SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/CS/SB 2606

SPONSOR: Appropriations Committee, Health, Aging, and Long-Term Care Committee and Senator Pruitt

SUBJECT: Certificates of Need

DATE: March 25, 2004 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HC	Fav/CS
2.	Peters	Coburn	AP	Fav/CS
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I. Summary:

This bill revises various provisions relating to the certificate-of-need (CON) program in chapter 408, F.S. The bill:

- Prohibits the Agency for Health Care Administration (AHCA or agency) from issuing or renewing a hospital's license if more than a specified percentage of the hospital's patients receive care and treatment classified in specified diagnosis-related groups, provides certain exemptions, and authorizes AHCA to adopt rules to implement the requirement;
- Moves oversight responsibility for local health councils from AHCA to the Department of Health and removes local health councils from involvement in the CON process;
- Provides for the costs of operating a local health council to come from assessments imposed on selected health care facilities, adds health care clinics to the facilities being assessed, and eliminates CON fees as a source of funding for local health councils;
- Directs the Department of Health to enter into contracts with the local health councils for certain services;
- Revises criteria for reviewing an application for a certificate-of-need;
- Revises health-care-related projects that are subject to the certificate-of-need comparative review process;
- Revises health-care-related projects that are subject to an expedited certificate-of-need review;
- Revises the list of projects exempt from the certificate-of-need process;
- Requires health care facilities and providers to notify AHCA of certain specified activities;
- Requires AHCA to adopt rules for licensure standards for adult interventional cardiology services and burn units and provides minimum criteria for inclusion in the rules;

- Provides that certain health care providers of adult interventional cardiology services are exempt from complying with the rules for 3 years following the date of their next license renewal, but must meet the licensure standards thereafter;
- Requires AHCA to license two levels of treatment for adult interventional cardiology services and provides criteria for the two levels of licensure;
- Directs the Secretary of Health Care Administration to appoint an advisory group to study the issue of replacing certificate-of-need review of organ transplant programs operating under chapter 408, F.S., with licensure regulation of organ transplant programs under chapter 395, F.S., and requires the advisory group to submit a report to the Governor, the Secretary of Health Care Administration, and the Legislature by a specific date;
- Directs the Secretary of Health Care Administration to appoint a work group to study certificate-of-need regulations and changing market conditions related to the supply and distribution of hospital beds and requires the work group to submit a report to the Secretary and the Legislature by January 1, 2005;
- Increases fees for certificate-of-need applications;
- Changes the review cycle for certificate-of-need applications from biennial to annual and revises the review procedures to reflect the removal of local health councils from the CON process;
- Provides for conditions and monitoring for holders of a certificate of need or an exemption certificate and provides that failure to report to the agency constitutes noncompliance with conditions of the certificate;
- Provides that rules of the agency in effect on June 30, 2004, shall remain in effect until amended or repealed; and
- Repeals a special provision for a sole acute care hospital in a high growth county.

This bill amends ss. 395.003, 408.032, 408.033, 408.034, 408.035, 408.036, 408.0361, 408.038, 408.039, 408.040, and 408.0455, F.S.

The bill repeals s. 408.043(5), F.S.

II. Present Situation:

Certificate of Need

The 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 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. 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 paragraph, 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 paragraph 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 chapter 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 chapter 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 paragraph 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.
- Mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 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 chapter 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 paragraph 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 paragraph 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 chapter 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 chapter 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 4 hours.
- The applicant is a general acute care hospital that is in operation for 3 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 and to review the list annually to determine whether services should be added or deleted.

Issues

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 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. In an August 2003 article 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. 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.

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.

Health Service Planning Districts and Local Health Councils

Section 408.032(5), F.S., identifies 11 health service planning districts in Florida used by AHCA in its CON program. Section 408.033(1), F.S., establishes local health councils as public or private nonprofit agencies serving the counties of a health service planning district. The functions of the local health councils are specified in s. 408.033(1)(b), F.S. The local health councils may develop a district or regional area health plan that must contain preferences for the development of health services and facilities, which may be considered by the agency in its review of certificate-of-need applications. Under s. 408.033(2), F.S., local health councils are funded by application fees for certificates of need and by assessments on selected health care facilities subject to facility licensure by AHCA and organizations subject to certification by AHCA.

Diagnosis-Related Groups (DRGs)

Diagnosis-Related Groups were developed by the Medicare program for reimbursing hospitals for services provided to Medicare beneficiaries. DRGs are a classification system that groups patients according to diagnosis, type of treatment, age, and other relevant criteria. Under the Medicare prospective payment system, hospitals are paid a set fee for treating patients in a single DRG category, regardless of the actual cost of care for the individual.

Data Reporting Under Section 408.061, F.S.

Under s. 408.061, F.S., AHCA may require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties. Data to be submitted by health care facilities may include, but are not limited to: case-mix data, patient admission or discharge data with patient and provider-specific identifiers included, actual charge data by diagnostic groups, financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, depreciation expenses based on the expected useful life of the property and equipment involved, and demographic data.

III. Effect of Proposed Changes:

Section 1. Amends s. 395.003, F.S., adding a new subsection (9) to provide that a hospital may not be licensed, or have its license renewed, if 65 percent or more of its discharged patients, as reported to AHCA under s. 408.061, F.S., received diagnosis, care, and treatment within the following diagnosis-related groups (DRGs):

- Cardiac-related diseases and disorders classified as DRGs 103-145, 478-479, 514-518, 525-527;
- Orthopedic-related diseases and disorders classified as DRGs 209-256, 471, 491, 496-503, 519-520;
- Cancer-related diseases and disorders classified as DRGs 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367, 400-414, 473, 492; or
- Any combination of the above discharges.

Also, a hospital may not be licensed, or have its license renewed, if it restricts its medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties.

A new subsection (10) provides that hospitals licensed as of June 1, 2004, will be exempt from these requirements if the hospital maintains the same ownership, facility street address, and range of services provided on June 1, 2004. Any transfer of beds or other agreements that result in the establishment of a hospital or hospital services within the intent of this section are subject to subsection (9).

Under new subsection (11), AHCA may adopt rules to administer the licensure requirements in subsection (9). Within 14 days after rendering its decision on a license application or revocation, AHCA must publish its proposed decision in the Florida Administrative Weekly. Within 21 days after publication of the agency's decision, any authorized person may file a request for an administrative hearing. In any administrative proceeding challenging the approval, denial, or revocation of a hospital's license under subsection (9), the hearing must be based on the facts and law in effect at the time of the agency's proposed agency action. Existing hospitals may initiate or intervene in an administrative hearing to approve, deny, or revoke licensure of a competing hospital located within the same district or service area on a showing that one of the hospital's established programs will be substantially affected if a license is issued or renewed to the competing hospital.

Section 2. Amends s. 408.032, F.S., to revise certain definitions relating to the CON program, as follows:

- In the definition of *health services*, diagnostic services that meet the definition are <u>inpatient</u> services and rehabilitative services that meet the definition are <u>comprehensive medical</u> rehabilitative services.
- A *long-term care hospital* is one that seeks exclusion from the <u>acute care</u> Medicare prospective payment system for inpatient hospital services.
- In the definition of *tertiary health service*, pediatric cardiac catheterization and pediatric open-heart surgery are added to the definition, and specialty burn units are deleted from the definition.
- The definition of *regional area*, as a regional health planning area is deleted from the statute.

Section 3. Amends s. 408.033, F.S., to:

- Delete a reference to a local health council regional area health plan and a requirement for local health council plans to be considered in the review of CON applications;
- Designates the Department of Health as the agency that:
    - Oversees the plan for services to persons with HIV,
    - Receives local health council financial reports and consolidates them into an annual report, and
    - Contracts with local health councils for services;

- Delete a requirement that AHCA personnel make presentations at local health councils' annual orientation;
- Delete CON fees as a source of funding for local health councils;
- Makes health care clinics subject to the assessment on selected health care facilities to support the work of local health councils; and
- Delete the requirement that AHCA coordinate with local health councils in coordinated planning of health care services in Florida.

Section 4. Amends s. 408.034, F.S., to:

- Delete AHCA's oversight responsibility for local health council district plans;
- Delete references to hospice services and parts of health care facilities to conform to the definition of health care facility in section 2 of the bill; and
- Require AHCA to establish by rule a nursing-home-bed-need methodology that has a goal of maintaining a subdistrict average occupancy rate of 94 percent.

Section 5. Amends s. 408.035, F.S., to delete the following from the review criteria for the CON program:

- The need in the service district for special health care services that are not reasonably and economically accessible in the adjoining areas; and
- The needs of research and educational facilities.

Section 6. Amends s. 408.036, F.S., to revise the list of health-care-related projects that are subject to the certificate-of-need process.

The following projects will be subject to *comparative review*:

- Addition of community nursing home beds and intermediate care facilities for the developmentally disabled (ICF/DD) beds by new construction or alteration;
- Establishment of new health care facilities or replacement facilities located more than one mile away from the existing facility, under certain conditions;
- Conversion of one type of health care facility to another;
- Establishment of a hospice program or inpatient hospice facility;
- An increase in the number of beds for comprehensive rehabilitation;
- Establishment of tertiary care services as they are redefined by the bill; and
- An increase in the number of beds for acute care in a hospital that is located in a low-growth county.

Projects that would not longer be subject to *comparative review* include:

- The addition of beds by new construction or alteration in health care facilities other than community nursing homes, and intermediate care facilities for the developmentally disabled;
- A replacement facility that is not on the same site, but is within 1 mile, if the number of beds in each licensed bed category does not increase;

- An increase in the total licensed bed capacity of a health care facility, other than a community nursing home or intermediate care facility for the developmentally disabled;
- The establishment of inpatient health services by a health care facility, or a substantial change in such services; and
- An increase in the number of beds for acute care, specialty burn units, neonatal intensive care units, mental health services, or hospital-based distinct part skilled nursing units, or at a long-term care hospital.

Projects subject to an *expedited review* are:

- CON transfers, except that, when an existing hospital is acquired, all CONs issued to the hospital which are not yet operational are acquired without the need for a transfer; and
- Replacement of a nursing home in the same CON district, under certain conditions; and
- Relocation of a portion of a nursing home's licensed beds to a facility within the same district if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the district does not increase.

Projects that would not longer be subject to *expedited review* include:

- Research, education, and training programs;
- Shared services contracts or projects;
- A 50 percent increase in nursing home beds for a specific facility;
- 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 health care facility; and
- Certain conversions of hospital mental health services beds or hospital-based distinct part skilled nursing unit beds or general acute care beds.

Projects eligible for an *exemption* from CON review are expanded to include the following:

- The addition of licensed hospital beds for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater;
- The addition of mental health services or beds if the applicant commits to provide services for Medicaid or charity patients at a level equal to or greater than the district average;
- The replacement of a licensed nursing home on the same site or within 3 miles of the same site if the number of licensed beds does not increase;
- The consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning subdistrict, by providers that operate multiple nursing homes within that planning subdistrict, if there is no increase in the planning subdistrict total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location;
- Beds in state mental health treatment facilities operated under s. 394.455, (30), F.S., and state mental health forensic facilities operated under s. 916.106(8), F.S.;
- Beds in state developmental services institutions as defined in s. 393.063, F.S.;
- The addition of nursing home beds licensed under chapter 400, F.S., at a facility that has been designated as a Gold Seal nursing home under s. 400.235, F.S., in a number not

exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded;

- The establishment of Level II and III neonatal intensive care unit (NICU) beds, provided: the applicant facility demonstrates it has had 1,500 annual births (for Level II) or 3,500 annual births and has operated a 10-bed Level II unit (for Level III); the applicant meets specified quality criteria; and the facility commits to providing services to Medicaid and charity care patients equal to or above the district average; and
- 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.

The bill provides requirements for the exemption from 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 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 pursuant 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:

    - 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, 7 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 agreements must be reviewed and tested, with appropriate documentation maintained at least every 3 months.
    - Hospitals implementing the service must first undertake a training program of 3 to 6 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 pursuant to 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 2 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.

The following projects are removed from the list of *exemptions*:

- On-site replacement facilities;
- Termination of inpatient health services;
- Delicensure of beds;
- Addition of hospital beds, both permanent and temporary, for any purpose except comprehensive rehabilitation
- The provision of adult inpatient diagnostic cardiac catheterization services in a hospital; and
- Other exemptions that are outdated.

The exemption for the provision of adult open-heart surgery in areas of geographic need is amended to remove a reference to certain counties and to provide the exemption within the boundaries of a health service planning district that has experienced an annual net out-migration of at least 600 open-heart surgery cases for 3 consecutive years according to the most recent data reported to AHCA and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district that meet the criteria

established in the bill will be eligible for the exemption on July 1, 2004, and shall receive the exemption upon filing for it, as follows:

- A hospital that has received a notice of intent to grant a CON or a final order of the agency granting a CON for an open-heart-surgery program is entitled to receive a letter of exemption for the establishment of an adult open-heart surgery program upon filing a request for exemption and complying with the criteria enumerated in the bill and is entitled to immediately commence operation of the program.

- An otherwise-eligible hospital that has not received a notice of intent to grant a CON or a final order of AHCA granting a CON for the establishment of an adult open-heart-surgery program is entitled to immediately receive a letter of exemption for the establishment of an adult open-heart surgery program upon filing a request for exemption and complying with the criteria enumerated in the bill but is not entitled to commence operation of its program until December 31, 2006.

- The criteria that must be met by an applicant for this exemption are:

    - 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 has discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period as reported to the agency.
    - The applicant is a general acute care hospital that is in operation for 3 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.

A new subsection (5) is added to s. 408.036, F.S., to require health care facilities to *notify* the agency of the following:

- Replacement of a health care facility within a 1-mile radius of the replaced health care facility;
- Termination of a health care service; and
- Addition or delicensure of beds.

Section 7. Amends s. 408.0361, F.S., to require the agency to adopt rules for licensure standards for adult interventional cardiology services and burn units. The bill provides minimum criteria for inclusion in the rules and provides that certain health care providers of adult interventional cardiology services are exempt from complying with the rules for 3 years following the date of their next license renewal, but must meet the licensure standards thereafter. The bill requires the agency to license two levels of treatment for adult interventional cardiology services and provides criteria for the two levels of licensure and to establish a technical advisory panel to develop procedures and standards for measuring outcomes of interventional cardiac programs.

The bill requires the Secretary of Health Care Administration to appoint an advisory group to study the issue of replacing certificate-of-need review of organ transplant programs operating under chapter 408, F.S., with licensure regulation of organ transplant programs under chapter 395, F.S.; provides for membership; requires the advisory group to make certain recommendations; and directs the advisory group to submit a report to the Governor, the Secretary, and the Legislature by a specific date.

The bill requires the Secretary of Health Care Administration to appoint a workgroup to study certificate-of-need regulations and changing market conditions related to the supply and distribution of hospital beds, and by January 1, 2005, the workgroup must submit a report to the secretary and the Legislature identifying specific program areas and recommending needed changes in statute and rule.

Section 8. Amends s. 408.038, F.S., to increase fees for certificate-of-need applications. The current range for CON fees—from $5,000 to $22,000—is increased to a range of from $10,000 to $50,000.

Section 9. Amends s. 408.039, F.S., to provide for an annual, rather than biennial, review cycle for certificate-of-need applications, and revises the review procedures to reflect the removal of local health council plans from the CON process.

Section 10. Amends s. 408.040, F.S., to provide for conditions and monitoring for holders of a certificate of need or an exemption certificate and to provide that failure to report to the agency constitutes noncompliance with conditions of the certificate.

Section 11. Repeals subsection (5) of s. 408.043, F.S., which authorizes a sole acute care hospital in a high growth county to add up to 180 additional beds without agency review.

Section 12. Amends s. 408.0455, F.S., to provide that rules of the agency in effect on June 30, 2004, shall remain in effect until amended or repealed.

Section 13. Provides that the bill will take effect July 1, 2004.

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 Article VII, Section 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 Article 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 Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The current range for CON fees—from $5,000 to $22,000—is increased to a range of from $10,000 to $50,000. However, providers of services that would no longer require CON review under this bill would no longer be subject to a fee.

Health care clinics will be subject to a $150 assessment annually to fund local health councils.

B. Private Sector Impact:

The private sector could see a decrease in the cost to provide health care services because of the deregulation of certain services from the certificate-of-need review process. However, for the projects that remain under CON review, the fees associated with these projects will increase.

C. Government Sector Impact:

According to AHCA, the Department of Health will receive reduced funds collected by the agency for support of the local health councils and their functions. While this funding has varied from year to year since the current relationship was established in 1997, it is reasonable to project that annual funds transferred from AHCA to DOH would drop from approximately $1.65 million per year to approximately $600,000 per year (the funding level represented by the fees assessed). With the addition of health care clinics in the list of facilities that are subject to an assessment to fund local health councils, however, some of the loss in revenue will be offset by the new assessment.

Under the existing statutory and rule requirements, the revenue to the CON program is generated from fees for project reviews and review of exemption requests. The current maximum fee for a project review application is $22,000 and the fee for review of

exemption request is $250. In Fiscal Year 2002-03, the fees generated from these reviews totaled $1,661,000. These revenues were generated through fees paid for all project review applications and exemption review requests and receipts from health care publications.

Staffing and support expenditures for the CON program totaled $1,061,559 for the 2002-03 Fiscal Year and $1,650,000 was provided to the LHCs, including the health facility fee assessment that was passed through to the LHCs following collection by the Agency. The net result of the existing fee and expense structure is a deficit in the funding to the overall CON and LHC operations of approximately $ 1.1 million.

The proposed fee structure would increase the maximum fee amount to $50,000 per CON review which was a recommendation of the CON Task Force. Based on fee computation criteria, this maximum fee would be applicable to a project that has a total projected cost of approximately $2.7 million. Projections for project reviews under the revised provisions take into consideration the projects that have been eliminated from CON review requirement.

Projects no longer subject to full review include the addition of acute care beds, acute rehabilitation beds, neo-natal intensive care beds, and adult open heart surgery programs. During the last 12 months the Agency received 102 CON applications and generated approximately $1.0 million in application fees. With the passage of this bill, the number of CON applications is expected to drop from 102 to 36. Application fees as increased by this bill would generate approximately $1 million in revenues for the 04-05 fiscal period.

The estimated mix of applications and potential revenues are outlined in the table below.

Applications and fees	Projected Volume	Fees	Average Fee
Hospice	17	$269,799	$15,871
Long-term acute care hospitals	11	454,680	41,335
New Acute Care Hospital	5	250,000	50,000
Nursing Home Beds	3	75,521	25,174
Total	36	$1,050,000	$29,167

Requests for exemption are estimated to total 180 per year, at a fee of $250 per exemption, for a total revenue projected to be $45,000. Fees projected from the revised fee structure and revised project review requirements and the requests for exemption total $1.1 million per year.

The CON expense budget as approved for 2004 is summarized in the following table.

Certificate of Need

Salaries	$986,032
OPS	
Expenses	210,680

OCO	
Casualty Insurance	11,466
Total	$1,208,178

Passage of this bill would eliminate the need for 3 FTEs from the CON program with a related cost savings of about $139,411. With salaries decreasing by $139,411, total expenses would be reduced to $1,068,767. The proposed increase in the maximum fee and the elimination of the support of LHCs from CON fees would permit the maintenance of the CON review program with the staffing reductions projected for that program. These positions were proposed for deletion in the Agency's FY 2004-05 Legislative Budget Request and were subsequently recommended for deletion in the Governor's recommended budget for FY 2004-05 (Issue code 33G0010).

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.