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HOUSE OF REPRESENTATIVES

COUNCIL FOR HEALTHY COMMUNITIES ANALYSIS

BILL #: CS/HB 771

RELATING TO: Certificate of Need/Open Heart Surgery

SPONSORS: Committee on Health Regulation and Representative Rubio

TIED BILL(S): None.

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

(1) HEALTH REGULATION YEAS 7 NAYS 4
(2) COUNCIL FOR HEALTHY COMMUNITIES YEAS 13 NAYS 0
(3)
(4)
(5)

I. SUMMARY:

CS/HB 771 creates legislative intent, specifying that the Legislature finds that it is difficult for the health care industry to be a competitive marketplace, when health regulations deter entrepreneurial market concepts that would allow the health care industry to independently develop ways in which to deliver quality health come outcomes in a more reasonable cost effective manner. The Legislature intents to provide a more competitive environment within the health care industry while supporting the development of cutting edge medical technology, thereby maintaining access to quality health care services for all citizens.

CS/HB 771 further amends section 408.036, F.S., to allow for an exception to the Certificate of Need (CON) review process for health facilities proposing to provide an open heart surgery program. The exemption is similar to the exemption statutorily created for diagnostic cardiac catheterization programs.

In addition, CS/HB 771 amends Section 15 of chapter 2000-318, Laws of Florida, to change the effective date of the CON workgroup's final report to the Governor and Legislature to January 7, 2002, and abolishes the work group effective May 3, 2002.

The Agency for Health Care Administration has not provided the requested fiscal information.

Provides for an effective date of July 1, 2001.

There is a strike all amendment traveling with this bill, please see the amendment section of this analysis for changes made by amendment.

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 []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

B. PRESENT SITUATION:

Many local industry proponents argue that fees associated with the CON review process are exorbitant and prohibitive in a competitive marketplace. Beginning with the letter of intent required by the Agency for Health Care Administration prior to the submission of an application, health care facilities routinely hire health planners, certified public accounts, and consultants. The CON application is reviewed in a batch cycle process, and once the Agency has made a determination, both competitive health care facilities and the actual applicant can challenge the outcome of the CON review process. Industry representatives argue that the majority of application determinations challenged in the Administrative Hearing process is too lengthy. After the submission of a formal challenge, the case is assigned a hearing officer with a scheduled hearing date, which may be months into the future. After the hearing process, each party involved in the case proposes a recommended order to the Administrative Law Judge. After careful consideration, the Administrative Law Judge then issues a recommended order to the Agency; all parties have a right to file an exception to the recommended order. Subsequently, the Agency issues a final order, and again all parties involved have the right to appeal the final order with the regional District Court of Appeals. The appellate process is lengthy, costly and time consuming to the applicant and the Agency.

Opponents to CON deregulation argue that by increasing the number of facilities that provide open heart surgery, the actual volume of surgery done in one locale will diminish. In addition, they argue that the higher volume of operations completed, the better a patient's chance of survival. However, one must consider the fact that it is not the hospital performing the open heart surgery, but the doctor. Furthermore, in larger facilities performing hundred of operations, it is likely that more than one physician is performing surgery. According to the *New England Journal of Medicine*, May 2000, "**…unlike the outcome of pharmacologic therapies, the outcome of invasive cardiac procedures depends on individual expertise... Also, the outcome for patients with myocardial infarction (heart attack) may be dependent on the early use of adjunctive medications…It is possible that hospitals treating large numbers of patients with myocardial infarction have superior outcomes simply because accepted therapies are administered more frequently or more quickly than at hospitals with smaller numbers of such patients."** The survival of open heart surgery greatly depends on the successful orchestration of many ancillary services, not just the open heart surgical procedure. It is believed that facilities performing larger volumes of open heart surgery may have better pre-operative and postoperative care that greatly contributes to increased patient survival.

The laws relating to the issuance of a certificate of need (CON) to health facilities are found in Chapter 408, Florida Statutes. The Certificate of Need review program is a regulatory process that

requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. For example, a certificate of need is required if a hospital requests to initiate tertiary health services.

Rule 59C-1.037, Florida Administrative Code, 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. By rule, examples include, but are not limited to: transplantation; adult **open heart surgery;** neonatal and pediatric cardiac and vascular surgery; and pediatric oncology and hematology services.

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. One open heart surgery operation equals one patient admission to the operating room. The code cites specific open heart surgery operations classified under diagnostic related groups (DRGs).

CON Review Process for Open Heart Surgery Program

Under current rules of ACHA, effective August 24, 1993, 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. Hospitals operating more than one hospital on separate premises under a single license shall obtain a separate certificate of need for the establishment of open heart surgery services in each facility. Separate certificates of need are required for the establishment of an adult or a pediatric open heart surgery program. Regardless of whether need for a new adult open heart surgery program is shown, a new adult open heart surgery program will not normally be approved for a district if the approval would reduce the 12 month total at an existing adult open heart surgery program in the district below 350 open heart surgery operations. In determining whether this condition applies, the agency will calculate (Uc X Px)/(OP + 1), **(see narrative: Need Methodology).** If the result is less than 350, no additional open heart surgery program shall normally be approved.

In determining the need for a new program, consideration is given to the following:

- 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 350 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 29 adult open heart surgery operations per month.

The Agency reviews CON applications submitted by health facilities wanting to establish an open heart surgery program and considers several factors: service availability; service accessibility; and service quality.

- **Service Availability:** Each adult or pediatric open heart surgery program must have the capability to provide a full range of open heart surgery operations, including, at a minimum: repair or replacement of heart valves; repair of congenital heart defects; cardiac revascularization; repair or reconstruction of intrathoracic vessels; and treatment of cardiac trauma. Each adult or pediatric open heart surgery program must document its ability to implement and apply circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary partial bypass. A health care facility with an adult or pediatric open heart surgery program is required to provide the following services: cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases; pathology, including anatomical, clinical, blood bank, and coagulation laboratory services; anesthesiology, including respiratory therapy; radiology, including diagnostic nuclear medicine; neurology; inpatient cardiac catheterization; non-invasive cardio graphics, including electro-cardiography, exercise stress testing, and echocardiography; intensive care; and emergency care available 24 hours per day for cardiac emergencies.
- **Service Accessibility:** Open heart surgery programs shall be available within a maximum **automobile travel time of 2 hours under average travel** conditions for at least 90 percent of the district's population; and are required to be available for elective open heart operations 8 hours per day, 5 days a week. Each open heart surgery program shall possess the capability for rapid mobilization of the surgical and medical support teams for emergency cases 24 hours per day, 7 days a week and emergency open heart surgery operations available within a maximum waiting period of 2 hours. All open heart procedures are required by rule to be available to all persons in need. A patient's eligibility for open heart surgery shall be independent of his or her ability to pay. Applicants for adult or pediatric open heart surgery programs shall document the manner in which they will meet this requirement. Adult open heart surgery shall be available in each district to Medicare, Medicaid, and indigent patients.
- **Service Quality:** Any institution proposing to provide adult or pediatric open heart surgery must meet the Joint Commission on Accreditation of Healthcare Organizations accreditation standards for special care units or standards for accreditation by the American Osteopathic Association. Also, any applicant proposing to establish an adult or pediatric open heart surgery program must document that adequate numbers of properly trained personnel will be available to perform in the following capacities during open heart surgery: a cardiovascular surgeon, board-certified by the American Board of Thoracic Surgery, or board-eligible; a physician to assist the operating surgeon; a board-certified or board-eligible anesthesiologist trained in open heart surgery; a registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties; and perfusionist to perform extracorporeal perfusion, or a physician or a specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.
- **Follow-up Care:** Following an open heart surgery operation, patients shall be cared for in an intensive care unit that provides 24 hour nursing coverage with at least one registered nurse for every two patients during the first hours of post-operative care for both adult and pediatric cases. There shall be at least two cardiac surgeons on the staff of a hospital with an adult open heart surgery program, at least one of whom is board-certified and the other at least board-eligible. One of these surgeons must be on call at all times. A clinical cardiologist must be available for consultation to the surgical team and responsible for the medical management of patients as well as the selection of suitable candidates for surgery along with the cardiovascular surgical team. Backup personnel in cardiology, anesthesiology, pathology, thoracic surgery and radiology shall be on call in case of an

emergency. Twenty-four hour per day coverage must be arranged for the operation of the cardiopulmonary bypass pump. All members of the team caring for cardiovascular surgical patients must be proficient in cardiopulmonary resuscitation.

- **Patient Charges:** Charges for open heart surgery operations in a hospital shall be comparable with the charges established by similar institutions in the service area, when patient mix, reimbursement methods, cost accounting methods, labor market differences and other extenuating factors are taken into account.

NEED METHODOLOGY

The Agency for Health Care Administration determines the need for establishing new open heart surgery programs twice a year. Existing open heart surgery providers are not reviewed under this methodology if they intend to add an additional open heart surgery suite unless the capital expenditure exceeds the CON threshold. The provider must notify and obtain authorization from the Agency.

Methodology for determining the numeric need for an adult open heart surgery program

NN = ((Uc x Px) / 350) - OP

NN = the need for one additional open heart surgery program in the district for the applicable planning horizon. One additional program may be approved when NN is equal to 0.5 or greater.

Uc = the actual use rate calculated by taking the number of adult open heart surgery operations performed in the district during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool divided by the population age 15 and over.

Px = the projected population age 15 and over in the district for the applicable planning horizon.

OP = the number of operational adult open heart surgery programs in the district

Regardless of whether need for one new adult open heart surgery program is shown, one new adult open heart surgery program is not normally approved for a district if the approval would **reduce** the 12 month total in an existing adult open heart surgery program within the district below the standard **threshold of 350 open heart surgery operations.** To determine if this condition applies, the Agency will calculate **(Uc x Px) / (OP + 1).** If the result is less than 350, no additional open-heart surgery program shall normally be approved.

Certain health planning districts raising concern about the accessibility of open heart surgery purports that the **2 hour travel time** that some patients experience when an open heart program is not available in their county is limiting access to care for local patients. In addition, they argue that traveling such distances is a hardship on the patient and their family, and may result in the patient losing contact with their local physician.

The Auditor General's Report, November 2000, The *Certificate of Need and Public Medical Assistance Assessments Programs, Agency for Health Care Administration, Operational Audit* reports that "ACHA had not diligently pursued the receipt of required reports, thereby limiting management's ability to timely evaluate: (1) whether providers adhered to the service conditions stipulated on issued Certificates of Need and related statutorily mandated fines should be imposed;

and (2) whether project costs were within the budgets set forth in the applications for the Certificate of Need."

CON Work Group

Section 15 of Chapter 2000-318, Laws of Florida (CS/CS/HB 591), created a **30-member certificate-of-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 required that workgroup report back to the Legislature with an interim report by December 31, 2001, and a final report by December 31, 2002. The workgroup is set to be abolished effective July 1, 2003. The workgroup has yet to meet.

In 2000, the Florida Legislature established the Florida Commission on Excellence in Health Care to facilitate the development of a comprehensive statewide strategy for improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement. As it relates to the CON process, the Commission recommended that "**the legislature should retain certificate of need regulations until after such time as systems for reporting useful clinical outcome data allowing consumers to analyze and choose between existing health care practitioners and providers are implemented.**"

C. EFFECT OF PROPOSED CHANGES:

CS/HB 771 creates legislative intent, specifying that the "…Legislature finds it is difficult for the health care industry to be a competitive market, when health regulations deter entrepreneurial market concepts that would allow the health care industry to independently develop ways in which to deliver quality health come outcomes in a more reasonable cost effective manner….It is therefore the intent of the Legislature to provide a more competitive environment within the health care industry while supporting the development of cutting edge medical technology, thereby maintaining access to quality health care services for all citizens." The legislative intent sends a strong message to health consumer groups and health providers that the rising health care costs are of great concern to the state, and that the health care industry needs to become more competitive while improving quality care outcomes for patients.

CS/HB 771 further amends section 408.036, F.S., to allow for an exception to the CON review process for health facilities purposing to provide an open heart surgery program. The exemption is similar to the exemption created for diagnostic cardiac catheterization programs. It is anticipated that by reducing the requirement for a CON for purposed open heart surgery programs, costs associated with litigation concerning Agency action on the final recommended order of the CON will be greatly reduced. As well, with the exemption created for open heart surgery programs, it is anticipated that additional facilities will offer this program in areas that are currently underserved.

In addition, CS/HB 771 amends Section 15 of chapter 2000-318, Laws of Florida, to change the effective date of the CON workgroup final report to the Governor and Legislature to January 7, 2002, and abolishes the work group effective May 3, 2002. Both proponents and opponents of CON deregulation have requested that an in-depth review of the CON process occur, prior to making any changes to the system. It is expected that the CON workgroup will have final recommendations to the Legislature before the legislative session begins in 2002 and it is assumed the Legislature will take into consideration the recommendations.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends section 408.036, F.S., creating a new subsection (1) providing legislative intent to provide a more competitive environment within the health care industry.

Creates a new paragraph (r) of section 408.036, F.S., providing an additional exemption to include open heart surgery from the CON regulatory process. Authorizes the Agency for Health Care Administration to adopt more stringent licensing rules for open heart surgery programs, ensuring that minimum service volumes are maintained; that the facility commit to provide at least 2 percent of its services to charity and Medicaid patients; and maintain sufficient appropriate equipment and specialty staff. The bill also authorizes the Agency to adopt rules allowing the exemption to expire if the facility fails to meet licensure requirements.

Creates a new subsection (6) section 408.036, F.S., a Grandfather Clause; authorizing facilities currently providing open heart surgery prior to the effective date of this act to continue to provide said services.

Sections 2-3. Amend sections 408.0361 and 408.039, F.S., to correct cross-references.

Section 4. Amends Section 15 of Chapter 2000-318, Laws of Florida, stipulating that the CON Task Force report to the Governor, President of the Senate, and the Speaker of the House by January 7, 2002, and abolishes the CON Task Force May 3, 2002.

Section 5. Provides for an effective date of July 1, 2001.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Agency for Health Care Administration has not provided the requested fiscal information.

2. Expenditures:

The Agency for Health Care Administration has not provided the requested fiscal information.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Counties currently without an open heart surgery program may experience a decrease in costs associated with transporting indigent patients to another county for treatment.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health facilities wanting to establish an open heart program will not be constrained by costs of litigation concerning the CON application process, and therefore will see a direct reduction in cost in establishing such a program. The bill eliminates up to $22,000 per health care facility for CON

application fee for an open heart surgery program. The bill will also eliminate consulting fees and any attorney fees associated with the approval of an application for Certificate of Need for open heart surgery programs. The actual dollar amount that will potentially be saved by health care facilities cannot be determined at this time.

D. FISCAL COMMENTS:

None.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require a municipality or county to expend funds or 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 state tax shared with municipalities or counties.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

The bill gives the Agency for Health Care Administration explicit authority for rulemaking.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

The original HB 771 effectively repealed the Certificate of Need (CON) review process thereby eliminating the regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. The bill codified existing agency rules for the CON review process as licensure requirements for hospitals, nursing homes, and hospices without the determination of need portion of such rules for tertiary health services. On March 15, 2001, the Committee on Health Regulation adopted a “strike everything amendment” to provide an exemption to the CON process for health facilities purposing to provide an open heart surgery program. The exemption is similar to the exemption created for diagnostic cardiac catheterization programs.

In addition, CS/HB 771 changes the effective date of the CON workgroup’s final report to the Governor and Legislature to January 7, 2002, and abolishes the work group effective May 3, 2002.

On April 4, 2001, the Council for Healthy Communities considered CS/HB 771. Representative Farkas offered a strike all amendment that amends Section 15 of Chapter 2000-318, Laws of Florida, by increasing the CON workgroup staffed by the Agency for Health Care Administration by one Senate member and one House member. The workgroup is required to report to the Governor and Legislature by January 7, 2002 and the workgroup is abolished effective May 3, 2002. In addition, the scope of responsibility is more clearly defined, requesting that the workgroup propose recommendations for the reform or elimination of the CON review process. The amendment also provides directive language to the Agency for rulemaking.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
Lisa Rawlins Maurer, Legislative Analyst	Lucretia Shaw Collins

AS REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by:	Council Director:
Lisa Rawlins Maurer, Legislative Analyst	Mary Pat Moore, Council Director