## CHAPTER 2007-248

## House Bill No. 7165

An act relating to hospitals; amending s. 395.003, F.S.; revising provisions designating disease classes; exempting certain cancer center hospitals from licensure restrictions; amending s. 408.0361, F.S.; revising provisions relating to licensing standards for adult cardiovascular services; revising period of validity for certain grandfathered licenses; revising criteria for adoption of rules by the Agency for Health Care Administration; requiring certain hospitals to participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons for purposes of such rule criteria; removing a requirement that the agency include specified data in rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (9) of section 395.003, Florida Statutes, is amended to read:

395.003  $\,$  Licensure; issuance, renewal, denial, modification, suspension, and revocation.—

(9) A hospital may not be licensed or relicensed if:

(a) The diagnosis-related groups for 65 percent or more of the discharges from the hospital, in the most recent year for which data is available to the Agency for Health Care Administration pursuant to s. 408.061, are for diagnosis, care, and treatment of patients who have:

1. Cardiac-related diseases and disorders classified as diagnosis-related groups <u>in major diagnostic category 5</u> 103-145, 478-479, 514-518, or 525-527;

2. Orthopedic-related diseases and disorders classified as diagnosisrelated groups <u>in major diagnostic category 8</u> 209-256, 471, 491, 496-503, or 519-520;

3. Cancer-related diseases and disorders classified as <u>discharges in</u> which the principal diagnosis is neoplasm or carcinoma or is for an admission for radiotherapy or antineoplastic chemotherapy or immunotherapy diagnosis-related groups 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367, 400-414, 473, or 492; or

4. Any combination of the above discharges.

(b) The hospital restricts its medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties.

(c) A hospital classified as an exempt cancer center hospital pursuant to 42 C.F.R. s. 412.23(f) as of December 31, 2005, is exempt from the licensure restrictions of this subsection.

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Section 2. Subsections (2), (3), and (4) of section 408.0361, Florida Statutes, are amended to read:

408.0361 Cardiovascular Cardiology services and burn unit licensure.—

Each provider of adult cardiovascular interventional cardiology ser-(2)vices or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular interventional cardiology services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult cardiovascular interventional cardiology services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult cardiovascular interventional cardiology services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or <u>until July 1, 2008</u> a period specified in the rule, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

(3) In establishing rules for adult <u>cardiovascular</u> interventional cardiology services, the agency shall include provisions that allow for:

(a) Establishment 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.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physi-

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cian training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(4)(<u>a</u>) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of <u>adult cardiovascular</u> <u>services</u> interventional cardiac programs. Members of the panel shall include representatives of the Florida Hospital Association, the Florida Society of Thoracic and Cardiovascular Surgeons, the Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and adopt rules for the <u>adult cardiovascular services</u> interventional cardiac programs that include at least the following:

(a) A standard data set consisting primarily of data elements reported to the agency in accordance with s. 408.061.

<u>1.(b)</u> A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.

<u>2.(c)</u> Outcome standards specifying expected levels of performance in Level I and Level II adult <u>cardiovascular</u> interventional cardiology services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.

 $\underline{3.(d)}$  Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

(b) Hospitals licensed for Level I or Level II adult cardiovascular services shall participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

Section 3. This act shall take effect July 1, 2007.

Approved by the Governor June 27, 2007.

Filed in Office Secretary of State June 27, 2007.

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