HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 21 Health Care Facility Market Barriers
SPONSOR(S): Health Market Reform Subcommittee, Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	14 Y, 0 N, As CS	Royal	Crosier
2) Health & Human Services Committee	14 Y, 3 N	Royal	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 constructing new facilities or 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 (IFC/DD).

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 The federal health planning legislation was repealed in 1986, but Florida retained its CON program.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, 12 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 for 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 21 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 has 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 CON decisions.

The bill provides an effective date of July 1, 2019.

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 (FTC) 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]

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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 October December 13, 2018).
[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 December 13, 2018).
[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 December 13, 2018): "[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).

In a statement by the FTC to the Alaska Senate on CON laws, the FTC's review of research on the impact of CON repeal found that repealing or narrowing CON laws can reduce the per-patient cost[8] of health care and improve the quality of certain types of care.[9]

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 that access to care for the underserved populations has increased in states with CON programs,[10] while another has found little, if any, evidence to support such a conclusion.[11] A study of New Jersey's CON requirements found that they actually contributed to historical disparities in the access to cardiac angiography services between white and African American patients.[12] The study also found that reform to New Jersey's CON laws that led to an increase in new providers contributed to reducing the disparity by creating competition for incumbent providers.[13] According to another study, states with hospital CON regulations have 13 percent fewer hospital beds per 100,000 persons than states without hospital CON regulations.[14] 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.[15]

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[8] *Statement of the Federal Trade Commission to the Alaska Senate Committee on Labor & Commerce on Certificate-of-Need Laws and SB 62*, February 6, 2018, at pp. 4 and 8, n. 15, available at https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-alaska-senate-committee-labor-commerce-certificate-need-laws/p859900_ftc_testimony_before_alaska_senate_re_con_laws.pdf (last viewed December 14, 2018). See, e.g., Vivian Ho and Meei-Hsiang Ku-Goto, *State Deregulation and Medicare Costs for Acute Cardiac Care*, 70 Medical Care Research & Review 185, 202 (2012) (finding an association between the lifting of CON laws and a reduction in mean patient costs for coronary artery bypass graft surgery, and finding that these cost savings slightly exceed the fixed costs of new entrants); Patrick A. Rivers et al., *The Effects of Certificate of Need Regulation on Hospital Costs*, 36 Journal of Health Care Finance 1, 11 (2010) (finding a positive relationship between the stringency of CON laws and health care costs per adjusted admission and concluding that the "results, as well as those of several previous studies, indicate that [CON] programs do not only fail to contain [hospital costs], but may actually increase costs as well" (emphasis in original)). While other studies evaluate the impact of repealing CON laws (with varying results), many of these studies are less persuasive because they do not account for preexisting cost differences between the states. Compare Michael D. Rosko and Ryan L. Mutter, *The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation*, 71 Medical Care Research & Review 1, 15 (2014) (finding "a plausible association between CON regulation and greater hospital cost-efficiency"), with Gerald Granderson, *The Impacts of Hospital Alliance Membership, Alliance Size, and Repealing Certificate of Need Regulation on Cost Efficiency of Non-profit Hospitals*, 32 Managerial and Decision Economics 159, 167-68 (2011) ("[R]epealing state CON programs contributed to an improvement in hospital cost efficiency.").

[9] Id at pp. 5 and 8, n. 17; See Suhui Li and Avi Dor, *How Do Hospitals Respond to Market Entry? Evidence from a Deregulated Market for Cardiac Revascularization*, 24 Health Economics. 990, 1006 (2015) (finding that repeal of Pennsylvania's CON program improved "the match between underlying medical risk and treatment intensity"); Ho and Ku-Goto, Supra, FN 8, at 199 (finding association between lifting of CON laws and shorter lengths of stay and fewer strokes during admission for coronary artery bypass patients, finding no significant association between lifting CON laws and three other complications during admission for coronary artery bypass graft patients, and finding no significant associations between lifting of CON laws and length of stay or need for coronary artery bypass graft surgery for percutaneous coronary intervention patients); David M. Cutler et al., *Input Constraints and the Efficiency of Entry: Lesson from Cardiac Surgery 2:1,* American Economic Journal: Economic Policy 51, 52 (2010) (finding that new entry after repeal of Pennsylvania's CON program "had a salutary effect on the market for cardiac surgery by directing more volume to better doctors and increasing access to treatment"). Additional empirical evidence suggests that, "[a]t least for some procedures, hospital concentration reduces quality." Martin Gaynor & Robert Town, *Impact of Hospital Consolidation- Update, Robert Wood Johnson Foundation: The Synthesis Project*; see also Patrick S. Romano and David J. Balan, *A Retrospective Analysis of the Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare* (Fed. Trade Comm'n Bureau of Econ., Working Paper No. 307, 2010), https://www.ftc.gov/reports/retrospective-analysis-clinical-quality-effects-acquisition-highland-park-hospital-evanston.

[10] 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 December 13, 2018) (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)).

[11] 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).

[12] Derek DeLia, Joel C. Cantor, Amy Tiedemann, and Cecilia S. Huang (2009), *Effects of Regulation and Competition on Health Care Disparities: The Case of Cardiac Angiography in New Jersey*, Journal of Health Politics, Policy, and Law Vol. 34, No. 1, pp. 63-91, available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.825.9156&rep=rep1&type=pdf (last viewed December 14, 2018).

[13] Id at p. 84.

[14] Supra, FN 11.

[15] 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 December 13, 2018).

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.

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.[16] 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.[17] 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 undergo a full comparative CON review, including:

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals; and
- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility.[18]

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;[19] and
- Establishing tertiary health services.[20]

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

[16] Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.
[17] S. 408.036, F.S.
[18] S. 408.036(1)(b), F.S.
[19] 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.
[20] 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.

services should be added or deleted.[21] 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;
- Comprehensive rehabilitation; and
- Organ transplantation, including
    - Heart;
    - Kidney;
    - Liver;
    - Bone marrow;
    - Lung; and
    - Pancreas.[22]

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.[23]

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[24] 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.[25]
- 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.

[21] Rule 59C-1.002(41), F.A.C.
[22] Id.
[23] S. 408.036(2), F.S.
[24] 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.
[25] 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.

- 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,[26] 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.
- 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;

[26] 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.

- 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.

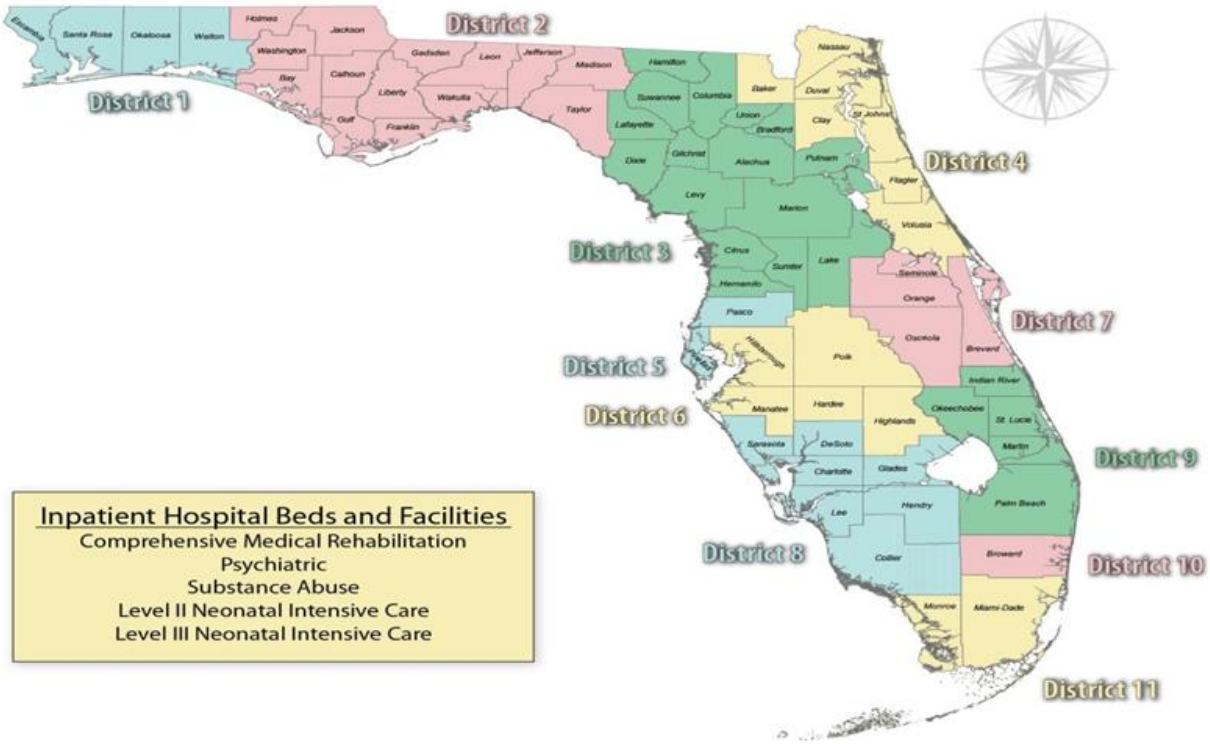
CON Determination of Need and Application and Review Process

A CON is predicated on a determination of need. The future need for services and projects is known as the "fixed need pool"[27], 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.[28] Chapter 59C-1, F.A.C., provides need formulas[29] to calculate the fixed need pool for certain services, including NICU services[30], adult and child psychiatric services[31], adult substance abuse services[32], and comprehensive rehabilitation services.[33]

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.

[27] 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.
[28] Rule 59C-1.002(5), F.A.C.
[29] Rule 59C-1.039(5), F.A.C., provides the need formula for comprehensive medical rehabilitation inpatient beds as follows: ((PD/P) x PP / (365 x .85)) – LB – AB = NN where: 1. NN equals the net need for Comprehensive Medical Rehabilitation Inpatient Beds in a District. 2. PD equals the number of inpatient days in Comprehensive Medical Rehabilitation Inpatient Beds in a district for the 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.
3. P equals the estimated population in the district. For applications submitted between January 1 and June 30, P is the population estimate for January of the preceding year; for applications submitted between July 1 and December 31, P is the population estimate for July of the preceding year. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool.
4. PP equals the estimated population in the district for the applicable planning horizon. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool. 5. .85 equals the desired average annual occupancy rate for Comprehensive Medical Rehabilitation Inpatient Beds in the district. 6. LB equals the district's number of licensed Comprehensive Medical Rehabilitation Inpatient Beds as of the most recent published deadline for Agency initial decisions prior to publication of the Fixed Bed Need Pool.
7. AB equals the district's number of approved Comprehensive Medical Rehabilitation Inpatient Beds.
[30] Rule 59C-1.042(3), F.A.C.
[31] Rule 59C-1.040(4), F.A.C.
[32] Rule 59C-1.041(4), F.A.C.
[33] Rule 59C-1.039(5), F.A.C.

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.[34] 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

[34] Rule 59C-1.008(1)(g), F.A.C.

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 2018.[35]

Action	2013	2014	2015	2016	2017	2018
Applications Received	32	116	96	51	36	45
Applications Reviewed	24	25	149	47	31	44
Exemptions	17	31	49	26	30	34

The next chart shows the total number of applications received for certain CON projects and the number of applications approved by AHCA between 2014 to 2018.[36]

Proposed Project	Applications Received	Applications Approved
Comprehensive Medical Rehabilitation Unit	21	7
Acute Care Hospital	33	19
Adult Inpatient Psychiatric Hospital	4	2
Long-Term Care Hospital[37]	0	0
Establish a Replacement Acute Care Hospital	3	3
Establish a Child/Adolescent Psychiatric Hospital	2	2
Establish Level III NICU	1	1
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.[38] 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.[39] Applications for CON review must be submitted by the specified deadline for the particular batch cycle.[40] AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.[41] The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.[42]

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.[43] AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.[44] If no administrative hearing is requested within

[35] Agency for Health Care Administration, *CON Applications*, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/applications.shtml (last viewed January 11, 2019) and E-mail correspondence with AHCA staff, December 17, 2018 (on file with Health Innovation Subcommittee staff).
[36] Agency Health Care Administration, *CON Decisions & State Agency Action Reports, Hospital Beds and Facilities*, Batching Cycles for August 2018, February 2018, August 2017, February 2017, 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 December 14, 2018).
[37] A federal moratorium on the construction of any new long-term care acute hospitals expired September 30, 2017.
[38] S. 408.039(2)(a), F.S.
[39] S. 408.039(2)(c), F.S.
[40] Rule 59C-1.008(1)(g), F.A.C.
[41] S. 408.039(3)(a), F.S.
[42] Id.
[43] S. 408.039(4)(b), F.S.
[44] 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.[45]

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.[46] 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.[47] A request for a CON exemption must be accompanied by a $250 fee payable to AHCA.[48]

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.[49] A challenge to a CON decision is heard by an Administrative Law Judge in the Division of Administrative Hearings.[50] AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.[51] A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review[52] within 30 days of receipt of a Final Order.[53]

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.[54] 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 from 2,362 to 1,911.[55]

In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.[56] Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I[57] adult cardiovascular services license has more than doubled from 25 to 61[58],

[45] S. 408.039(4)(d), F.S.
[46] S. 408.038, F.S.
[47] Id.
[48] S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.
[49] S. 408.039(5)(c), F.S.
[50] Id.
[51] S. 408.039(5)(e), F.S.
[52] 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.
[53] S. 408.039(6), F.S.
[54] Ch. 2000-256, Laws of Fla.
[55] 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 December 13, 2018); Agency for Health Care Administration, Facility/Provider Search Results, *Home Health Agencies*, available at http://www.floridahealthfinder.gov.
[56] Ch. 2007-214, Laws of Fla.
[57] 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-3.2046, F.A.C., provides the licensure requirements for Level I and Level II adult cardiovascular services licensure.
[58] Supra, FN 35; 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 December 11, 2018).

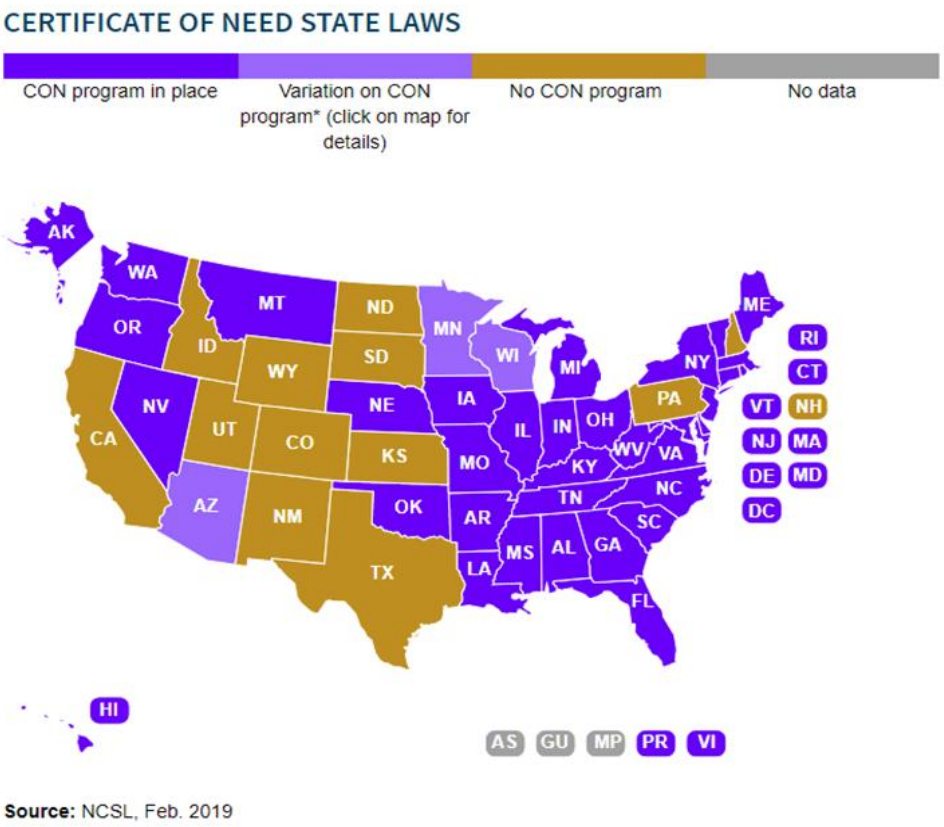
while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased from 73 to 81.[59]

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.[60]
In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.[61] 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 could 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.[62] AHCA reached the cap of 3,750 beds in February of 2016 and a moratorium on additional beds was in place until June 30, 2017.[63] AHCA published a fixed need pool for additional community nursing home beds on September 29, 2017 and began taking applications for additional nursing home beds during the October 2017 batching cycle.[64] In the most recent need projections, AHCA found a net need for 414 beds statewide.[65]

CON Nationwide

Twelve states do not have CON requirements for any type of health care facility or service, while three states have a variation on CON requirements.[66] 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.[67]

[59] Supra, FN 35; 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 December 11, 2018).
[60] Rule 59A-3.2046, F.A.C.
[61] Ch. 2014-110, Laws of Fla.
[62] S. 408.0436, F.S.
[63] Agency for Health Care Administration, *Certificate of Need (CON) Program-Presentation before the Health Innovation Subcomittee, January 11, 2017*, slide 12 (on file with the Health Market Reform Subcommittee staff).
[64] *Florida Nursing Home Need Projections by District and Subdistrict, July 2016 – June 2017*, available at https://ahca.myflorida.com/mchq/con_fa/Publications/docs/FlNursingUtilization/FloridaNH_UtilizationbyDistrict_Subdistrict-July2016-June2017.pdf (last viewed December 13, 2018).
[65] Florida Nursing Home Bed Need Projections by District and Subdistrict, Background Information for Use in Conjunction with the July 2021 Planning Horizon, available at: https://ahca.myflorida.com/mchq/con_fa/Publications/docs/FlNursingUtilization/FloridaNH_UtilizationbyDistrict_Subdistrict-July2017-June2018.pdf (last visited December 13, 2018).
[66] Supra, FN 1. New Hampshire was the last state to repeal its CON program, in 2016. Indiana was the most recent state to establish a certificate of need program, which went into effect July 1, 2018. It is not reflected on the map.
[67] 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).[68]

On average, states with CON programs regulate 14 different services, devices, and procedures.[69] Florida's CON program currently regulates 11 services or procedures, which is slightly below the

[68] Id.
[69] Id.

national average.[70] Vermont has the most CON laws in place, with more than 30 regulations. Arizona and Ohio have the least number of services subject to CON laws.[71]

CON Reform in Other States

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…".[72] 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.[73] The study also found no evidence that safety-net hospitals are financially stronger in states with CON programs than other states.[74] Currently, the CON program is scheduled to sunset on December 31, 2029.

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.[75] 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.[76]

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.[77]

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.[78] In conducting its review and developing its recommendations, the work group considered data and information about the current COPN process, the impact of such

[70] S. 408.036, F.S.
[71] Supra, FN 1, Arizona has a CON requirement for ambulance services and Ohio has a CON requirement for long-term care facilities.
[72] Ill. House Resolution 1497 (2006).
[73] 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 December 13, 2018).
[74] Id.
[75] State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.
[76] 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 December 13, 2018).
[77] SB 1283, Virginia General Assembly, 2015.
[78] 2015 Va. Acts Chapter 541.

process, and any data or information about similar processes in other states.[79] A final report with recommendations was provided to the General Assembly by December 1, 2015.[80]

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.[81] 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.[82] As the statement describes, CON laws create barriers to expansion, limit consumer choice, and stifle innovation.[83] Additionally, incumbent providers seeking to thwart or delay entry by new competitors may use CON laws to that end.[84] Finally, the statement asserts that CON laws can deny consumers the benefit of an effective remedy for antitrust violations and can facilitate anticompetitive agreements.[85] 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.[86]

The workgroup's final report recommended keeping the COPN program, but included several recommendations to improve the program. These recommendations included[87]:

- 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 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.

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.[88] 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.[89]

[79] Id.
[80] Id.
[81] *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 December 13, 2018).
[82] Id. at pg. 2.
[83] Id.
[84] Id.
[85] Id.
[86] Id. at pg. 13.
[87] Virginia Department of Health, Certificate of Public Need Program, *Certificate of Public Need Workgroup – Final Report*, pages 2-7, December 2015, available at http://www.vdh.virginia.gov/content/uploads/sites/96/2017/10/Certificate-of-Public-Need-Workgroup-Final-Report.pdf (last viewed December 13, 2018).
[88] S.395.002(12), F.S.
[89] Id.

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.[90]

AHCA must maintain an inventory of hospitals with an emergency department.[91] 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 December 13, 2018, 217 of the 309 licensed hospitals in the state have an emergency department.[92]

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.[93] The inspection fee is $8.00 to $12.00 per bed, but at a minimum $400.00 per facility.[94]

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.[95] 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.[96]

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

Specialty Hospitals

Federal Law

Under Sec. 6001 of the Patient Protection and Affordable Care Act (2010), Medicare-certified hospitals that are partly or wholly owned by physicians as of December 31, 2010 are barred from increasing their aggregate percentage of physician ownership and expanding their number of operating and procedure rooms and beds unless they qualify for an exemption. Federal law also prohibits physicians from referring Medicaid or Medicare patients to any hospital in which they have an ownership share if the hospital was formed after December 31, 2010.

A study of physician owned hospitals in Texas found that the ban on Medicare and Medicaid reimbursement has effectively banned the formation of new physician-owned hospitals.[97] Prior to the

[90] S. 395.002(28), F.S.
[91] S. 395.1041(2), F.S.
[92] Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals, Emergency Department,* available at http://www.floridahealthfinder.gov, (report generated on December 13, 2018).
[93] Rule 59A-3.066(3), F.A.C.
[94] S. 395.0161(3)(a), F.S.
[95] S. 395.1055(2), F.S.
[96] S. 395.1055(1), F.S.

restrictions going into effect, there was a surge in the formation of physician owned hospitals in Texas that receded almost immediately afterwards. Between 2004 and 2009, 64 new physician owned hospitals were formed, representing just under 66% of all new for-profit hospitals in the state.[98] In 2010, 20 new physician owned hospitals were formed, amounting to more than 83% of new Texas hospitals.[99] From 2011 through 2013, after the restrictions went into effect, only 9 new physician owned hospitals were formed, accounting for 41% of new for-profit hospitals.[100] As of June 2016, all physician owned hospitals formed after 2011 were either sold or in bankruptcy proceedings.[101]

The study also found that physician owned hospitals' mean number of staffed beds increased 15.1 percent, total surgeries per operating room increased 16.3 percent, revenue per square foot increased 21.0 percent, and revenue per full-time equivalent employee increased 20.1 percent, which may be an indication that the federal restrictions led physicians to order unnecessary medical services to boost revenues.[102]

Florida Law

Florida law defines a specialty hospital[103] as a hospital that offers:

- The range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population; or
- 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.[104]

Specialty hospitals may not provide any service or regularly serve any population group other than those services or groups specified in its license.[105]

Florida law bans certain types of specialty hospitals.[106] Florida law prohibits the licensure of hospitals that restricts its medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties.[107] Florida law also prohibits the licensure of hospitals if 65% of more of the hospital's discharges are for the diagnostic care and treatment of patients who have:

- Cardiac-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 5;
- Orthopedic-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 8;
- Cancer-related diseases and disorders classified as discharges in which the principal diagnosis is neoplasm or carcinoma or is for an admission for radiotherapy or antineoplastic chemotherapy or immunotherapy; or
- Any combination of the above discharges.[108]

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[97] Elizabeth Plummer and William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician Owned Hospitals*, Health Affairs 2016; 35(8).
[98] Id.
[99] Id.
[100] Id.
[101] Id.
[102] Id.
[103] S. 395.002(28), F.S.
[104] "Intensive residential treatment programs for children and adolescents" means a specialty hospital accredited by an accrediting organization as defined in subsection (1) which provides 24-hour care and which has the primary functions of diagnosis and treatment of patients under the age of 18 having psychiatric disorders in order to restore such patients to an optimal level of functioning. See S. 395.002(15), F.S.
[105] S. 395.003(6)(a), F.S.
[106] S. 395.003(8), F.S.
[107] S. 395.003(8)(b), F.S
[108] S. 395.003(8)(a), F.S

Florida law exempts from the ban hospitals classified as an exempt cancer center hospital pursuant to 42 C.F.R. s. 412.23(f) as of December 31, 2005[109] and hospitals licensed as of June 1, 2004 as long as the hospital maintains the same ownership, facility street address, and range of services that were in existence on June 1, 2004.[110]

Nursing Homes

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.[111] 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 687 nursing homes in Florida, with 83,098 licensed beds.[112]

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.[113] 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.

There are 100 ICF/DDs in Florida, with 2,806 licensed treatment beds.[114]

Adult Cardiovascular Care

Adult cardiovascular services (ACS) were previously regulated through the Certificate-of-Need (CON)[115] program. In 2007, CON review was eliminated for adult cardiac catheterization and adult open-heart surgery services[116] and regulation was accomplished through the licensure process. However, the regulatory requirements for ACS remain under the CON law. Hospitals that provided ACS at the time the CON review process was eliminated were grandfathered into the current licensure program; however, those hospitals were required to meet licensure standards applicable to existing programs for every subsequent licensure period.[117]

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[109] S. 395.003(8)(c), F.S
[110] S. 395.003(9), F.S
[111] S. 400.021(7), F.S.
[112] Agency for Health Care Administration, Florida Health Finder, *Nursing Homes,* available at: http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx (last viewed on December 11 2108).
[113] 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 December 13, 2018).
[114] Agency for Health Care Administration, Florida Health Finder, *Intermediate Care Facilities for the Developmentally Disabled ,* available at: http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx (last viewed on December 11 2108).
[115] 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.
[116] 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.
[117] 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.S. 408.0361(2), F.S.

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.[118]

Current CON law and rules establish extensive quality standards for these hospital-based programs, including but not limited to:

- Compliance with national standards set by physician specialty groups;
- Staff;
- Procedure and patient-specific volume requirements;
- Data reporting requirements; and
- Personnel qualifications.

As of December 11, 2018, there are 18 general acute care hospitals with an adult diagnostic cardiac catheterization program, [119] 61 general acute care hospitals with a Level I ACS program[120] and 81 general acute care hospitals[121] with a Level II ACS program in Florida.[122]

Hospice

Hospice care is a continuum of palliative and supportive care for a terminally ill patient and his or her family members.[123] 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.[124] 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.[125]

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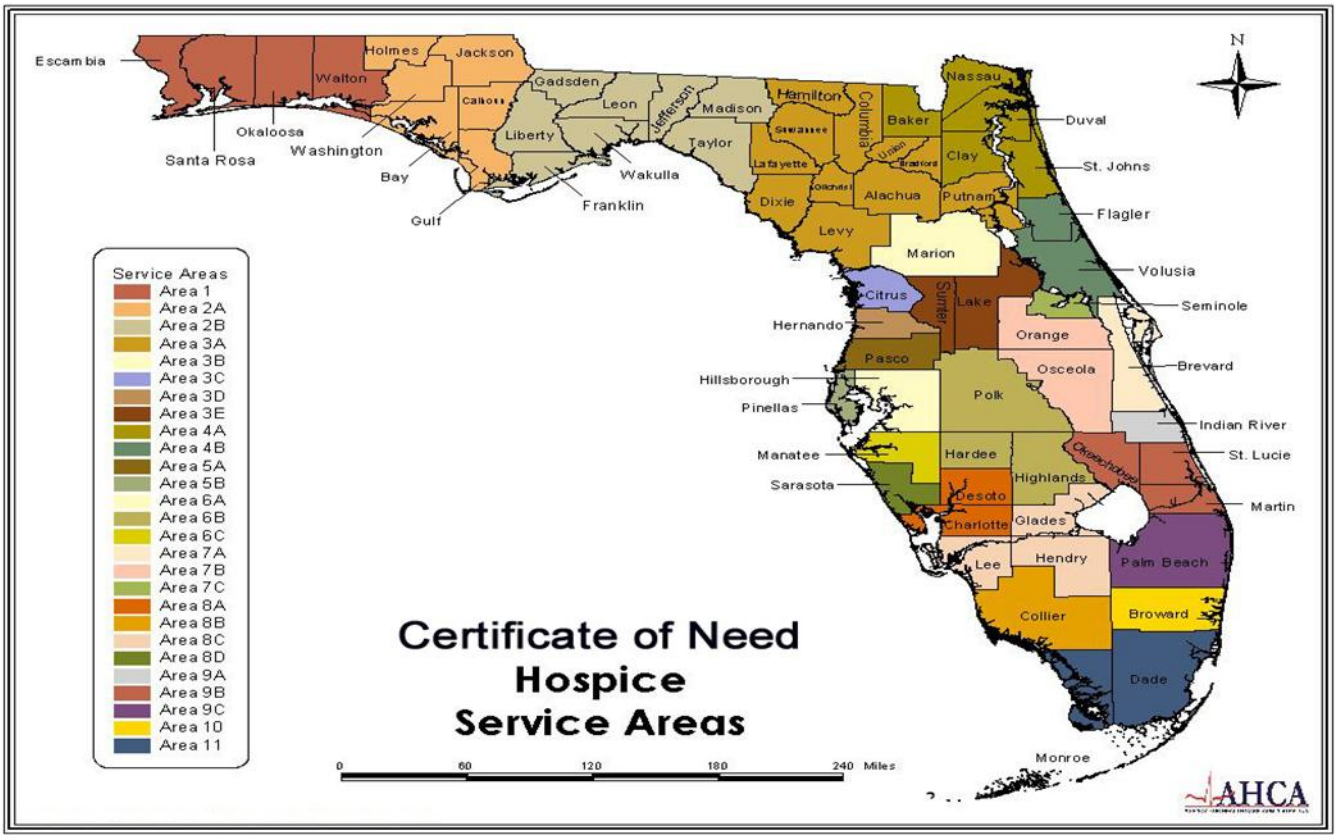
[118] S. 408.0361(3)(a), F.S.
[119] Agency for Health Care Administration, *Hospital & Outpatient Services Unit: Reports*, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/reports/Adult_Inpatient_Diagnostic_Cath_Labs.pdf (last viewed December 11, 2018).
[120] 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 December 11, 2018).
[121] 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).
[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_II_ACS_Listing.pdf (last viewed December 11, 2018).
[123] 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.
[124] Florida Hospice and Palliative Care Association, *About Hospice*, available at http://www.floridahospices.org/hospice-palliative-care/about-hospice/, (last visited December 13, 2108).
[125] Id.

Hospices in Florida

As of December 11, 2018, there are 47 licensed hospice providers in the state, across 27 service areas. The chart below illustrates the location of each service area.[126]



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 2018, AHCA found a net need for one new hospice provider in subdistrict 9B, consisting of Martin, Okeechobee, and St. Lucie Counties, which currently has three providers.[127]

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.[128] Each council's district is designated

[126] Agency for Health Care Administration, *Service Area Maps, Hospices*, available at http://ahca.myflorida.com/MCHQ/CON_FA/maps/images/hospice.jpg (last viewed December 13, 2018).
[127] Agency for Health Care Administration, *Florida Need Projections for Hospice Programs-Background Information for Use in Conjunction with the October 2018 Batching Cycle for the January 2020 Hospice Planning Horizon,* available at https://ahca.myflorida.com/MCHQ/CON_FA/Publications/docs/FlNeedProjections/October2018_HospiceNeedProjections.pdf (last visited December 13, 2018).
[128] 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 December 13, 2018).

in Section 408.032, F.S. The Board of Directors of each council is composed of health care providers, purchasers, and nongovernmental consumers. Members serve for two years and are eligible for reappointment. Local health councils develop district health plans containing data, analysis, and recommendations that relate to health care status and needs in the community. The recommendations are designed to improve access to health care, reduce disparities in health status, assist state and local governments in the development of sound and rational health care policies, and advocate on behalf of the underserved.[129]

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.[130]

Effect of Proposed Changes

CON Program

CS/HB 21 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 obtain a license from AHCA.

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.

Quality Standards

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.

[129] Id.
[130] Id.

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.

Hospice

The bill requires that any hospice initially licensed on or after July 1, 2019, 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.

Specialty Hospitals

The bill repeals the prohibition on the licensure of specialty hospitals whose discharges are over 65% or more of the following:

- Cardiac-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 5;
- Orthopedic-related diseases and disorders classified as diagnosis-related groups in major diagnostic category 8;
- Cancer-related diseases and disorders classified as discharges in which the principal diagnosis is neoplasm or carcinoma or is for an admission for radiotherapy or antineoplastic chemotherapy or immunotherapy; or
- Any combination of the above discharges

The bill moves the section of law establishing local health councils from 408.033, which is repealed by the bill, to a newly created section of law.

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; Repeals s. 154.246, F.S., relating to validation of certain bonds and proceedings.
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. 395.003, F.S., relating to licensure; denial, suspension, and revocation.
Section 11: Amends s. 395.0191, F.S., relating to staff membership and clinical privileges.
Section 12: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 13: Amends s. 395.1065, F.S., relating to criminal and administrative penalties; moratorium.
Section 14: Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.
Section 15: Amends s. 400.071, F.S., relating to application for license for nursing homes.
Section 16: Amends s. 400.606, F.S., relating to license; application; renewal;

conditional license or permit; certificate of need.

Section 17: Amends s. 400.6085, F.S., relating to contractual services.

Section 18: Repeals s. 408.031, F.S., relating to short title; Repeals s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act; Repeals s. 408.033, F.S., relating to local and state health planning; Repeals s. 408.034, F.S., relating to duties and responsibilities of agency; rules; Repeals s. 408.035, F.S., relating to review criteria; Repeals s. 408.036, F.S., relating to projects subject to review; exemptions; Repeals s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure; Repeals s. 408.037, F.S., relating to application content; Repeals s. 408.038, F.S., relating to fees; Repeals s. 408.039, F.S., relating to review process; Repeals s. 408.040, F.S., relating to conditions and monitoring; Repeals s. 408.041, F.S., relating to certificate of need; penalties; Repeals s. 408.042, F.S., relating to limitation on transfer; Repeals s. 408.043, F.S., relating to special provisions; Repeals s. 408.0436, F.S., relating to limitation on nursing home certificates of need; Repeals s. 408.044, F.S., relating to injunction; Repeals s. 408.045, F.S., relating to certificate of need; competitive sealed proposals; Repeals s. 408.0455, F.S., relating to rules; pending proceedings.

Section 19: Amends s. 408.07, F.S., relating to definitions.

Section 20: Amends s. 408.806, F.S., relating to license application process.

Section 21: Amends s. 408.808, F.S., relating to license categories.

Section 22: Amends s. 408.810, F.S., relating to minimum licensure requirements.

Section 23: Amends s. 408.820, F.S., relating to exemptions.

Section 24: Repeals s. 651.118, F.S., relating to Agency for Health Care Administration; certificates of need; sheltered beds; community beds.

Section 25: Provides an effective date of July 1, 2019.

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. However, this reduction should be offset by an increase in licensure and plan review fees.[131]

2. Expenditures:

   AHCA may experience increased workload resulting from an increase in licensure applications. However, staff working on review of CON applications will be transitioned to assist with the additional licensure workload.[132]

   AHCA will also likely see significant savings in litigation expenses from no longer defending decisions to award or deny CONs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

[131] Agency for Health Care Administration, *Agency Analysis of HB 21 2019 Legislative Session*, February 21, 2019 (on file with the Health Market Reform Subcommittee).
[132] Id.

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care facilities subject to CON will experience a positive fiscal impact resulting from elimination of the CON fees, which range from $10,000 to $50,000. Facilities will also avoid the costs of litigating the award of, or failure to award, a CON by AHCA.

By removing the CON program, established facilities 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 to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 7, 2019, the Health Market Reform Subcommittee adopted an amendment and reported HB 21 favorably as amended. The amendment:

- Makes a technical conforming change by removing a provision related to specialty-bed-need methodology.
- Makes a technical conforming change by removing a requirement for appointments to a technical advisory panel to be contingent on maintenance of certificate of need.

The analysis is drafted to the bill as amended by the Health Market Reform Subcommittee.