HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1699 Certificate of Need
SPONSOR(S): Mayfield
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2606 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Services (Sub)	10 Y, 1 N	Rawlins	Collins
2) Health Care			
3) Finance & Tax			
4) State Administration			
5) Health Appropriations (Sub)			
6) Appropriations			

SUMMARY ANALYSIS

Florida is one of 36 states that have a Certificate of Need (CON) program, and compared to other states, the program is viewed as "limited," in that it regulates fewer aspects of the health care delivery system than most. Florida first began its program in July 1973, and over the last 30 years, the program has experienced limited reform. Originally, the principle rationale for CON was to control health care costs, although in Florida, as in many states, both quality and access were important reasons that CON was adopted.

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.

The bill provides CON reform in that burn and adult cardiac services are no long subject to review, but rather licensure standards. The bill establishes a mechanism to determine the need of CON regulation for organ transplantation services in the future. It also provides for an exemption from CON review for the addition of beds at existing hospitals. Projects that are added to the list of CON review: bed additions at skilled nursing homes and intermediate care facilities for the developmentally disabled. Tertiary health care services are redefined to include pediatric cardiac catheterization and pediatric open-heart surgery and to exclude specialty burn units and comprehensive rehabilitation. The bill increase CON application fees.

The CON program currently considers local preferences for additional beds and services as reported by the 11 local health councils (LHC) in bi-annual district health plans. The bill eliminates routine consideration of local preferences as determined by the LHC. These 11 local health councils are funded in part by CON fees as well as by the collection of health facility assessments under s. 408.033(2), F.S. The bill eliminates funding for the LHC through the certificate of need fees.

HB 1699 provides authority to the Agency for Health Care Administration (AHCA) to fine facilities found in noncompliance of a CON, or a CON exemption. The bill prohibits the licensure of boutique hospitals that provide a majority of cardiac services, oncology or orthopedics care. It amends the definition of long-term care hospital to comply with changes in the federal definition of this provider type.
The bill repeals special provisions relating to osteopathic acute care hospitals, hospice programs, rural health networks, private accreditation requirements for hospitals, and sole acute care hospitals in high growth areas and the provision allowing for competitive sealed proposals for facilities in which funding in whole or in part is authorized by the Legislature.

The bill provides for an effective date of July 1, 2004.

See "Fiscal Comments" section of the analysis for a detailed explanation of the fiscal impact.

See " Amendments/Committee Substitute Changes" for a detailed explanation of the strike all amendment.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[x]	No[]	N/A[]
2. Lower taxes?	Yes[]	No[x]	N/A[]
3. Expand individual freedom?	Yes[x]	No[]	N/A[]
4. Increase personal responsibility?	Yes[x]	No[]	N/A[]
5. Empower families?	Yes[x]	No[]	N/A[]

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

This bill doubles the CON application fees from $22,000 to $50,000 and the minimal base fee from $5,000 to $10,000.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida is one of 36 states that have a Certificate of Need (CON) program, and compared to other states, the program is viewed as "limited," in that it regulates fewer aspects of the health care delivery system than most.[1] Florida first began its program in July 1973, and over the last 30 years, the program has experienced limited reform. Originally, the principle rationale for CON was to control health care costs, although in Florida, as in many states, both quality and access were important reasons that CON was adopted. However, since the adoption of the program and through the 1990s, Florida has experienced changes in its health care delivery system. As in most states, the rapid emergence of managed care and vertical integration in the health care market have combined to make the market considerably more competitive. The recent return of double-digit rates of medical inflation, the combination of pressures for cost containment from both public and private payers, and the excess of hospital beds, assure that market pressures squeeze out excess capacity. It is believed that this trend will continue unabated.

Within the last three years, the Legislature has debated several proposals for CON reform aimed at correcting the perceived problems of the regulatory scheme. Opponents of CON have argued that:

- ✓ The program protects existing providers, locking out newcomers and stifling innovation.
- ✓ CON rules fail to respond to changing demographics, preventing minority providers from entering the market even when target populations have evolved into largely minority populations.
- ✓ The program is subject to political favoritism and manipulation.
- ✓ Prolonged litigation eliminates some applicants from the process because of fiscal limitations.
- ✓ The program is manipulated by insider groups who succeed more because of their knowledge of the process rather than the inherent value of their health care proposals.
- ✓ The program is subject to "gaming" by insiders who acquire CONs and treat them as assets to be sold on the open market without intending to deliver health care services.
- ✓ The program has failed to meet its goals relating to health care cost containment, access to care, and quality assurance.

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[1] 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.

- ✓ It is considered intrusive government for the state to determine “need” for health services.
- ✓ Current planning areas allow relatively far-removed providers to block proposals for new health services.
- ✓ Expenditures related to the CON litigation should be spent on patient care, in that CON-related litigation is wasteful.
- ✓ Free market competition, rather than government regulation, should allocate resources in the health care system.[2]

Proponents of the system argue that:

- ✓ The program protects the safety net providers that provide indigent care and care for the uninsured.
- ✓ The program assures quality by limiting availability of services and creating high service volumes of specialty care in a concentrated area.
- ✓ The program provides a cost containment system.
- ✓ The program expands access to needed health services.

States across the nation are critically examining their CON programs in that many states have commissioned independent studies to determine the effectiveness of their programs. A recent study, commissioned by the Michigan Department of Health, conducted by the Center for Heath Policy, Law and Management, Terry Stanford Institute of Public Policy at Duke University, concluded that the sweeping changes that continue to occur in the evolution of medical technology, as well as in health care delivery and financing, offer considerable potential for curbing cost, and that CON is becoming clearly less relevant as a cost containment mechanism.[3]

This study focused on the evaluation of CON for acute care services, with particular attention given to CON for hospital beds, MRI services, and cardiac services which includes cardiac catheterization laboratories and open heart surgery units. In review of Michigan’s Certificate Need program, the study finds that:

- ✓ There is little evidence that CON results in a reduction in cost and some evidence to suggest the opposite.
- ✓ Removal of CON does not consistently lead to a “surge” in either acquisition of new facilities or medical expenditures.
- ✓ Because it is reasonably well-established that higher volume facilities generally achieve better health outcomes, the higher volumes that accompany specialization of facilities should improve health outcomes. While the general evidence that CON actually achieves such specialization is relatively weak, the study finds evidence that the CON program constrains supply of specialty services such as MRI units, open heart programs, and cardiac catheterization facilities.
- ✓ It is an open question whether any quality improvements achieved through CON might be effectively or more efficiently achieved using alternative mechanisms such as hospital outcomes enforced through a licensure process.
- ✓ CON may have a beneficial impact on access to care for the uninsured and underinsured, but the evidence is thin and even if true, such an impact is relatively modest in the context of the state’s 1 million uninsured (compared to Florida’s 2.8 million uninsured).

Although Michigan’s CON regulatory process is more stringent than Florida’s in that Michigan regulates more services, a comparison of regulatory requirements specific for cardiac programs reveals that the

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[2] Presentation by Jeff Gregg, Bureau Chief, Health Facility Regulation, Agency for Health Care Administration, at the CON Workgroup meeting, Orlando Florida, April 27, 2001.
[3] Conover, Christopher, Ph.D., et al.; “Evaluation of Certificate of Need in Michigan, Volume 1: Final Report.” The Center for Health Policy, Law and Management, Terry Sanford Institute of Public Policy. May 2003.

regulation is very similar. Therefore, the findings of the Michigan study, as it pertains to cardiac services, make a valid comparison to Florida's CON program for cardiac services. Findings of the Michigan study specific to CON for cardiac services conclude that:

- ✓ The empirical evidence regarding CON's impact on costs and availability of cardiac services is mixed: individual cases suggest that lifting CON does [not] typically lead to a surge in acquisition of new facilities or equipment (although some states have experienced this). Moreover, the multivariate analysis used in this study was able to control for many factors that might otherwise affect the proliferation of open heart / cardiac catheterization services and found that if anything, controlling for all these factors, lifting CON was associated with a reduction of cardiac care services in the short run, but not for the long run.
- ✓ Analysis further showed that stringent CON had no significant effects (although other studies have found that states with stringent CON achieve significant reductions in the number of cardiac programs deployed).
- ✓ Interviews provide fairly good evidence that Michigan's CON has inhibited growth in the supply of cardiac services, but there is mixed views on whether this is good or bad for the consumer.

The concluding observation of the study: "…it does seem reasonable to conclude from these findings that retaining CON program unchanged probably is undesirable."

In another 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 in all 50 states for a 6-year period to Medicare patients undergoing coronary artery bypass graft (CABG) surgery. 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.

As cited in the aforementioned studies, 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.

It is well documented that the increase level in service availability leads to increased utilization. The Dartmouth Atlas documents huge differences in health care spending across US regions, and the primary reason cited for the differences in spending is the availability of service. For example, age, sex and race adjusted spending for traditional (fee-for-service) Medicare in the Miami region was $8,414 in 1996, compared to the $3,431 spent in the Minneapolis region. The greater than two fold differences observed across U.S. regions are not due to differences in the prices of medical services or to differences in average levels of illness or socioeconomic status across regions. Rather, they are driven primarily by differences in the aggregate amount of medical services provided to apparently similar populations.

Because many specific treatments are known to be beneficial, such as emergency treatment of heart attacks, or surgery to replace a failing hip joint, most Americans assume that more medical care in general must also be beneficial.

Research, however, shows that those who reside in high cost communities are no more likely to receive specific treatments of proven benefit or discretionary procedures that are likely to improve their function. Spending more, within the range observed in the U.S., results in greater use of "supply-sensitive" services: more frequent physician and specialist visits, greater use of diagnostic tests and minor procedures, and more frequent use of the hospital as a site of care.

Researchers now have good reason to believe that those who receive more "supply-sensitive" care have no improvement in survival and are unlikely to have better quality of life. Specific to cardiac care, Florida ranks as one of the highest in hospitalization for congestive heart failure. Hospitalization for congestive heart failure accounts for 10% of medical hospitalizations among the Medicare population. As pointed out in the Dartmouth Atlas, rates of hospitalization for this condition are significantly more variable than rates of hip fractures. The rates of hospitalization for congestive heart failure ranged from 9.7 per 1,000 Medicare enrollees to 41.3; the average rate in the United States was 22.6.

With this evidence presented, policymakers may balance two significant realities in creating health policy as it pertains to cardiac services:

1. The immediate treatment of patients with acute myocardial infraction with angioplasty will be less likely to die or suffer reinfraction or a stroke; and
2. The increase of “supply-sensitive” care is likely to result in the increase utilization of services, thereby increasing overall cost of health care services within a region.

Current Regulations

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.

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[4] in December 2002, which included recommendations to provide limited reform to the CON program, which many of the concepts are incorporated into 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.

Application Fees

Section 408.038, F.S. sets forth the applicable fees for the CON program. The fee structure was originally designed to have the bureau responsible for administering the program to operate on the revenue generated from fees. Since the implementation of the CON program, statutory changes have lessen the number of project subject to review and therefore diminished the revenues collect from CON application fees. CON fees collected do not cover the entire cost of administering the CON program. Additionally, a portion of the fees collected is used to help fund 11 local health councils, as statutorily defined.

Long Term Care Facilities

Long-term care hospitals are currently defined under s. 408.032(13), F.S., as hospitals licensed under chapter 395 which meet the requirements of 42 Code of Federal Regulations (CFR) 421.23, (e) and seek exclusion from the Medicare prospective payment system for inpatient hospitals services. This definition is not in accord with recently changed federal reimbursement requirements.

Certificate of Need Compliance

Section 408.040(1) (d), F.S., does not address conditions on CON exemptions or a CON holder's failure to report on meeting the conditions predicated upon award of its CON. Currently the agency has an option as to whether or not it will fine a CON holder for not meeting conditions printed on the face of the CON and the current law does not clearly indicate that not meeting a condition equates to non-compliance. For example, rules established for open heart programs requires a certain number of procedures to be performed each year, however, some hospitals that have an open heart CON are not meeting the volume requirements.

[4] 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).

Specific Considerations

Section 408.043, F.S., currently directs the agency to look at osteopathic need when new applications are received for osteopathic beds, to create a formula that discourages regional monopolies and promotes competition for hospice programs, to award a CON to members of certified rural health networks, and, under certain conditions, not to require CON applicants to achieve or maintain private accreditation.

Section 408.045, F.S., currently allows the agency to use competitive sealed proposal procedure for health care facilities or services where funding is authorized by the Legislature.

CON Staff Duties

Certificate of Need staff currently review projects subject to comparative review, expedited review, and projects exempt from review. Staff also monitor the implementation of a CON and monitor CON holders to ensure compliance with CON conditions, give depositions and testify at CON hearings involving all aspects of the CON process.

HB 1699

This bill expands the ability of existing health care systems to better and more quickly address local needs by eliminating a state review process and lengthy administrative hearing process for the addition of certain beds and types of services at existing hospitals including cardiac, burn, neonatal intensive care, comprehensive medical rehabilitation, long-term care hospital, acute, mental health, and inpatient hospice beds at existing freestanding inpatient hospice facilities.

The addition and ongoing operation of specialty burn units and adult cardiac programs at existing hospitals will be subject to licensure and regulation by the agency's hospital licensure program. With proposed changes to s. 395.003, F.S., the bill gives the hospital licensure program the authority to deny or withhold renewal of a license when the percentage of cardiac, orthopedic or oncology discharges exceeds 65 percent of the hospitals total inpatient discharges. It will also require the agency to provide criteria and standards for two new areas of hospital licensure (adult interventional cardiology and burn units), and require rule writing under chapter 395, F.S. This bill exempts for two years hospitals that have operational or CON-approved interventional cardiology programs or burn units on June 1, 2004, from meeting the new requirements.

The bill allows the agency to have only one batching cycle per year should the number of applications that shall be reviewed. This change eliminates duplicate reviews in the same year of the same proposal. Under this bill, consideration of identified local needs listed as CON preferences in local health plans will not be given in CON reviews. The bill reduces the number of programs for which a CON is issued and increase the number of programs for which a CON exemption can be given.

Relating to the repeal of CON special provision regulation relating to osteopathic acute care hospitals, hospice programs, rural health networks, private accreditation requirements for hospitals, and sole acute care hospitals in high growth areas and the provision allowing for competitive sealed proposals for facilities in which funding in whole or in part is authorized by the Legislature, with the exception of private accreditation requirements for hospitals, the proposed changes would have little or no effect.

C. SECTION DIRECTORY:

Section 1. Amends s. 395.003, F.S., prohibits the Agency for Health Care Administration 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 diagnostic-related groups; providing an exemption; and authorizes the agency to adopt rules.

Section 2. Amends s. 408.032, F.S., revises the definitions relating to health facilities and services pertaining to the certificate of need review process.

Section 3. Amends s. 408.033, F.S., requires that local health councils serve counties in a health service planning district; directs the local health council to develop a plan for services at the local level with the Department of Health; provides for the costs of operating a local health council to come from assessments imposed on selected health care facilities; directs the department to enter into contracts with the local health councils for certain services; and places health councils under the jurisdiction of the Department of Health.

Section 4. Amends s. 408.034, F.S., conforms provisions to changes made by the act.

Section 5. Amends s. 408.035, F.S., revises criteria for reviewing an application for a certificate-of-need.

Section 6. Amends s. 408.036, F.S., revises health-care-related projects that are subject to the certificate-of-need process; revises health-care-related projects that are subject to an expedited certificate-of-need process; revises the list of projects exempt from the certificate- of-need process; and requires health care facilities and providers to notify the agency of certain specified activities.

Section 7. Amends s. 408.0361, F.S., requires the agency to adopt rules for licensure standards for adult interventional cardiology services and burn units, 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 2 years following the date of their next license renewal, but must meet the licensure standards thereafter; requires the agency to license two levels of treatment for adult interventional cardiology services; and provides criteria for the two levels of licensure.

Section 8. 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 ch. 408, F.S., with licensure regulation of organ transplant programs under ch. 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.

Section 9. Amends s. 408.038, F.S., increases fees for certificate-of-need applications.

Section 10. Amends s. 408.039, F.S., provides for an annual review cycle for certificate-of-need applications, and revises the review procedures.

Section 11. Amends s. 408.040, F.S., 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.

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

Section 13. Repeals s. 408.043(2), F.S., which relates to special provisions for hospice facilities; and repeals s. 408.045, F.S., which relates to the use of a competitive sealed proposal to obtain a certificate of need for an intermediate care facility for the developmentally disabled.

Section 14. Provides for the act to become effective July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See “FISCAL COMMENTS” section.

2. Expenditures:

   See "FISCAL COMMENTS" section.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The private sector will see a decrease in cost to provide health care services by 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.

D. FISCAL COMMENTS:

According to the AHCA, the Department of Health will receive reduced funds collected by the Agency for support of the Local Health Councils (LHC) and its 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).

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.

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. The net result of the existing fee and expense structure is a deficit in the funding to the overall CON and LHC operations.

The proposed fee structure would increase the maximum fee amount to $50,000 per CON review. Based on fee computation criteria, this maximum fee would be applicable to a project that has a total projected cost of approximately $3.4 million. Projections for project reviews under the revised provisions take into consideration the projects that have been eliminated from CON review requirement. Based on these requirements, it would be anticipated that a total of 32 projects would require reviews. These reviews would include applications from hospices, long-term acute care facilities, acute care hospitals, and nursing home beds (relocations). It would be anticipated that the maximum fee amount would apply to only 5 of these projects involving acute care hospitals. Requests for exemptions are estimated to total 180 per year, at a fee of $250 per exemption, for 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 $984,794 per year.

According to AHCA, 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 of 3 FTEs.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides rule-making authority for the provisions within this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Agency for Health Care Administration did not clarify the methodology used in calculating the projected loss revenue in the assessment of fees for licensed facilities as it relates to the funding of the local health councils. By statute, local health councils are funded from both CON fees and licensing fees. While the funding from the CON application fees is eliminated by this bill, assessments for licensed health care facilities should increase in the forthcoming years due to the implementation of 2003 legislation requiring the licensing of medical clinics (also known as P.I.P. clinics). As of March 2004, AHCA has received 2,434 applications for clinic licensure.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 15, 2004, the Subcommittee on Health Services passed HB 1699 favorably with a strike-all amendment. The strike-all amendment differs from the original bill in that it:

- ✓ Strengthens the definition of “boutique” hospitals as it relates to the prohibition of licensure by specialty service.
- ✓ Removes the CON exemption in law for adult cardiac catheterization.
- ✓ Strengthens the exemption created by the bill for the establishment of neonatal intensive care units (NICUs), specifying that the applicant must demonstrate that it meets the quality of care, nurse staffing levels, physician staffing levels, physical plant, equipment, emergency transportation, and data reporting as required currently when establishing a Level II and Level III NICU.
- ✓ Strengthens the licensure requirements created in the bill for adult cardiac care services and burn units.
- ✓ Creates a CON work group, in addition to the one established in the bill to review the necessity of CON for organ transplantation, to study CON regulations and changing market conditions related to the supply and distribution of hospital beds. The workgroup is required to study the appropriateness of current CON methodologies and the criteria for evaluating CON proposals. The workgroup shall consider additional factors in the study that shall consider the viability of safety net hospitals, market competition, and the accessibility of services. The work group is required to report to the Governor and the Legislature by January 1, 2005.
- ✓ Reinstates the provisions of law relating to osteopathic acute care hospitals, rural health networks, and hospices which were originally removed by the bill.