HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 865 Certificate of Need/Open-Heart Surgery
SPONSOR(S): Harrell
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/SB 460 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)		Rawlins	Collins
2) Health Care			
3)			
4)			
5)			

SUMMARY ANALYSIS

The bill authorizes an exemption from certificate-of-need (CON) review for adult open-heart surgery services in a hospital that meets certain criteria in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties. By December 31, 2004, the Agency for Health Care Administration must report to the Legislature the number of requests for exemptions received under the provisions of this bill and the number granted or denied.

The provisions of this bill will be repealed July 1, 2006.

The bill specifies the act shall take effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[x]	No[]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[x]
3. Expand individual freedom?	Yes[x]	No[]	N/A[]
4. Increase personal responsibility?	Yes[x]	No[]	N/A[]
5. Empower families?	Yes[x]	No[]	N/A[]

For any principle that received a "no" above, please explain:

B. EFFECT OF PROPOSED CHANGES:

The Certificate-of-Need (CON) regulatory process under chapter 408, F.S., requires that before specified health care services and facilities may be offered to the public they must be approved by the Agency for Health Care Administration (AHCA). Section 408.036, F.S., specifies which health care projects are subject to review. Subsection (1) of that section lists the projects that are subject to full comparative review in batching cycles by AHCA against specified criteria. Subsection (2) lists the kinds of projects that can undergo an expedited review. These include: research, education, and training programs; shared services contracts or projects; a transfer of a certificate of need; certain increases in nursing home beds; replacement of a health care facility when the proposed project site is located in the same district and within a 1-mile radius of the replaced facility; and certain conversions of hospital mental health service beds to acute care beds. Subsection (3) lists projects that may be exempt from full comparative review upon request.

All tertiary health services are subject to CON review under s. 408.036(1)(h), F.S. The term "tertiary health service" is defined in s. 408.032(17), F.S., as a health service that is concentrated in a limited number of hospitals due to the high intensity, complexity, and specialization of the care. The goal of such limitations is the assurance of quality, availability, and cost-effectiveness of the service. AHCA determines need for the expansion of tertiary health services by health planning district or multi-district service planning area. Health planning districts are comprised of more than one county, with the exception of District 10, Broward County. Section 408.032(17), F.S., requires AHCA to establish by rule a list of all tertiary health services and to review the list annually to determine whether services should be added or deleted.

Adult open-heart surgery is on the list of tertiary health services under rule 59C-1.002(41)(h), Florida Administrative Code (F.A.C.) The procedure of open-heart surgery is defined under rule 59C-1.033(2)(g), F.A.C., as surgical procedures that are used to:

> treat conditions such as congenital heart defects, heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma. . . . Open-heart surgery operations are classified under the following diagnostic related groups (DRGs): DRGs 104, 105, 106, 107, 108, and 109.

An open-heart surgery program is defined as 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.

The formula for projecting the need for additional adult open-heart surgery programs in each of the 11 health planning districts is contained in rule 59C-1.033, F.A.C. The projections apply to each district as

a whole and the revised rule provides a method by which to authorize county-specific special circumstances for additional adult open-heart surgery programs.

Current Need Methodology

Hospitals operating more than one hospital on separate premises under a single license must obtain a separate CON for the establishment of adult open-heart surgery services in each facility. Separate CONs are required for the establishment of adult and pediatric open-heart surgery programs.

Non-numeric criteria used by the agency in evaluating adult open-heart surgery CON applications include service availability, service accessibility, service quality, and comparable patient charges.

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 cardiographics, including electrocardiography, exercise stress testing, and echocardiography; intensive care; and emergency care available 24 hours per day for cardiac emergencies.

Service Accessibility

Open-heart surgery programs must 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 must 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 must be 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 must be independent of his or her ability to pay. Applicants for adult or pediatric open-heart surgery programs must document the manner in which they will meet this requirement. Adult open-heart surgery must be available in each district to Medicare, Medicaid, and indigent patients.

Service Quality

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 in open heart surgery to perform circulating duties; and a perfusionist to perform extracorporeal perfusion, or a physician or a specially trained nurse, technician, and physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.

Following open-heart surgery, patients must 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 must be at least two cardiac surgeons on the staff of the hospital, 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 must be on call in case of an

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

Comparable Patient Charges

Charges for open-heart surgery in a hospital must be comparable with the charges established at 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.

Numerical Need Calculation

Rule 59C-1.033, F.A.C., provides that in order for an applicant to be granted a CON for a new open-heart surgery program, there must be a demonstration of minimum requirements for staffing and equipment, and the agency must find numeric need for a new program under the rule formula. Regardless of whether numeric need is calculated for a new adult open-heart surgery program, a new program will not normally be approved if: there is an approved adult open-heart surgery program in the district; or if any well-established adult open-heart program in the district is performing less than 300 surgeries annually; or if any new adult open-heart program in the district is performing less than an average of 25 surgeries monthly.

If the above requirements are met, the agency determines need for a new adult open-heart surgery program based on the following formula:

NN = [(POH/500) – OP] < 0.5

Where:

NN is the need for an additional adult open-heart surgery program in the district for the applicable planning horizon.

POH is the projected number of adult open-heart surgery operations that will be performed in the district in the 12-month period beginning with the planning horizon. The POH is calculated as COH/CPOP x PPOP, where:

COH is the current number of adult open-heart surgeries 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.

CPOP is the current population age 15 and over in the district.

PPOP is the projected population age 15 and over in the district.

OP is the number of currently operational adult open-heart surgery programs in the district.

If the computation of NN yields a number of 0.5 or greater, an additional program may be approved for the district. Regardless of the numerical need calculation, an additional program is not normally approved for a district if the approval would reduce the 12-month total of surgeries at an existing district program below 300 open-heart surgery operations.

If there is a demonstrated numeric need for an open-heart surgery program in a district, preference will be given to an applicant for a county in which none of the hospitals has an open-heart surgery program and where residents of the county are projected to generate at least 1,200 annual hospital discharges with a principal diagnosis of ischemic heart disease.

AHCA's projection of the need for adult open-heart surgery programs for the January 2005 planning horizon does not indicate a need for a new adult open-heart surgery program anywhere in the state.

Challenges to Applications

Section 408.039(5)(c), F.S., allows existing hospitals to initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need. Applicants competing for a CON may also challenge the Agency's intended issuance or denial of a certificate of need. Challenges to an application and the cost of defending against challenges are major reasons for the perception that the CON process is burdensome.

Certificate-of-Need Workgroup

As required by Section 15 of Chapter 2000-318, Laws of Florida, a workgroup on CON was established to study issues pertaining to the CON program including the impact of trends in health care delivery and financing. The group produced a final report in December 2002, which includes a recommendation to amend s. 408.032(17), F.S., to add adult and pediatric open-heart surgery to the list of tertiary health services. This recommendation would place in the statute clear authority for the current rule, which makes open-heart surgery a tertiary service. The workgroup considered but did not adopt a proposal to exempt adult open-heart surgery from CON review.

Issues

In the past few years, the Legislature has considered proposals related to CON that call into question whether or not CON is still an appropriate market entry and quality control mechanism for Florida hospitals. Several issues are brought to the discussion. One issue is the question of whether the CON process is a mechanism for maintaining quality or an outdated planning mechanism that thwarts competition among providers. CON programs emerged in the late 1960s and early 1970s as a way to regulate growth of facilities and costs in health care at a time when many hospitals were being built with federal funds, known as Hill-Burton Grants. After the passage of the National Health Planning and Resources Development Act of 1974 (PL93-641) most states implemented CON programs. After the act was repealed in the 1980s, a number of states abolished their CON programs.

There is research to show that CON may be ineffective as a mechanism for cost control and other research to show that it is an effective mechanism for maintaining quality of patient outcomes. In a study published in the Journal of Health Politics, Policy and Law in 1998, Christopher Conover and Frank Sloan looked at the effects of lifting CON through the year 1993. The authors found that mature CON programs are associated with a modest long-term reduction in acute care spending per capita, but with no significant reduction in total per capita spending. Further, they found that lifting CON requirements did not result in a surge in health care costs. In a current study of the potential impact of CON on outcomes for patients, Gary Rosenthal and Mary Sarrazin at the University of Iowa, examined the delivery of care to Medicare patients undergoing coronary artery bypass graft (CABG) surgery in all 50 states for a 6-year period. Patients fared better in CON regulated states on measures of in-hospital mortality and deaths within 30 days after surgery. The undesirable outcomes were 21 percent more likely in states that do not regulate the procedure through CON review.

Many studies have shown that the volume of procedures performed at a facility is related to quality of outcomes for patients. However, the length of time that a patient in need of open-heart surgery must wait before receiving the surgery is also related to quality. Anecdotal stories of patients referred for open-heart surgery in a distant city who died, or whose condition deteriorated, before the surgery was performed are offered in support of the case for repealing CON requirements for open-heart surgery. Unfortunately, there is no data to indicate whether there really is an access problem for patients from rural areas in Florida.

Changes in Medical Treatment for Heart Disease

Traditional adult open-heart surgery and related interventional cardiology procedures such as angioplasty or percutaneous coronary intervention have been one of the most competitive areas of hospital operations in recent years. Rapidly changing technology is decreasing the percentage of adult open-heart procedures and increasing the percentage of less invasive procedures such as angioplasty and stent insertion. This change could be accompanied by a change in the prevailing medical opinion

about the need for open-heart backup when providing the less invasive procedures. Open-heart backup has traditionally been seen as essential for the less invasive procedures, but this medical opinion appears to be changing. If prevailing medical opinion supports angioplasty and stent procedures without open-heart backup, it is reasonable to predict that the competitive environment among hospitals will change.

The bill amends s. 408.036, F.S., to authorize an exemption from certificate-of-need (CON) review for adult open-heart surgery services in a hospital in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties. A hospital that meets the following criteria will be exempt from CON review:

- The hospital must certify that it will meet and continuously maintain the minimum licensure requirements adopted by AHCA for adult open-heart surgery programs and the most current guidelines of the American College of Cardiology and the American Heart Association.

- The hospital must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.

- The hospital must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

- The hospital must demonstrate that it is referring 300 or more patients per year from the hospital for cardiac services at a hospital with cardiac services, or that the average wait for transfer for 50 percent or more of the cardiac patients exceeds 4 hours.

- The hospital is a general acute care hospital that has been in operation for three years or more.

- The hospital performs more than 300 diagnostic cardiac catheterization procedures per year (combined inpatient and outpatient).

- The hospital's payor mix, at a minimum, reflects the community average for Medicaid, charity care, and self-pay patients, or the facility must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart surgery patients.

- If the hospital fails to meet the established criteria for open-heart programs or fails to perform 300 surgeries per year by the end of its 3rd year of operation, it must show cause why its exemption should not be revoked.

By December 31, 2004, AHCA must report to the Legislature the number of requests for exemptions received under the provisions of this bill and the number granted or denied.

The provisions of this bill will be repealed July 1, 2006.

The bill will take effect upon becoming a law.

C. SECTION DIRECTORY:

Section 1. Amends s. 408.036, F.S., providing an exemption to the CON review process for open-heart surgery programs for hospitals in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties, specifying certain criteria must be met; requires that by December 31, 2004, AHCA must report to the Legislature the number of requests for exemptions received under the provisions of this bill and the number granted or denied; and provides that this paragraph is repealed effective July 1, 2006.

Section 2. Provides the act shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See "Fiscal Comments."

2. Expenditures:

   See "Fiscal Comments."

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Qualifying hospitals in the affected counties could establish adult open-heart surgery programs without the necessity of CON review.

D. FISCAL COMMENTS:

There would be some reduction in revenue associated with fewer CON application fees for adult open-heart surgery programs. The maximum CON fee is $22,000, depending on the proposed capital expenditure. The fee for a CON exemption is $250.

However, anticipated rule challenges could delay the impact of a reduction at least until the second year. At the same time, rapidly changing medical opinion related to the delivery of adult open-heart surgery and the related less invasive procedures has the potential to change this area of health care very significantly. For these reasons, the impact on CON fees that might result from the proposed changes cannot be predicted.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The provisions of the exemption require “that the hospital meet all current licensure requirements for cardiac programs.” Currently, there are no licensure requirements for cardiac programs, therefore, the language is ineffective.

If the provisions of the bill are repealed July 1, 2006, the requirement that the hospital perform 300 surgeries by the end of its third year of operation will be repealed before, or just at the time that, the hospitals that receive the exemption would have to meet the provisions of the law.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES