# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 56

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Wise

SUBJECT: Hospital Licensing and Regulation

DATE: April 2, 2003 REVISED: _____ _____ _____ _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Harkey | Wilson | HC | Favorable/CS |
| 2. | | | JU | |
| 3. | | | AHS | |
| 4. | | | AP | |
| 5. | | | | |
| 6. | | | | |

## I. Summary:

This bill creates an exemption from certificate-of-need review for an adult open-heart surgery program to be located in a new hospital that is being established in the location of an existing hospital when the existing hospital and existing adult open-heart surgery program are relocated to a replacement hospital that will use a closed-staff model. The bill provides criteria that the hospital must meet in order to be eligible for the exemption. If the open-heart surgery program fails to meet these criteria or fails to reach 300 surgeries per year by the end of its third year of operation, the hospital must show cause why its exemption should not be revoked.

The bill requires the Agency for Health Care Administration to report to the Legislature by December 31, 2004, and annually thereafter, concerning the number of requests for exemptions granted or denied.

The exemption established in the bill is repealed January 1, 2008.

This bill amends s. 408.036, F.S.

## II. Present Situation:

### The Certificate-of-Need Process

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. Those projects are:

- The addition of beds by new construction or alteration.
- The new construction or establishment of additional health care facilities, including a replacement health care facility when the proposed project site is not located on the same site as the existing health care facility.
- The conversion from one type of health care facility to another.
- An increase in the total licensed bed capacity of a health care facility.
- The establishment of a hospice or hospice inpatient facility, except as provided in s. 408.043, F.S.
- The establishment of inpatient health services by a health care facility, or a substantial change in such services.
- An increase in the number of beds for acute care, nursing home care, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, mental health services, or hospital-based distinct part skilled nursing units, or at a long-term care hospital.
- The establishment of tertiary health services[1].

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 services beds to acute care beds. Subsection (3) lists projects that may be exempt from full comparative review upon request. These include:

- Replacement of a licensed health care facility on the same site;
- Hospice services or swing beds in a rural hospital;
- Conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital;
- The addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides a variety of residential settings and supportive services and that has been incorporated and operated in this state for at least 65 years on or before July 1, 1994;

[1] The term "tertiary health services" is defined in s. 408.032(17), F.S., as those medical interventions which are 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. Under s. 408.032(17), F.S., "organ transplantation, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature", are tertiary services along with those listed by AHCA in rule. Under Rule 59C-1.002, F.A.C., in addition to the tertiary services named in the statute, the following services are designated as tertiary services: heart transplantation, kidney transplantation, liver transplantation, bone marrow transplantation, lung transplantation, pancreas and islet cells transplantation, heart/lung transplantations, adult open-heart surgery, neonatal and pediatric cardiac and vascular surgery, and pediatric oncology and hematology.

- An increase in the bed capacity of a nursing home licensed for at least 50 beds as of January 1, 1994, which is not part of a continuing care facility;
- An inmate health care facility built by or for the exclusive use of the Department of Corrections;
- The termination of an inpatient health care service, upon 30 days' written notice to the agency;
- The delicensure of beds, upon 30 days' written notice to the agency;
- The provision of adult inpatient diagnostic cardiac catheterization services in a hospital;
- Mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility;
- State veterans' nursing homes for which at least 50 percent of the construction cost is federally funded and for which the Federal Government pays a per diem rate not to exceed one-half of the cost of the veterans' care;
- Combination within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict;
- Division into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict;
- The addition of hospital beds for acute care, mental health services, or a hospital-based distinct part skilled nursing unit in a number that may not exceed 10 total beds or 10 percent of the licensed capacity of the bed category being expanded, whichever is greater;
- The addition of acute care beds in a number that may not exceed 10 total beds or 10 percent of licensed bed capacity, whichever is greater, for temporary beds in a hospital that has experienced high seasonal occupancy within the prior 12-month period or in a hospital that must respond to emergency circumstances;
- Nursing home beds in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater;
- Establishment of a specialty hospital offering a range of medical service restricted to a defined age or gender group of the population or a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical illnesses or disorders, through the transfer of beds and services from an existing hospital in the same county;
- The conversion of hospital-based Medicare and Medicaid certified skilled nursing beds to acute care beds, if the conversion does not involve the construction of new facilities; and
- For fiscal year 2001-2002 only, for transfer by a health care system of existing services and not more than 100 licensed and approved beds from a hospital in district 1, subdistrict 1, to another location within the same subdistrict in order to establish a satellite facility that will improve access to outpatient and inpatient care for residents of the district and subdistrict and that will use new medical technologies, including advanced diagnostics, computer assisted imaging, and telemedicine to improve care. [2]

[2] This exemption is repealed on July 1, 2002.

**Adult Open-Heart Surgery**

Adult 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 for Adult Open-Heart Surgery**

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. 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 programs in the district are performing less than 300 surgeries annually; or if any new adult open-heart programs in the district are performing less than an average of 25 surgeries monthly.

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

$$\mathbf{NN = [(POH/500) - OP] \leq 0.5}$$

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**

Challenges to a CON application and the cost of defending against challenges are a major reason for the perception that the CON process is burdensome. Applicants competing for a CON may challenge the agency's intended issuance or denial of a certificate of need. 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. AHCA must issue its final order within 45 days of its receipt of the recommended order, but the applicant and AHCA may agree to a different timing for the final order.

Under s. 408.039(6), F.S., a party to an administrative hearing for a CON application may seek judicial review in the District court of Appeal, and AHCA must be a party in such proceedings. The court may award attorney's fees and costs to the prevailing party if the court finds that there was a complete absence of a justiciable issue of law or fact raised by the losing party.

**Transferring a Certificate of Need**

Transfer of a CON is subject to an expedited review under s. 408.032(2)(c), F.S., and under the requirements of Rule 59C-1.0085, F.A.C. In an expedited review, upon the signing of the Agency Action Report, which must take place 60 days from the date the application is deemed complete, AHCA must send a CON or a denial letter to the applicant.

**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.

**Hospital Staffing**

Staff membership and clinical privileges at hospitals are based on the applicant's background, experience, health, training, demonstrated competency, adherence to professional ethics, reputation and ability to work with others pursuant to established and nationally recognized criteria such as those contained in the hospital licensure requirements in s. 395.0191, F.S., the conditions of participation in the Medicaid and Medicare programs in 42 CFR 482.22, and the accreditation standards of the Joint Commission on Accreditation of Healthcare Organizations and the American Osteopathic Association.

Currently, ch. 395, F.S., and the Code of Federal Regulations, 42 CFR 482, governing hospitals, do not distinguish between "open" or "closed" medical staff. All physicians can apply for admitting privileges to all hospitals and the approval or disapproval of privileges for all physicians, salaried employees or not, must be based on criteria for each specialty established by the hospital's governing body.

**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. 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 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.

## III. Effect of Proposed Changes:

This bill amends s. 408.036, F.S., to create an exemption for an adult open-heart surgery program to be located in a new hospital that is being established in the location of an existing hospital when the existing hospital and existing adult open-heart surgery program are being relocated to a replacement hospital that will use a closed-staff model. AHCA may grant the exemption provided the applicant:

- Meets and maintains current and future requirements of Florida rules and current guidelines of the American College of Cardiology and American Heart Association for Adult Open Heart Surgery.
- Certifies that it will maintain the appropriate equipment and personnel.
- Certifies that it will maintain appropriate times of operation and protocols to ensure appropriate referrals.
- Is a newly licensed hospital in a physical location previously owned and licensed to a hospital that performed more than 300 open-heart surgeries per year including heart transplants.
- Certifies that it can perform more than 300 diagnostic cardiac catheterization procedures per year combined inpatient and outpatient, by the end of its third year of operation.
- Has a payer mix that reflects the community average for Medicaid, charity care, and self-pay patients or certifies that it will provide a minimum of 5 percent Medicaid, charity care, and self-pay services to open-heart surgery patients.

If the applicant fails to meet these criteria or fails to reach 300 surgeries per year by the end of its third year of operation, the applicant must show cause why its exemption should not be revoked.

AHCA must report to the Legislature by December 31, 2004, and annually thereafter concerning the number of requests for exemptions granted or denied.

The provision is repealed January 1, 2008.

The bill provides an effective date of July 1, 2003.

## IV. Constitutional Issues:

### A. Municipality/County Mandates Restrictions:

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

### B. Public Records/Open Meetings Issues:

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

### C. Trust Funds Restrictions:

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

## V. Economic Impact and Fiscal Note:

### A. Tax/Fee Issues:

None.

B. Private Sector Impact:

A hospital that qualified for the exemption would be able to operate an adult open-heart surgery program without incurring the cost of apply for a CON and defending against challenges.

C. Government Sector Impact:

None.

## VI. Technical Deficiencies:

None.

## VII. Related Issues:

Inpatient hospital services for the Mayo Clinic in Jacksonville – including adult open-heart surgery – are presently provided at St. Luke's Hospital. The Mayo Clinic has CON approval to construct a new hospital at the site of its present outpatient clinic, and then transfer open-heart surgery (and other services) from St. Luke's to the new hospital. It is expected that the new hospital will have a closed medical staff, consistent with the definition in SB 56, meaning that all physicians on the medical staff would be salaried employees of the hospital. The approval for the new hospital is currently under an administrative challenge.

Under approved plans, the present physical plant of St. Luke's Hospital will be acquired by St. Vincent's Hospital, once the new facility is operational at the Mayo Clinic site. St. Vincent's will also continue to operate at its present location, which is the site of the St. Vincent's open-heart surgery program. There is no current intention to relocate that particular service to the site acquired from St. Luke's. Such a proposal would require CON approval, but the application date could occur no sooner than the first batching cycle after St. Vincent's Hospital completes its acquisition of St. Luke's Hospital. Jacksonville (Duval County) is located in CON District 4 along with six other northeast Florida counties. There are currently seven operational and one approved open-heart surgery programs in the District.

## VIII. Amendments:

None.