Health Innovation Subcommittee adopted one amendment to HB 7 that changed the title to "Certificate of Need."

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