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 Health and Human Services Appropriations Committee

BILL:	PCS/SB 2326
INTRODUCER:	Health and Human Services Appropriations Committee
SUBJECT:	Hospital Regulation
DATE:	March 31, 2008
REVISED:	3/31/2008

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Peters	HA	**Pre-meeting**
2.			HR	
3.			RC	
4.				
5.				
6.				

I. Summary:

The proposed committee substitute modifies the application and review process for applications for a certificate-of-need (CON) for general hospitals. The bill authorizes interested parties to request a public hearing related to any type of CON application and requires the Agency to conduct a public hearing if requested. A continuance for an administrative hearing related to a CON application for a general hospital may not exceed four months. A party appealing a final order that grants a general hospital CON must file a $1 million dollar bond and if the party appealing the final order is unsuccessful, that party must pay the appellee's attorney's fees and costs, up to $1 million. The bill provides that the Agency will not be liable for any other party's attorney's fees and costs unless the court finds that the Agency improperly rejected or modified findings of fact in a recommended order or the Agency's action which precipitated the appeal was a gross abuse of discretion. The provisions in the bill do not apply to a project that is under review for which the Agency has not made an initial decision as of the effective date of the act.

This bill substantially amends the following sections of the Florida Statutes: 408.035, 408.037, 408.039, and 408.040. The bill contains one undesignated section.

II. Present Situation:

Hospitals Generally

Hospitals are licensed by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of part II, ch. 408, F.S. A hospital offers more intensive services than those required for room, board, personal services, and general nursing care. A range of health care services is offered with beds for use beyond 24 hours by individuals

requiring diagnosis, treatment, or care. 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 of similar extent.[1] Hospitals are not required to provide emergency services.

A specialty hospital makes available either:

- A range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population,
- 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 under the age of 18 who have psychiatric disorders to restore these patients to an optimal level of functioning.[2]

The AHCA maintains an inventory of hospitals with an emergency department and all services within the service capability of these hospitals. According to the AHCA's inventory, as of January 7, 2008, 221 out of the 282 hospitals in the state have an emergency department and provide at least one emergency service while most of these hospitals provide almost all of the 38 services identified by the AHCA's rule.[3]

Hospital Licensure

Facilities must meet initial licensing requirements set forth in state regulations by submitting a completed application, required documentation, and satisfactory completion of a facility survey. The license fee is $1,542.00 or $31.00 per bed, whichever is greater. The survey/inspection fee is $400.00 or $12.00 per bed, whichever is greater. To meet federal requirements, the hospital must be surveyed for certification as directed by the Centers for Medicare and Medicaid Services.

A license application for a change in ownership must be submitted at least 60 days prior to the date of acquisition of the hospital. Facilities must meet federal and state licensing requirements, and submit a completed application with required documentation. The change of ownership application fee is $1,542.00 or $31.00 per bed, whichever is greater. When the change of ownership has occurred, a copy of the closing documents or sales document must be submitted to the AHCA.

Florida follows the general rule that a change in a licensure statute that occurs during the pendency of an application for licensure is operative as to the application, so that the law as changed, rather than as it existed at the time the application was filed determines whether the license should be granted.[4]

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[1] Section 395.002(12), Florida Statutes.
[2] S. 395.002(28), F.S.
[3] See *Hospital ER Services as of 01/07/2008, Listed Alphabetically by County*. Found at: <http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/forms/HospitalERServicesInventory.pdf > (Last visited on March 21, 2008).
[4] Lavernia v. Department of Professional Regulation, Board of Medicine, 616 So.2d 53 ((Fla.1st DCA 1993).

Certificate of Need Overview

The CON program is a regulatory review process that requires specified health care providers to obtain prior authorization before offering certain new or expanded services. Florida's CON program has been in operation since July, 1973, and has undergone several changes over the years. The changes primarily have involved a reduction in the types of facilities or services subject to review and the extent of review of facilities or services.

Provisions related to the CON program are set forth in ss. 408.031 – 408.045, F.S., and Rule Chapters 59C-1 and 59C-2, Florida Administrative Code. The AHCA administers the CON program.

A CON is defined as a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[5] Health care facilities and health services subject to CON review include hospitals, long term care hospitals, skilled nursing facilities, hospices, intermediate care facilities for the developmentally disabled, inpatient diagnostic, curative, or comprehensive medical rehabilitative services, and tertiary health services. Tertiary health services are highly intense, complex, specialized, and costly. Examples of such services include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, and comprehensive rehabilitation. A CON is not required for outpatient services, home health services, or the purchase of major medical equipment. Currently there is a moratorium in effect for nursing homes until July 1, 2011.[6]

CON Review Levels

The Florida CON program has three levels of review: full, expedited, and the granting of an exemption.[7]

Projects subject to full review include:

- The addition of beds in community nursing home[8] or intermediate care facilities for the developmentally disabled by new construction or alteration;
- The new construction or establishment of additional health care facilities, including a replacement health care facility when the proposed project site is not located on the same site as or within 1 mile of the existing health care facility, if the number of beds in each licensed bed category will not increase;
- The conversion from one type of health care facility to another, including the conversion from a general hospital, a specialty hospital, or a long-term care hospital;
- The establishment of a hospice or hospice inpatient facility;
- An increase in the number of beds for comprehensive rehabilitation;

[5] S. 408.032(3), F.S.
[6] S. 408.0435, F.S.
[7] S. 408.036, F.S.
[8] See s. 408.0435, F.S., regarding the moratorium on nursing home beds until July 1, 2011.

- The establishment of tertiary health services, including inpatient comprehensive rehabilitation services; and
- An increase in the number of beds for acute care in a hospital that is located in a low-growth county. This provision is scheduled for repeal on July 1, 2009.

Projects subject to an expedited review include:

- A transfer of a CON, except a purchaser of a hospital acquires all CONs which are not yet operational;
- Replacement of a nursing home within the same district, if the proposed site is within a geographic area that contains at least 65 percent of the facility's current residents and is within a 30-mile radius of the nursing home to be replaced; and
- Relocation of a portion of a nursing home's licensed beds to a facility within the same district, if the total number of beds in the district does not increase and the new location is within a 30-mile radius of the current facility.

Upon request to the AHCA, the following projects are exempt from review and filing an application for a CON:

- For hospice services or for swing beds in a rural hospital in a number that does not exceed one-half of the rural hospital's licensed beds;
- For the conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, if the conversion does not involve construction of new facilities;
- For the addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides multiple levels of care, was operating before July 1, 1994, and limits use of the beds to community residents;
- For an inmate health care facility built by or for the exclusive use of the Department of Corrections;
- For mobile surgical facilities and related health care services;
- For the creation of a single nursing home within a district by combining already licensed beds within that district. This provision is repealed on July 1, 2011;
- For certain state veterans' nursing homes;
- For combining nursing home facilities within a sub-district into an existing facility;
- For dividing authorized nursing home beds and services within a sub-district;
- For the addition of hospital beds for comprehensive rehabilitation, not to exceed the greater of 10 total beds or 10 percent of licensed capacity;
- For the addition of nursing home beds, not to exceed the greater of 10 total beds or 10 percent of the number of licensed beds, or 20 total beds or 10 percent of the number of licensed beds in a facility that has been designated as a Gold Seal nursing home;
- For the establishment of a Level II neonatal intensive care unit, the number of beds depends upon the number of births at the applicant hospital;

- For an adult open-heart surgery program to be located in a new hospital meeting certain conditions;[9]
- For the provision of adult open-heart services in a hospital, under certain conditions;
- For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart surgery program;
- For the addition of mental health services or beds if the applicant commits to providing a certain level of services to Medicaid or charity care patients;
- For replacement of a licensed nursing home on the same site, or within 3 miles of the same site, if the number of licensed beds does not increase;
- For consolidation or combination of licensed nursing homes or transfer of beds between providers within a planning sub-district, if the total number of beds does not increase and the relocation is not more than 30 miles from the original location;
- For beds in state mental health treatment facilities; and
- For beds in state developmental disabilities institutions.

CON Fees

Applications for the full CON review or expedited review require a minimum base fee of $10,000 plus 0.015 of each dollar of proposed expenditures, however the total fee may not exceed $50,000. A request for an exemption must be accompanied with a $250 fee.

CON Application and Review Process[10]

Requests for an expedited review or exemption may be made at any time and are not subject to batching requirements. Projects subject to full competitive review are handled in batched cycles. There are two batching cycles each year for two project categories: hospital beds and facilities, and other beds and programs. Applicants are compared against each other and one, many, or none may be approved.

The AHCA publishes projections of future needs. Rules identify the factors used in developing the need projections and considerations include but are not limited to: demographic characteristics of the population, the health status of the population, service use patterns, standards and trends, geographic accessibility, and market economics.[11]

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with the AHCA. A letter of intent describes the proposal; specifies the number of beds sought, if any; identifies the services to be provided; and identifies the applicant and sub-district location of the project. An application is not required to be submitted even though a letter of intent is filed with the AHCA.

[9] This provision was ruled unconstitutional by the Supreme Court of Florida on September 6, 2007, in *St. Vincent's Medical Center, Inc. vs. Memorial Healthcare Group, Inc, etc., et al., 967 So.2d 794 (2007).*
[10] S. 408.039, F.S.
[11] S. 408.034, F.S.

The AHCA publishes a notice in the Florida Administrative Weekly and provides for a public hearing, if requested, to be held at the local level.

An application must be submitted by the specified deadline for the particular batch cycle. The AHCA has 15 days to review the application and request additional information for an incomplete application. The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration. Interested parties can submit information (pro or con) regarding the application until the 21-day omissions deadline.

Each application is reviewed by a health services and facilities consultant, a certified public accountant, an architect, the health services and facilities consultant supervisor, the chief of health facility regulation, and the deputy secretary of health quality assurance. Statutory and rule review criteria are considered, a site visit is conducted when appropriate, and a public hearing held when requested. A recommendation is made after briefing the Secretary of the AHCA.

Within 60 days of receipt of the completed applications for that batch, the AHCA issues 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. This action is published within 14 days in the Florida Administrative Weekly. If no administrative hearing is requested within 21 days, the State Agency Action Report and the Notice of Intent become a final order of the AHCA. The full CON process takes approximately 120 days if an administrative hearing challenging a determination is not requested.

Decisions of the AHCA may be challenged by competing applicants in the same review cycle or existing providers in the same district who can show that they will be substantially affected if the CON is awarded. Challenges to CON decisions are heard by Administrative Law Judges with the Division of Administrative Hearings. The AHCA renders the Final Order upon review of the Recommended Order of the Administrative Law Judge and exceptions filed by parties. Final Orders may be challenged to the District Court of Appeals. If an AHCA decision is challenged, the timeframe for reaching an ultimate decision and initiation of an approved project is indeterminable. The AHCA has estimated that 90 percent of the decisions are initially challenged. Approximately half of those are settled and the other half proceed to an administrative hearing.[12]

The AHCA monitors implementation of an approved project until it is licensed. The AHCA may issue a CON or an exemption, predicated upon a statement of intent expressed by an applicant.[13] A CON that is approved with conditions is monitored every year to assure that the required services are being provided.

Court Ordered Attorney's Fees and Costs in CON Appeals

In ch. 408.039, F.S., related to the review process for CONs, a party to an administrative hearing for an application for a certificate of need has the right to appeal a final order in the District Court of Appeal. The Agency must be a party in the proceeding. The court, in its discretion, may

[12] Presentation by the AHCA before the House Health Innovation Committee on January 8, 2007.
[13] S. 408.040, F.S.

award reasonable attorney's fees and costs to the prevailing party if the court finds that there was a complete absence of a judiciable issue of law or fact raised by the losing party.

In the Administrative Procedure Act, specifically, at s. 120.595(5), F.S., the court may award reasonable attorney's fees and costs to the prevailing party if the court finds that the appeal was frivolous, without merit, or an abuse of the appellate process, or that the agency action which precipitated the appeal was a gross abuse of the agency's discretion. Upon review of agency action that precipitates an appeal, if the court finds that the agency improperly rejected or modified findings of fact in a recommended order, the court shall award reasonable costs to a prevailing appellant for the administrative proceeding and the appellate proceeding.

National and Historical CON Perspective[14]

The basic assumption underlying CON regulation is that excess capacity (in the form of facility overbuilding) directly results in health care price inflation. When a hospital cannot fill its beds, fixed costs must be met through higher charges for the beds that are used. Bigger institutions have bigger costs, so CON supporters say it makes sense to limit facilities to building only enough capacity to meet actual needs.

In 1964, New York became the first state to enact a statute granting the state government power to determine whether there was a need for any new hospital or nursing home before it was approved for construction. Four years later the American Hospital Association (AHA) expressed an interest in CON laws. The AHA started a national campaign for states to generate their own CON laws. By 1975, 20 states had enacted CON laws; by 1978, 36 states had enacted them.

The 1974 federal "Health Planning Resources Development Act" required all 50 states to submit proposals and obtain approval from a state health planning agency before beginning any major capital projects such as building expansions or ordering new high-tech devices. Many states implemented CON programs, in part because of the incentive of federal funds.

The federal mandate was repealed in 1987, along with its federal funding. In the decade that followed, 14 states discontinued their CON programs. However, 36 states currently maintain some form of CON program, and even the 14 that repealed their state CON laws still retain some mechanisms intended to regulate costs and duplication of services. Puerto Rico and the District of Columbia also have CON programs.

States that have retained CON programs currently tend to concentrate activities on outpatient facilities and long-term care. This is largely due to the trend toward free-standing, physician owned facilities that constitute an increasing segment of the health-care market.

In some states, the debate regarding the future of CON remains intense. For example, Georgia spent 18 months examining the role of CON, with a final Commission report issued in December 2006.[15] The report stated, "The Commission has been able to reach consensus on a number of

[14] National Conference of State Legislatures, *Certificate of Need: State Health Laws and Programs* (updated November 2007), found at: <http://www.ncsl.org/programs/health/cert-need.htm> (Last visited on March 21, 2008).
[15] See *An Analysis and Evaluation of Certificate of Need Regulation in Georgia* by the State Commission on the Efficacy of the Certificate of Need Program online found at:

ways to improve upon Georgia's Certificate of Need Program. However, sharp disagreement remains with regard to a number of areas of regulation…." The Commission did not reach consensus on the regulation of general, short stay, acute care hospitals.[16]

The following provides a summary of arguments related to the retention or abolishment of CON provisions as published on the National Conference of State Legislatures' website.[17]

CON Supporters' Views

- Advocates of CON programs say that health care cannot be considered as a "typical" economic product. They argue that many "market forces" do not obey the same rules for health care services as they do for other products. In support of this argument, it is often pointed out that, since most health services (like an x-ray) are "ordered" for patients by physicians, patients do not "shop" for these services the way they do for other commodities. This makes hospital, lab and other services insensitive to market effects on price, and suggests a regulatory approach based on public interest.

- The American Health Planning Association (AHPA) is the professional group of state agencies responsible for regulation and planning. They identify three factors that suggest the need for CON programs. The primary argument is that CON programs limit health-care spending. CONs can promote appropriate competition while maintaining lower costs for treatment services. The AHPA argues that by controlling construction and purchasing, state governments can oversee what expenditures are necessary and where funds will be used most effectively. This helps eliminate projects that detract attention from more urgent and useful investments and reduces excessive costs. AHPA also asserts that CONs have a valuable impact on the quality of care. When facilities and equipment are monitored, hospitals and other treatment centers can acknowledge what sort of services are in demand and how effectively patients are being taken care of.

- Additionally, according to supporters, the programs distribute care to areas that could be ignored by new medical centers. CON programs are a resource for policymakers. CON regulations are described as a reliable way to implement basic planning policies and practices, and aid in distributing health care to all demographic areas. The CON process can call attention to areas in need because planners can track and evaluate the requests of hospitals, doctors and citizens and see which areas are underserved or need to be improved and developed.

CON Opponents' Views

- CON programs also have been subject to wide criticism. To start, it is not clear that these state-sponsored programs actually controlled health care costs. For example, by restricting new construction, CON programs may reduce price competition between facilities, and may actually keep prices high. Barriers to new building were seen as unfair restrictions, sometimes by both existing facilities and their potential new competitors. There is little

<http://dch.georgia.gov/vgn/images/portal/cit_1210/61/51/72484934FINAL_Georgia_CON_Commission_Report.pdf> (Last visited on March 21, 2008).

[16] *Ibid, at page ES-11.*

[17] *Supra* at 9.

direct broad proof that overcapacity or duplication leads to higher charges. In 2004, the Federal Trade Commission (FTC) and the Department of Justice both claimed that CON programs actually *contribute* to rising prices because they inhibit competitive markets that should be able to control the costs of care and guarantee quality and access to treatment and services.

- Some opponents felt that changes in the Medicare payment system (such as paying hospitals according to Diagnostic Related Groups – "DRGs") would make external regulatory controls unnecessary, because health care organizations would be more subject to market pressures. Some pointed out that the CON programs are not consistently administered. A 'flexible' program could allow development, to the dismay of competitors. A 'restrictive' program could limit competition, with the same effect. Many argued that health facility development should be left to the economics of each institution, in light of its own market analysis, rather than being subject to political influence.

- Some evidence suggests that lack of competition paradoxically *encouraged* construction and additional spending. Some opponents of CON programs believe an open health care market, based on quality rather than price, might be the best principle for containing rising costs. Proponents of CON programs disagree. This debate rests on the same arguments as many other "Regulated market" vs. "Open market" discussions.

- In theory, Certificates of Need are granted based on objective analysis of community need, rather than the economic self-interest of any single facility. However, opponents of CON programs claim that the programs have not worked this way. They cite examples in which CONs were apparently granted on the basis of political influence, institutional prestige or other factors apart from the interests of the community. Furthermore, it is sometimes a matter of debate what sort of development is actually in the community's interest, with people of good will sharply divided on how to determine this.

III. Effect of Proposed Changes:

Section 1. Amends s. 408.035, F.S., to revise the Agency's review criteria for a CON application related to a general hospital. The Agency must consider the following criteria when reviewing a CON application for a general hospital:

- The need for the hospital and the health services being proposed;
- The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant;
- The extent to which the proposed services will enhance access to health care for residents of the service district;
- The extent to which the proposal will foster competition that promotes quality and cost-effectiveness; and
- The applicant's past and proposed provisions of health care services to Medicaid patients and the medically indigent.

Section 2. Amends s. 408.037, F.S., to revise the required contents for a CON application for a general hospital. An application for a CON for a general hospital must contain:

- A detailed description of the proposed general hospital project;
- A statement of its purpose and need;
- Identification of the proposed project's location and its primary and secondary service areas must be identified by zip code; and
- A statement of intent, that if the CON application for the general hospital is approved, the licensure application will include, in addition to all other requirements for initial licensure as a hospital, the submission of:
  - A detailed financial projection, including a statement of the projected revenue and expenses for the first 2 years of operation after completion of the proposed project. This statement must include a detailed evaluation of the impact of the posed project on the cost of other services provided by the applicant, and
  - An audited financial statement of the applicant. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition document must include, but need not be limited to, a balance sheet and a profit –and-loss statement of the 2 previous fiscal years' operation.

Section 3. Amends s. 408.039, F.S., to:

- Prohibit an applicant with a pending CON application for a general hospital from submitting a letter of intent;
- Require the Agency to hold a public hearing upon the request of any applicant, substantially affected person or interested party. Currently the Agency has the discretion, based on its determination whether a proposed project involves issues of great local public interest, to hold a public hearing upon the request of an applicant or a substantially affected person;
- Limit the period of any continuance related to an administrative hearing for a CON application for a general hospital to four months after the original date of assignment to the administrative law judge; and
- Require a party appealing a final order that grants a general hospital CON to post a $1 million bond in order to maintain the appeal, and if the appealing party loses, to pay the appellee's attorney's fees and costs, up to $1 million. The attorney's fees and costs are calculated from the beginning of the original administrative action. The Agency may not be liable for any other party's attorney's fees and costs unless the court finds that the Agency improperly rejected or modified findings of fact in a recommended order or that the Agency's action which precipitated the appeal was a gross abuse of the Agency's discretion.

Section 4. Repeals s. 408.040, F.S., to delete the requirement for an architect's certification of final payment for a completed CON project that involves construction.

Section 5. Provides that the act will not apply to a CON project under review for which the Agency has not made an initial decision as of the effective date of the act.

Section 6. Provides that the act will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill provides interested parties an opportunity to request and participate in a public hearing in the CON review process. The limitation on the length of time for a continuance in an administrative hearing might reduce the timeframe for issuing a final order related to a CON application for a general hospital. In addition, the prerequisite of a $1 million bond in order to file an appeal for judicial review of a final order and the potential to pay up to $1 million in attorney's fees and costs if unsuccessful in the appeal, should minimize appeals motivated by the delay factor.

C. Government Sector Impact:

The Agency may have to conduct more public hearings in the review process of CONs. Litigation costs associated with contested CONs for general hospitals should be reduced.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

None.