

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government – the bill standardizes data reporting elements and requires the Agency for Health Care Administration to develop rules requiring licensed hospitals providing Level I and Level II adult cardiovascular services to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

B. EFFECT OF PROPOSED CHANGES:

Background

Certificate-of-Need (CON) Review

The CON is a regulatory review process administered by the Agency for Health Care Administration (AHCA) which requires specified health care providers to obtain prior authorization before offering certain new or expanded services or making major capital expenditures. A “Certificate of Need” is defined as: “...a written statement issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.”¹

Florida’s CON program has been in operation since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986.

Currently, chapter 408, part I, F.S., specifies those health providers and services subject to CON review and includes hospitals, long term care facilities, hospices, intermediate care facilities for the developmentally disabled,² inpatient diagnostic, curative, or comprehensive medical rehabilitative services³ and tertiary health services, which due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service. Examples of such service include, but are not limited to pediatric, cardiac catheterization, pediatric open-heart surgery, organ transplantation, and comprehensive rehabilitation.⁴

In 2004, the Legislature amended s. 408.036(3), F.S., to provide for an exemption from CON review for hospitals providing diagnostic cardiac catheterization services without an approved adult open-heart surgery program. Section 408.036(3)(o), F.S., establishes criteria with which a hospital must comply in order to be granted and keep an exemption.

In 2004, the Legislature also amended s. 408.0361, F.S., to require the agency to adopt administrative rules for the licensure of adult inpatient diagnostic cardiac catheterization programs and adult interventional cardiology services and burn units, in Florida hospitals. This licensure would revise the regulation of these services to create licensure of services rather than a service that is authorized through an exemption from CON review.

¹ See s. 408.032(3), F.S.

² See s. 408.032(8), F.S.

³ See s. 408.032(9), F.S.

⁴ See s. 408.032(17), F.S.

With regard to diagnostic cardiac catheterization services, rules must ensure that such programs comply with the guidelines of the American College of Cardiology and the American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. With regard to providers of adult interventional cardiology services⁵ agency staff was to develop rules governing providers of adult interventional cardiology services or operators of a burn unit that establish standards governing the provision of such services, and that such rules must consider, at a minimum, staffing, equipment, physical plant, operating protocols, Medicaid services and services to charity care patients, accreditation, licensure period and fees, and minimum standards enforcement

Existing providers and any provider with a notice of intent to grant a certificate of need or agency final order granting a certificate of need for adult interventional services or burn units were to be "grandfathered in" and receive a license for their programs effective July 1, 2004. The grandfathered licensure period was established for at least 3 years or a period specified in rule, whichever was longer, and subject to licensure standards applicable to existing programs for every subsequent licensure period.

Effect of Proposed Changes

The bill revises the term *adult interventional cardiology services*, to *adult cardiovascular services*, which is a more general service term that includes adult interventional cardiology, according to the Agency for Health Care Administration. The bill extends the "grandfathered in" provision applied to adult cardiovascular services until July 1, 2008. The bill specifies the mechanism for hospitals licensed for Level I or Level II adult cardiovascular services to use in clinical outcome reporting--requiring such hospitals to use reporting systems operated by the American College of Cardiology and the Society of Thoracic Surgeons. This reporting system requirement is already used by many hospitals⁶ and should have the effect of providing patients, families, employers, payers and other interested parties with increased access to information about the quality of hospital services. The bill provides updated references to diagnostic codes to reflect a more comprehensive disease category and also exempts center cancer hospitals from licensure restrictions.

C. SECTION DIRECTORY:

Section 1. Amends s. 395.003, F.S., relating to hospital licensure; issuance, renewal, denial, modification, suspension and revocation.

Section 2. Amends s. 408.0361, F.S., Cardiology services and burn unit licensure.

Section 3. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

⁵ See s. 408.0361, F.S., see also Senate Bill 182, 2004 Legislative Session

⁶ Agency for Health Care Administration analysis, April 2007, on file with the committee.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals that wish to be licensed to provide adult cardiovascular services will be required to participate in outcome measurement systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take 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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

None.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On **April 10, 2007**, the Healthcare Council adopted 1 strike all amendment and 1 amendment to the strike all. These amendments:

- Provides updated terminologies relating to cardiovascular services and diagnostic codes; revises the grandfather provisions relating to hospital-based adult cardiovascular services until July 1, 2008; directs the Agency for Health Care Administration to develop rules that would require licensed hospitals that provide Level I and Level II adult cardiovascular services to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic surgeons.
- Exempts certain cancer center hospitals from licensure restrictions.

The analysis reflects the bill as amended.