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 182

SPONSOR: Senator Atwater

SUBJECT: Certificate of Need

DATE: March 1, 2004 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Favorable
2.	Kruse	Maclure	CM	Favorable
3.			AHS	
4.			AP	
5.				
6.				

I. Summary:

Senate Bill 182 provides an exemption from certificate-of-need review for the provision of emergency percutaneous coronary intervention at hospitals without open-heart-surgery programs. The bill also establishes certain requirements, provides standards of care, and authorizes the Agency for Health Care Administration to promulgate rules regarding this exemption.

This bill amends s. 408.036, F.S.

II. Present Situation:

Certificate-of-Need Process

The certificate-of-need (CON) regulatory process under ch. 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 or agency). 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. Exemptions from CON review may be granted for:

- Replacement of a licensed health care facility on the same site, provided that the number of beds in each licensed bed category will not increase.
- Hospice services or for swing beds in a rural hospital, as defined in s. 395.602, F.S., in a number that does not exceed one-half of its licensed beds.
- The conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities. The total number of skilled nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of July 1, 1993. Certified skilled nursing beds designated under this provision, excluding swing beds, shall be included in the community nursing home bed inventory. A rural hospital which subsequently decertifies any acute care beds exempted under this provision shall notify the agency of the decertification, and the agency shall adjust the community nursing home bed inventory accordingly.
- The addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides a variety of residential settings and supportive services and that has been incorporated and operated in this state for at least 65 years on or before July 1, 1994. All nursing home beds must not be available to the public but must be for the exclusive use of the community residents.
- An increase in the bed capacity of a nursing facility licensed for at least 50 beds as of January 1, 1994, under part II of ch. 400, F.S., which is not part of a continuing care facility if, after the increase, the total licensed bed capacity of that facility is not more than 60 beds and if the facility has been continuously licensed since 1950 and has received a superior rating on each of its two most recent licensure surveys.
- An inmate health care facility built by or for the exclusive use of the Department of Corrections as provided in ch. 945, F.S. This exemption expires when such facility is converted to other uses.
- The termination of an inpatient health care service, upon 30 days' written notice to the agency.
- The delicensure of beds, upon 30 days' written notice to the agency. A request for exemption submitted under this provision must identify the number, the category of beds, and the name of the facility in which the beds to be delicensed are located.
- The provision of adult inpatient diagnostic cardiac catheterization services in a hospital.
  - In addition to any other documentation otherwise required by the agency, a request for an exemption submitted under this authority must comply with the following criteria:
    - The applicant must certify it will not provide therapeutic cardiac catheterization pursuant to the grant of the exemption.
    - The applicant must certify it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing such programs.
    - The applicant must certify it will provide a minimum of 2 percent of its services to charity and Medicaid patients.
  - The agency shall adopt licensure requirements by rule which govern the operation of adult inpatient diagnostic cardiac catheterization programs established pursuant to the exemption provided in the statute. The rules shall ensure that such programs:
    - Perform only adult inpatient diagnostic cardiac catheterization services authorized by the exemption and will not provide therapeutic cardiac catheterization or any other services not authorized by the exemption.

    - Maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
    - Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
    - Maintain appropriate program volumes to ensure quality and safety.
    - Provide a minimum of 2 percent of its services to charity and Medicaid patients each year.
- Mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to ch. 957, F.S.
- State veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs in accordance with part II of ch. 296, F.S., for which at least 50 percent of the construction cost is federally funded and for which the Federal Government pays a per diem rate not to exceed one-half of the cost of the veterans' care in such state nursing homes. These beds shall not be included in the nursing home bed inventory.
- Combination within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict. An exemption granted under this provision shall extend the validity period of the certificates of need to be consolidated by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption. The longest validity period among the certificates shall be applicable to each of the combined certificates.
- Division into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict. An exemption granted under this provision shall extend the validity period of the certificate of need to be divided by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption.
- The addition of hospital beds licensed under ch. 395, F.S., for acute care, mental health services, or a hospital-based distinct part skilled nursing unit in a number that may not exceed 10 total beds or 10 percent of the licensed capacity of the bed category being expanded, whichever is greater. Beds for specialty burn units, neonatal intensive care units, or comprehensive rehabilitation, or at a long-term care hospital, may not be increased under this paragraph.
- The addition of acute care beds, as authorized by rule consistent with s. 395.003(4), F.S., in a number that may not exceed 10 total beds or 10 percent of licensed bed capacity, whichever is greater, for temporary beds in a hospital that has experienced high seasonal occupancy within the prior 12-month period or in a hospital that must respond to emergency circumstances.
- The addition of nursing home beds licensed under ch. 400, F.S., in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater.
- Establishment of a specialty hospital offering a range of medical service restricted to a defined age or gender group of the population or a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical illnesses or disorders, through the transfer of beds and services from an existing hospital in the same county.

- The conversion of hospital-based Medicare and Medicaid certified skilled nursing beds to acute care beds, if the conversion does not involve the construction of new facilities.
- An adult open-heart-surgery program to be located in a new hospital provided the new hospital is being established in the location of an existing hospital with an adult open-heart-surgery program, the existing hospital and the existing adult open-heart-surgery program are being relocated to a replacement hospital, and the replacement hospital will utilize a closed-staff model. A hospital is exempt from the CON review for the establishment of an open-heart-surgery program if the application for exemption complies with specified criteria.
- The provision of adult open-heart services in a hospital located within the boundaries of Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties. The exemption must be based upon objective criteria and address and solve the twin problems of geographic and temporal access. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:

    - The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult 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 that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
    - The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
    - The applicant can demonstrate that it is referring 300 or more patients per year from the hospital, including the emergency room, for cardiac services at a hospital with cardiac services, or that the average wait for transfer for 50 percent or more of the cardiac patients exceeds four hours.
    - The applicant is a general acute care hospital that is in operation for three years or more.
    - The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.
    - The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.
    - If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.

    By December 31, 2004, and annually thereafter, AHCA must submit a report to the Legislature providing information concerning the number of requests for exemption from CON review for the provision of adult open-heart services in a hospital located within the boundaries of Palm Beach, Polk, Martin, St. Lucie, and Indian River counties received and the number of exemptions granted or denied.

All tertiary health services are subject to CON review under s. 408.036(1)(h), F.S. The term "tertiary health service" is defined in s. 408.032(17), F.S., as a health service that is 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.

Percutaneous Coronary Intervention as Treatment for Acute Myocardial Infarction

A heart attack, or acute myocardial infarction, occurs when one of the arteries that supply the heart muscle becomes blocked. Emergency treatment for acute myocardial infarction includes thrombolitics—the use of drugs to break up the clot—or percutaneous coronary intervention—the use of angioplasty or the insertion of a stent into the artery. *Angioplasty* is the dilatation of an obstructed artery, which is most commonly achieved by the passage of a balloon catheter through the vessel to the area of disease. Inflation of the catheter compresses the plaque against the vessel wall. A *stent* is a short narrow metal or plastic tube that is inserted into the artery to keep a previously blocked passageway open.

Rule 59C-1.032(6)(b), F.A.C., prohibits therapeutic cardiac catheterization and therefore also prohibits the provision of emergency percutaneous coronary intervention in a hospital without an open-heart-surgery program. Therapeutic cardiac catheterization is a general term that applies to angioplasty, stent insertion, and related procedures that are generally performed in cardiac catheterization laboratories. This term is distinguished from diagnostic cardiac catheterization, in which cardiac catheterization procedures are used to establish the patient's diagnosis.

Certificate-of-Need Workgroup

As required by s. 15 of ch. 2000-318, L.O.F., a workgroup on CON was established to study issues pertaining to the CON program, including the impact of trends in health care delivery and financing. The group produced a final report[1] in December 2002, which included a recommendation to amend s. 408.036(3), F.S., to exempt from CON review the provision of percutaneous coronary intervention for patients presenting with acute myocardial infarction in a hospital without an operational adult open-heart-surgery program. The workgroup recommended criteria for the exemption that are very similar to those in this bill.

Challenges to Applications

Section 408.039(5)(c), F.S., allows existing hospitals to initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need. Applicants competing for a CON may also challenge the agency's intended issuance or denial of a certificate of need. Challenges to an application and the cost of defending against challenges are a major reason for the perception that the CON process is burdensome.

[1] Florida CON Workgroup, *Final Report*, December 2002, *available at* http://www.fdhc.state.fl.us/MCHQ/CON_FA/finalrpt/tablecontent.htm (last visited February 24, 2004).

CON-Related Research

In the past few years, the Legislature has considered proposals related to CON that call into question whether or not CON is still an appropriate market-entry and quality-control mechanism for Florida hospitals. Several issues are brought to the discussion. One issue is the question of whether the CON process is a mechanism for maintaining quality or an outdated planning mechanism that thwarts competition among providers. CON programs emerged in the late 1960s and early 1970s as a way to regulate growth of facilities and costs in health care. After the passage of the National Health Planning and Resources Development Act of 1974 (PL 93-641), most states implemented CON programs. After the act was repealed in the 1980s, a number of states abolished their CON programs. Fourteen states (Arizona, California, Colorado, Idaho, Indiana, Kansas, Minnesota, New Mexico, North Dakota, Pennsylvania, South Dakota, Texas, Utah and Wyoming) no longer have CON laws.

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[2] 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[3] of the potential impact of CON on outcomes for patients, Gary Rosenthal and Mary Vaughan-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.

Changes in Medical Treatment for Heart Disease

Traditional adult open-heart surgery and related interventional cardiology procedures such as angioplasty have been one of the most competitive areas of hospital operations in recent years. Rapidly changing technology is decreasing the percentage of adult open-heart procedures and increasing the percentage of less invasive procedures such as angioplasty and stent insertion. This change could be accompanied by a change in the prevailing medical opinion about the need for open-heart backup when providing the less invasive procedures. Open-heart backup has traditionally been seen as essential for the less invasive procedures, but this medical opinion appears to be changing. If prevailing medical opinion supports angioplasty and stent procedures without open-heart backup, it is reasonable to predict that the competitive environment among hospitals will change.

[2] Frank Sloan & Chris Conover, "Does Removing Certificate of Need Lead to a Surge in Health Care Spending?", *J. Health Pol, Pol'y. & L.*, No. 23(3), at 455 (1998).
[3] Mary Vaughan-Sarrazin et al., "Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation," 288 *JAMA* 15, 1859-66 (2002).

In an August 2003 article[4] in *The New England Journal of Medicine,* Henning R. Andersen, et al., compared coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. Danish researchers randomly assigned 1,572 patients with acute myocardial infarction to treatment with angioplasty or accelerated treatment with intravenous alteplase. The patients who were treated with angioplasty were less likely to die or suffer reinfarction or a stroke than the patients who were treated with fibrinolytic therapy (8.5 percent of the patients in the angioplasty group as compared with 14.2 percent of patients in the fibrinolysis group). This research indicates that treatment with angioplasty within 60 minutes of the onset of the heart attack is preferable to treatment with intravenous drugs, and the researchers suggested changing the existing triage procedure accordingly. This research suggests that, instead of taking a patient to the nearest hospital, a better emergency procedure would be to take the patient to a center where angioplasty could be performed.

III. Effect of Proposed Changes:

The bill adds a new paragraph (j) to s. 408.036(3), F.S., to provide an exemption from certificate-of-need (CON) review for the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program. In addition to any other documentation required by the Agency for Health Care Administration (AHCA), a request for an exemption submitted under this paragraph must comply with the following:

- The applicant must certify that it will meet and continuously maintain the requirements adopted by AHCA for the provision of these services. These licensure requirements must be adopted by rule under to ss. 120.536(1) and 120.54, F.S., and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum, the rules shall require the following:

    - Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.
    - The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.
    - The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, seven days a week.
    - Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on previous experience in dedicated interventional laboratories or surgical centers.
    - Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.
    - Formalized written transfer agreements must be developed with a hospital with an adult open-heart-surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport

[4] Henning R. Anderson et al., "A Comparison of Coronary Angioplasty with Fibrinolytic Therapy in Acute Myocardial Infarction," 349 *New Eng. J. Med.* 8, 733-42 (2003).

agreements must be reviewed and tested, with appropriate documentation maintained at least every three months.
- Hospitals implementing the service must first undertake a training program of three to six months, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.

- The applicant must certify that it will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the:

  - Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.
  - Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.

- The applicant must agree to submit a quarterly report to AHCA detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions under this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.

The exemption from CON review for percutaneous coronary intervention does not apply unless AHCA determines that the hospital has taken all necessary steps to be in compliance with all requirements of the bill, including the training program. Failure of the hospital to continuously comply with the requirements for round-the-clock availability, staff qualifications, transfer agreements, adherence to the criteria of the American College of Cardiology and the American Heart Association referenced above, and submission of reports to AHCA will result in the immediate expiration of this exemption.

Failure of the hospital to meet the volume requirements within 18 months after the program begins offering the service will result in the immediate expiration of the exemption.

If the exemption for this service expires, AHCA may not grant another exemption for this service to the same hospital for two years, and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused expiration of the exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted under this paragraph.

The bill will take effect July 1, 2004.

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:

A hospital without an open-heart-surgery program that used the exemption from the certificate-of-need (CON) review to establish a program of emergency percutaneous coronary intervention would not incur the costs associated with the CON process.

C. Government Sector Impact:

The Agency for Health Care Administration would incur the cost of adopting rules and enforcing the requirements of the bill. The cost is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.