

## Senate Bill No. 182

An act relating to certificates of need; amending s. 408.036, F.S., relating to health-care-related projects subject to review for a certificate of need; exempting certain projects involving percutaneous coronary intervention from review; providing requirements by which certain hospitals may obtain an exemption; amending s. 408.0361, F.S.; requiring the agency to adopt rules to develop licensing standards for cardiology services and burn units; providing criteria for such rules; requiring certain providers to comply with such rules; requiring the agency to include certain provisions in establishing the rules; requiring the agency to establish a technical advisory panel and adopt rules based on the panel's recommendations; requiring the secretary of the agency to appoint an advisory group; providing membership criteria for such group; requiring the group to make certain recommendations; requiring the secretary to appoint a workgroup; providing the components of such workgroup's assessment; requiring a report; providing an effective date.

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

Section 1. Present paragraphs (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), and (t) of subsection (3) of section 408.036, Florida Statutes, are redesignated as paragraphs (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), and (u), respectively, and a new paragraph (j) is added to that subsection, to read:

408.036 Projects subject to review; exemptions.—

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(j) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart-surgery program. In addition to any other documentation required by the agency, a request for an exemption submitted under this paragraph must comply with the following:

1. The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements shall be adopted by rule pursuant to ss. 120.536(1) and 120.54 and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum, the rules shall require the following:

a. Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.

b. The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.

c. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.

d. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on previous experience in dedicated interventional laboratories or surgical centers.

e. Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.

f. Formalized written transfer agreements must be developed with a hospital with an adult open-heart-surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be reviewed and tested, with appropriate documentation maintained at least every 3 months.

g. Hospitals implementing the service must first undertake a training program of 3 to 6 months, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.

2. The applicant must certify that it will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the following:

a. Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.

b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.

3. The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.

4. The exemption provided by this paragraph does not apply unless the agency determines that the hospital has taken all necessary steps to be in compliance with all requirements of this paragraph, including the training program required under sub-subparagraph 1.g.

5. Failure of the hospital to continuously comply with the requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. and 3. will result in the immediate expiration of this exemption.

6. Failure of the hospital to meet the volume requirements of sub-subparagraphs 1.a.-b. within 18 months after the program begins offering the service will result in the immediate expiration of the exemption.

If the exemption for this service expires under subparagraph 5. or subparagraph 6., the agency may not grant another exemption for this service to the same hospital for 2 years and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused expiration of the exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted pursuant to this paragraph.

Section 2. Notwithstanding conflicting provisions in House Bill 329, section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiology services and burn unit licensure ~~Diagnostic cardiac catheterization services providers; compliance with guidelines and requirements.—~~

(1) Each provider of diagnostic cardiac catheterization services shall comply with ~~the requirements of s. 408.036(3)(i)2.a.-d., and rules adopted by~~ of the agency that establish licensure standards for Health Care Administration governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules shall ensure that such programs:

(a) Comply with, ~~including~~ the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

(b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(d) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(e) Demonstrate a plan to provide services to Medicaid and charity care patients.

(2) Each provider of adult interventional cardiology services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult 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 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 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 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 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, physician 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) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of 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 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.

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

(c) Outcome standards specifying expected levels of performance in Level I and Level II adult 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.

(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.

(5) The Secretary of Health Care Administration shall appoint an advisory group to study the issue of replacing certificate-of-need review of organ transplant programs under this chapter with licensure regulation of organ transplant programs under chapter 395. The advisory group shall include three representatives of organ transplant providers, one representative of an organ procurement organization, one representative of the Division of Health Quality Assurance, one representative of Medicaid, and one organ transplant patient advocate. The advisory group shall, at minimum, make recommendations regarding access to organs, delivery of services to Medicaid and charity care patients, staff training, and resource requirements for organ transplant programs in a report due to the secretary and the Legislature by July 1, 2005.

(6) The Secretary of Health Care Administration shall appoint a workgroup to study certificate-of-need regulations and changing market conditions related to the supply and distribution of hospital beds. The assessment by the workgroup shall include, but not be limited to, the following:

(a) The appropriateness of current certificate-of-need methodologies and other criteria for evaluating proposals for new hospitals and transfer of beds to new sites.

(b) Additional factors that should be considered, including the viability of safety net services, the extent of market competition, and the accessibility of hospital services.

The workgroup shall submit a report by January 1, 2005, to the secretary and the Legislature identifying specific problem areas and recommending needed changes in statutes or rules.

Section 3. This act shall take effect July 1, 2004.

Approved by the Governor June 28, 2004.

Filed in Office Secretary of State June 28, 2004.