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2 An act relating to certificates of need;
3 amending s. 408.036, F.S., relating to
4 health-care-related projects subject to review
5 for a certificate of need; exempting certain
6 projects involving percutaneous coronary
7 intervention from review; providing
8 requirements by which certain hospitals may
9 obtain an exemption; amending s. 408.0361,
10 F.S.; requiring the agency to adopt rules to
11 develop licensing standards for cardiology
12 services and burn units; providing criteria for
13 such rules; requiring certain providers to
14 comply with such rules; requiring the agency to
15 include certain provisions in establishing the
16 rules; requiring the agency to establish a
17 technical advisory panel and adopt rules based
18 on the panel's recommendations; requiring the
19 secretary of the agency to appoint an advisory
20 group; providing membership criteria for such
21 group; requiring the group to make certain
22 recommendations; requiring the secretary to
23 appoint a workgroup; providing the components
24 of such workgroup's assessment; requiring a
25 report; providing an effective date.

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

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29 Section 1. Present paragraphs (j), (k), (l), (m), (n),
30 (o), (p), (q), (r), (s), and (t) of subsection (3) of section
31 408.036, Florida Statutes, are redesignated as paragraphs (k),

1 (l), (m), (n), (o), (p), (q), (r), (s), (t), and (u),
2 respectively, and a new paragraph (j) is added to that
3 subsection, to read:

4 408.036 Projects subject to review; exemptions.--

5 (3) EXEMPTIONS.--Upon request, the following projects
6 are subject to exemption from the provisions of subsection
7 (1):

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

15 1. The applicant must certify that it will meet and
16 continuously maintain the requirements adopted by the agency
17 for the provision of these services. These licensure
18 requirements shall be adopted by rule pursuant to ss.
19 120.536(1) and 120.54 and must be consistent with the
20 guidelines published by the American College of Cardiology and
21 the American Heart Association for the provision of
22 percutaneous coronary interventions in hospitals without adult
23 open-heart services. At a minimum, the rules shall require the
24 following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 408.0361 Cardiology services and burn unit licensure
5 ~~Diagnostic cardiac catheterization services providers;~~
6 ~~compliance with guidelines and requirements.--~~

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

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

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

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

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

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

28 (2) Each provider of adult interventional cardiology
29 services or operator of a burn unit shall comply with rules
30 adopted by the agency that establish licensure standards that
31 govern the provision of adult interventional cardiology

1 services or the operation of a burn unit. Such rules shall
2 consider, at a minimum, staffing, equipment, physical plant,
3 operating protocols, the provision of services to Medicaid and
4 charity care patients, accreditation, licensure period and
5 fees, and enforcement of minimum standards. The
6 certificate-of-need rules for adult interventional cardiology
7 services and burn units in effect on June 30, 2004, are
8 authorized pursuant to this subsection and shall remain in
9 effect and shall be enforceable by the agency until the
10 licensure rules are adopted. Existing providers and any
11 provider with a notice of intent to grant a certificate of
12 need or a final order of the agency granting a certificate of
13 need for adult interventional cardiology services or burn
14 units shall be considered grandfathered and receive a license
15 for their programs effective on the effective date of this
16 act. The grandfathered licensure shall be for at least 3 years
17 or a period specified in the rule, whichever is longer, but
18 shall be required to meet licensure standards applicable to
19 existing programs for every subsequent licensure period.

20 (3) In establishing rules for adult interventional
21 cardiology services, the agency shall include provisions that
22 allow for:

23 (a) Establishment of two hospital program licensure
24 levels: a Level I program authorizing the performance of adult
25 percutaneous cardiac intervention without onsite cardiac
26 surgery and a Level II program authorizing the performance of
27 percutaneous cardiac intervention with onsite cardiac surgery.

28 (b) For a hospital seeking a Level I program,
29 demonstration that, for the most recent 12-month period as
30 reported to the agency, it has provided a minimum of 300 adult
31 inpatient and outpatient diagnostic cardiac catheterizations

1 or, for the most recent 12-month period, has discharged or
2 transferred at least 300 inpatients with the principal
3 diagnosis of ischemic heart disease and that it has a
4 formalized, written transfer agreement with a hospital that
5 has a Level II program, including written transport protocols
6 to ensure safe and efficient transfer of a patient within 60
7 minutes.

8 (c) For a hospital seeking a Level II program,
9 demonstration that, for the most recent 12-month period as
10 reported to the agency, it has performed a minimum of 1,100
11 adult inpatient and outpatient cardiac catheterizations, of
12 which at least 400 must be therapeutic catheterizations, or,
13 for the most recent 12-month period, has discharged at least
14 800 patients with the principal diagnosis of ischemic heart
15 disease.

16 (d) Compliance with the most recent guidelines of the
17 American College of Cardiology and American Heart Association
18 guidelines for staffing, physician training and experience,
19 operating procedures, equipment, physical plant, and patient
20 selection criteria to ensure patient quality and safety.

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

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

26 (4) The agency shall establish a technical advisory
27 panel to develop procedures and standards for measuring
28 outcomes of interventional cardiac programs. Members of the
29 panel shall include representatives of the Florida Hospital
30 Association, the Florida Society of Thoracic and
31 Cardiovascular Surgeons, the Florida Chapter of the American

1 College of Cardiology, and the Florida Chapter of the American
2 Heart Association and others with experience in statistics and
3 outcome measurement. Based on recommendations from the panel,
4 the agency shall develop and adopt rules for the
5 interventional cardiac programs that include at least the
6 following:

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

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

12 (c) Outcome standards specifying expected levels of
13 performance in Level I and Level II adult interventional
14 cardiology services. Such standards may include, but shall not
15 be limited to, in-hospital mortality, infection rates,
16 nonfatal myocardial infarctions, length of stay, postoperative
17 bleeds, and returns to surgery.

18 (d) Specific steps to be taken by the agency and
19 licensed hospitals that do not meet the outcome standards
20 within specified time periods, including time periods for
21 detailed case reviews and development and implementation of
22 corrective action plans.

23 (5) The Secretary of Health Care Administration shall
24 appoint an advisory group to study the issue of replacing
25 certificate-of-need review of organ transplant programs under
26 this chapter with licensure regulation of organ transplant
27 programs under chapter 395. The advisory group shall include
28 three representatives of organ transplant providers, one
29 representative of an organ procurement organization, one
30 representative of the Division of Health Quality Assurance,
31 one representative of Medicaid, and one organ transplant

1 patient advocate. The advisory group shall, at minimum, make
2 recommendations regarding access to organs, delivery of
3 services to Medicaid and charity care patients, staff
4 training, and resource requirements for organ transplant
5 programs in a report due to the secretary and the Legislature
6 by July 1, 2005.

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

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

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

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

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