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 698

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

SUBJECT: Certificate of Need

DATE: January 30, 2002 REVISED: _____ _____ _____ _____

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

I. Summary:

This bill revises criteria for exemptions from Certificate-of-Need (CON) review. The bill increases flexibility for hospitals increasing acute care beds or adding neonatal intensive care unit (NICU) beds. Certain projects that are currently subject to an expedited review would be exempt from CON review. Adult open-heart surgery services in a hospital would be exempt from the requirements for a CON review, provided the program met certain criteria.

This bill amends s. 408.036, F.S.

II. Present Situation:

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 services 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 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.

Adult open-heart surgery is on the list of tertiary health services under rule 59C-1.002(41)(h), 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.

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 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. 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.

Rule Challenges

In October 2000, AHCA proposed amendments to the adult open-heart surgery need 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 existing version of the rule was adopted in 1991.

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 provided 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; 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.

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). Complete transcripts of all three events are available.

An administrative lawsuit challenging the existing adult open-heart need methodology was filed last year, 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 then existed. 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. The issues were a mirror image of the initial rule challenge in that the petitioners were 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.

The amendments, as validated at DOAH on November 15, 2001, retain adult open-heart surgery as a tertiary health service, 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 the numeric standard that defines an acceptable hospital-specific minimum annual volume of adult open-heart surgeries.

Certificate of Need Workgroup

As required by Section 15 of Chapter 2000-318, Laws of Florida, a workgroup on CON has been meeting to consider and make recommendations regarding implementation of the CON program. An interim report was submitted to the Legislature in December 2001. The report contained the following recommendations regarding CONs for hospitals:

- Hospitals operating at 80 percent of acute care occupancy over the most recent 12 month period, or hospitals having 90 percent occupancy for any three 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.

After issuing the interim report, the workgroup addressed adult open-heart surgery at its January 2002 meeting. The workgroup voted to recommend that open-heart surgery remain subject to CON review with no exceptions.

Issues

In considering the proposal to eliminate CON review for adult open-heart surgery programs in Florida, 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.

III. Effect of Proposed Changes:

This bill amends s. 408.036, F.S., to revise criteria for exemption from certificate-of-need review. The maximum number of acute care beds a hospital may add without going through the CON review process is increased from 10 beds to 30 beds, or 10 percent of licensed capacity, whichever is greater, in a hospital that has experienced an acute care occupancy rate of 80 percent in the prior 12 months or 90 percent for any consecutive 3 months. The number of beds in a pediatric unit or an obstetric unit will not be considered in the determination of the hospital's occupancy rate.

The bill creates an exemption from CON review for the addition of neonatal intensive care unit (NICU) beds equal to 10 percent of licensed capacity or 8 beds, whichever is greater in a hospital that provides NICU services and that had an occupancy rate of 80 percent or more in the previous 12 months. A hospital that provides NICU Level III services may shift capacity between its level III unit and its Level II unit as long as staffing levels are appropriate and architectural requirements are met.

The bill creates an exemption from CON review for projects that are now subject to expedited review, except for replacement hospitals and the conversion of mental health beds to acute beds. The conversion of mental health beds must be reviewed to determine the effect on the availability of mental health services in the community. This exemption would apply to research,

education, and training programs; shared services contracts or programs; a transfer of a CON; and a 50-percent increase in nursing home beds for a facility incorporated and operating in the state before July 1, 1988.

The bill exempts certain adult open-heart surgery services in a hospital from the requirements for a certificate-of-need review provided certain criteria are met. The hospital must certify that:

- Prior to initiating adult open-heart surgery services, it will meet and continuously maintain the minimum licensure requirements adopted by AHCA, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Open-Heart Programs.
- It will provide a minimum of 2 percent of its services to charity or Medicaid patients.
- It will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
- It will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in an emergency.
- It will provide a minimum of 300 open-heart surgery procedures per year by completion of the third year of operation.
- Within 90 days of completion of its third year of operation, if it has failed to provide 300 open-heart surgery procedures, the agency will initiate revocation procedures against its open-heart surgery license.

AHCA is required to monitor open-heart surgery programs that operate under this exemption to ensure compliance with these requirements.

The bill takes effect upon becoming a 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 the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Hospitals establishing adult open-heart surgery programs would no longer incur the CON fees or the cost for appealing, or defending their application against the appeal of CON decisions. Hospitals that do a high volume of open-heart surgery procedures could see a reduction in the number of procedures they perform.

Hospitals increasing acute care beds or NICU beds; establishing research, education, and training programs; sharing service contracts or programs; or transferring a CON would not incur the cost of an expedited CON review.

C. Government Sector Impact:

If adult open-heart surgery programs no longer required a CON, AHCA would no longer collect approximately $352,000 in CON application fees each year.

AHCA's workload for expedited CON reviews would be reduced.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.