

# 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/CS/SB 698

SPONSOR: Banking and Insurance Committee, Health, Aging and Long-Term Care Committee,  
Senator Clary and others

SUBJECT: Certificates of Need-Adult Open Heart Surgery

DATE: February 25, 2002      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable/CS
2.	Emrich	Deffenbaugh	BI	Favorable/CS
3.	_____	_____	AHS	_____
4.	_____	_____	AP	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

## I. Summary:

Florida’s health care Certificate of Need (CON) program regulates entry into the marketplace for specified health care facilities and services. The CON review process is under the Agency for Health Care Administration (AHCA) and requires that health facilities like hospitals obtain approval from AHCA before offering tertiary health services. Open-heart surgery programs are considered tertiary health services by AHCA. That agency determines the need for the expansion of tertiary health services by health planning district and there are specified formulas for projecting the need for additional open-heart surgery programs in each of the agency’s eleven districts.

This bill would create a “special circumstances” provision in the CON review process for a hospital applying for an adult open heart surgery program in a county in which none of the hospitals has an existing or approved adult open heart surgery program and there is no existing or approved program located within 30 miles. The bill provides that the need shall be evaluated under special circumstances to promote reasonable access to such a surgery program within the county.

The bill further provides that the CON review criteria must favor approval of a new adult open-heart surgery program under special circumstances 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.

Based on information provided by ACHA, this bill will affect hospitals in two counties: Okaloosa County and Highlands County. Ft. Walton Beach Regional Medical Center is located in Okaloosa County, while Highlands Regional Medical Center and Florida Hospital Heartland are located in Highlands County.

This bill amends section 408.043, F.S., of the Florida Statutes.

## II. Present Situation:

### Certificate of Need Process

Florida's health care certificate of need (CON) program regulates entry into the marketplace for state-licensed hospitals, nursing homes, and hospices. Established in 1973, the CON program was part of the federal health planning system. Currently 36 states have CON programs.

The CON regulatory process is under chapter 408, F.S., which mandates 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.<sup>1</sup> Subsection (2) lists the kinds of projects that can undergo what is termed an "expedited review."<sup>2</sup> 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 or hospital-based nursing unit beds to general acute care beds. Subsection (3) lists projects that may be "exempt" from full comparative review upon request.

All tertiary health services are subject to full CON review.<sup>3</sup> The term "tertiary health services" is defined as those medical interventions which are concentrated in a limited number of hospitals due to the high intensity, complexity, and specialization of the care.<sup>4</sup> The goal of such limitations is the assurance of quality, availability and cost-effectiveness of the service. The agency (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.

Adult open-heart surgery is on the list of tertiary health services<sup>5</sup> and the procedure for open-heart surgery<sup>6</sup> is defined as surgical procedures that are used to:

---

<sup>1</sup> "Full comparative CON review" is known as a comparative batched review and is applied to major applications for new or expanded beds or services.

<sup>2</sup> Expedited review is a process whereby such projects are not subject to the full review cycle requirements and the letter of intent requirements under ch. 408, F.S. Such a review is for smaller projects.

<sup>3</sup> S. 408.036(1)(h), F.S.

<sup>4</sup> S. 408.032(17), F.S.

<sup>5</sup> Rule 59C-1.002(41)(h), F.A.C.

<sup>6</sup> Rule 59C-1.033(2)(g), F.A.C.,

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 specified diagnostic related groups (DRGs).<sup>7</sup>

### **Open Heart Surgery Procedures and CON Review**

Currently, 62 of the 271 hospitals licensed in Florida are approved for adult open-heart surgery.<sup>8</sup> According to representatives with the Florida Hospital Association, 35,000 open-heart procedures are performed in Florida hospitals each year with the average volume per program of 582 such operations in 2000. These representatives report that the “use rates” for open-heart surgery have stabilized in recent years at about 2.7 procedures per 1,000 residents while, during this same period, angioplasty use rates have increased to 3.8 procedures per 1,000 residents. This reflects a trend for medical professionals to utilize “less intrusive procedures” in the treatment of patients with heart problems, according to these representatives.

Officials with AHCA report that eleven new open-heart surgery programs were authorized via CON review by the agency in the last 9 years. During the period between 1996 and 2000, 47 CON applications for adult open-heart surgery were filed and 40 of those applications were denied by the agency.<sup>9</sup> During the past 3 years, there has been considerable interest in establishing adult open-heart surgery services according to the agency because it reviewed 48 CON applications for service - an average of 16 applications per year. According to AHCA officials, typical CON reviews for such procedures take about 4 months. If there is an appeal of a CON decision, it could take up to 1 year or more.

In October 2000, AHCA proposed amendments to the adult open-heart surgery CON methodology in rule 59C-1.033, F.A.C., which would allow approval of more programs than the existing methodology. The amendments also recognized changes in open-heart surgery procedures that have occurred since the present version of the rule was adopted in 1991. During the ensuing 14 months, the proposed amendments were thoroughly debated – notably at a rule development workshop, a public hearing, and a trial at the Division of Administrative Hearings (DOAH).<sup>10</sup>

In summary, those supporting the amendments stressed the need for additional programs to improve geographic access to adult open-heart surgery services, given the emergency needs of some of the patients receiving open-heart surgery. Those opposing the amendments were concerned that new programs would draw patients and staff away from existing programs, and cited evidence that outcomes from the surgery are poorer at hospitals with a low volume of open-heart surgery.

The amendments, as approved on January 24, 2002, retain adult open-heart surgery as a tertiary health service and subject to CON review, update the definition of open-heart surgery, recognize that there are circumstances in some counties that indicate need for a such a program, and reduce

---

<sup>7</sup> DRGs: 104, 105, 106, 107, 108, and 109.

<sup>8</sup> Florida Hospital Association

<sup>9</sup> Florida Hospital Association. These figures include several repeat hospital applications.

<sup>10</sup> Complete transcripts of all three events are available.

the numeric standard that defines an acceptable hospital-specific minimum annual volume of adult open-heart surgeries. Further, the formula for projecting the need for additional adult open-heart surgery programs in each of the 11 health planning districts is contained in the rule. 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.<sup>11</sup> In effect, these rule amendments attempt to streamline the CON process.

---

<sup>11</sup> The specific provisions of the rule provide for the following: 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*.

As to *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 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 a large number of services ranging from cardiology and hematology to pulmonary medicine, intensive and emergency care.

As to *service accessibility*: adult 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 adult and pediatric elective open-heart surgery is required to be available for 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.

As to *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. Other requirements involve cardiac surgeons, clinical cardiologists, and specified backup personnel.

As to *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.

As to *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 a detailed formula.

## Certificate of Need Workgroup

Legislation enacted in 2000 mandated a CON Workgroup be established to study issues pertaining to the CON program and to make recommendations.<sup>12</sup> An interim report was submitted to the Legislature in December 2001. The report contained specific recommendations regarding CONs for hospitals and stated that all tertiary services should continue to be subject to full CON review and should be defined in statute.<sup>13</sup> For example, pursuant to that recommendation, tertiary services such as adult open-heart surgery would continue to be regulated under full CON review and defined in law. After issuing the report, the Workgroup also addressed the issue of adult open-heart surgery at its January 2002 meeting and voted to recommend that open-heart surgery remain subject to full CON review with “no exceptions.” Other key recommendations made by the Workgroup provided that projects now subject to expedited CON review, with the exception of replacement hospitals and conversion of mental health beds to general acute beds, be exempt, along with exemption provisions for requirements for the addition of acute care beds or neonatal intensive care unit (NICU) beds in hospitals that met certain occupancy criteria.

### III. Effect of Proposed Changes:

This bill establishes additional parameters for the determination of need in the CON application review process for hospitals to offer adult open-heart surgery programs. It provides that when an application is made by a hospital for a CON to establish an adult open heart surgery program in a county in which none of the hospitals has an existing or approved adult open heart surgery program, and there is no existing or approved program located within 30 miles, that need shall be

---

<sup>12</sup> Ch. 2000-318, F.S.

<sup>13</sup> Hospitals operating at 80 percent of acute care occupancy over the most recent 12 month period, or hospitals having 90 percent occupancy for any 3 consecutive months, will be exempt from CON review for the greater of 10 percent of their licensed capacity or 30 beds. For those hospitals with organized obstetric and pediatric units, the beds and utilization of those units will be included in the acute care occupancy calculations; tertiary services will continue to be subject to CON; all tertiary services subject to CON review should be defined in statute.

In addition to tertiary services that are currently included in statute (NICU Level III beds, organ and bone marrow transplant programs, inpatient rehabilitation beds, burn units, pediatric open-heart programs, and therapeutic cardiac catheterization programs), NICU Level II beds and adult open-heart surgery programs should also be included; providers of tertiary services will cooperate with the state in the development of outcome and quality measures; criteria for new tertiary services will be more detailed; a medical advisory group should be established to determine which existing services and what new emerging services should be classified as tertiary (generally requiring some minimal volume as a threshold indicator of quality); AHCA is directed to redefine the measure of hospital occupancy; providers of NICU unit services will be exempt from CON review on proposals to expand their beds by 10 percent or eight beds, whichever is greater, if their occupancy exceeds 80 percent for the preceding 12 months.

Providers of NICU Level III services will be allowed to shift their capacity between their Level III unit and their Level II unit, subject to providing appropriate staffing and meeting architectural requirements; projects now subject to expedited review—other than replacement hospitals and conversion of mental health beds to general acute beds—will be exempt from CON review; the Certificate of Need Task Force should be allowed to continue its work through 2002, to address in more detail tertiary care services, transplantation, and new technology; all providers of invasive services, to at least include diagnostic catheterization and outpatient surgery—regardless of setting—will report utilization data to the State of Florida; the CON Workgroup recognizes the need to make recommendations about streamlining the CON process. Recommendations related to a streamlined process will be a priority when the group reconvenes in 2002.

evaluated under special circumstances to promote reasonable access to such a program within the county. The special circumstances criteria upon which the CON is reviewed will favor those counties that can support a designated minimum projected volume of residents discharged from a hospital with a principal diagnosis of ischemic heart disease.

According to representatives with AHCA, the effect of this bill would be limited to hospitals in two counties: Okaloosa County and Highlands County. Ft. Walton Beach Regional Medical Center (Okaloosa County) is in AHCA District 1, while Highlands Regional Medical Center and Florida Hospital Heartland are located in Highlands County which is AHCA District 6.<sup>14</sup> The two hospitals in Highlands County have not applied to AHCA for a CON for an adult open-heart surgery program. However, the Ft. Walton Beach hospital has applied for a CON for an adult open heart surgery program and has been denied twice in the past 2 years primarily because there are currently three open heart programs in that district which are located in Pensacola (60 miles away), but two of the three hospital programs are below the minimum of 300 open heart procedures per year which is the CON minimum, according to these representatives.

Proponents of this bill seek to initiate an adult open-heart surgery program for the specified counties noted above. However, there are five other counties and cities in the state which are growing rapidly and have sought to begin such surgery programs, but do not qualify under the parameters of this bill.<sup>15</sup> Proponents assert that additional open-heart surgery programs will improve access to such surgeries by allowing patients to receive prompt treatment at a local hospital rather than being transported to a distant county or city.

**Section 1.** Subsection (5) is added to section 408.043, Florida Statutes, establishing additional parameters for the determination of need in the CON application review process for health care facilities. It provides that when an application is made by a hospital for a CON to establish an adult open heart surgery program in a county in which none of the hospitals has an existing or approved adult open heart surgery program, and there is no existing or approved program located within 30 miles, that need shall be evaluated under special circumstances to promote reasonable access to such a program within the county.

The special circumstances criteria upon which the CON is reviewed will favor those counties that can support a designated minimum projected volume of residents discharged from a hospital with a principal diagnosis of ischemic heart disease. According to AHCA staff, “special circumstances” methodology is defined under Rule 59C-1.033, F.A.C., to allow one new program per county in addition to and independent of numerical need where the county has no existing or approved open heart surgery program, and residents of the county are projected to generate at least 1,200 hospital discharges annually with a primary diagnosis of ischemic heart disease. Ischemic heart disease is defined under rule 59C-1.033, F.A.C., based on diagnostic related groups (DRGs).

County-specific need identified under special circumstances will exist independently of, and in addition to, any district need identified under the standard numeric need formula.

---

<sup>14</sup> District 1 consists of Escambia, Santa Rosa, Okaloosa, and Walton counties and District 6 consists of Hillsborough, Manatee, Polk, Hardee, and Highlands counties.

<sup>15</sup> These hospitals are located in Boynton Beach, Boca Raton, Stuart, Winter Haven, and Indian River.

**Section 2.** The bill takes effect upon becoming a law.

**IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

**V. Economic Impact and Fiscal Note:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

According to staff with AHCA, the provisions of this bill only apply to two counties which are Okaloosa and Highlands. Staff with AHCA state that adult open-heart surgery is a specialized set of services utilized primarily by Medicare beneficiaries. 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 the adult open heart surgery program approved through special circumstances would have on programs elsewhere in District 1 or in District 6. However, 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.

C. Government Sector Impact:

Since the provisions of this bill will only affect two counties (Okaloosa and Highlands), it is not expected to impact the revenue from CON application fees for AHCA.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Amendments:**

None.

---

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

---