

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 437 Certificates of Need for Hospitals

SPONSOR(S): Sprowls

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access	10 Y, 4 N	Guzzo	Calamas
2) Health Care Appropriations Subcommittee	9 Y, 4 N	Clark	Pridgeon
3) Health & Human Services Committee	12 Y, 3 N	Guzzo	Calamas

SUMMARY ANALYSIS

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

Florida's CON program was established in 1973, and has undergone several changes over the years. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986, but Florida retained its CON program. Nationally, 22 states do not require CON review to add hospital beds. Of those states, 14 have no CON requirements for any health care facility or service.

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

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

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

An applicant for CON review must submit a fee with the application. The minimum CON application filing fee is \$10,000. In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however the total fee may not exceed \$50,000. The fee for a CON exemption is \$250.

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

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

The bill is expected to have a negative fiscal impact on AHCA resulting from the loss of CON application and exemption fees; however, the loss will be offset by an increase in project and licensure fees for new hospitals and services.

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

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

STORAGE NAME: h0437e.HHSC

DATE: 1/25/2016

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.¹ Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment.²

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

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

AHCA must maintain an inventory of hospitals with an emergency department.⁴ The inventory must list all services within the capability of each hospital, and such services must appear on the face of the hospital's license. As of November 13, 2015, 219 of the 306 licensed hospitals in the state have an emergency department.⁵

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is \$1,565.13 or \$31.46 per bed, whichever is greater.⁶ The survey fee is \$400.00 or \$12.00 per bed, whichever is greater.⁷

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.⁸ The rules for general and specialty hospitals must include minimum standards to ensure:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.⁹

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

¹ S.395.002(12), F.S.

² Id.

³ S. 395.002(28), F.S.

⁴ S. 395.1041(2), F.S.

⁵ Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (report generated on November 13, 2015).

⁶ Rule 59A-3.006(3), F.A.C.

⁷ S. 395.0161(3)(a), F.S.

⁸ S. 395.1055(2), F.S.

⁹ S. 395.1055(1), F.S.

Certificate of Need (CON)

CON laws require approval by a state health planning agency before a health care facility may construct or expand, offer a new service, or purchase equipment exceeding a certain cost.

CON programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities.¹⁰ Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, for example, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation.¹¹ When a hospital or health care service provider cannot meet its obligations, fixed costs must be met through higher charges for the beds that are used or for the number of patients using the service.¹² Larger institutions have higher costs, so CON supporters say it makes sense to limit facilities to building only enough capacity to meet actual needs.¹³

In addition to cost containment, CON regulation is intended to create a "quid pro quo" in which profitability of covered medical services is increased by restricting competition and, in return, medical providers cross-subsidize specified amounts of indigent care, or medical services to the poor that are unprofitable to the provider.¹⁴ Some states require facilities and providers that obtain a CON to provide a certain amount of indigent care to underinsured or uninsured patients.¹⁵

Studies have found that CON programs do not meet the goal of limiting costs in health care. A literature review conducted in 2004 by the Federal Trade Commission (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.¹⁶

The FTC has conducted hearings and studies, and issued reports for multiple states on the effect of CON programs, and has a longstanding position in favor of the repeal of CON laws.¹⁷

¹⁰ National Conference of State Legislators, Certificate of Need: State Laws and Programs, available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last viewed January 15, 2016).

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ Thomas Stratmann and Jacob Russ, "Do Certificate-of-Need Laws Increase Indigent Care?" Mercatus Center at George Mason University, July 2014, pg. 2, available at: <http://mercatus.org/publication/do-certificate-need-laws-increase-indigent-care> (last viewed January 15, 2016).

¹⁵ For example, Delaware (Del. Code Ann. tit. 16 § 9303), Georgia (Ga. Code Ann. §111-2-2.40), Rhode Island (R.I. Code R. §6.2.4(B)), and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270) require CON applicants to comply with such provisions.

¹⁶ "Improving Health Care: A Does of Competition: A Report by the Federal Trade Commission and the Department of Justice," July 2004, available at: <https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice> (last viewed January 15, 2016): "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"; Daniel Sherman, Federal Trade Comm'n, The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); Monica Noether, Federal Trade Comm'n, Competition Among Hospitals 82(1987) (empirical study concluding that CON regulation led to higher prices and expenditures).

¹⁷ E.g., Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform at pgs. 1-2 (Sept. 15, 2008) ("Together, we support the repeal of [CON] laws, as well as steps that reduce their scope."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2008/09/ftc-and-department-justice-written-testimony-illinois> [hereinafter 2008 FTC-DOJ Joint Statement]; Prepared Statement of the Federal Trade Commission Before Florida State Senate at pg. 2 (April 2, 2008) ("[T]he Commission generally supports the repeal of [CON] laws as well as steps . . . to reduce significantly the scope of CON laws."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2008/04/ftc-prepared-statement-florida-senate-concerning>; Prepared Statement of the Federal Trade Commission Before the Alaska House of Representatives Standing Committee on Health, Education & Social Services at pg. 1 (Feb. 15, 2008) ("The Commission believes that

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,¹⁸ while another has found little, if any, evidence to support such a conclusion.¹⁹ In Florida, the Statewide Medicaid Managed Care (SMMC) program requires all managed care plans to comply with provider network standards to ensure access to care for beneficiaries and imposes significant penalties if access to care is impeded within the program. While Florida maintains a CON program for several types of health care facilities and services, accountability standards within the SMMC program would ensure access to care for Medicaid patients should the CON program be repealed.

According to one study, states with hospital CON regulations have 13 percent fewer hospital beds per 100,000 persons than states without hospital CON regulations.²⁰ The impact of CON regulations in Florida has been examined as well. A study found that, in Miami-Dade County, CON regulations result in approximately 3,428 fewer hospital beds, between 5 and 10 fewer hospitals offering MRI services, and 18 fewer hospitals offering CT scans.²¹

Another study used data from 21 states that have CON regulations for imaging services to determine whether such regulations affect the use of those services across provider types.²² The study concluded that market entry for nonhospital providers is limited by CON regulations, but hospital providers remain largely unaffected.²³ According to the study, this may explain why hospital providers of imaging services have a stronger market presence in CON states.²⁴

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

CON laws such as Alaska's can be a barrier to entry to the detriment of health care competition and consumers, and that the legislature should consider their repeal."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2008/02/ftc-written-testimony-alaska-house-representatives>; FTC Staff Statement Before North Carolina State Goals and Policy Board at pg. 1 (March 6, 1989) ("To promote competition in health care markets, the Federal Trade Commission and its staff have been active both in antitrust enforcement and in advocacy of regulatory reforms, including advocating the repeal of Certificate of Need regulation."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/1989/03/ftc-staff-comment-north-carolina-state-goals-and>; FTC Staff Comments Concerning Repeal of Nebraska's CON law at pg. 1 (Feb. 22, 1989) ("While we believe the outright repeal of CON regulation proposed in LB 745 would likely best serve the interests of consumers, we believe that passage of either of the other CON reform bills would likely also have significant positive effects on health care markets."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/1989/02/ftc-staff-comment-hon-bernice-labeledz-concerning>; FTC Staff Comments Concerning Repeal of Pennsylvania's CON Law at pg. 14 (Mar. 30, 1988) ("We believe that the continued existence of CON regulation would be contrary to the interests of consumers in Pennsylvania."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/1988/03/ftc-staff-comment-hon-john-f-pessman-and-hon-donald>; FTC Staff Comments Concerning the Effectiveness of Michigan's CON Law at pg. 14 (Mar. 7, 1988) ("We believe that the continued existence of CON regulation would be contrary to the interests of consumers in Michigan."), available at <https://www.ftc.gov/policy/policy-actions/advocacy-filings/1988/03/ftc-staff-comment-hon-gerald-h-law-concerning>.

¹⁸ Tracy Yee, Lucy B. Stark, et al, "Health Care Certificate-of-Need Laws: Policy or Politics?," Research Brief, National Institute for Health Care Reform, No. 4, May 2011, pg. 6, available at: <http://www.nihcr.org/index.php?download=119ncl17> (citing Elana C. Fric-Shamji and Mohammed F. Shamji, "Impact of U.S. Government Regulation on Access to Elective Surgical Care," *Clinical & Investigative Medicine*, vol. 31, no. 5 (October 2008) and Ellen S. Campbell and Gary M. Fournier, "Certificate-of-Need Deregulation and Indigent Hospital Care," *Journal of Health Politics, Policy and Law*, vol. 18, no. 4 (Winter 1993)).

¹⁹ Christopher J. Conover and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy and Law*, vol. 23, no. 3, pg. 478 (June 1998).

²⁰ *Id.*

²¹ Christopher Koopman and Thomas Stratman, "Certificate-of-Need Laws: Implications for Florida," March 2015, pg. 2, available at: <http://mercatus.org/sites/default/files/Koopman-Certificate-of-NeedFL-MOP.pdf>. (last viewed January 15, 2016).

²² Thomas Stratmann and Matthew C. Baker, "Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans." Mercatus Working Paper, Mercatus Center at George Mason University, January 2016, available at <http://mercatus.org/publication/are-certificate-need-laws-barriers-entry-how-they-affect-access-mri-ct-and-pet-scans> (last viewed January 22, 2016).

²³ *Id.* at p. 19

²⁴ *Id.*

"Act), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.²⁵ Each state was required to have a CON program in compliance with the Act as a condition for obtaining federal funds for health programs. The Act was repealed in 1986.

In Florida, a CON is a written statement issued by AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full, expedited and exempt.²⁶ Unless a hospital project is exempt from the CON program, it must undergo a full comparative review. Expedited review is primarily targeted towards nursing home projects.

Projects Subject to Full CON Review

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

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals; and
- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility.²⁷

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

- Establishing comprehensive medical rehabilitation inpatient services or increasing the number of beds for comprehensive rehabilitation;²⁸ and
- Establishing tertiary health services.²⁹

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.³⁰

Section 408.032(17), F.S., requires AHCA to establish by rule a list of all tertiary health services subject to CON review. The list of tertiary health services must be reviewed annually by AHCA to determine if services should be added or deleted.³¹

²⁵ Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.

²⁶ S. 408.036, F.S.

²⁷ S. 408.036(1)(b), F.S.

²⁸ S. 408.036(1)(e), F.S.

²⁹ S. 408.036(1)(f), F.S., and s. 408.032(17), F.S., which defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of tertiary health services include pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service.

³⁰ Rule 59C-1.039(2)(c), F.A.C.

³¹ Rule 59C-1.002(41), F.A.C.

Hospitals must undergo full comparative CON review for the establishment of the following tertiary health services:

- Pediatric cardiac catheterization;
- Pediatric open-heart surgery;
- Neonatal intensive care units;
- Adult open heart surgery; and
- Organ transplantation; including
 - Heart;
 - Kidney;
 - Liver;
 - Bone marrow;
 - Lung; and
 - Pancreas.³²

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.³³

Exemptions from CON Review

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

- Adding swing beds³⁴ in a rural hospital, the total of which does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities.
- Adding hospital beds licensed under chapter 395, F.S., for comprehensive rehabilitation, the total of which may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
- Establishing a level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 15 beds, and if the hospital had a minimum of at least 3,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 5 beds, and is a verified trauma center,³⁵ and if the applicant has a level II NICU.

³² Rule 59C-1.002(41), F.A.C.

³³ S. 408.036(2), F.S.

³⁴ 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.

³⁵ 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.

- Establishing an adult open heart surgery program in a hospital located within the boundaries of a health service planning district, which:
 - Has experienced an annual net out-migration of at least 600 open heart surgery cases for 3 consecutive years; and
 - Has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.
- For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.

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”³⁶, 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.³⁷ Chapter 59C-1, F.A.C., provides need formulas³⁸ to calculate the fixed need pool for certain services, including NICU services³⁹, adult and child psychiatric services⁴⁰, adult substance abuse services⁴¹, and comprehensive rehabilitation services.⁴²

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.

³⁶ 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.

³⁷ Rule 59C-1.002(5), F.A.C.

³⁸ Rule 59C-1.039(5), F.A.C., provides the need formula for comprehensive medical rehabilitation inpatient beds as follows: $((PD/P) \times PP / (365 \times .85)) - LB - AB = NN$ where: 1. NN equals the net need for Comprehensive Medical Rehabilitation Inpatient Beds in a District. 2. PD equals the number of inpatient days in Comprehensive Medical Rehabilitation Inpatient Beds in a district for the 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.

3. P equals the estimated population in the district. For applications submitted between January 1 and June 30, P is the population estimate for January of the preceding year; for applications submitted between July 1 and December 31, P is the population estimate for July of the preceding year. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool.

4. PP equals the estimated population in the district for the applicable planning horizon. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool. 5. .85 equals the desired average annual occupancy rate for Comprehensive Medical Rehabilitation Inpatient Beds in the district. 6. LB equals the district’s number of licensed Comprehensive Medical Rehabilitation Inpatient Beds as of the most recent published deadline for Agency initial decisions prior to publication of the Fixed Bed Need Pool.

7. AB equals the district’s number of approved Comprehensive Medical Rehabilitation Inpatient Beds.

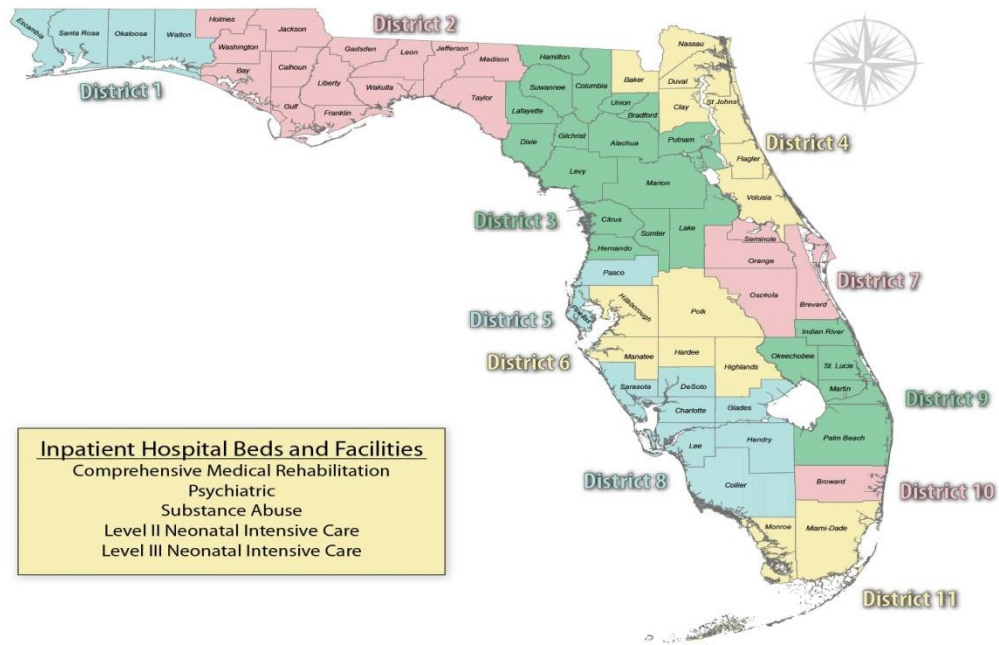
³⁹ Rule 59C-1.042(3), F.A.C.

⁴⁰ Rule 59C-1.040(4), F.A.C.

⁴¹ Rule 59C-1.041(4), F.A.C.

⁴² 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.⁴³ 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.⁴⁴

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.⁴⁵

⁴³ Rule 59C-1.008(1)(g), F.A.C.

⁴⁴ Rule 59C-1.008(1), F.A.C.

⁴⁵ Id.

Hospital Beds & Facilities Applications for Last 4 Batching Cycles 2013-2015⁴⁶

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

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.⁴⁷ 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.⁴⁸

Applications for CON review must be submitted by the specified deadline for the particular batch cycle.⁴⁹ AHCA must review the application within 15 days of the filing deadline and, if necessary, request additional information for an incomplete application.⁵⁰ The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.⁵¹

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.⁵² AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.⁵³ If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent to Award the CON become a final order of AHCA.⁵⁴

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 \$10,000.⁵⁵ 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 \$50,000.⁵⁶ A request for a CON exemption must be accompanied by a \$250 fee payable to AHCA.⁵⁷

CON Litigation

⁴⁶ AHCA, CON Decisions & State Agency Action Reports, Hospital Beds and Facilities, February 2015 batching cycle, August 2014 batching cycle, February 2014 batching cycle, and August 2013 batching cycle, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/decisions.shtml (last viewed January 15, 2016). Pursuant to s. 408.036, F.S., and rule 59C-1.004(1), F.A.C., requests for an expedited review or exemption may be made at any time and are not subject to batching requirements.

⁴⁷ S. 408.039(2)(a), F.S.

⁴⁸ S. 408.039(2)(c), F.S.

⁴⁹ Rule 59C-1.008(1)(g), F.A.C.

⁵⁰ S. 408.039(3)(a), F.S.

⁵¹ Id.

⁵² S. 408.039(4)(b), F.S.

⁵³ S. 408.039(4)(c), F.S.

⁵⁴ S. 408.039(4)(d), F.S.

⁵⁵ S. 408.038, F.S.

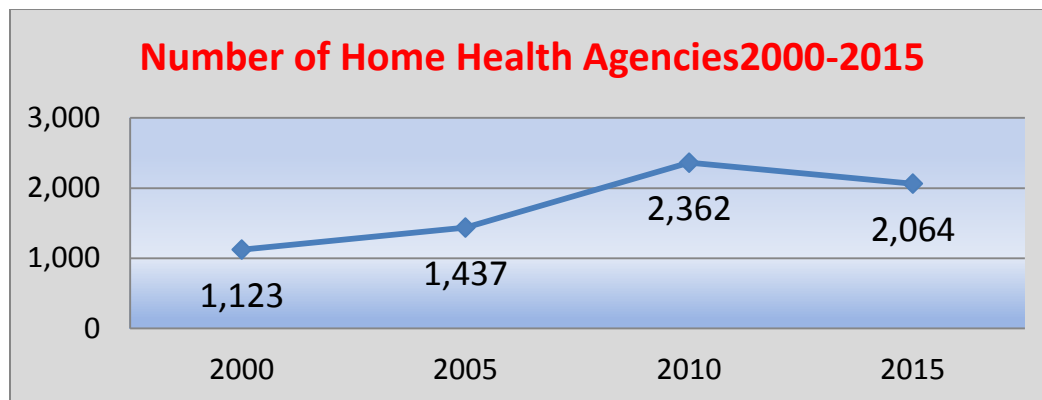
⁵⁶ Id.

⁵⁷ S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.

Florida law allows competitors to challenge CON decisions. A Notice of Intent to Award a CON may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that the challenge will be substantially affected if the CON is awarded.⁵⁸ A challenge to a CON decision is heard by an Administrative Law Judge under the Division of Administrative Hearings.⁵⁹ AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.⁶⁰ A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review⁶¹ within 30 days of receipt of a Final Order.⁶²

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.⁶³ 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.⁶⁴



In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.⁶⁵ Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I⁶⁶ adult cardiovascular services license has doubled while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased.⁶⁷

⁵⁸ S. 408.039(5)(c), F.S.

⁵⁹ Id.

⁶⁰ S. 408.039(5)(e), F.S.

⁶¹ 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.

⁶² S. 408.039(6), F.S.

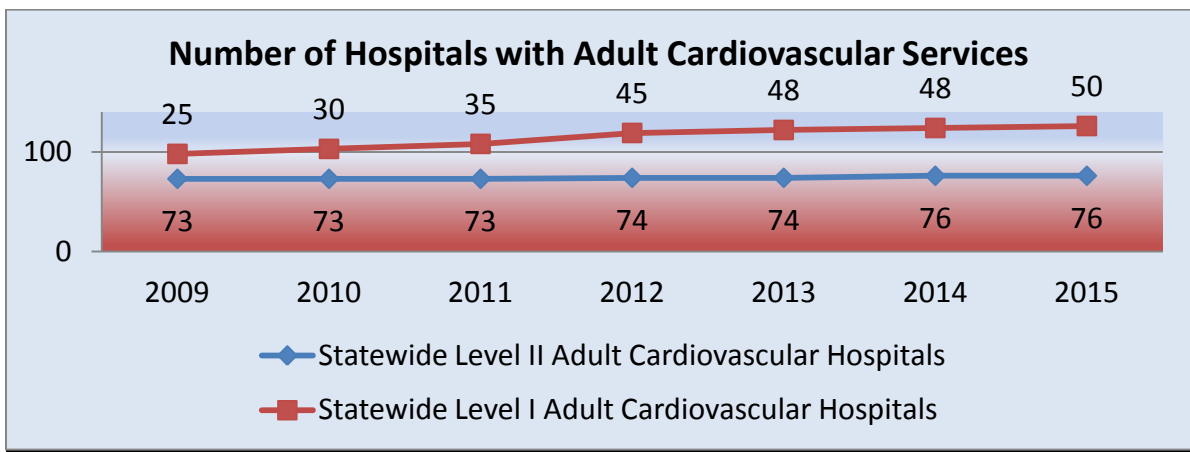
⁶³ Ch. 2000-256, Laws of Fla.

⁶⁴ AHCA, Current Status of Certificate of Need, Effects of Deregulation, October 20, 2015, available at <http://healthandhospitalcommission.com/Meetings.shtml> (last viewed January 15, 2016).

⁶⁵ Ch. 2007-214, Laws of Fla.

⁶⁶ S. 408.0361, F.S., requires AHCA to adopt rules for the establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery. Rule 59A-3.2085(16) and (17), F.A.C., provides the licensure requirements for Level I and Level II adult cardiovascular services licensure.

⁶⁷ Supra, FN 62 at pg. 7.



In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.⁶⁸ In addition to the repeal, the legislature imposed limitations on the issuance of CONs for community nursing home beds to limit the growth through July 1, 2017. AHCA may not approve a CON application for new community nursing home beds following the batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2017, equals or exceeds 3,750.⁶⁹ As of October, 2015, 3,373 nursing home beds have been approved since the moratorium has been lifted.⁷⁰

Nursing Home CON Applications Since July 2014 ⁷¹					
	Oct. 2014 ⁷²	April 2015 ⁷³	Expedited Reviews	Exemptions	Total
Bed Need Published	3,115	657			3,772
Notices of Intent Filed	179	28			207
Applications Submitted	87	19			106
Approved Beds	2,447	381	240	305	3,373
Denied Beds	5,827	519			6,346
New Facilities	22	2	2		26
Additions to Existing Facilities	12	8			20

CON Nationwide

⁶⁸ Ch. 2014-110, Laws of Fla.

⁶⁹ S. 408.0436, F.S.

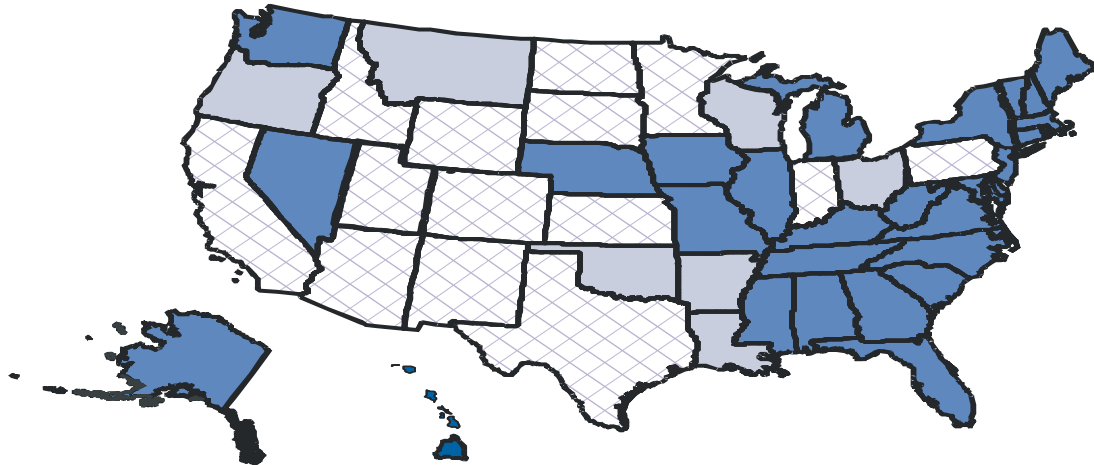
⁷⁰ AHCA, Nursing Home Licensure and Regulation, Presentation to the Health Innovation Subcommittee, October 6, 2015, (on file with Select Committee on Affordable Healthcare Access staff).

⁷¹ Id.

⁷² The decision date for this batching cycle was February 20, 2015.

⁷³ The decision date for this batching cycle was August 21, 2015.

Fourteen states do not have CON requirements for any type of health care facility or service.⁷⁴ 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.⁷⁵



CON Required
 No CON Required
 No CON Program

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

- Arizona (1985 – still retains CON requirements for ambulance service providers);
- California (1987);
- Idaho (1983);
- Indiana (1996);
- Kansas (1985);
- Minnesota (1985);
- New Mexico (1983);
- North Dakota (1995);
- Pennsylvania (1996);
- South Dakota (1988);
- Texas (1985);
- Utah (1984);
- Wisconsin (2011); and
- Wyoming (1989).⁷⁶

On average, states with CON programs regulate 14 different services, devices, and procedures.⁷⁷ Florida’s CON program currently regulates 11, which is slightly below the national average.⁷⁸ Vermont has the most CON laws in place. Arizona has the least number of CON laws.⁷⁹

⁷⁴ National Conference of State Legislators, Certificate of Need: State Laws and Programs, available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last viewed January 15, 2016).

⁷⁵ Id.

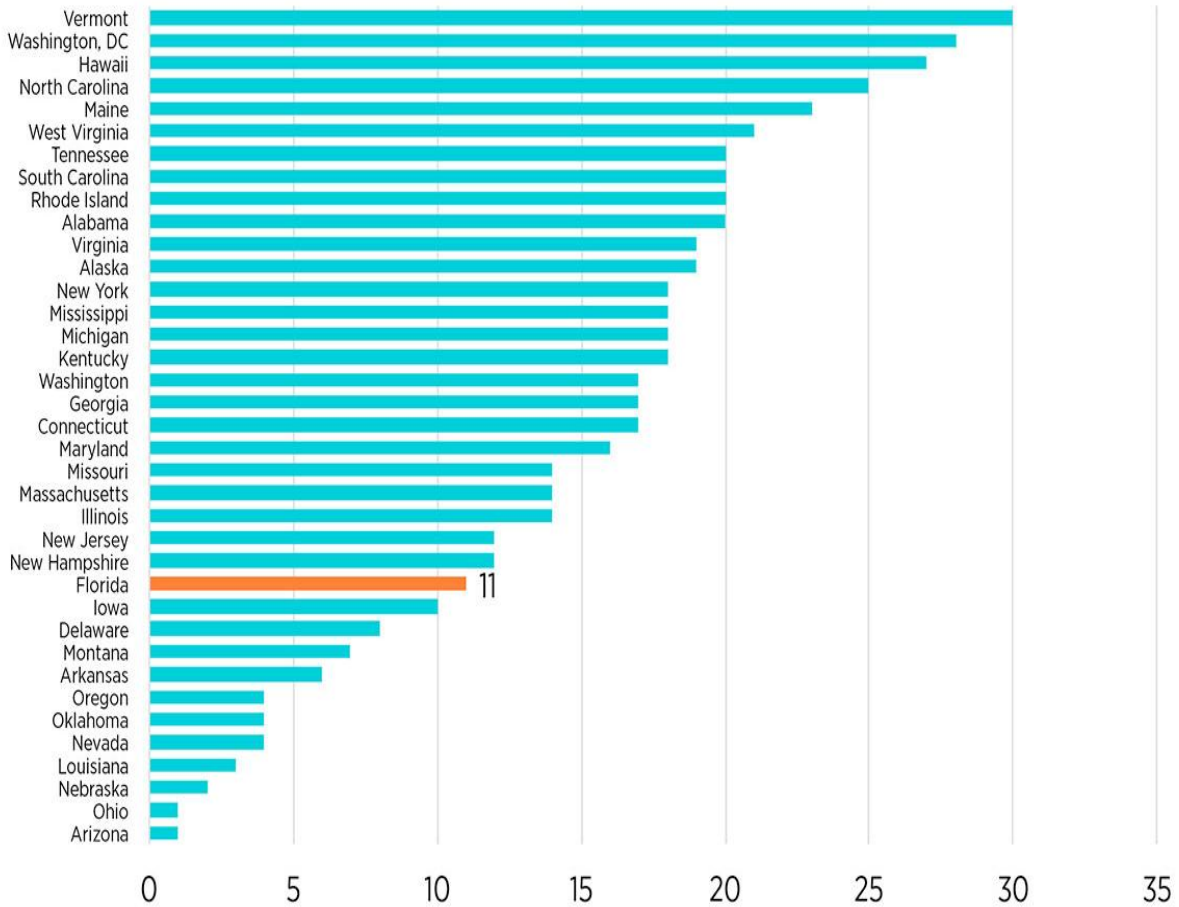
⁷⁶ Id.

⁷⁷ Supra, FN 18 at pg. 3.

⁷⁸ Id.

⁷⁹ Id.

State Ranking by Number of CON Laws



CON Reform in Other States

Georgia

The State Commission on the Efficacy of the Certificate of Need Program recommended that CON be maintained and improved after spending 18 months examining the role of CON. The final Commission report, issued in 2006, recommended that Georgia maintain existing CON regulations for hospital beds, adult open heart surgery, and pediatric cardiac catheterization and open heart surgery.⁸⁰ The report did not recommend deregulation of any hospital CON project. The CON program for hospital facilities and services remains intact.

Illinois

In 2006, the Legislature passed a law requiring the Commission (Commission) on Government Forecasting and Accountability to “conduct a comprehensive evaluation of the Illinois Health Facilities Planning Act, including a review of the performance of the Illinois Health Facilities Planning Board, to determine if it is meeting the goals and objectives that were originally intended in the law...”⁸¹ The Commission contracted with The Lewin Group to conduct a study on CON, which found that CONs rarely reduce health care costs and, on occasion, increase cost in some states. The study recommended that, while the traditional arguments for CON are empirically weak, based on the preponderance of hard evidence, the CON program should be allowed to sunset. However, the study cautioned that, given the potential for harm to specific critical elements of the health care system, the Legislature should move forward with an abundance of caution.⁸²

⁸⁰ Supra, FN 71 at pgs. 62 and 82.

⁸¹ Ill. House Resolution 1497 (2006).

⁸² 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 January 15, 2016).

In 2008, the Legislature decided to study the issue further and passed legislation to create the Task Force on Health Planning Reform (task force).⁸³ The task force evaluated the current CON program and recommended changes to the structure and function of both the Health Facilities Planning Board and the Department of Public Health in the review of applications to establish, expand, or modify health facilities and related capital expenditures.⁸⁴ The task force recommended that the state maintain the CON process and extend the sunset date.⁸⁵ Currently, the CON program is scheduled to sunset on December 31, 2019.

Washington State

In 1999, the Joint Legislative Audit Review Committee contracted with the Health Policy Analysis Program of the University of Washington to conduct a legislatively mandated study of the CON program.⁸⁶ The study examined the effects of CON, and its possible repeal, on the cost, quality, and availability health care. The results of the study were based on a literature review, information gathered from service providers and other experts in Washington, and analyses of states where CON has been completely or partially repealed.⁸⁷

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 adopted legislation during the 2015 legislative session requiring the Secretary of Health and Human Resources to convene a workgroup to review the state's Certificate of Public Need (COPN) process.⁸⁸

The workgroup is required to develop specific recommendations for changes to the COPN process to be introduced during the 2016 Session of the General Assembly and any additional changes that may require further study or review.⁸⁹ In conducting its review and developing its recommendations, the work group must consider data and information about the current COPN process, the impact of such process, and any data or information about similar processes in other states.⁹⁰ A final report with recommendations was provided to the General Assembly on November 23, 2015.⁹¹ The final report recommended repealing CON for lithotripsy, obstetrical services, magnetic source imaging, nuclear medicine imaging services, and replacement of a medical facility within the same primary service area.

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.⁹² The statement explains that the agencies historically have urged states to consider

⁸³ Ill. Senate Bill 244 (PA 95-0005) of the 95th General Assembly, 2008

⁸⁴ The Illinois Task Force on Health Planning Reform, Final Report, December 31, 2008.

⁸⁵ Id.

⁸⁶ State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.

⁸⁷ State of Washington Joint Legislative Audit and Review Committee, Effects of Certificate of Need and its Possible Repeal, Report 99-1, January 8, 1999, available at <http://www.leg.wa.gov/JLARC/AuditAndStudyReports/1999/Documents/99-1.pdf> (last viewed January 15, 2016).

⁸⁸ SB 1283, Virginia General Assembly, 2015.

⁸⁹ 2015 Va. Acts Chapter 541.

⁹⁰ Id.

⁹¹ Virginia Certificate of Public Need Workgroup, *Final Report*, available at <http://www.vdh.state.va.us/Administration/COPN.htm> (last viewed January 15, 2016).

⁹² Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group, October 26, 2015, available at <http://www.vdh.state.va.us/Administration/documents/COPN/Federal%20Trade%20Commission%20and%20Department%20of%20Justice.pdf> (last viewed January 15, 2016).

repeal or reform of their CON laws because they can prevent the efficient functioning of health care markets, and thus can harm consumers.⁹³ As the statement describes, CON laws create barriers to expansion, limit consumer choice, and stifle innovation.⁹⁴ Additionally, incumbent providers seeking to thwart or delay entry by new competitors may use CON laws to that end.⁹⁵ Finally, the statement asserts that CON laws can deny consumers the benefit of an effective remedy for antitrust violations and can facilitate anticompetitive agreements.⁹⁶ For these reasons, the agencies suggested that the workgroup and the General Assembly consider whether Virginia's citizens are well served by its CON laws and, if not, whether they would benefit from the repeal or retrenchment of those laws.⁹⁷

Currently, both North Carolina and South Carolina are considering legislation to repeal or limit their CON programs.⁹⁸

On July 10, 2015, the FTC submitted a letter to the North Carolina House of Representatives, in response to a request for comment on the possible competitive effects of a legislative proposal to narrow North Carolina's CON laws.⁹⁹ The FTC concluded that, to the extent that the legislation narrows the application of North Carolina's CON law, it likely represents a pro-competitive improvement in the law.¹⁰⁰ In addition, Joshua D. Wright, a Commissioner of the FTC, provided a separate response to the North Carolina House of Delegates. In his response, Commissioner Wright clarified that, while narrowing the application of North Carolina's CON law will improve competition, the FTC supports the full repeal of CON laws.¹⁰¹

Effect of Proposed Changes

The bill eliminates CON review requirements for hospitals and hospital services and makes necessary conforming changes throughout part I of chapter 408, F.S. The bill also removes the CON review requirement for increasing the number of comprehensive rehabilitation beds in a facility that offers comprehensive rehabilitation services. Hospitals will be able to expand the number of beds and the types of services without seeking prior authorization from the state. Similarly, facilities that offer comprehensive rehabilitation services will be able to increase the number of beds to meet demand without first seeking prior authorization from the state.

The bill also makes a conforming change to s. 395.1055, F.S., to ensure that AHCA has rulemaking authority, after the repeal of the CON review requirements for hospitals, to maintain quality requirements for tertiary services that may be offered by a hospital. Current CON rules for tertiary services, such as comprehensive medical rehabilitation, neonatal intensive care services, organ transplantation, and pediatric cardiac catheterization, include quality standards for those programs.¹⁰²

⁹³ Supra, FN 87 at pg. 2.

⁹⁴ Id.

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Supra, FN 87 at pg. 13.

⁹⁸ The North Carolina General Assembly is considering two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposes to repeal the CON program in its entirety. House Bill 200 proposes to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The legislative session begins in April. The South Carolina General Assembly is also considering legislation during the 2016 legislative session to reform the CON program. Currently, South Carolina's CON program requires review for 20 different health care projects and services including hospitals. House Bill 3250 proposes to repeal the CON program effective January 1, 2018, and proposes to reduce CON regulations in the interim by providing several exemptions from CON review. The legislative session begins in January.

⁹⁹ Letter from the Federal Trade Commission, Office of Policy Planning, Bureau of Economics, and Bureau of Competition, to the Honorable Representative Marilyn W. Avila, N.C. House of Representatives (July 10, 2015); Comments on Effect of N.C. House Bill 200, 2015 Gen. Assemb., Reg. Sess. (N.C. 2015) available at <https://www.ftc.gov/news-events/press-releases/2015/07/ftc-staff-supports-north-carolina-legislative-proposal-limit> (last viewed January 22, 2016).

¹⁰⁰ Id.

¹⁰¹ Letter from Joshua D. Wright, Commissioner of the Federal Trade Commission, to the Honorable Representative Marilyn W. Avila, N.C. House of Representatives (July 10, 2015); Comments on Effect of N.C. House Bill 200, 2015 Gen. Assemb., Reg. Sess. (N.C. 2015) available at <https://www.ftc.gov/news-events/press-releases/2015/07/ftc-staff-supports-north-carolina-legislative-proposal-limit> (last viewed January 22, 2016).

¹⁰² The current CON rules which include quality standards, in addition to the CON market-entry requirements, are 59C-1.039, F.A.C. (comprehensive medical rehabilitation); 59C-1.042, F.A.C. (neonatal intensive care services); 59C-1.044, F.A.C. (organ transplantation); 59C-1.032, F.A.C. (pediatric cardiac catheterization); 59C-1.033, F.A.C. (adult and pediatric open heart surgery programs); and 59A-3.2085(16)-(17), F.A.C. (adult cardiovascular services).

The bill deletes the definition of "tertiary health service" in s. 408.032, F.S., to repeal the CON review requirement for a hospital to establish such services. This eliminates authority for CON rules, including quality standards. The conforming change transfers rulemaking authority for the quality standards from the CON law to the hospital licensure law. The change eliminates any implication or interpretation that AHCA loses rulemaking authority to impose and maintain licensure requirements for tertiary health services as a result of the repeal of the CON review requirements for hospitals.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act.

Section 2: Amends s. 408.034, F.S., relating to duties and responsibilities of the agency; rules.

Section 3: Amends s. 408.035, F.S., relating to review criteria.

Section 4: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.

Section 5: Amends s. 408.037, F.S., relating to application content.

Section 6: Amends s. 408.039, F.S., relating to review process.

Section 7: Amends s. 408.043, F.S., relating to special provisions.

Section 8: Amends s. 395.1055, F.S., relating to rules and enforcement.

Section 9: Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.

Section 10: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.

Section 11: Amends s. 395.604, F.S., relating to other rural hospital programs.

Section 12: Amends s. 395.605, F.S., relating to emergency care hospitals.

Section 13: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.

Section 14: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will experience a reduction in revenue resulting from the loss of CON application and exemption fees for hospital services which may be mitigated by a reduction in workload. Fees collected in Fiscal Year 2014-2015 resulted in revenue of approximately \$450,000.¹⁰³ Any decrease in CON application fees will be offset by an approximate 10 percent increase in hospital projects resulting in almost \$450,000 in new plans and construction fees.¹⁰⁴

¹⁰³ AHCA, Agency Bill Analysis of HB 437, October 26, 2015 (on file with the Select Committee on Affordable Healthcare Access staff).

¹⁰⁴ Id.

2. Expenditures:

AHCA will experience increased workload resulting from an increase in hospital licensure applications. The expenditure associated with any increase in workload is indeterminate yet likely insignificant; however, the increased workload will be offset by the reduced workload resulting from the repeal of the CON review process for hospitals.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES