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HOUSE OF REPRESENTATIVES
AS FURTHER REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES
ANALYSIS

BILL #: CS/HB 339

RELATING TO: Certificate of Need/Open Heart Surgery

SPONSOR(S): Committee on Local Government & Veterans Affairs, Representative Mayfield and others

TIED BILL(S): None.

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

(1) HEALTH REGULATION YEAS 7 NAYS 3
(2) LOCAL GOVERNMENT & VETERANS AFFAIRS YEAS 9 NAYS 0
(3) COUNCIL FOR HEALTHY COMMUNITIES YEAS 8 NAYS 6
(4)
(5)

I. SUMMARY:

The current Certificate of Need (CON) regulatory process requires that health facilities obtain approval from the Agency of Health Care Administration (AHCA) before offering tertiary health services. **The definition of tertiary health services include open heart surgery programs by ACHA's administrative rule.**

AHCA determines need for the expansion of tertiary health services by a health planning district. Health planning districts are comprised of more than one county, with the exception of District 10: Broward County. Current CON rule 59C-1.033, F.A.C., contains a formula for projecting the need for additional open heart surgery programs in each of the agency's 11 districts. The projections are for the district as a whole, and there is no language authorizing county-specific need projections within the districts.

In December 2000, the agency published a proposed amendment to the rule which, among other things, would show need for an open heart surgery program in any county where there is no current program, and where there is a projected annual total of at least 1200 residents discharged from a hospital with the primary diagnosis of ischemic heart disease. The county specific need would exist independent of and in addition to any district-wide need. In addition, the **proposed rule change will reduce the volume standard for open heart procedures from 350 to 250 annually.** The proposed rule amendment has been challenged, and is presently scheduled for an administrative hearing in March. As well, HB 339 may affect the 22 pending litigated cases between Health Care Facilities and the Agency for Health Care Administration regarding challenges to a final recommended order for a CON application to provide an open heart surgery program.

CS/HB 339 establishes additional parameters for the determination of need in the CON application review process for health care facilities; **it does not alter the standards of care established by rule**. Health facilities applying for a CON to provide open heart surgery programs are still **required to meet or exceed all standard of care provisions and only the determination of need shall be evaluated under special circumstances.** Additional consideration is given when a projected minimum volume of residents discharged with the principal diagnosis of ischemic heart disease exist. County-specific need identified under these circumstances shall exist independently of and in addition to any district need identified under the standard numeric need formula.

Based on information provided by ACHA, CS/HB 339 will directly affect the counties of Hernando, Highlands, Indian River, Martin, Okaloosa, and St. Johns. However, there are 33 additional counties this bill may affect in the future if one of the 33 counties, which do not have an open heart surgery program, experiences a **large increase** in population and the total number of patients discharged with the diagnosis of ischemic heart disease reaches threshold requirements.

The provisions of this bill shall take effect upon becoming law.

AHCA indicates the bill has no fiscal impact on the agency. The fiscal impact on health care facilities is indeterminate.

See amendment section of this analysis for changes made by amendment.

SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1. Less Government Yes [] No [] N/A [x]

2. Lower Taxes Yes [] No [] N/A [x]

3. Individual Freedom Yes [x] No [] N/A []

CH/HB 339 will allow citizens additional choices in selecting health care providers.

4. Personal Responsibility Yes [] No [] N/A [x]

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

B. PRESENT SITUATION:

Introduction

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,** "**…u**nlike 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.

CON WORKGROUP

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 is 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 is scheduled to meet April 27, 2001, in Orlando, regardless of further legislative action.**

The laws relating to the issuance of a certificate of need (CON) to health facilities are in Chapter 408, F.S. The Certificate of Need review program is a regulatory process that requires certain health care providers to obtain state approval from the Agency for Health Care Administration (AHCA) 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 it's 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 CON for the establishment of an open heart surgery program will 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 must obtain a separate certificate of need for the establishment of open heart surgery services in each facility. Separate CONs 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 applies a formula discussed under **"Need Methodology" below**. 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:

a. There is an approved adult open heart surgery program in the district,

b. 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,

c. 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

AHCA 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 AHCA. The Methodology for determining the numeric need for an adult open heart surgery program is:

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.

Concerns with Current Methodology

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.

Proposed AHCA Rule

In December 2000, AHCA published a proposed amendment to the rule which, among other things, would show need for an open heart surgery program in any county where there is no current program, and where there is a projected annual total of at least 1200 residents discharged from a hospital with the primary diagnosis of ischemic heart disease. The county specific need would exist independent of and in addition to any district-wide need. **In addition, the proposed rule changes the volume standard for open heart surgery procedures from 350 a year to 250 procedures a year.** The proposed rule amendment has been challenged, and is presently scheduled for an administrative hearing in March.

Section 408.032(5), F.S., defines *service districts* for adult open heart surgery programs. According to AHCA, there are 39 counties, which currently do not have an open heart surgery program. Six counties currently meet the threshold requirements for patients discharged with ischemic heart disease.

Applications/Litigation

Information provided demonstrates the litigation activity as it relates to CON applicants for an open heart surgery program. The number of pending litigation/applications for open-heart surgery, and the latest AHCA list of letters of intent for the March 2001 batching cycle are as follows:

	Counties	# of applications in litigation	# of Intent letters filed in current batch
District 1:	Escambia, Santa Rosa, Okaloosa, Walton	2	0
District 2:	Holmes, Washington, Bay, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison and Taylor	0	0
District 3:	Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion,		

Citrus, Hernando, Sumter, and Lake	6*	3
District 4: Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia	1	0
District 5: Pasco and Pinellas	0	1
District 6: Hillsborough, Manatee, Polk, Hardee, Highlands	1	2
District 7: Seminole, Orange, Osceola, and Brevard	0	0
District 8: Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier	4*	0
District 9: Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach	4	5
District 10: Broward	2*	1
District 11: Dade and Monroe	2	2
TOTAL	22	14

* In each instance, this number represents repeat applications in separate batching cycles. The actual number of different applicants would be half the number indicated.

C. EFFECT OF PROPOSED CHANGES:

This bill establishes additional parameters for the determination of need in the certificate of need (CON) application review process for adult open heart surgery programs. When an application is made for a CON to provide an adult open heart surgery program in a county in which none of the hospitals has an existing or approved program, the bill requires need to be evaluated under special circumstances to promote reasonable access to such a program in the county. Under such circumstances, the bill requires the criteria on which the CON is reviewed to favor approval in those counties that can support a designated minimum projected volume of residents discharged with a principal diagnosis of ischemic heart disease. The bill provides that county-specific need identified under these circumstances shall exist independently of and in addition to any district need identified under the standard numeric need formula. This bill does not compromise facility and staff requirements for the approval of an open heart program.

Thus, HB 339 legislates the intent of the proposed rule amendment, except for identifying the specific number of 1200 discharges. If implemented pursuant to AHCA's current proposed rule, the bill will directly affect the counties of Hernando, Highlands, Indian River, Martin, Okaloosa, and St. Johns. It is probable that at least six hospitals may apply for a CON to provide an open heart surgery program, resulting in a minimum increase of CON review activity by the Agency for Health Care Administration.

This bill will directly affect any pending litigation with Health Facilities that have applied for a CON to provide an open heart surgery program. It is known that one health facility located in Martin County is currently in litigation regarding the final rule challenge of the CON for an open heart surgery program.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Subsection (5) is added to section 408.043, F.S., establishing additional parameters for the determination of need in the CON application review process for health care facilities. The subsection provides that when an application is made for a CON to provide an adult open heart surgery program in a county in which none of the hospitals has an existing or approved program, the need must be evaluated under special circumstances to promote reasonable access to such a program in the county. Under such circumstances, the subsection requires the criteria on which the CON is reviewed to favor approval in those counties that can support a designated minimum projected volume of residents discharged with a principal diagnosis of ischemic heart disease. The subsection provides that county-specific need identified under these circumstances shall exist independently of and in addition to any district need identified under the standard numeric need formula.

Section 2. An effective date of upon becoming a law is provided.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

AHCA indicates this bill will have no fiscal impact on the agency. This bill may reduce legal fees for AHCA that are associated with challenges made to the final CON recommended order. That amount is indeterminate at this time.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

This bill may reduce the transportation cost incurred by counties that transport open heart indigent patients to another county for services.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill may reduce legal fees for health facilities that are associated with challenges made to the final CON recommended order. That amount is indeterminate at this time.

Open heart surgery is a specialized set of services utilized primarily by Medicare beneficiaries. Reimbursement rates are established prospectively and the addition of providers to the marketplace would not be expected to increase price competition, as would be in the case on other sectors of the economy.

According to information provided by ACHA, open heart surgery programs are sought by hospitals in areas where there are large numbers of Medicare beneficiaries. In contrast to some other

specialized services, these programs are widely considered to be revenue producers and help offset spending for other needed programs that result in a loss for the hospital.

There is no way to estimate the effect that programs approved through special consideration would have on programs elsewhere in the district. Each situation is unique and depends on such factors as the size and location of existing programs, as well as the availability of specialized practitioner teams.

D. FISCAL COMMENTS:

None.

III. 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 state tax shared with counties or municipalities.

IV. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

This bill does not explicitly require AHCA to amend its rules, but implies that AHCA is to amend current rules as they pertain to the CON application review process for open heart surgery programs.

C. OTHER COMMENTS:

None.

V. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 15, 2001, the Committee on Local Government & Veterans Affairs considered HB 339, adopted one amendment, and passed the bill as a committee substitute. CS/HB 339 differs from the original filed HB 339 in that it restricts the requirement that need be evaluated under special circumstances to promote reasonable access to such a program in the county to one program.

In addition, language in HB 339 requiring that the criteria on which CON is reviewed in certain circumstances favor approval in those counties that can support a designated minimum projected volume of residents discharged with a principal diagnosis of ischemic heart disease, is revised in

CS/HB 339. CS/HB 339 requires the criteria on which the CON is reviewed to favor approval in those counties that can generate at least 1200 annual hospital discharges with a principal diagnosis of ischemic heart disease.

On March 29, 2001, the Council for Healthy Communities considered CS/HB 339; as well as one amendment which failed. CS/HB 339 passed the Council as presented.

VI. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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

AS REVISED BY THE COMMITTEE ON LOCAL GOVERNMENT & VETERANS AFFAIRS:

Prepared by:	Staff Director:
Thomas L. Hamby, Jr.	Joan Highsmith-Smith

AS FURTHER REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

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