

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 329 Certificate of Need
SPONSOR(S): Harrell
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 1308 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	19 Y, 5 N	Rawlins	Collins
2) _____	_____	_____	_____
3) _____	_____	_____	_____
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

This bill exempts from Certificate-of-Need (CON) review the provision of adult open-heart services in a hospital located within the boundaries of Health Service Planning District 9, as defined in s. 408.032(5), F.S., or Acute Care Subdistrict 6-2, as defined in Rule 59C-2.100(3)(f)2., Florida Administrative Code (F.A.C.), provided the hospital meets specified requirements. The bill deletes from the statute the exemption granted to hospitals in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties and deletes the statement that those exemptions must be based on objective criteria and addresses the problems of geographical and temporal access.

The bill amends the requirement that the Agency for Health Care Administration (AHCA or agency) submit an annual report to the Legislature regarding the number of requests for exemptions, and AHCA's decisions regarding the requests, to clarify that each annual report shall include the number of requests received and the number of exemptions granted or denied during the calendar year.

This bill provides that this act shall take effect upon becoming law.

AHCA anticipates a minimal fiscal impact associated with the bill of approximately \$43,500. Four of the six hospitals that have previously indicated an interest in pursuing the exemption have already been approved by AHCA, through the regular CON review process, to operate an adult open-heart-surgery program. These include Winter Haven Hospital, Indian River Memorial Hospital, Martin Memorial Medical Center and Boca Raton Community Hospital. Other hospitals that have expressed an interest in the exemption that have not been previously approved by the agency include Heart of Florida Regional Medical Center and Bethesda Memorial Hospital. The possible loss in state revenue assumes that the two remaining programs will seek a CON exemption.

The 2003 Legislature passed SB 460 (ch. 2003-289, L.O.F.) which provided an exemption from CON review for adult open-heart-surgery programs in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties, an exemption quite similar to the one provided in this bill. The provisions of ch. 2003-289, L.O.F, were challenged on the grounds that the law violated Article 3, Section 10 of the Florida Constitution, i.e., that it was a local bill and that no prior notice had been published prior to its enactment. Those defending the law argued that it was a general law under the provisions of Article 3, Section 11(b) of the Florida Constitution, i.e., one in which political subdivisions or governmental entities could be classified on a basis reasonably related to the subject of the law. The circuit court upheld the challenge, finding that the five counties named in the law constituted a closed classification and therefore the bill was a local law, *Tenet Healthsystem Hospitals, dba Delray Medical Center; Lifemark Hospitals of Florida, Inc., dba Palmetto General Hospital; and Laura Cillo v. AHCA, Case no. 03-CA-1584*. This decision is being appealed.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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DATE: February 17, 2004

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|-----------------------------|---|
| 1. Reduce government? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

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

B. EFFECT OF PROPOSED CHANGES:

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.
- ✓ 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.

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.

- ✓ 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 Health 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 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:

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.

- ✓ 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, reveals 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 infarction with angioplasty will be less likely to die or suffer reinfarction 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 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. Currently there are 23 exemptions from CON in place.

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. Adult open-heart surgery is on the list of tertiary health services under rule 59C-1.002(41)(h), F.A.C. The procedure of open-heart surgery is defined under rule 59C-1.033(2)(g), F.A.C., as surgical procedures that are used to:

"...treat conditions such as congenital heart defects, heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma. . . . Open-heart surgery operations are classified under the following diagnostic related groups (DRGs): DRGs 104, 105, 106, 107, 108, and 109."

An open-heart-surgery program is defined as a program established in a room or suite of rooms in a hospital, equipped for open-heart surgery operations and staffed with qualified surgical teams and support staff.

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.

Certificate-of-Need Workgroup

As required by Section 15 of Chapter 2000-318, Laws of Florida, 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 in December 2002, which included a recommendation to amend s. 408.032(17), F.S., to add adult and pediatric open-heart surgery to the list of tertiary health services. This recommendation would place in the statute clear authority for the current rule which makes open-heart surgery a tertiary service. The workgroup considered but did not adopt a proposal to exempt adult open-heart surgery from CON review.

Changes in Medical Treatment for Heart Disease

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

Health Service Planning Districts

Section 408.032(5), F.S., identifies 11 health service planning districts in Florida used by AHCA in its CON program. These districts include the following counties:

- ✓ District 6: Hillsborough, Manatee, Polk, Hardee, and Highlands.
- ✓ District 9: Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach.

Current administrative rules for the CON program, in 59C-2.100(3)(f), F.A.C., identify the counties that constitute Acute Care Subdistricts, including: Acute Care Subdistrict 6-2: Polk County.

The Courts

Legislative Intent

Courts consider legislative intent the primary controlling factor in interpreting statutes. *State v. J.M.*, 824 So.2d 105 (Fla. 2002); *McGhee v. Volusia County*, 679 So.2d 729 (Fla. 1996); *Parker v. State*, 406 So.2d 1089 (Fla. 1981); *Tyson v. Lanier*, 156 So.2d 833 (Fla. 1963).

Plain Meaning

Courts must adhere to the plain meaning of words or phrases in legislation, unless it can be affirmatively demonstrated that the Legislature intended something else. *Silva v. Southwest Florida Blood Bank, Inc.*, 601 So.2d 1184 (Fla. 1992); *Holly v. Auld*, 450 So.2d 217 (Fla. 1984); *Deltona Corp., v. Florida Public Service Commission*, 220 So.2d 905 (Fla. 1969); *Gay v. City of Coral Gables*, 47 So.2d 529 (Fla. 1950); *Department of Revenue v. Central Dade Malpractice Trust Fund*, 673 So.2d 899 (Fla. 1st DCA 1996). When the meaning of statutory language is reasonably free from doubt, courts may not depart from that plain meaning. *State v. Bradford*, 787 So.2d 811 (Fla. 2001); *Starr Tyme, Inc. v. Cohen*, 659 So.2d 1064 (Fla. 1995); *State v. Egan*, 287 So.2d 1 (Fla. 1973); *State ex rel. Florida Jai Alai Inc. v. State Racing Commission*, 112 So.2d 825 (Fla. 1959); *Wagner v. Botts*, 88 So.2d 611 (Fla.

1956). Under such circumstances, courts cannot interpret a statute in a manner that would betray its express terms or obvious implications. *McLaughlin v. State*, 721 So.2d 1170 (Fla. 1998). To do so would be a judicial abrogation of legislative power. *Nicoll v. Baker*, 668 So.2d 989 (Fla. 1996); *Holly v. Auld*, 450 So.2d 217 (Fla. 1984). Moreover, “the Legislature is conclusively presumed to have a working knowledge of the English language” *State Racing Commission v. McLaughlin*, 102 So.2d 574, 575 (Fla. 1958)⁴

Courts may also adduce the Legislature’s intent by examining the public policy advanced by the statute and by comparing it with analogous positions taken by the Legislature. Courts consider the Legislature’s own statement of policy, if included in the legislation, as persuasive. *E.g.*, *State v. Smith*, 547 So.2d 613 (Fla. 1989). Courts have also looked toward legislative staff analyses when attempting to discern legislative intent. *E.g.*, *McGhee v. Volusia County*, 679 So.2d 729 (Fla. 1996); *Travelers Insurance Co. v. Warren*, 678 So.2d 324 (Fla. 1996); *Dilallo By and Through Dilallo v. Riding Safely, Inc.*, 687 So.2d 353 (Fla. 4th DCA 1997). Finally, placement of a law within a particular chapter of the statutes may be persuasive under circumstances where legislative intent is unclear.

General Laws, Special Laws, and General Laws of Local Application.

Article III, Section 10 of the Florida Constitution provides that the Legislature shall not enact any special law (local law) unless notice is first published. However, such notice may be avoided if a referendum is conducted among those affected by the law.

There are three basic categories of laws and it is important to distinguish between general laws, general laws of local application, and special laws (local laws).

General Laws - Most laws enacted by the Legislature are general laws; they operate uniformly throughout the state. A general law relates to subjects or persons based on proper distinctions and appropriate differences. General laws need not apply to every person across the state, but must consistently apply to those persons or entities affected by their provisions. *Department of Legal Affairs v. Sanford-Orlando Kennel Club, Inc.*, 434 So.2d 879 (Fla. 1983); *West Flagler Kennel Club, Inc. v. State Racing Comm’n*, 153 So.2d 5 (Fla. 1963). As long as a law applies equally to a category of persons or entities, which have a reasonable relationship to the subject matter of the law, it is a general law. *Catogas v. Southern Fed. Savings & Loan Ass’n*, 369 So.2d 922 (Fla. 1979); *Cesary v. Second National Bank*, 369 So.2d 917 (Fla. 1979). For instance, with respect to legislation which created probation officer positions for counties in which the county commissions had determined probation officers were needed, the Florida Supreme Court, in *State ex rel. Crim v. Juvenal*, 163 So. 569 (1935), found a general law.

General Laws of Local Application - A general law of local application applies to a distinct region or set of subdivisions within the state. Its classification scheme is based on population or some other reasonable characteristic which distinguishes one locality from another. *City of Miami Beach v. Frankel*, 363 So.2d 555 (Fla. 1978). On the other hand, laws which distinguish on the basis of population may be classified as special laws if their objectives bear no reasonable relationship to differences in population. *State ex rel. Utilities Operating Co. v. Mason*, 172 So.2d 225 (Fla. 1964). Article III, Section 11, of the Florida Constitution prohibits certain categories of general laws of local application. General laws of local application, unlike special laws (local laws), do not require published notice or a referendum.

Special Laws - A special law, or “local law,” as it is sometimes referred to, does not apply with geographic uniformity across the state. It operates only upon designated persons or discrete regions, and bears no reasonable relationship to differences in population or other legitimate criteria. See

⁴ Tedcastle, Tom; Billmeier, Michael; Bond, Nathan; and Jaroslav, David. “Federal & State Constitutional Law: A Guide for Legislative Staff”, The Florida House of Representatives. 2003.

Housing Authority v. City of St. Petersburg, 287 So.2d 307, 310 (Fla. 1973)(defining a special law). Laws which arbitrarily affect one subdivision of the state, but which fail to encompass other similarly situated subdivisions, may be classified as special laws. *Department of Business Regulation v. Classic Mile, Inc.* 541 So.2d 1155 (Fla. 1989). Even if a bill is enacted as a “general law,” courts will treat it as a special law if its effect is more like that of a special law. *Anderson v. Board of Public Instruction for Hillsborough County*, 136 So. 334 (Fla. 1931). Under Article III, Section 10, those types of special laws permitted by the constitution require published notice or a referendum.

Prohibited Special Laws and General Laws of Local Application - Twenty-one categories of special laws and general laws of local application are forbidden by the constitution. Article III, Section 11, requires state-wide uniformity for laws affecting elections, criminal law, divorce, and numerous other subjects. Even adequate notification, or a referendum, will not bring such laws into conformity with constitutional requirements.⁵

HB 329

The bill provides 20 WHEREAS clauses establishing the critical state importance of access to adult cardiac care for all citizens of the state; a lack of geographic and temporal access to such care in Health Service Planning District 9 and Acute Care Subdistrict 6-2; and the critical importance to the whole state of timely access to adult cardiac care in these districts for residents, tourists, and migrant workers, including the working poor and indigents. The clauses note that advanced interventional treatment for heart attack must be accessed by the patient within one hour of the onset of the attack for the treatment to be most effective, and in Florida, a hospital cannot provide these advanced interventions unless it has an open-heart-surgery program. The clauses point out that the temporal access to advanced cardiac care is limited not only by the geographic distance of the patient from the facility but also by the length of time it takes to transfer a patient from a hospital that does not have an open-heart-surgery program to one that does.

This bill amends general law⁶ to exempt hospitals from CON review for the provision of adult open-heart services in a local area defined as the boundaries of Health Service Planning District 9, as defined in s. 408.032(5), F.S., or Acute Care Subdistrict 6-2, as defined in Rule 59C-2.100(3)(f)2., F.A.C.

The bill deletes from the statute the exemption granted to hospitals in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties and deletes the statement that those exemptions must be based on objective criteria and address the twin problems of geographical and temporal access.

The bill requires the applicant for an exemption to certify, not simply 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 bill amends the requirement that AHCA must submit an annual report to the Legislature regarding the requests for exemptions, and AHCA’s decisions regarding the requests, to clarify that each annual report would include requests and decisions made during the calendar year.

The bill will take effect upon becoming a law.

⁵ Ibid.

⁶ s. 408.036(3)(t), F.S.

C. SECTION DIRECTORY:

Section 1. Amends s. 408.036, F.S., revising an exemption from the certificate-of-need requirements for certain open-heart surgery programs to apply the exemption to any hospital located within a specified health service planning district or a specified acute care subdistrict.

Section 2. Provides that the act shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See "Fiscal Comments" section of the analysis.

2. Expenditures:

See "Fiscal Comments" section of the analysis.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

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. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Qualifying hospitals in the affected counties could establish adult open-heart-surgery programs without the necessity of CON review. To the extent that additional adult open-heart-surgery programs are established because of the exemption, existing programs would face increased competition for the specialized staff needed for an open-heart- surgery program. If hospitals need to increase salaries and benefits to attract or retain specialized staff, health care costs could increase.

D. FISCAL COMMENTS:

AHCA anticipates a minimal fiscal impact associated with the bill of approximately as much as \$43,500. Four of the six hospitals that have previously indicated an interest in pursuing the exemption have already been approved by AHCA, through the regular CON review process, to operate an adult open-heart-surgery program. These include Winter Haven Hospital, Indian River Memorial Hospital, Martin Memorial Medical Center and Boca Raton Community Hospital. Other hospitals that have expressed an interest in the exemption that have not been previously approved by the agency include Heart of Florida Regional Medical Center and Bethesda Memorial Hospital. The possible loss in state revenue assumes that the two remaining programs will seek a CON exemption.

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:

A constitution emanates from the people, not from the government. *Collier v. Gray*, 157 So. 40 (Fla. 1934); *State ex rel Church v. Yeats*, 77 So. 262 (Fla. 1917). It is a framework of fundamental principles by which the government is formed and under which the government operates. The constitution is the supreme law of the land, distinguished from other law by its permanency, brevity, and generality. *Advisory Opinion to the Attorney General -- Limited Marine Net Fishing*, 620 So.2d 997, 999-1000 (Fla. 1993)(McDonald, J., concurring). If statutes, treaties, or administrative rules directly conflict with the constitution, the constitution must prevail. *Department of Revenue v. Kuhnlein*, 646 So.2d 717 (Fla. 1994); *Shands Teaching Hospital & Clinics, Inc. v. Smith*, 480 So.2d 1366 (Fla. 1985).

In determining the constitutionality of any bill, several questions are call into order:

“Does this legislation distinguish between different groups or classes of persons when dispensing benefits, enforcing rights, or regulating behavior?”

If so, then there may be a consideration of Equal Protection, as set forth in the United States Constitution, Amendment XIV, Section 1 (Equal Protection Clause) and the Florida Constitution, Article I, Section 2 (Basic Rights - Equal Protection). The Equal Protection Clause of the Fourteenth Amendment, while originally enacted to protect former slaves from discrimination has evolved into a general restraint on the use of classifications. It shields groups and individuals from arbitrary categorization through state action. Although the Equal Protection Clause does not apply to the federal government, federal classifications may be invalidated under the Due Process Clause of the Fifth Amendment. Because state governments often establish classifications or attempt to confer advantages upon particular groups, the equal protection clause frequently comes into play when evaluating the constitutionality of state legislation.

Generally, the state must intend to discriminate before the courts will find a violation of the Equal Protection Clause. *Washington v. Davis*, 426 U.S. 229 (1976); *Snowden v. Hughes*, 321 U.S. 1 (1944). The fact that a law or policy produces a disproportionate impact on a protected group does not, in itself, necessitate a finding that the state violated the group's equal protection rights. Disproportionate impact is, however, one of several factors that courts consider when trying to determine the state's intent. *Mayor of Philadelphia v. Educational Equality League*, 415 U.S. 605 (1974).

Suspect Classifications - Equal protection rarely becomes an issue unless state action impacts a suspect class or fundamental right. When no suspect class is disturbed, and when no fundamental rights or liberties are violated, the Equal Protection Clause “is offended only if the classification rests on grounds wholly irrelevant to the achievement of the State's objective.” *McGowan v. Maryland*, 366 U.S. 420, 425 (1961). While the Constitution permits disparate treatment of some groups, it strictly prohibits other types of classifications. Distinctions based on race and national origin, which lead to unequal treatment, almost invariably violate the Equal Protection Clause. *Loving v. Virginia*, 388 U.S. 1 (1967); *McLaughlin v. Florida*, 379 U.S. 184 (1964); *Brown v. Board of Education*, 347 U.S. 483 (1954). The courts subject such classifications to “strict scrutiny.” To withstand strict scrutiny, a law must be necessary to advance a compelling state interest and must be narrowly tailored to achieve this objective. Although strict scrutiny is not invariably fatal, it is a difficult hurdle to overcome.

Questions called into order when determining if a bill is unconstitutional based on the Florida Constitution: “Does this legislation apply unevenly to distinct regions or localities?” Article III, section 10. of the Constitution of the State of Florida specifies that:

“No special law shall be passed unless notice of intention to seek enactment thereof has been published in the manner provided by general law. Such notice shall not be necessary when the law, except the provision for referendum, is conditioned to become effective only upon approval by vote of the electors of the area affected.”

The 2003 Legislature passed SB 460 (ch. 2003-289, L.O.F.) which provided an exemption from CON review for adult open-heart-surgery programs in Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties, an exemption quite similar to the one provided in this bill. The law required the exemption to address and solve the twin problems of geographic and temporal access to open-heart-surgery programs by individuals experiencing a heart attack. The provisions of ch. 2003-289, L.O.F, were challenged on the grounds that the law violated Article 3, Section 10 of the Florida Constitution, i.e., that it was a local bill and that no prior notice had been published prior to its enactment. Those defending the law argued that it was a general law under the provisions of Article 3, Section 11(b) of the Florida Constitution, i.e., one in which political subdivisions or governmental entities could be classified on a basis reasonably related to the subject of the law. The circuit court upheld the challenge, finding that the five counties named in the law constituted a closed classification and therefore the bill was a local law, *Tenet Healthsystem Hospitals, dba Delray Medical Center; Lifemark Hospitals of Florida, Inc., dba Palmetto General Hospital; and Laura Cillo v. AHCA, Case no. 03-CA-1584*. This decision is being appealed. If a lower court declares a law unconstitutional, and if that decision is subsequently reversed, the law will be held valid from its initial effective date. *State v. White, 194 So.2d 601 (Fla. 1967)*.

A law which violates the constitution is void and inoperative from the date it became effective. *Amos v. Mathews, 126 So. 308 (Fla. 1930)*. Courts generally cannot declare a law constitutional as to its retroactive operation, but unconstitutional as to its prospective application. *State ex rel. Nuveen v. Greer, 102 So. 739 (Fla. 1924)*. However, *the United States Supreme Court in Chicot County Drainage Dist. v. Baxter State Bank, 308 U.S. 371 (1940)*, refused to uphold an absolute principle of retroactive invalidity. Even after the high court has declared a statute unconstitutional, the statute may still appear in the Florida Statutes.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill specifies that the applicant must certify that it will meet and continuously maintain minimum licensure requirements adopted by the Agency for Health Care Administration governing adult open-heart programs. However, there are no such licensure requirements in place.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES