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HOUSE OF REPRESENTATIVES

COUNCIL FOR HEALTHY COMMUNITIES
ANALYSIS

BILL #: HB 1153

RELATING TO: Certificate of Need

SPONSOR(S): Representative Harrell and others

TIED BILL(S): none

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

(1) HEALTH REGULATION YEAS 9 NAYS 0
(2) JUDICIAL OVERSIGHT (W/D)
(3) COUNCIL FOR HEALTHY COMMUNITIES YEAS 15 NAYS 0
(4)
(5)

I. SUMMARY:

Since the implementation of CON, current national and state health financing trends have made the original intent of CON obsolete. All federal health planning legislation was abolished in 1986 with each state delegated the determination of whether to have a CON program. A report from the American Health Planning Association, published in 2001 shows that currently 15 states have no CON review. Florida ranks 27th in the nation as it pertains to CON regulation, with the number one state being the most restrictive. Florida has moved steadily toward deregulating CON since 1987.

This bill expands the CON process by giving legal standing to any health facility located within the regional organ transplant planning district, rather than the 11 statutorily defined health planning districts. For proposed organ transplantation programs, HB 1153 removes the limitation in current statutes created by a reference to district boundaries:

> "A hospital may initiate or intervene in an administrative proceeding involving the issuance or denial of a certificate of need for an organ transplantation program upon a showing that an established organ transplantation program at the hospital will be substantially affected by the issuance of the certificate of need to a competing program or facility within the same service planning area delineated under rules adopted by the Agency for Health Care Administration."

Thus, challenges to a proposed CON approval of an organ transplantation program could originate from hospitals located in a broader geographic area than would be permitted under current statutes.

An increase in litigation over the issuance of a CON is the expected result of this bill. As well, the bill will impede the development of any new proposed programs.

Despite the superior performance of Florida's Organ Procurement Organization (OPOs), the fact remains that the lack of available organ donors will continue to control the ability to expand organ transplantation services.

The Agency of Health Care Administration reports a zero financial impact from this bill.

Provides for an effective date of July 1, 2001.

See amendment section of this bill analysis for changes made by a substitute amendment that is traveling with the bill.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1. Less Government Yes [] No [x] N/A []

This bill increases the possible number of litigants on the final order of a CON application for an organ transplant program.

2. Lower Taxes Yes [] No [] N/A [x]

3. Individual Freedom Yes [] No [x] N/A []

This bill may ultimately limit the number of organ transplant providers, limiting recipients' choice of providers.

4. Personal Responsibility Yes [] No [] N/A [x]

5. Family Empowerment Yes [] No [x] N/A []

By limiting the number of organ transplant programs; separation of family members will occur if the organ recipient is forced to seek treatment great distances from home.

B. PRESENT SITUATION:

The Certificate of Need program is a regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. A certificate of need is required for hospitals proposing to provide organ transplant programs. By statutory definition, a transplant program is a tertiary heath service.

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

Since the implementation of CON, current national and state financing trends have made the original intent of CON obsolete. All federal health planning legislation was abolished in 1986 with each state delegated the determination of whether to have a CON program. A report from the American Health Planning Association, published in 2001 shows that currently 15 states have no

CON review. Florida ranks 27th in the nation as it pertains to CON regulation, with the number one state being the most restrictive.

Florida has moved steadily toward deregulating CON since 1987. Major statutory revisions include:

2000

- **Increases in Licensed Bed Capacity - As** of July 2000, an exemption was created so that a proposed increase of up to 10 beds or 10 percent of a hospital's licensed capacity for acute care, mental health services, or hospital based SNU (skilled nursing unit) beds are not subject to review; and conditionally granted exemptions specify the necessity of maintaining a predetermined occupancy level and may require meeting other conditions. Previously, all projects proposing an increase in the licensed bed capacity of a hospital or nursing home were subject to CON review.
- **Establishment of a Medicare Certified Home Health Agency - As** of July 2000, there is no CON review of proposed Medicare certified home health agencies, and no exemption is required. Prior to the implementation of the "Patient Protection Act of 2000", proposed establishment of a Medicare certified home health agency was subject to CON review with exemptions possible for certain types of providers.
- **Cost Overruns -** As of July 2000, there is no CON review of cost overruns, and no exemption is required. Previously, increases in the cost of an approved project were subject to CON review if the increase exceeded specific thresholds.

1987 – 1997

- **Obstetric services** – From October 1987 to present, proposals for OB services are exempt unless the total licensed bed capacity of the hospital increases. Before legislative action in 1987, proposals to initiate or expand obstetric services were reviewable.
- **Outpatient services** - From October 1987 to present, proposals for exclusively outpatient services were excluded from certificate of need review, regardless of the dollar amount involved. Before legislative action in 1987, there was not any exclusion for outpatient capital expenditures and these expenditures were subject to review.
- **Tertiary services** – From October 1987 to present, specified tertiary services are reviewable. A rule promulgated in 1988 specifies a list of tertiary services, including organ transplantation; specialty burn units; neonatal intensive care units (Level II and Level III); comprehensive medical rehabilitation; adult open heart surgery; neonatal and pediatric cardiac and vascular surgery; and pediatric oncology and hematology.
- **Capital expenditure threshold** - From July 1997 to present, no project is reviewable based solely on the amount of capital expenditure proposed. From October 1987 through June 1997, capital expenditures of $1 million or more for inpatient services were subject to CON review, unless new or expanded beds or services were proposed, and the agency adjusted the $1 million threshold annually for inflation. Prior to October 1987, the threshold for review of a proposed capital expenditure was $600,000.
- **Major medical equipment** - From July 1997 to present, acquisition of medical equipment, regardless of cost, is not reviewable. From October 1987 through June 1997, the amended definition of major medical equipment is that of equipment costing more than $1 million and which the United States Food and Drug Administration (FDA) approve for less than 3 years required review. The agency adjusted the $1 million threshold annually for inflation. Prior to October 1987, major medical equipment was defined as equipment used to provide health services and costing more than $400,000.
- **Applicable CON fees required** - From 1991 to present, the base fee for a CON application has been $5,000, plus 0.015 of each dollar of proposed capital expenditure, with the total not to exceed $22,000. In 1989, the ceiling amount to the CON application fee increased

from $9,500 to $10,000. While in the previous year, October 1987, a revision to the structure occurred to a base fee of $750, plus 0.006 of each dollar of proposed capital expenditure, with the total not to exceed $9,500. Prior to October 1987, the fee for processing a CON application calculated with a base fee of $500, plus 0.004 of each dollar of proposed capital expenditure, with the total fee not to exceed $4,000.

Sections 408.034 - 408.0455, F.S., designate the Agency for Health Care Administration as the single state agency to issue, revoke, or deny certificates of need.

The Auditor General's Report, November 2000, The *Certificate of Need and Public Medical Assistance Assessments Programs, Agency for Health Care Administration, Operational Audit* reports: that "ACHA had not diligently pursued the receipt of required reports, thereby limiting management's ability to timely evaluate: (1) whether providers adhered to the service conditions stipulated on issued Certificates of Need and related statutorily mandated fines should be imposed; and (2) whether project costs were within the budgets set forth in the applications for the Certificate of Need."

In 2000, the Florida Legislature established the Florida Commission on Excellence in Health Care to facilitate the development of a comprehensive statewide strategy for improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement. As it relates to the CON process, the Commission recommended that: "the legislature should retain certificate of need regulations until after such time as systems for reporting useful clinical outcome data allowing consumers to analyze and choose between existing health care practitioners and providers are implemented".

The Agency for Health Care Administration Long Range Program Plan for FY 2001-2002 to 2005-2006 proposes that "elimination of unnecessary health facility regulation will play an important role in the Governor's and Legislature's initiatives to improve the business climate in Florida and streamline government operations. Certificates of Need, once considered mandatory for the control of both public and private health care cost in nursing facilities, hospital and home health agencies, have increasingly come to be viewed as overly restrictive deterrents to healthy competition among providers". The agency expresses two major concerns:

- The CON review has been used to give what is perceived as necessary preferences to safety net providers; and

- To control the supply of nursing home beds in order to manage the demand of services from Medicaid Recipients, thereby reducing expenditures to the Medicaid budget.

Various CON **proponents** believe that since government is the number one payor of all health services, it has a right to expect regulatory oversight to focus at a minimum on those services still paid on a fee-for-service basis, lack quality of care standards, are subject to over-utilization, or for quality purposes should be regionalized. A 1996 Dartmouth Atlas on Health Care comprehensive study of our nation's health care system reports that no other competitive industry depends so much on government for its funding and concluded that free enterprise does not exist in the health care industry. The author of the study, Veazey, believes that CON contributes to the preservation of quality services in programs such as open heart surgery, angioplasty, and neonatal intensive care by promoting a concentration of skilled staffs and preventing the proliferation of low volume programs. "Practice makes perfect: higher volumes result in higher quality and lower mortality". Additionally, according to Veazey, CON can help assure financial viability for safety net hospitals by reducing the threat from "cream-skimming" investor owned hospitals and ambulatory care centers.

Opponents of CON most often cite the movement toward a more competitive marketplace as the rationale to dismantle CON. In a recent article from T*he Journal of the James Madison Institute,* Winter 2001, argues that in the 1990s, the manner of paying for medical care is moving rapidly toward prospective market-based capitation payment methods (i.e., managed care). Increasingly, hospitals and doctors are competing for contracts to provide a full range of services in exchange for a negotiated fixed payment. This payment method makes it less likely that the creation of excess hospitals and services will occur, thereby eliminating the possibility that additional cost to the public is passed on to maintain these services. In citing this theory, proponents of deregulation often recognize that even in a more competitive environment, quality and access to health care services for all citizens is of utmost concern. Thus, even among proponents of deregulation, there is a belief there is a need to strengthen licensure oversight to assure access and quality of health care.

According to Rule, 59C-1.044, F.A.C., transplant services are restricted to teaching or research hospitals with exception of kidney transplant. Some transplant providers feel they are denied legal standing to contest approval of a new competing program. They argue this results from an inequity in the CON law that limits standing in CON cases to existing providers located in the same service-planning district as a new proposed program. Organ transplant services are planned according to regional planning areas, consisting of multiple districts, rather than on a limited district wide basis.

Section 408.039(5)(c), F.S., provides that existing health care facilities may initiate or intervene in an administrative hearing regarding the issuance of a CON to a competing facility located within the same district. Facilities located outside the district do not have this opportunity to challenge a proposed CON action.

Current CON rule 59C-1.044(2)(f), F.A.C., establishes four "service planning areas" used in review of proposed organ transplantation programs. Each service planning area encompasses two or more of the Agency's 11 districts.

Three other current CON rules establish multi-district service planning areas for other health services: pediatric open heart surgery (rule 59C-1.033); pediatric cardiac catheterization (rule 59C-1.032); and specialty burn units (rule 59C-1.043).

Organ Availability

The United Network for Organ Sharing (UNOS) recognizes that the number one problem in increasing organ transplantation programs is the critical shortage of donor organs. UNOS has noted that "the tragic truth is, despite continuing advances in medicine and technology, the demand for organs drastically outstrips the amount of organ donors." From 1990 through 1998, there was a steady increase in the number of persons placed onto the waiting list for transplants, rising from a waiting list of approximately 20,000 people in 1990 to over 65,000 people in 1998. As of March 2001, there were 75,069 men, women, and children on the national organ transplantation waiting list, according to the United Network of Organ Sharing. With organs currently available to perform just over 20,000 transplants a year, approximately 15 of the people on the waiting list die each day, never receiving the organ that could have saved their lives. Of the 75,000 on the waiting list, 48,162 are waiting for a kidney; 17,207 for a liver; 4,236 for a heart; 3736, for a lung; 2,456 for both a kidney and pancreas; 1061 for a pancreas; 214 for a heart and lung; 186 for pancreas islet cells, and 157 for intestines.

The lack of available donor organs is not the result of any deficiency in Florida's system for organ procurement. According to Shands Healthcare at the University of Florida, Florida's five existing Organ Procurement Organizations do an excellent job in procuring donor organs. In fact, three out of Florida's five OPOs rank as the top three programs in the country in terms of the number of organ donors per million population.

Despite the superior performance of Florida's OPOs, the fact remains that the lack of available organ donors will continue to control the ability to expand organ transplantation services.

C. EFFECT OF PROPOSED CHANGES:

This bill expands the CON review process by giving legal standing to any health facility located within the regional organ transplant planning district, rather than the 11 statutorily defined health planning districts. For proposed organ transplantation programs, HB 1153 removes the limitation in current statutes created by a reference to district boundaries:

> "A hospital may initiate or intervene in an administrative proceeding involving the issuance or denial of a certificate of need for an organ transplantation program upon a showing that an established organ transplantation program at the hospital will be substantially affected by the issuance of the certificate of need to a competing program or facility within the same service planning area delineated under rules adopted by the Agency for Health Care Administration."

Thus, challenges to a proposed CON approval of an organ transplantation program could originate from hospitals located in a broader geographic area than would be permitted under current statutes.

An increase in litigation over the issuance of a CON is the expected result of this bill. As well, the bill will impede the development of any new proposed programs.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates paragraph (e) of subsection (5), section 408.039, Florida Statutes, allowing hospitals within the same service planning area for organ transplantation as delineated under rules adopted by the Agency for Heath Care Administration to intervene in an administrative proceeding relative to the issuance of a certificate of need.

Section 2. Provides for an effective date of July 1, 2001.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to the Agency for Health Care Administration, there is no fiscal impact associated with this bill.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There is a direct relation between the number of facilities that are allowed to challenge the final order of a CON application and the cost of litigating.

D. FISCAL COMMENTS:

Although the Agency reports a zero fiscal impact of this bill to State government, by expanding the standing in the issuance of a CON application, there is an increase cost to the State for purposes of litigation.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

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

B. REDUCTION OF REVENUE RAISING AUTHORITY:

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

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

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

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

This bill will require the Agency for Health Care Administration to amend current rules.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On April 3, 2001, the Committee on Health Regulation considered a strike all amendment offered by Representative Harrell. The strike all amendment creates an Organ Transplant Task Force. The Task Force will meet for the purpose of studying and making recommendations regarding current and future supply of organs in relation to the number of existing organ transplant programs and the future necessity of the issuance of a certificate of need for proposed organ transplant programs. There is directive language to the Agency for Health Care Administration to determine the selection process for Task Force members. The Task Force is required to report to the Legislature and the Governor by January 15, 2002 and the Task Force is abolished effective December 31, 2002.

Representative Harrell, directing the Agency for Health Care Administration to create the Task Force, offered an amendment-to-the-amendment. Both the amendment-to-the-amendment and the strike all amendment passed without objection. The strike all amendment, as amended, is traveling with the bill.

On April 18, 2001, the Council for Healthy Communities considered and adopted a substitute amendment to the strike all amendment. The substitute amendment creates legislative intent and provides for additional appointments to the Organ Transplant Task Force.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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

AS REVISED BY THE COMMITTEE ON JUDICIAL OVERSIGHT:

Prepared by:	Staff Director:
Nathan L. Bond, J.D.	Lynne Overton, J.D.

AS FURTHER REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by:	Council Director:
Lisa Rawlins Maurer, Legislative Analyst	Mary Pat Moore, Council Director