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HOUSE OF REPRESENTATIVES

COUNCIL FOR HEALTHY COMMUNITIES
ANALYSIS

BILL #: CS/HB 581

RELATING TO: Certificates of Need

SPONSOR(S): Council for Healthy Communities, Representative Mayfield and others

TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH REGULATION YEAS 8 NAYS 3
(2) COUNCIL FOR HEALTHY COMMUNITIES YEAS 10 NAYS 6
(3)
(4)
(5)

I. SUMMARY:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

Over the past year, the Florida Legislature took into consideration the total repeal and reform of the Certificate of Need process, which created fervent debate among health care providers.

Requirements for the Certificate of Need (CON) review process are set forth in Chapter 408, Florida Statutes. The CON review process is a regulatory program that requires health care providers to obtain state approval from the Agency of Health Care Administration (AHCA) before offering new or expanded services.

Rule 59C-1.002, Florida Administrative Code (F.A.C.), defines *tertiary health service* as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service.

According to AHCA, there has been considerable provider interest in establishing adult open heart surgery services. During the last 3 years, the agency has reviewed 48 applications for the service, an average of 16 applications per year. The bill exempts establishment of adult open-heart surgery program from the CON review process. The exemption requires the applicant to certify that it will provide a minimum of 2 percent of such services to charity or Medicaid patients.

According to AHCA, there is a negative fiscal impact of $352,000 associated with this bill, however, although AHCA anticipates a large reduction in CON application reviews for open heart surgery programs, the fiscal analysis AHCA provided did not project a need to reduce staff or expenses in relation to the reduced volume of activity.

See section VI AMENDMENTS OR COMMITTEE SUSBTITUTE CHANGES of this analysis for amendments adopted in the Council for Healthy Communities.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [x]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes [x]	No []	N/A []
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes [x]	No []	N/A []

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

B. PRESENT SITUATION:

The laws relating to the issuance of a certificate of need (CON) for health facilities are in Chapter 408, Florida Statutes. The Certificate of Need review program is a regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services. For example, a certificate of need is required if a hospital requests to initiate tertiary health services, such as an open heart surgery program.

Rule 59C-1.002, Florida Administrative Code (F.A.C.), defines *tertiary health service* as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service. By rule, examples include, but are not limited to: transplantation; adult **open heart surgery;** neonatal and pediatric cardiac and vascular surgery; and pediatric oncology and hematology services.

Rule 59C-1.033, Florida Administrative Code, defines ***Open Heart Surgery Operation*** as surgery 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.

In October 2000, the agency 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 technological/medical changes in open heart surgery procedures that have occurred since the present version of the rule was adopted in 1991. Related proposed amendments would have eliminated adult open-heart surgery from the list of tertiary services.

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). 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 to the rule, 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.

According to AHCA, there has been considerable provider interest in establishing adult open heart surgery services. During the last 3 years, the agency has reviewed 48 applications for the service, an average of 16 applications per year.

Each day, people suffering from heart disease are transported by emergency vehicle to an emergency room. Many need emergency access to a life-saving procedure called angioplasty. This procedure will open their blocked heart vessel saving their life and their heart muscle from further damage. Others must undergo the more serious open heart surgery. Either way, if a patient is taken to a hospital that is not approved to perform these procedures, he or she must be transferred to an open heart surgery facility. Critically important time will pass before the patient receives an angioplasty. Cardiologists have coined the phrase "time is muscle" when referring to heart attack victims. The sooner blood flow can be restored to the heart muscle the higher the probability the victim will not suffer permanent heart damage or death.[1]

Currently, there are 271 hospitals licensed in Florida; 263 are Medicare certified, 234 are accredited, and 59 offer an open heart surgery program. The inventory of Florida hospitals that offer programs is categorized by health planning district and is outlined as follows:

District	County(ies)	Approved/ Operational Programs	Approved/Non-Operational Programs	Total Approved Programs	Total Population In District
1	Escambia, Santa Rosa, Okaloosa, & Walton	3	0	3	644,215
2	Bay, Holmes, Washington, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, & Taylor	3	0	3	659,368
3	Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilcrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, & Lake	6	1	7	1,373,198
4	Baker, Nassau, Duval, Clay, St. Johns, Flagler, & Volusia	7		7	1,682,483
5	Pasco & Pinellas	5	0	5	1,295,793
6	Hillsborough, Manatee,	6	1	7	1,945,487

[1] Tallahassee Democrat, January 23, 2002.

	Hardee, Highlands & Polk				
7	Brevard, Orange, Seminole, & Osceola	6	0	6	2,020,901
8	Charlotte, Desoto, Lee, Sarasota, Glades, Hendry, & Collier	5	1	6	1,310,715
9	Indian River, Okeechobee, Martin, Palm Beach, St. Lucie	4	2	6	1,666,744
10	Broward	6	1	7	1,678,940
11	Dade & Monroe	8	0	8	2,397,292
Total	**State Wide**	**53**	**6**	**59**	**16,635,136**

The table above indicates that District 3 has a population of 1,373,198, with 7 approved programs, while District 7, with a population of 2,020,901 has 6 approved programs (with a hospital recently denied a CON in this service planning area), which has more than 700,000 additional residents in the planning district. It is unclear what criteria AHCA used to deny the recent CON request in District 7.

Exemptions to the CON Review Process

Currently, there are 19 statutorily defined exemptions to the CON review process. An exemption is not automatic under the current statutory language in s. 408.036(3) and (4), F.S. The applicant must request an exemption, and must support the request with documentation required by agency rule. Several of the current statutory exemptions contain provisions specifying limitations or other conditions that must be met by the applicant; and three of the exemptions specifically require the applicant to "certify" that it will meet specified conditions. The exemption created by HB 581 would require the applicant to certify that: "... it will provide a minimum of 2 percent of such services to charity or Medicaid patients."

In comparison with the bill, current s. 408.036(3)(i), F.S., provides an exemption for adult inpatient diagnostic cardiac catheterization services, specifies provision of services to charity and Medicaid patients, specifies timeframes for reporting utilization, and states that the exemption expires if the conditions are not met.

CON Review Process for Open Heart Surgery Program

Under current rules of ACHA, specifications for open heart surgery programs require that in order to establish an adult or pediatric open heart surgery program, a health facility must show specified minimum requirements for staffing and equipment; and it specifies a **methodology for determining the numeric need for a new program.** A certificate of need for the establishment of an open heart surgery program shall not normally be approved unless the applicant meets the applicable review criteria in section 408.035, F.S., and the standards and need determination criteria set forth by rule. Rule 59C-1.33. F.A.C., Open Heart Surgery Program, **effective January 24, 2002 states:**

An additional open heart surgery program shall not normally be approved in the district if any of the following conditions exist:

- There is an approved adult open heart surgery program in the district;
- One or more of the operational adult open heart surgery programs in the district that were operational for at least 12 months as of 3 months prior to the beginning date of the quarter

of the publication of the fixed need pool performed less than 300 adult open heart surgery operations during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool; or,

- One or more of the adult open heart surgery programs in the district that were operational for less than 12 months during the 12 months ending 3 months prior to the beginning date of the quarter of the publication of the fixed need pool performed less than an average of 25 adult open heart surgery operations per month.

CON Workgroup

Section 15 of Chapter 2000-318, Laws of Florida (CS/CS/HB 591), created a **30-member certificate-of-need workgroup** staffed by the Agency for Health Care Administration. The Legislature specified that the workgroup study issues pertaining to the certificate-of-need program, including the impact of trends in health care delivery and financing. In addition, the workgroup was charged with studying issues relating to implementation of the certificate-of-need program and was required to report to the Legislature with an interim report by December 31, 2001, with a final report by December 31, 2002. The workgroup is set to be abolished effective July 1, 2003. The recommendations for hospitals include:

- Hospitals operating at 80% acute care occupancy over the most recent 12 month period, or hospital having 90% occupancy for any 3 consecutive months, will be exempt from CON review for the greater of 10% of their licensed capacity or 30 beds.
- 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 II beds and adult open heart programs should 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.
- AHCA is to be directed to redefine the measures of hospital occupancy.
- 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.
- Projects now subject to expedited review (other than replacement hospitals and conversion of mental health beds to general acute beds) will now be exempt.
- The Certificate of Need Task Force should be allowed to continue its work through 2002 to address in more detail tertiary 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.

Over the past year, the Florida Legislature took into consideration the total repeal and reform of the Certificate of Need process, which created fervent debate among health care providers.

Proponents of deregulation of the Certificate of Need (CON) review process argue that, …"Florida's Certificate of Need Program (CON) should be scrapped. It has outlived any usefulness it may once have had, and is today used primarily as a tool for keeping competition out of the health care marketplace and as a funding mechanism for locally based Health Planning Councils. The former purpose is antithetical to every responsible economic theory and it harms consumers. The latter

purpose could be adequately met by alternate means."[2] In addition, proponents of deregulation suggest that fees associated with the CON review process are exorbitant and prohibitive in a competitive marketplace. Beginning with the letter of intent required by the Agency for Health Care Administration before the submission of an application, health care facilities routinely hire health planners, certified public accounts, and consultants. The CON application is reviewed in a batch cycle process, and once the Agency has made a determination, both competitive health care facilities and the actual applicant can challenge the outcome of the CON review process. Industry representatives argue that the majority of application determinations challenged in the Administrative Hearing process are too lengthy. After the submission of a formal challenge, the case is assigned a hearing officer with a scheduled hearing date, which may be months into the future. After the hearing process, each party involved in the case proposes a recommended order to the Administrative Law Judge. After careful consideration, the Administrative Law Judge then issues a recommended order to the Agency; all parties have a right to file an exception to the recommended order. Subsequently, the Agency issues a final order, and again all parties involved have the right to appeal the final order with the regional District Court of Appeals. The appellate process is lengthy, costly and time consuming to the applicant and the Agency.

Opponents to CON deregulation argue that by increasing the number of facilities that provide tertiary services, such as open heart surgery, the actual volume of surgery done in one locale will diminish, thereby decreasing mortality. In addition, they argue that the higher volume of operations completed, the better a patient's chance of survival.

However, one must consider the fact that it is not the hospital performing the open heart surgery, but the doctor. Furthermore, in larger facilities performing hundred of operations, it is likely that more than one physician is performing surgery. According to the *New England Journal of Medicine*, May 2000, "…unlike the outcome of pharmacologic therapies, the outcome of invasive cardiac procedures depends on individual expertise... Also, the outcome for patients with myocardial infarction (heart attack) may be dependent on the early use of adjunctive medications…It is possible that hospitals treating large numbers of patients with myocardial infarction have superior outcomes simply because accepted therapies are administered more frequently or more quickly than at hospitals with smaller numbers of such patients." The survival of open heart surgery greatly depends on the successful orchestration of many ancillary services, not just the open heart surgical procedure. It is believed that facilities performing larger volumes of open heart surgery may have better pre-operative and postoperative care that greatly contributes to increased patient survival. Advocates of deregulation suggest that quality care measures are a more definitive tool in measuring patient care outcomes than service volumes.

Florida Hospital Association suggests that there is data to support the theory that facilities providing a minimum standard of 250 open heart procedures a year have better patient outcomes. AHCA's need methodology is based on a service volume of a facility providing 350 procedures, 100 more procedures a year than what the Florida Hospital Association supports.

C. EFFECT OF PROPOSED CHANGES:

The bill exempts establishment of adult open-heart surgery program from CON review by adding that service to the list of exemptions contained in s. 408.036(3), F.S.

The exemption created by HB 581 would require the applicant to certify that: "... it will provide a minimum of 2 percent of such services to charity or Medicaid patients."

[2] The Journal of the James Madison Institute, *Certificate of Need: a Primer on a Program that Needs to Go*, Fall, 2001.

The bill does not specify any time frame during which the 2 percent must occur. For clarity, the bill should provide some guidance for the agency's rulemaking. For example, the bill could require that the 2 percent must be provided within the 12-month period commencing with operation of the adult open-heart surgery program, and again during each following 12-month period. The bill also does not specify any penalty to be imposed on the hospital if it fails to meet the required level of service to charity or Medicaid patients.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates a new paragraph (t) to s. 408.036(3), F.S., providing an exemption from CON review for the establishment of a new adult open-heart surgery program, provided the applicant certifies that it will provide at least 2 percent of such services to charity or Medicaid patients.

Section 2. Specifies that the bill is effective upon becoming a law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to AHCA:	Year 1 FY 02-03	Year 2 FY 03-04
Licenses:	$0	$0
Fees:	$(352,000)	$(352,000)
Grants:	$0	$0
Transfers In/ Another Agency	$0	$0
Total Recurring Revenues	**$(352,000)**	**$(352,000)**

2. Expenditures:

According to AHCA:	Year 1 FY 02-03	Year 2 FY 03-04
Salaries:	$0	$0
OPS	$0	$0
Expense	$0	$0
OCO	$0	$0
Total Recurring Expenditures:	**$0**	**$0**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals meeting the requirements of providing 2% of open heart surgery procedures to Medicaid and Charity patients, would no longer be required to apply for a CON for an open heart surgery program, thereby eliminating the CON application fees (statutorily defined fee based at a minimum

of $5,000 and which is capped at $22,000), any related cost of preparing the applications, and possible legal cost if the agency's action is challenged. It is unknown whether the agency's grant of an exemption would result in a legal challenge from a competing hospital.

According to AHCA, assuming that new programs take patients away from the existing programs, and assuming that exemptions would authorize more new adult open heart surgery programs than the amended current review requirements, then the annual revenue from open heart surgery programs could be reduced at existing facilities.

D. FISCAL COMMENTS:

The analysis received from AHCA anticipates a reduction in CON application reviews for open heart surgery programs; however, the fiscal analysis did not project a need to reduce staff or expenses in relation to the reduced volume of activity. Nor is it clear whether AHCA anticipates increased revenues from the application for an exemption for an open heart surgery program.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require a city or county to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

The bill does not authorize AHCA to promulgate additional rules for hospitals that may apply for an exemption for a CON for open heart surgery programs. According to AHCA, promulgation of rules regarding this exemption may result in a challenge based upon AHCA exceeding its statutory authorization.

C. OTHER COMMENTS:

Provisions of open heart surgery programs at medical facilities require specialized medical and nursing professionals. Competition among hospitals for the limited number of professionals with specialized training may result in an increase demand for such professionals, thereby increasing the hospital's cost for salary and wages.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On January 30, 2002, the Committee on Health Regulation considered HB 581 and adopted a strike-all amendment, and favorably passed the bill. The strike-all amendment provides:

- 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; and

- 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.

In addition, the amendment to 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.

As amended, 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 10 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.
- If the program has failed to provide 300 open-heart surgery procedures annually, after the third year, the exemption will automatically expire.

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

On February 26, 2002, the Council for Health Communities adopted both a substitute amendment and an amendment-to-the-substitute amendment, to the strike-all amendment and reported the bill favorably as a Council Substitute. CS/HB 581 recognizes that when a problem exist in access to needed cardiac services, consideration must be given to creating an exemption to the CON process and further recognizes that the exemption needs to be based upon objective criteria. The provisions for the exemption from the CON review process for open heart surgery programs specifies that facilities must meet the following criteria:

- The applicant for exemption must demonstrate that they are referring 300 or more cardiac patients from the hospital for cardiac open heart surgery or that the average wait time for transfer to another facility for treatment for 50% of more of the cardiac patients exceeds four hours.
- The applicant is a general acute care hospital that has been in operation for more than 3 years.
- The applicant is performing more than 500 diagnostic cardiac catheterization procedures per year, a combination of both inpatient and outpatient procedures.
- The applicant must create a formal peer review program with an existing statutory teaching hospital or cardiac program doing 750 open heart cases and that the peer review program will conduct quarterly reviews the first year and biannually the second yeas and subsequent years until either the program reaches 350 cases per year or demonstrates consistency with state adopted quality outcome standards for the service.
- The hospital payor mix, at a minimum reflects the community average for Medicaid, charity care, and self-pay for open heart surgery patients. If the applicant fails to reach the required minimum volume of 300 procedures per year, it must show cause why its exemption should not be revoked.
- Maintain minimum licensure requirements adopted by the agency governing open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult open-heart programs.
- The applicant must certify it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
- The applicant shall certify it will maintain sufficient appropriate times of operation and protocols to ensure the availability and appropriate referrals in the event of emergencies.

In addition, an exemption is created for the establishment of a satellite hospital through the relocation of 100 general acute care beds from an existing hospital located in the same district, as defined in s. 408.032(5).

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
Lisa Rawlins Maurer, Legislative Analyst	Lucretia Shaw Collins

AS REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by:	Council Director:
Lisa Rawlins Maurer, Legislative Analyst	David De La Paz