



# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government** --- The bill requires AHCA to adopt rules providing alternative criteria for a hospital to gain licensure as a Level I adult interventional cardiology program.

### B. EFFECT OF PROPOSED CHANGES:

#### **Background**

The Certificate of Need (CON) regulatory review 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. Pursuant to s. 408.036(1), F.S., the establishment of tertiary health services,<sup>1</sup> such as adult interventional cardiology,<sup>2</sup> in hospitals is generally subject to such review. Section 408.036(3), F.S., provides certain exemptions from the CON review requirements.

#### *Section 408.036(3)(o), F.S.*

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.

#### *Section 408.0361, F.S.*

The Legislature also revised s. 408.0361, F.S., in 2004 to require that AHCA adopt administrative rules for the licensure of diagnostic cardiac catheterization services and adult interventional cardiology services in hospitals.<sup>3</sup> This licensure revised the regulation of adult interventional cardiology services to create licensure of this service, rather than a service that is authorized through an exemption from CON review. AHCA has initiated rule development which will establish standards based on the guidelines of the American College of Cardiology and the American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

#### **Effect of Proposed Legislation**

The bill amends s. 408.0361, F. S., to allow a hospital to gain licensure as a Level I adult interventional cardiology program, providing the following criteria are met:

- The hospital must be a newly licensed hospital established pursuant to a certificate of need in a physical location previously licensed and operated as a hospital.
- The former hospital must have provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period.
- The newly licensed hospital must have a formal, written transfer agreement with a hospital that has a Level II program, including transport protocols ensuring safe and efficient patient transfer within 60 minutes;

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<sup>1</sup> A "tertiary health service" is one which is highly intense, complex, specialized or of limited applicability, and costly. Accordingly, the Legislature has determined that, in order to maintain quality and cost-effectiveness, its availability should be limited. See s. 408.032(17), F.S.

<sup>2</sup> See, generally, Rule 59A-3.2085, F.A.C.

<sup>3</sup> Section 408.0361(3) (a), F.S., provides an explanation of two hospital program licensure levels: a level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

The newly-licensed hospital meeting these requirements may apply for and be granted Level I program status regardless of whether rules relating to Level I programs have been adopted. The Level I program effective date shall be concurrent with the effective date of the newly issued hospital license.

C. SECTION DIRECTORY:

Section 1. Amends s. 408.0361, F.S.; relating to cardiology services and burn unit licensure.

Section 2. 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.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Providers authorized to perform Level I programs would benefit from revenues received under this bill. Hospitals relocating to other facilities could also receive potential benefits from increased values of the vacated facilities.

D. FISCAL COMMENTS:

None.

**III. COMMENTS**

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

The bill will effectively change the requirements for obtaining a certificate of need (CON) for hospitals providing diagnostic cardiac catheterization services. This bill will greatly benefit St. Luke's Hospital in Jacksonville and other hospitals that meet the same criteria.

**IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES**

On **March 20, 2007**, the Health Innovation Committee adopted one strike-all amendment to the bill. This amendment:

- Provides licensure criteria for a hospital Level I adult interventional cardiology program.

The bill was reported favorable with one amendment.

On **April 17, 2007**, the Healthcare Council adopted a substitute amendment to the strike-all amendment adopted in the Health Innovation Committee on March 20, 2007.

The amendment provides specific criteria to allow a hospital to gain licensure as a Level I adult interventional cardiology program, as follows:

- The hospital must be a newly licensed hospital established pursuant to a certificate of need in a physical location previously licensed and operated as a hospital.
- The former hospital must have provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period.
- The newly licensed hospital must have a formal, written transfer agreement with a hospital that has a Level II program, including transport protocols ensuring safe and efficient patient transfer within 60 minutes;

The amendment specifies that a newly-licensed hospital meeting these requirements may apply for and be granted Level I program status regardless of whether rules relating to level I programs have been adopted.

The bill was reported favorable as a Council Substitute. The analysis reflects the Council Substitute.