HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 7 Certificates of Need for Hospitals
SPONSOR(S): Health & Human Services Committee, Health Innovation Subcommittee, Miller and others
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	9 Y, 5 N	Clark	Pridgeon
3) Health & Human Services Committee	12 Y, 5 N, As CS	Poche	Calamas

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 The federal health planning legislation was repealed in 1986, but Florida retained its CON program.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/CS/HB 7 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. 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 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 hospitals and hospital services. However, the negative fiscal impact will be offset by collecting planning, construction, and licensure fees for new hospitals 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.

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 2004 literature review by the Federal Trade Commission and the Department of Justice concluded that:

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

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

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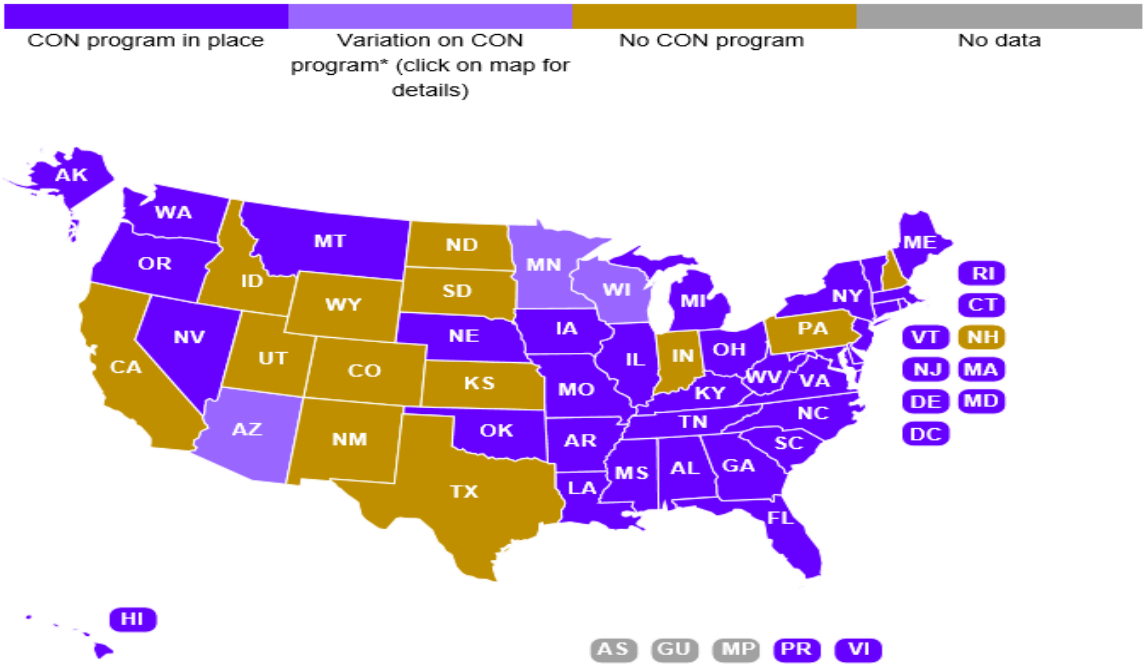
[1] National Conference of State Legislators, *CON-Certificate of Need State Laws,* available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed April 6, 2017).
[2] Id.
[3] Id.
[4] Id.
[5] Thomas Stratmann and Jacob Russ, *Do Certificate-of-Need Laws Increase 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 April 6, 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 April 6, 2017).
[12] New Hampshire was the last 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 April 6, 2017).
[13] Id.

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

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

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

Florida's CON Program

Overview

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

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

Projects Subject to Full CON Review

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

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

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

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

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

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

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

Projects Subject to Expedited CON Review

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

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

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

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

Exemptions from CON Review

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

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

[25] S. 408.036(2), F.S.
[26] S. 395.602(2)(g), F.S., defines "swing bed" as a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.
[27] S. 408.036(3)(c). F.S. This exemption is limited to a retirement community that had been incorporated in Florida and operating for at least 65 years as of July 1, 1994.
[28] S. 395.4001(14), F.S., defines "trauma center" as a hospital that has been verified by the Department of Health to be in substantial compliance with the requirements in s. 395.4025, F.S., and has been approved to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated as a Level II trauma center pursuant to s. 395.4025(14), F.S.

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

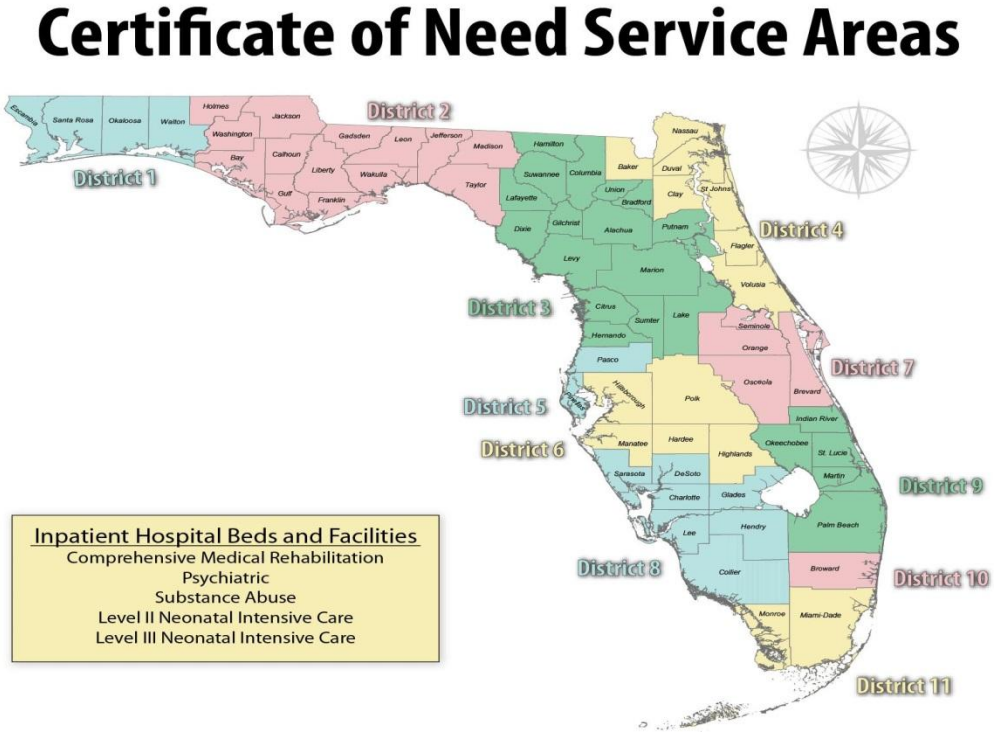
CON Determination of Need and Application and Review Process

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

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

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

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



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

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

The "other beds and programs" batching cycle includes:

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

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

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

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

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

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

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

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

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

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

[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 and Human Services Committee 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 April 6, 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.

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

CON Fees

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

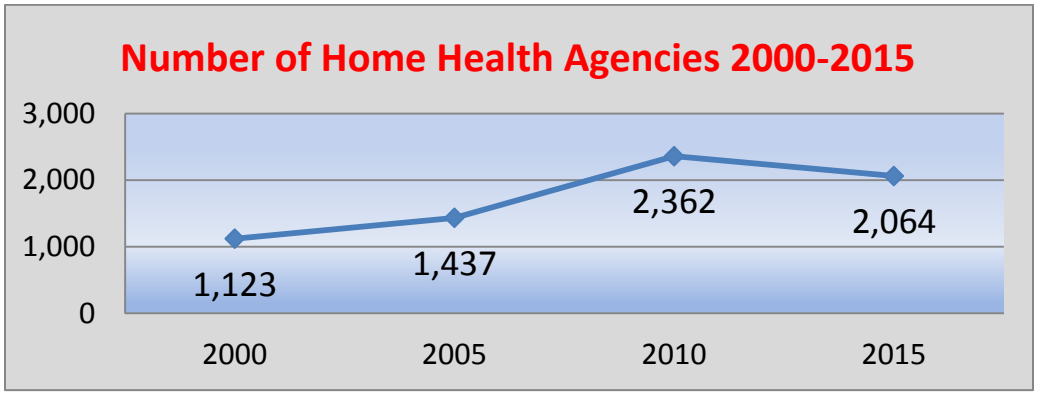
CON Litigation

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

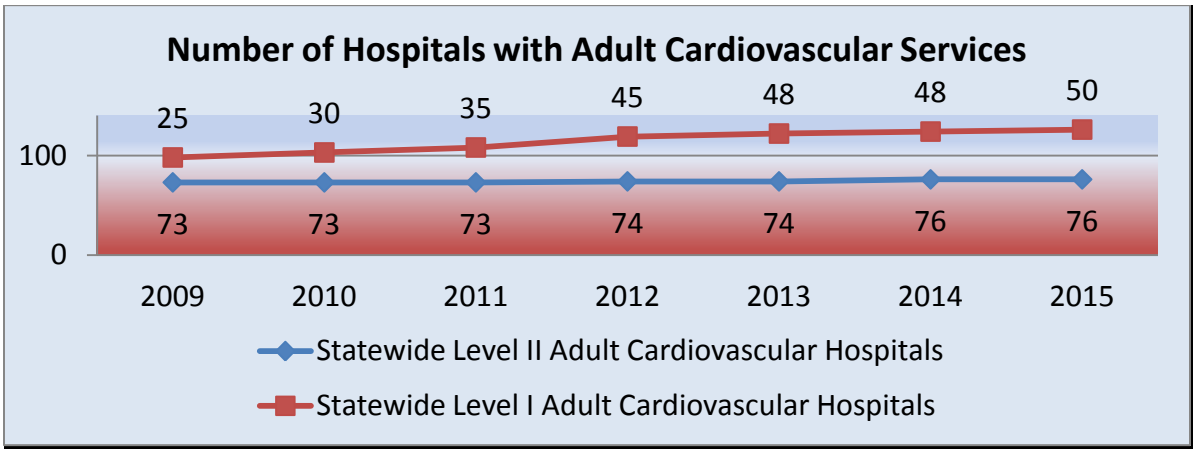
CON Deregulation

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

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



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



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

In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.[62] In addition to the repeal, the legislature imposed limitations on the issuance of CONs for community nursing home beds to limit the growth through July 1, 2017. AHCA may not approve a CON application for new community nursing home beds following the batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2017, equals or exceeds 3,750.[63] AHCA reached the cap of 3,750 beds in February of 2016 and a moratorium on additional beds is in place until June 30, 2017.[64] As a result, AHCA is not currently publishing a fixed need pool for additional community nursing home beds;[65]however, beginning with the October 2017

[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 37 at slide 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/FlNursingUtilization/FloridaNH_UtilizationbyDistrict_Subdistrict-July2015-June2016.pdf (last viewed April 6, 2017).

batching cycle AHCA will begin taking applications for additional nursing home beds, assuming that AHCA determines a need for such beds.

CON Reform in Other States

Georgia

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

Illinois

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

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

Washington State

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

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[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 April 6, 2017).
[67] Ill. House Resolution 1497 (2006).
[68] The Lewin Group, *An Evaluation of Illinois' Certificate of Need Program*, Prepared for the State of Illinois Commission on Government Forecasting and Accountability, February 15, 2007, available at http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf (last viewed April 6, 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 April 6, 2017).

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

Virginia

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

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

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

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

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

[74] SB 1283, Virginia General Assembly, 2015.
[75] 2015 Va. Acts Chapter 541.
[76] Id.
[77] Id.
[78] *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*, October 26, 2015, available at https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf (last viewed April 6, 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.

- Requiring a wide range of program-related information to be made more readily available to the public to increase program transparency.

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

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

Hospital Licensure

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

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

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

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

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is $1,565.13 per 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]

[85] The North Carolina General Assembly considered two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposed to repeal the CON program in its entirety. House Bill 200 proposed to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The bills were not approved, but the CON repeal may return during the 2017 regular session, which convenes on January 11, 2017. The South Carolina General Assembly considered legislation during the 2016 legislative session to reform the CON program. Currently, South Carolina's CON program requires review for 20 different health care projects and services including hospitals. House Bill 3250 proposed to repeal the CON program effective January 1, 2018, and proposed to reduce CON regulations in the interim by providing several exemptions from CON review. On January 13, 2016, the Senate amended the bill by removing the provision of the bill that sunsets the CON law in 2018. The removal may end up rendering the entire bill meaningless.
[86] S.395.002(12), F.S.
[87] Id.
[88] S. 395.002(28), F.S.
[89] S. 395.1041(2), F.S.
[90] Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals, Emergency Department,* available at http://www.floridahealthfinder.gov, (report generated on April 6, 2017).
[91] Rule 59A-3.066(3), F.A.C.
[92] S. 395.0161(3)(a), F.S.

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.

Effect of Proposed Changes

CS/CS/HB 7 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. 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.[95] 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.

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

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 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.

[93] S. 395.1055(2), F.S.
[94] S. 395.1055(1), F.S.
[95] 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).

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, 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 CON program for hospitals and hospital-based services. The reduction may be mitigated by a reduction in workload and by an increase in fees collected for licensure. The portion of CON fees paid by provider type varies widely from year to year. In fiscal year 2015-16, hospitals made up 33 percent of CON fees, for a total of $662,268.

AHCA expects an increase in initial and biennial licensure fees for hospitals and hospital-based services which are no longer subject to the CON program. Although an exact figure on growth is difficult to know, AHCA anticipates growth in hospital beds of 600 per year, equivalent to 10 additional construction projects. Each new or additional project will submit fees and other costs in order to meet planning, construction, and operating requirements.

2. Expenditures:

AHCA may experience increased workload resulting from an increase in licensure applications for hospitals and hospital-based services. 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 for hospital facilities, beds, and services.

AHCA will likely see a significant amount of savings in litigation expenses from defending its decision to award or deny a CON for a hospital or hospital-based services. Legal costs associated with CON will also be eliminated. 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. 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 the repeal of the CON program for hospitals and hospital-based services.

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, should such facilities seek to establish new facilities, beds, or services. 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 hospitals 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.”

On April 6, 2017, the Health and Human Services Committee adopted a strike-all amendment to CS/HB 7. The amendment:

- Eliminated the CON program for hospitals and hospital services only.
- Removed nursing homes, hospices, and intermediate care facilities for the developmentally disabled from the proposed CON program repeal in the underlying bill.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.