The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1712
INTRODUCER:	Senator Harrell
SUBJECT:	Hospital Licensure
DATE:	March 15, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1712 amends and repeals various sections of the Florida Statutes to eliminate the requirement that a new freestanding hospital must obtain a certificate of need (CON) from the Agency for Health Care Administration (AHCA) prior to being licensed. The bill maintains the existing CON program for other facility types, such as nursing homes and hospice facilities, and for existing hospitals that wish to provide tertiary services, such as neonatal intensive care, comprehensive rehabilitation, and pediatric cardiac catheterization services.

The bill also establishes additional licensure requirements applicable to hospitals licensed on or after July 1, 2019, including that such hospitals must participate in the Medicaid program and must provide certain amounts of charity care or equivalent donations to the AHCA's Grants and Donations Trust Fund. The bill establishes penalties for a new hospital that does not comply with the charity care requirements and increases penalties for existing hospitals that violate any conditions related to providing Medicaid services or charity care that were agreed to by the hospital when the hospital was issued a CON.

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

II. Present Situation:

Hospital Licensure

Hospitals are licensed by the AHCA under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must, at a minimum, make clinical laboratory services, diagnostic X-ray services, and treatment

[1] Section 395.002(12), F.S.

facilities for surgery or obstetrical care, or other definitive medical treatment, regularly available.[2]

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

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

Section 395.1041(2), F.S., requires the AHCA to maintain an inventory of hospitals with an emergency department. The inventory must list all services within the service capability of each hospital, and such services must appear on the face of the hospital's license. As of March 12, 2019, 217 of the 308 licensed hospitals in the state have an emergency department.[4]

Unless exempt, a hospital must obtain a CON prior to licensure. Facilities must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is $1,565.13 or $31.46 per bed, whichever is greater.[5] The survey fee is $400 or $12 per bed, whichever is greater.[6]

Section 395.1055, F.S., requires the AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.[7] 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.[8]

The minimum standards for hospital licensure are provided under Rule 59A-3, F.A.C. The AHCA may perform inspections of hospitals, including:

- Inspections directed by the federal Centers for Medicare & Medicaid Services;
- Validation inspections;
- Life safety inspections;
- Licensure complaint investigations; and

[2] Id.
[3] Section 395.002(27), F.S.
[4] Agency for Health Care Administration, Facility/Provider Search Results, Hospitals, *available at* http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (reports generated on March 13, 2019).
[5] Rule 59A-3.066(3), F.A.C.
[6] Section 395.0161(3)(a), F.S.
[7] Section 395.1055(2), F.S.
[8] Section 395.1055(1), F.S.

- Emergency access complaint investigations.[9]

The AHCA must accept an inspection performed by an accrediting organization in lieu of its own periodic licensure inspection.[10]

Florida's CON Program

Overview

In Florida, a CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full, expedited, and exempt.[11] 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.

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 (Act), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.[12] 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.

Projects Subject to Full CON Review

Some hospital projects are required to undergo a full comparative CON review under the statute, including:

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals;
- 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;[13]
- Increasing the number of beds for comprehensive rehabilitation; and
- Establishing tertiary health services.[14]

[9] Section 395.0161(1), F.S.
[10] Section 395.0161(2), F.S.
[11] Section 408.036, F.S.
[12] Pub. Law No. 93-641, 42 U.S.C. s. 300k et seq.
[13] Section 395.6025, F.S., exempts rural hospitals from the requirement to obtain a CON for building a new hospital, or replacing a hospital, located in a county with a population between 15,000 and 18,000 and a population density of less than 30 persons per square mile as long as the new or replacement hospital is located within 10 miles of the current rural hospital.
[14] Section 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. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. Pursuant to this section, AHCA established a list of all tertiary health services in Rule 59C-1.002, F.A.C.

Projects Subject to Expedited CON Review

Section 408.036(2), F.S., permits certain projects to undergo 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 the transfer of a CON and certain replacements, relocations, and new construction of nursing homes.[15]

Exemptions from CON Review

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

- Adding swing beds[16] in a rural hospital, the total of which does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities.
- Adding hospital beds licensed under ch. 395, F.S., for comprehensive rehabilitation, the total of which may not exceed the greater of 10 total beds or 10 percent of the licensed capacity.
- 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 Level II NICU and a minimum of at least 3,500 births during the previous 12 months.
- Establishing a Level III NICU if the unit has at least five beds, and is a verified trauma center,[17] 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 three consecutive years; and
  - Has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.
- For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients as a level equal to or greater than the district average.

CON Determination of Need, Application, and Review Processes

A CON is predicated on a determination of need. The future need for services and projects is known as the "fixed need pool,"[18] which the AHCA publishes for each batching cycle.

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[15] Section 408.036(2), F.S.

[16] Section 395.602(2)(c), 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.

[17] Section 395.4001(15), F.S., defines "trauma center" as a hospital that has been verified by the DOH 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(15), F.S.

[18] 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.

Rule 59C-1, F.A.C., provides need formulas to calculate the fixed need pool for certain services, including NICU services,[19] adult and child psychiatric services,[20] adult substance abuse services,[21] and comprehensive rehabilitation services.[22]

Upon determining that a need exists, the AHCA accepts applications for CON based on batching cycles. A batching cycle is a means of grouping, for comparative review, of 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.[23]

The CON review process consists of four batching cycles each year, including two batching cycles each year for two project categories: hospital beds and facilities, and other beds and programs.[24] The "hospital beds and facilities" batching cycle includes applicants for new or expanded:

- Comprehensive medical rehabilitation beds;
- Adult psychiatric beds;
- Child and adolescent psychiatric beds;
- Adult substance abuse beds;
- NICU level II beds; and
- NICU level III beds.[25]

The "other beds and programs" batching cycle includes:

- Nursing home beds;
- Hospice beds;
- Pediatric open heart surgery;
- Pediatric cardiac catheterization services; and
- Organ transplantation services.[26]

Requests for an expedited review or exemption may be made at any time and are not subject to batching requirements.[27]

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with the AHCA.[28] 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.[29]

[19] Rule 59C-1.042(3), F.A.C.
[20] Rule 59C-1.040(4), F.A.C.
[21] Rule 59C-1.041(4), F.A.C.
[22] Rule 59C-1.039(5), F.A.C.
[23] Rule 59C-1.002(5), F.A.C. Note: s. 408.032(5), F.S., establishes the 11 district service areas in Florida.
[24] Rule 59C-1.008(1)(g), F.A.C.
[25] Rule 59C-1.008(1), F.A.C.
[26] Id.
[27] Section 408.036, F.S., and Rule 59C-1.004(1), F.A.C.
[28] Section 408.039(2)(a), F.S.
[29] Section 408.039(2)(c), F.S.

Applications for CON review must be submitted by the specified deadline for the particular batch cycle.[30] The AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.[31] The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.[32]

Within 60 days of receipt of the completed applications for that batch, the AHCA must issue a State Agency Action Report and Notice of Intent to grant a CON for a project in its entirety, to grant a CON for identifiable portions of a project, or to deny a CON for a project.[33] AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.[34] If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent become a final order of the AHCA.[35]

In 2008, the Legislature significantly modified the application and review process for hospital CONs. The revisions included new and separate requirements for general hospital CONs, including:

- Revised contents for CON applications;
- Revised criteria which the AHCA must consider when reviewing a CON application;
- Prohibiting an applicant with a current CON application from submitting a letter of intent for to file another application;
- Requiring the AHCA to hold a public heating upon the request of any applicant or substantially affected person;
- Limiting the period of a continuance for any CON related hearings to four months; and
- Requiring a party appealing a final order for a CON to post a $1 million bond which is forfeited for attorney's fees and costs if the appellant loses.[36]

CON Fees

An applicant for CON review must submit a fee to the AHCA at the time of application submission. The minimum CON application filing fee is $10,000.[37] 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.[38] A request for a CON exemption must be accompanied by a $250 fee payable to AHCA.[39]

CON Litigation

Florida law authorizes competitors to challenge CON decisions. A Notice of Intent to Award may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that they will be substantially affected if the CON is

[30] Rule 59C-1.008(1)(g), F.A.C.
[31] Section 408.039(3)(a), F.S.
[32] Id.
[33] Section 408.039(4)(b), F.S.
[34] Section 408.039(4)(c), F.S.
[35] Section 408.039(4)(d), F.S.
[36] Chapter 2008-29, L.O.F.
[37] Section 408.038, F.S.
[38] Id.
[39] Section 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.

awarded. For general hospital CONs, only competing applicants and existing hospitals that submitted a written statement of opposition may initiate or intervene in an administrative hearing.[40] A challenge to a CON decision is heard by an administrative law judge under the Division of Administrative Hearings.[41] A recommended order must be issued by the administrative law judge by the earlier of within 30 days after the receipt of the proposed recommended order or the deadline for submission for a proposed recommended order. The AHCA must render a Final Order within 45 days of receiving the recommended order of the administrative law judge.[42] A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review within 30 days of receipt of a Final Order. Parties challenging a general hospital CON must post a $1 million bond which will be used to pay attorney fees and costs if the appeal is lost.[43]

CON Nationwide

Thirty-five states have some form of CON program while 12 states do not have CON requirements for any type of health care facility or service.[44] The types of facilities covered and the requirements of each CON program vary from state to state.

Purpose and Effect of Certificate of Need

Cost Containment

CON programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities. Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, for example, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation. 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.[45]

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.[46] Some states address indigent care to underinsured or uninsured patients and the provision of care for the Medicaid program in their CON process.[47] In

[40] Section 408.039(5)(c), F.S.
[41] Id.
[42] Section 408.039(5)(e), F.S.
[43] Section 408.039(6), F.S.
[44] National Conference of State Legislators, *Certificate of Need State Laws* (Feb. 28, 2019), *available at* http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed March 13, 2019).
[45] Id.
[46] Thomas Stratmann and Jacob Russ, *Do Certificate-of-Need Laws Increase Indigent Care?* Mercatus Center at George Mason University (July 2014) p. 2, *available at* https://www.mercatus.org/publication/do-certificate-need-laws-increase-indigent-care (last viewed March 13, 2019).
[47] For example, Delaware (Del. Code Ann. tit. 16 s. 9303), Georgia (Ga. Code Ann. §111-2-2.03) (providing an exemption from CON with a certain percentage of Medicaid and charity care), Rhode Island (216-RICR-40-10-22.14) requiring findings of indigent and Medicaid care that will be offered, and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270) require CON applicants to comply with such provisions.

Florida applicants may apply a conditions to increase their chances of being issued a CON, including by committing to providing services to Medicaid and charity patients at certain levels.

Some studies have found that CON programs do not meet the goal of limiting costs in health care. One study found that "at best, CON has had a modest cost-containing influence on hospital and other acute care services."[48] Additionally, a literature review conducted in 2004 by the Federal Trade Commission and the Department of Justice concluded that "[O]n balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. . . .[i]ndeed, 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."[49]

Indigent Care

Studies are split, however, on whether CON regulation has improved access to care for the underinsured and uninsured. Some studies have found that access to care for the underserved populations has increased in states with CON programs,[50] while another has found only insignificant evidence to support such a conclusion.[51] A study of the Illinois CON program, while not opposing the removal of CON in Illinois, was concerned about the effect of eliminating CON on the financial health of safety-net hospitals, stating that "for some of [those hospitals]…new pressures could lead to failures [which] could force the remaining providers to serve an ever-larger number of less profitable patients, which could lead to a cascade of failures."[52]

Medically Underserved Areas

A medically underserved area (MUA) is a geographic area with a lack of access to primary care services. MUAs have a shortage of primary care health services for residents within a geographic area such as:

- A whole county;
- A group of neighboring counties;
- A group of urban census tracts; or
- A group of county or civil divisions.[53]

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[48] 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, June 1998, p. 478, *available at* https://read.dukeupress.edu/jhppl/article-abstract/23/3/455/82081/Does-Removing-Certificate-of-Need-Regulations-Lead

[49] Improving Health Care: *A Dose of Competition*: A Report by the Federal Trade Commission and the Department of Justice (July 23, 2004) p. 22, *available at* https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice (last viewed March 13, 2019). Note: this report is based on 27 days of joint hearings, an FTC-sponsored workshop, and independent research (see p. 1).

[50] 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), *available at* http://nihcr.org/analysis/improving-care-delivery/prevention-improving-health/con-laws/ (last visited on March 13, 2019).

[51] *Supra* note 46

[52] An Evaluation of Illinois' Certificate of Need Program, The Lewin Group, p. 31 (Feb. 22, 2007) *available at* http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeedPresentation.pdf

[53] See https://bhw.hrsa.gov/shortage-designation/muap (last visited on March 13, 2019)

MUAs are designated by the Health Resources and Services Administration (HRSA) within the federal Department of Health and Human Services. Eligibility for MUA designation depends on the Index of Medical Underservice (IMU) calculated for the area proposed for designation. Under the established criteria, an area or population with an IMU of 62.0 or below qualifies for designation as an MUA.[54]

The IMU scale is from 0 to 100, where 0 represents completely underserved and 100 represents best served or least underserved. The HRSA calculates the IMU by assigning a weighted value to an area or population's performance on four demographic and health indicators, then adding the weighted values together. The HRSA uses the following indicators:

- Provider per 1,000 population ratio (28.7 points max);
- Percent of population at 100 percent of the Federal Poverty Level (25.1 points max);
- Percent of population age 65 and over (20.2 points max); and
- Infant Mortality Rate (26 points max).[55]

Currently, there are 70 MUAs designated in Florida. Five of those MUAs have IMU scores of 0 while the other 65 have scores ranging from 43.3 to 61.5.[56]

III. Effect of Proposed Changes:

SB 1712 amends multiple statutes related to hospital licensure and CON.

Section 1 amends s. 395.003, F.S., to apply new licensure criteria to hospitals that are licensed on or after July 1, 2019. Each such hospital must:

- Participate in the Medicaid program;
- Provide charity care, defined as "uncompensated care delivered to uninsured patients having incomes at or below 200 percent of the federal poverty level when such services are preauthorized by the licensee and not subject to collection procedures," in an amount equal to or greater than the district average;
  - If a hospital is located in an MUA, the amount of charity care that the hospital must provide is reduced so that it is equal in percentage to that area's IMU;
  - In lieu of providing the required charity care, the hospital may donate to the AHCA's Grants and Donations Trust Fund an amount determined by the AHCA to be functionally equivalent to the amount of charity care required;
- Annually report compliance with these requirements to the AHCA. If a hospital does not report compliance or fails to comply with these requirements, the AHCA must assess a fine equal to one percent of the hospital's net revenue for each 0.5 percent of the required charity care the hospital did not provide or donate.

The section also strikes obsolete language related to off-site hospital emergency departments and makes cross-reference changes.

[54] See https://bhw.hrsa.gov/shortage-designation/muap-process. (last visited on March 13, 2019).
[55] Id.
[56] See https://data.hrsa.gov/tools/shortage-area/mua-find. (last visited on March 14, 2019).

Section 11 amends s. 408.040, F.S., to require the AHCA to assess a fine of $2,500 per day if a health care facility fails to comply with a condition of its CON related to providing charity care or providing care under the Florida Medicaid program. Currently, the AHCA is authorized to assess a fine of up to $1,000 per day.

Sections 2-10, 12, and 13 amend and repeal various sections of the Florida statutes to remove all provisions related to requiring a CON for the establishment of a new, freestanding hospital and to make conforming and cross-reference changes.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 1712 may have an indeterminate negative fiscal impact on existing hospitals if additional hospitals are licensed in the same area and if such hospital projects would not have been licensed under current law.

This bill may have an indeterminate positive fiscal impact on individuals who receive medical services in a hospital if the individual is paying for the services directly, or if there is an increase in the number of hospitals that are licensed under the provisions of the bill and such increase results in a decrease in the amount that hospital charge for such services.

The bill may have an indeterminate positive fiscal impact on individuals who receive the benefits of charity care that new hospitals will be required to offer.

C. Government Sector Impact:

This bill may have an indeterminate fiscal impact on the AHCA by eliminating the CON program for hospitals including the elimination of revenues received from CON application fees.[57]

The bill may have indeterminate fiscal impact on the AHCA by potentially increasing the number of hospitals the AHCA will be required to regulate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.003, 395.0191, 395.1055, 408.032, 408.034, 408.035, 408.036, 408.037, 408.039, 408.040, 408.043, and 395.1065.

This bill repeals section 395.6025 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[57] Hospital CON application fees were $703,120 in CY 2018. See AHCA, *Senate Bill 1712 Analysis* (March 5, 2019) (on file with Senate Committee on Health Policy)