HOUSE OF REPRESENTATIVES COMMITTEE ON HEALTH REGULATION ANALYSIS

- BILL #: HB 1693 (PCB HR 02-03)
- **RELATING TO:** Certificates of Need
- **SPONSOR(S):** Committee on Health Regulation, Representative Farkas and others.
- TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH REGULATION YEAS 7 NAYS 2
- (2)
- (3)
- (4)
- (5)

I. <u>SUMMARY</u>:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

Requirements for the Certificate of Need (CON) review process are set forth in Chapter 408, Florida Statutes. The CON review process is a regulatory program that requires health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services.

Currently, there are 19 statutorily defined exemptions to the CON review process. An exemption is not automatic under the current statutory language in s. 408.036(3) and (4), F.S. The applicant must request an exemption, and must support the request with documentation required by agency rule. Similar to the proposed committee bill, several of the current statutory exemptions contain provisions specifying limitations or other conditions that must be met by the applicant; and three of the exemptions specifically require the applicant to "certify" that it will meet specified conditions.

Over the past year, the Florida Legislature took into consideration the total repeal or reform of the Certificate of Need process, which created fervent debate among health care providers.

The Organ Transplant Task Force, created in Chapter 2001-167, Laws of Florida, reported that the CON process for organ transplant programs is ineffective, as it has existed. The task force recommended in its January 15, 2002, report that the CON regulation for adult kidney, pancreas, liver, heart, and lung programs be abolished, unless all the suggested changes are implemented.

The Interim Report of the CON Workgroup to the Florida Legislature states: "Although preliminary recommendations were made in the Interim Report of the CON Workgroup, the CON Workgroup recognizes the need to make recommendations about streamlining the CON process; recommendations related to a streamlined process will be a priority when the group reconvenes in 2002."

This bill, in effect, eliminates the need for a CON review process for facilities utilizing existing licensed bed capacity. Hospitals could build a new facility transferring existing beds to the new location, provide health services, long-term hospital care and tertiary care services excluding solid organ transplants with the approved application for an exemption from AHCA.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [x]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes [x]	No []	N/A []
4.	Personal Responsibility	Yes [x]	No []	N/A []
5.	Family Empowerment	Yes [x]	No []	N/A []

B. PRESENT SITUATION:

Over the past year, the Florida Legislature took into consideration the total repeal or reform of the Certificate of Need process, which created fervent debate among health care providers. Debate among the members of the 2001 Legislature primarily focused on two main concerns:

 If total deregulation of the CON review process occurred, that would allow for an open market, thereby creating a scenario for new providers to come into the area and cherry pick for services. Those new providers are apt to create boutique hospitals, performing only the more lucrative services, thereby leaving emergency and charity care for the existing hospitals to absorb.

Another important issue, was that:

By placing in licensing statute the rules for health service programs, it did not allow for any
flexibility in regulating health services programs to advance with the corresponding
advancement of medical technology. For example, by specifying equipment types in
statutes, that may be state-of-the-art today, two years from now, industry standards may be
replaced with less invasive technology, making statutory requirements obsolete compared to
industry standards.

The 2001 Legislative session ended without any notable changes to the CON review process. However, the 2001 Legislature did create Chapter 2001-167, Laws of Florida (CS/SB 684) directing the Agency for Health Care Administration to create a 15-member Organ Transplant Task Force. The summarized purpose of the task force was to study organ transplant programs and to make recommendations to the Governor and Legislature regarding: 1) the need to issue certificates of need (CON) for transplant programs; and 2) funding for organ transplants. A report was submitted by the task force to the Governor and the Legislature, January 15, 2002.

The Task Force reported that the CON process for organ transplant programs is ineffective, as it has existed. The task force recommended that:

• The CON regulation for adult kidney, pancreas, liver, heart, and lung programs be abolished unless all the suggested changes are implemented; and

• The CON process be maintained for pediatric patients and the changes recommended for the adult programs be implemented for pediatric kidney, pancreas, liver, heart and lung programs.

Section 15 of Chapter 2000-318, Laws of Florida (CS/CS/HB 591), created a 30-member certificateof-need workgroup staffed by the Agency for Health Care Administration. The Legislature specified that the workgroup study issues pertaining to the certificate-of-need program, including the impact of trends in health care delivery and financing. In addition, the workgroup was charged with studying issues relating to implementation of the certificate-of-need program and was required to report to the Legislature with an interim report by December 31, 2001, with a final report by December 31, 2002. The workgroup is set to be abolished effective July 1, 2003. The recommendations for hospitals include:

- Hospitals operating at 80% acute care occupancy over the most recent 12 month period, or hospital having 90% occupancy for any 3 consecutive months, will be exempt from CON review for the greater of 10% of their licensed capacity or 30 beds.
- Tertiary services will continue to be subject to CON.
- All tertiary services subject to CON review should be defined in statute. In addition to tertiary services that are currently included in statute, NICU Level II beds and adult open heart programs should be included.
- Providers of tertiary services will cooperate with the State in the development of outcome and quality measures.
- Criteria for new tertiary services will be more detailed.
- A medical advisory group should be established to determine which existing services and what new emerging services should be classified as tertiary.
- AHCA is to be directed to redefine the measures of hospital occupancy.
- Providers of NICU Level III services will be allowed to shift their capacity between their Level III unit and their Level II unit, subject to providing appropriate staffing.
- Projects now subject to expedited review (other than replacement hospitals and conversion of mental health beds to general acute beds) will now be exempt.
- The Certificate of Need Task Force should be allowed to continue its work through 2002 to address in more detail tertiary services, transplantation and new technology.
- All providers of invasive services, to at least include diagnostic catheterization and outpatient surgery, regardless of setting, will report utilization data to the State of Florida.

As stated in the recommendations of the CON Interim report, "The CON Workgroup recognizes the need to make recommendations about streamlining the CON process. Recommendations related to a streamlined process will be a priority when the group reconvenes in 2002."

Currently, there are 19 statutorily defined exemptions to the CON review process. An exemption is not automatic under the current statutory language in s. 408.036(3) and (4), F.S. The applicant must request an exemption, and must support the request with documentation required by agency rule. Similar to the proposed committee bill, several of the current statutory exemptions contain provisions specifying limitations or other conditions that must be met by the applicant; and three of the exemptions specifically require the applicant to "certify" that it will meet specified conditions.

Requirements for the Certificate of Need (CON) review process are set forth in Chapter 408, Florida Statutes. The CON review process is a regulatory program that requires health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services.

Terminology specific to exemptions created in this bill include:

- Acute Care Hospital Bed, A patient accommodation or space in a hospital licensed by the agency pursuant to Chapter 395, F.S. Acute care hospital beds exclude neonatal intensive care beds, comprehensive medical rehabilitation beds, hospital inpatient psychiatric beds, hospital inpatient substance abuse beds, beds in distinct-part skilled nursing units, and beds in long term care hospitals. All other inpatient beds enumerated on a hospital's license issued under Chapter 395, F.S., are acute care hospital beds subject to the provisions of AHCA rule.
- As defined in sections 409.2663(2) and 409.911(1), F.S., *charity care* is that portion of hospital charges for which there is no compensation for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 150 percent of the current Federal Poverty Guidelines (FPG), as published in the Federal Register; or for which there is no compensation for care provided to a patient whose family income for the 12 months preceding the determination is greater than 150 percent of the current FPG but not more than four times the current FPG for a family of four and the amount of hospital charges due from the patient exceeds 25 percent of the 12-month family income. *Charity care* does not include bad debt, which is the portion of health care provider charges for which there is no compensation for care provided to a patient who fails to qualify for charity care; and does not include administrative or courtesy discounts, contractual allowances to third-party payors, or failure of the hospital to collect full charges due to partial payment by government programs.
- By rule and statute, *Tertiary health service*, means 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, organ transplantation, specialty burn units, 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. The types of tertiary services to be regulated under the Certificate of Need Program not listed in statute, but instead. AHCA [within their statutory authority] develops the list of services, which include: heart transplantation; kidney transplantation; liver transplantation; bone marrow transplantation; lung transplantation; pancreas and islet cells transplantation; heart/lung transplantation; adult open heart surgery; Neonatal and pediatric cardiac and vascular surgery; and Pediatric oncology and hematology. Furthermore, by rule, AHCA is authorized to determine whether services should be added or deleted to this list of tertiary care services, the listing is reviewed annually by the agency.
- Neonatal Care Services. The aspect of perinatal medicine pertaining to the care of neonates. Hospital units providing neonatal care are classified according to the intensity and specialization of the care that can be provided. The agency distinguishes three levels of neonatal care services: Level I, Level II and Level III.
- Burn Unit. A burn unit is a discrete unit within a hospital that occupies designated physical space separate from other areas of the hospital. A burn unit shall have a minimum of five dedicated burn beds and shall be equipped and staffed to provide specialized care solely for severely burned persons.
- Bone Marrow Transplantation. Human blood precursor cells, stem cells, administered to a patient to restore normal hematological and immunological functions following ablative

therapy with curative intent. Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood. If chemotherapy is an integral part of the treatment involving bone marrow transplantation, the term "bone marrow transplantation" includes both the transplantation and the chemotherapy. (Section 627.4236(1), Florida Statutes).

- Transplantation Program. The offering of surgical services by a hospital through which one or more types of organ transplants are provided to one or more patients; and the offering of some or all phases of bone marrow transplantation. Organ transplants are defined as organs as used in rule include heart, kidney, liver, bone marrow, lung, heart and lung, pancreas and islet cells, and intestines.
- Open Heart Surgery Program. A program established in a room or suite of rooms in a hospital, equipped for open heart surgery operations and staffed with qualified surgical teams and support staff. Rule 59C-1.033, Florida Administrative Code, defines Open Heart Surgery Operation as surgery assisted by a heart-lung by-pass machine that is used to treat conditions such as congenital heart defects, heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma.

Under current rules of ACHA, specifications for open heart surgery programs require that in order to establish an adult or pediatric open heart surgery program, a health facility must show specified minimum requirements for staffing and equipment; and it specifies a **methodology for determining the numeric need for a new program.** A certificate of need for the establishment of an open heart surgery program shall not normally be approved unless the applicant meets the applicable review criteria in section 408.035, F.S., and the standards and need determination criteria set forth by rule. Rule 59C-1.33. F.A.C., Open Heart Surgery Program, **effective January 24, 2002 states:**

An additional open heart surgery program shall not normally be approved in the district if any of the following conditions exist:

- There is an approved adult open heart surgery program in the district;
- One or more of the operational adult open heart surgery programs in the district that were operational for at least 12 months as of 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than 300 adult open heart surgery operations during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool; or,
- One or more of the adult open heart surgery programs in the district that were operational for less than 12 months during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than an average of 25 adult open heart surgery operations per month.

The Administrative Hearing Procedures for the CON review process are defined by Rule 59C-1.012, F.A.C., and are conducted pursuant to the timeframes and conditions specified in s. 408.039(5), F.S.

 A request for an administrative hearing is filed with the agency within 21 days after publication of the Notice of Intent in the Florida Administrative Weekly by the agency. The failure of a noticed intended denied applicant to timely file a proper request for administrative hearing challenging the denial of its application shall result in the denial becoming final agency action with respect to such applicant, and the application being severed from the remainder of the batch.

- If a valid request for administrative hearing is timely filed challenging the noticed intended award of any certificate of need application in the batch, that challenged granted applicant shall have ten days from the date the notice of litigation is published in the Florida Administrative Weekly to file a petition challenging any or all other co-batched applications.
- If no valid request for administrative hearing is timely filed challenging the noticed intended award of a certificate of need to an applicant, there is no pending challenge to the applicable published fixed need pool projection, and there has been no petition filed pursuant to sub-paragraph (2)(a), the noticed intended granted application shall be severed from the rest of the batch and become final agency action with respect to such application. If there are pending challenges to the applicable published fixed need pool projection, no noticed intended granted application can be severed from the batch and become final agency action, unless the application is withdrawn.
- If all requests for administrative hearings challenging a noticed intended award of a CON, and all challenges to the relevant published fixed need pool projection, if any, are subsequently voluntarily dismissed, the unchallenged noticed intended granted application shall be severed from the remainder of the batch and the noticed intended award shall become final agency action with respect to such applicant. If there remain any pending challenges to the applicable published fixed need pool projection, no noticed intended granted application can be severed from the batch and become final agency action, unless the application is withdrawn.
- For purposes of comparative hearing on any remaining applications in the batch, the beds or services awarded to unchallenged noticed intended granted applications in the batch which have become final agency action shall automatically be subtracted from the unchallenged numeric fixed need pool projection applicable to the batch, even if the projection is zero, and it shall be conclusively presumed that the award of beds or services in the batch which have become final agency action will become operative in the service area in accordance with the representations contained in the certificate of need application leading to approval.

The difficulties encountered in this process are best described by Martin Memorial Hospital, in a situation where a CON was granted by AHCA for an adult open heart surgery program in 1985. Although the Agency approved the CON application, this issue has been tied up in litigation since the original approval and 17 years later; the hospital still does not have an operating open heart surgery program.

Hospital Licensure

Chapter 395, F.S., provides for the licensing requirements of hospitals and other licensed health facilities. A hospital is defined as offering services more intensive than those required for room, board, personal services and general nursing care. Hospital services include beds offered for use beyond 24 hours by individuals requiring medical, surgical, or psychiatric testing and diagnosis; and treatment for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy. Other recognized hospital services include: clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

Unaccredited facilities and initial licenses require a certification and/or licensing survey. Currently, under state and federal regulations, accredited hospitals are "deemed" to meet the requirements and do not receive an annual license and certification survey. Life-Safety and Risk Management

surveys are conducted annually. In addition, each hospital must be surveyed for certification as directed by the Centers of Medicare and Medicaid Services (a federal agency) to receive Medicare reimbursement.

In ordered to be licensed by ACHA, facilities must meet federal and state licensing requirements, submit a completed application, required documentation and have a satisfactory survey completed. Renewal applications must be submitted every two years, 90 days in advance of expiration of a license. The initial and renewal fee is \$1,500 or \$30 per bed, whichever is greater. The survey/inspection fee is \$400 or \$12 per bed, whichever is greater. The life safety inspection fee is \$40 or \$1.50 per bed, whichever is greater.

Currently, there are 271 hospitals licensed in Florida; 263 are Medicare certified, and 234 are accredited. As required by Rule 59A-3.202, Florida Administrative Code, hospitals are licensed by the following classification:

- (1) Class I are general hospitals which include: general acute care hospitals with an average length of stay of 25 days or less for all beds; long term care hospitals, which meet the provisions of Rule 59A-3.201(31), Florida Administrative Code; and rural hospitals designated under Chapter 395, Part III, Florida Statutes.
- (2) Class II are specialty hospitals offering the same range of medical services offered by general hospitals, but restricted to a defined age or gender group of a population which includes; specialty hospitals for children; and specialty hospitals for women.
- (3) Class III are specialty hospitals offering a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders. Class III facilities include: specialty medical hospitals; specialty rehabilitation hospitals; specialty psychiatric hospitals, which may include beds licensed to offer intensive residential treatment programs; specialty substance abuse hospitals, which may include beds licensed to offer intensive residential treatment programs.
- (4) Class IV is specialty hospitals restricted to offering intensive residential treatment programs for children and adolescents, pursuant to section 395.002(16), Florida Statutes.

According to Rule 59A-3.203, F.A.C., a person or governmental unit proposing to establish, conduct, or maintain a hospital in this state, must first obtain a license. All persons requesting licensure for the operation of a hospital under the provisions of Chapter 395, Florida Statutes, must make application to the agency and must receive a regular or provisional license prior to the acceptance of patients for care or treatment. The following documents must accompany the <u>initial application</u>: the hospital's zoning certificate; articles of incorporation; registration of a fictitious name; the name and address of the ultimate owner of the hospital; a valid certificate of need or letter of exemption as required by s. 408.031 through 408.045, F.S. As well as, approval for licensure from the agency's Office of Plans and Construction; and evidence of medical malpractice insurance through the Patient Compensation Fund or other means of demonstrating financial responsibility as provided for under Chapter 766, Florida Statutes.

An application for <u>biennial licensure renewal</u> must be accompanied by evidence of medical malpractice insurance through the Patient Compensation Fund or other means of demonstrating financial responsibility as provided for under Chapter 766, Florida Statutes. In lieu of an agency licensure inspection, a copy of the hospital's most recent accreditation report may be submitted, if

the hospital is accredited by an accrediting organization and has evidence of accreditation. Each license shall specifically state the name of the licensed operator of the hospital, and the class of hospital. A license, unless suspended or revoked, automatically expires two years from date of issuance, and is renewable biennially upon application for renewal and payment of the fee prescribed, provided that the applicant and hospital meet the requirements established under the Chapter 395, Part I, F.S., and Rules 59A-3.077–3.093 and 59A-3.200–3.232, F.A.C. Application for renewal of license shall be made not less than 90 days before expiration of a license.

AHCA also issues a provisional license for any hospital in substantial compliance with the statute and Rules 59A-3.077–3.093 and 59A-3.200–3.232 or 59A-3.100–3.111, F.A.C. Provisional licenses are issued only after AHCA is satisfied that preparations are being made by the hospital to qualify for regular license, and that the health and safety of patients will not be endangered during the interim. Any new hospital will be issued a provisional license before opening date, provided plans, specifications for the building have been approved by the licensing agency, and the hospital has been surveyed and found to meet construction standards and health and safety surveys. A provisional license may be granted for a period of no more than one (1) year and expires automatically at the end of its term. A provisional license may not be renewed.

A regular license may be issued after the proposed hospital becomes operational and after the completion of a resurvey to determine compliance with rules. Florida Department of Law Enforcement, FBI fingerprinting, and Abuse Registry screening must be completed on the administrator/chief executive officer prior to the facility being licensed.

C. EFFECT OF PROPOSED CHANGES:

This bill addresses the concerns raised in the 2001 Legislative Session that concluded that the total deregulation of the CON review process would open the market to new providers. Thereby placing existing providers at financial risk; and that placing strict licensure requirements in statute would limit the effectiveness of regulation due to the fact that requirements may or may not keep up with the fast pace of changing medical technology.

The bill creates an exemption for the CON review process for only existing facilities. New providers will continue to be subject to the CON review process. In effect, the bill eliminates the CON review process for facilities utilizing existing licensed bed capacity for new and expanded services. A hospital Organization could build a new facility, transferring existing beds to the new location, provide health services, long-term hospital care and tertiary services excluding solid organ transplant services with the approved application for exemption from AHCA.

Permissive rule-making authority is given to AHCA in developing requirements for licensure. Rules shall be developed that will provide:

- Only the services covered in the exemption will be preformed;
- Hospitals will maintain sufficient and appropriate equipment and staffing levels;
- Maintain times and operation for emergencies;
- Provide at a minimum of 10% of its services to charity and Medicaid patients each year; and
- For the first time, establish quality outcome measures for care; and as a base-line for rule making authority, these standards will be at least the 50th percentile of national and state standards.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends subsection (3) of s. 408.036, F.S., creating paragraph (t), providing an exemption to the CON review process for providers that offer health services, long-term care hospitals services, new construction, or tertiary health services excluding solid organ transplant services, by an existing hospital provided that the hospital does not exceed the current licensed bed capacity for that facility. The hospital may offer services, utilizing existing bed capacity within the hospital's respective health planning district.

The Agency for Health Care Administration is authorized to develop rules requiring licensure requirements for the services exempted from the CON review process. The Rules are to include that the facility maintain sufficient staff, maintain appropriate referrals in the event of an emergency, provide 10% of services to charity and Medicaid patients, and to develop quality outcome measures that must be at least at the 50th percentile of national and state standards for care. In the event the facility fails to meet the required provisions of licensure, the facility will have an opportunity to correct any deficiencies before the expiration of the granted exemption.

If the exemption for a program expires, the Agency may not grant another exemption for a program in the same facility until 2 years following the date of the determination.

Section 2. Provides an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

- A. FISCAL IMPACT ON STATE GOVERNMENT:
 - 1. <u>Revenues</u>:

Indeterminate at the time of publication.

2. Expenditures:

Indeterminate at the time of publication.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. <u>Revenues</u>:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals meeting the requirements of providing 10% of services to Medicaid and Charity patients would no longer be required to apply for a CON for hospital services, long-term care hospital services, tertiary services excluding solid organ transplants, thereby eliminating the CON application fees (statutorily defined fee based at a minimum of \$5,000 and which is capped at \$22,000), any related cost of preparing the applications, and possible legal cost if the agency's

action is challenged. It is unknown whether the agency's grant of an exemption would result in a legal challenge from a competing hospital.

According to AHCA, if new programs take patients away from the existing programs, and if exemptions would authorize more programs than the amended current review requirements, then the annual revenue from lucrative programs could be reduced at existing facilities.

D. FISCAL COMMENTS:

AHCA anticipates a reduction in CON application reviews for services that were previously subject to CON review. There may be a need to reduce staff or expenses in relation to the reduced volume of activity of CON reviews. However, there would be an increase in exemption reviews and it is unclear weather or not the decrease in CON reviews will provide for greater activity of exemption review.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. <u>COMMENTS</u>:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

This bill gives AHCA the authority to promulgate rules for the exemption of services.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On January 30, 2002, the Committee reported the PCB out favorably.

VII. <u>SIGNATURES</u>:

COMMITTEE ON HEALTH REGULATION:

Prepared by:

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