

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: SB 968

SPONSOR: Senator Clary

SUBJECT: Certificate of Need Applications for Adult Open Heart Surgery Programs

DATE: March 21, 2001 REVISED: 03/28/01 _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Thomas	Wilson	HC	Fav/1 amendment
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill creates a special circumstances provision in the Certificate-of-Need 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. The review criteria under the bill will favor approval of a new program under special circumstances where there exists a designated minimum projected volume of residents discharged from a local hospital with a principal diagnosis of ischemic heart disease. This special circumstances option will exist independently of, and in addition to, any adult open heart surgery program identified under the standard numeric need formula.

This bill amends section 408.043, Florida Statutes.

II. Present Situation:

The Certificate-of-Need (CON) regulatory process under chapter 408, F.S., requires that specified health care services and facilities be approved by the Agency for Health Care Administration (AHCA) prior to being offered to the public. All tertiary health services are subject to CON review under s. 408.036(1)(h), F.S. 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., provides that AHCA must establish by rule a list of all tertiary health services.

Adult open heart surgery is on the list of tertiary health services¹ under rule 59C-1.002(41)(h), F.A.C.² The procedure of open heart surgery is defined under rule 59C-1.033(2)(g), F.A.C., as surgery that is:

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. . . . Open heart surgery operations are classified under the following diagnostic related groups (DRGs): DRGs 104, 105, 106, 107, 108, and 100.

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 there is no method by which to authorize county-specific special circumstances for additional adult open heart surgery programs.³

Current Methodology

AHCA determines the need for new adult open heart surgery programs twice a year. 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

¹ *Lawnwood Medical Center, Inc. v. Agency for Health Care Administration*, 17 FALR 3511 (AHCA 1995), reversed on other grounds, 678 So.2d 421 (Fla. 1st DCA 1996); *St. Anthony's Hospital, Inc. v. Agency for Health Care Administration*, 17 FALR 3720 (AHCA 1995).

² Previously numbered rule 59C-1.002(43)(h), F.A.C., prior to rule amendments of December 12, 2000.

³ *St. Anthony's Hospital, supra*; *Halifax Hospital Medical Center v. Agency for Health Care Administration*, 19 FALR 2484 (AHCA 1997).

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 available within a maximum waiting period of 2 hours. All open heart procedures are required by rule to be available to 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 institution proposing to provide adult or pediatric open heart surgery must meet the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation standards for special care units or standards for accreditation by the American Osteopathic Association (AOA). 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 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 an 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.

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.,⁴ 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.⁵ 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 but not yet operational adult open heart surgery program in the district; or if any well-established⁶ adult open heart programs in the district are performing less than 350 surgeries annually; or if any new⁷ adult open heart programs in the district are performing less than an average of 29 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:

$$\mathbf{NN} = (\mathbf{Uc} \times \mathbf{Px}) / 350 - \mathbf{OP}$$

Where:

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

Uc is the actual use rate calculated by taking the 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 divided by the population age 15 and over.

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

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, one new program may be approved for the district. Regardless of the numerical need calculation, a new program is not normally approved for a district if the approval would reduce the 12 month total of surgeries at existing

⁴ Last amended August 24, 1993.

⁵ *St. Mary's Hospital v. Department of Health and Rehabilitative Services*, 13 FALR 2096 (HRS 1991).

⁶ Defined as programs operational for at least 12 months as of the 3 months prior to the beginning date of the publication of the fixed need pool.

⁷ Defined as programs operational for less than 12 months during the year ending 3 months prior to the beginning date of the publication of the fixed need pool.

district programs below an average of 350. This is calculated by $(Uc \times Px)/(OP + 1)$, where a new program will not normally be approved if the result is less than 350.

Rule Challenges

AHCA published a notice of proposed rule development in the October 6, 2000, Florida Administrative Weekly, at Vol.26, No.40, pp.4562-64. The proposed rule amendments addressing open heart surgery CONs provide for: the elimination of open heart surgery from the list of tertiary health services; the addition of coronary bypass surgery without cardiac catheterization (DRG 109) to the list of open heart surgery operations; the removal of the JCAHO or AOA accreditation requirement; the lowering of the district minimum number of procedures at other hospitals to 250 from 350;⁸ the elimination of the limit of one new approvable program per district; and the creation of a new “special circumstances” methodology to allow one new program per county in addition to and independent of numerical need where the county has no currently operating, or approved but not yet operational, adult open heart program, and at least 1,200 hospital discharges annually with a primary diagnosis of ischemic heart disease.

An administrative lawsuit challenging the existing adult open heart need methodology was filed last year,⁹ but prior to going to final hearing, the suit was voluntarily dismissed by the petitioners on February 14, 2001, and the case was closed on February 20, 2001. The petitioners represented unsuccessful CON applicants that sought adult open heart surgery programs but were barred under the rule as it currently exists. The lawsuit alleged that the existing open heart rule was arbitrary and capricious, and that it exceeded the scope of the CON statutes. Specific items challenged included the 350 minimum number of procedures required at existing programs, the categorization of open heart surgery as a tertiary health service, and the lack of a “special circumstances” provision. The basis for the voluntary dismissal was the filing of proposed rule amendments by AHCA.

On January 26, 2001, the operators of several currently operating adult open heart surgery programs filed suit in response to the proposed rule.¹⁰ The issues are a mirror image of the initial rule challenge in that the petitioners are suing to *maintain* the 350 minimum number of procedures at current programs, to keep adult open heart surgery as a tertiary health service, and to preclude the initiation of a “special circumstances” provision. Final hearing for the litigation is currently set for May 14, 2001.

Applications and Litigation

Information provided demonstrates the litigation activity as it relates to CON applicants for an adult open heart surgery program. The number of pending applications or litigation for adult

⁸ For current district programs in operation for more than a year. For district programs in operation less than a year, the number is lowered to a monthly average of 21 operations from an average of 29.

⁹ *Indian River Memorial Hospital, Inc. v. Agency for Health Care Administration*, DOAH Case No. 00-2692RX, -- FALR -- (AHCA 2000).

¹⁰ *Tenet HealthSystem Hospitals, Inc. d/b/a Delray Medical Center v. Agency for Health Care Administration*, DOAH Case Nos. 01-0372RP through 01-0457RP, -- FALR -- (AHCA 2001).

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:	Homes, Washington, Bay, Jackson, Franklin, Gulf Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, Taylor	0	0
District 3:	Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, Lake	6*	3
District 4:	Baker, Nassau, Duval, Clay, St. Johns, Flagler, Volusia	1	0
District 5:	Pasco, Pinellas	0	1
District 6:	Hillsborough, Manatee, Polk Hardee, Highlands	1	2
District 7:	Seminole, Orange, Osceola, Brevard	0	0
District 8:	Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, Collier	4*	0
District 9:	Indian River, Okeechobee, St. Lucie, Martin, Palm Beach	4	5
District 10:	Broward	2*	1
District 11:	Dade, Monroe	2	2
TOTAL		22	14

* Represents repeat applications in separate batching cycles. The actual number of different applicants would be half the number indicated.

The bill will directly affect Hernando, Highlands, Indian River, Martin, Okaloosa, and St. Johns counties, which may all have hospitals qualifying for a special circumstances adult open heart surgery CON. It is likely that at least 6 hospitals may apply for a CON under the new provisions, resulting in an increase in CON application review by the agency. This bill will directly affect any pending litigation regarding adult open heart surgery CONs.

III. Effect of Proposed Changes:

Section 1. Amends s. 408.043, F.S., to provide 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, need shall be evaluated under special circumstances.

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.

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.

Section 2. Provides that if the bill becomes law, it will take effect upon becoming law.

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 Art. VII, s. 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 public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals seeking to initiate a new adult open heart surgery program in counties where no current program exists will be afforded a new special circumstances CON option. Current

programs seeking to limit competition will be disadvantaged due to the new special circumstances option for the establishment of new programs.

C. Government Sector Impact:

The Agency for Health Care Administration will be charged with the task of reviewing special circumstances adult open heart surgery CON applications.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

#1 by Health, Aging and Long-Term Care:

Provides that the language of the bill is entirely deleted and replaced with a provision that the CON workgroup created by section 15 of chapter 2000-318, Laws of Florida, address in its final report the issue of access to open heart surgery in areas currently lacking programs or deemed underserved. The workgroup is to submit its final recommendations on or before January 1, 2002.