

# SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 684

SPONSOR: Health, Aging and Long-Term Care Committee, Senator Cowin and others

SUBJECT: Organ Transplantation Certificates of Need

DATE: March 28, 2001

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Thomas	Wilson	HC	Favorable/CS
2.				
3.				
4.				
5.				
6.				

## I. Summary:

Committee Substitute for Senate Bill 684 requires the Agency for Health Care Administration to perform an impact study regarding organ transplantation programs and report to the Legislature by January 1, 2002.

This bill creates an undesignated section of law.

## II. Present Situation:

### *CON Process*

The Certificate-of-Need (CON) regulatory process under chapter 408, F.S., requires that specified health care services and facilities submit applications for approval by the Agency for Health Care Administration (AHCA) prior to being offered to the public. The basic premise of the CON process is that competing applications to establish or expand health care facilities or programs in a given geographical area to meet a projected need for such facility or program, be “batched” and comparatively reviewed.<sup>1</sup> The applications proposing the best program will be approved, up to the point that the need in the geographical area is met, and the remainder of the applications will be denied.<sup>2</sup>

<sup>1</sup> *First Hospital Corporation of Florida v. Department of Health and Rehabilitative Services*, 566 So.2d 917 (Fla. 1<sup>st</sup> DCA 1990); *St. Joseph Hospital of Charlotte, Florida, Inc. v. Department of Health and Rehabilitative Services*, 559 So.2d 595 (Fla. 1<sup>st</sup> DCA 1989); *Sarasota County Public Hospital Board v. Department of Health and Rehabilitative Services*, 553 So.2d 189 (Fla. 2<sup>d</sup> DCA 1989).

<sup>2</sup> *Id.*

AHCA establishes CON application review cycles in order to batch comparable applications and requires letters of intent to be filed prior to submission of an application under s. 408.039, F.S. The agency reviews the applications submitted and makes findings of fact and determinations as to whether an application should be approved or denied under s. 408.039(4), F.S. After notification of the agency determination as to each application, the applicant may request an administrative hearing to review the agency determination prior to the decision becoming final under s. 408.039(4), F.S. Existing providers in the service area may initiate or intervene in such administrative hearings if they are substantially affected by the approval of any applications for services they currently provide under s. 408.039(5), F.S.

### ***Organ Transplantation***

All tertiary health services are subject to CON review under s. 408.036(1)(h), F.S. The term “tertiary health services” is defined in s. 408.032(17), F.S., as those medical interventions that are 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. Organ transplantation is expressly named as a tertiary health service in s. 408.032(17), F.S. The organ transplant procedures contemplated by the statute are listed in rule 59C-1.002, F.A.C., to include: heart transplantation, kidney transplantation, liver transplantation, bone marrow transplantation, lung transplantation, pancreas and islet cell transplantation, and heart/lung transplantation.

AHCA determines need for the expansion of tertiary health services by either individual health-service planning district (district), or by multi-district service planning area (multi-district), depending upon the type of service. The 11 districts are comprised of aggregated counties, with the exception of District 10, Broward County, under s. 408.032(5), F.S. The 4 multi-districts are composed of aggregated blocks of individual districts.

The tertiary health services reviewed on a district basis are: neonatal intensive care units, comprehensive rehabilitation, adult open heart surgery, and pediatric oncology and hematology. The tertiary health services reviewed on a multi-district basis are: organ transplantation (rule 59C-1.044(2)(f), F.A.C.), pediatric open heart surgery (rule 59C-1.033, F.A.C.), pediatric cardiac catheterization (rule 59C-1.032, F.A.C.), and specialty burn units (rule 59C-1.043, F.A.C.).

Regardless of whether a service is reviewed on a district basis or a multi-district basis, legal standing to initiate or enter a lawsuit regarding a CON is limited to providers within the *district* at issue under s. 408.039(5)(c), F.S.<sup>3</sup>

### **III. Effect of Proposed Changes:**

**Section 1.** Creates an undesignated section of law to require AHCA to perform an impact study to determine the effect, if any, of any organ transplantation programs and report to the Legislature by January 1, 2002.

**Section 2.** Provides that the bill, if it becomes law, will take effect July 1, 2001.

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<sup>3</sup> *Public Health Trust of Miami-Dade County, Florida v. Agency for Health Care Administration*, 751 So.2d 112, 114 (Fla. 1<sup>st</sup> DCA 2000); *Shands Teaching Hospital v. Agency for Health Care Administration*, 695 So.2d 793 (Fla. 1<sup>st</sup> DCA 1997).

**IV. Constitutional Issues:****A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

**B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

**C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

**V. Economic Impact and Fiscal Note:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

None.

**C. Government Sector Impact:**

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Amendments:**

None.