

588-2456-07

Proposed Committee Substitute by the Committee on Health Regulation

1                                   A bill to be entitled

2           An act relating to hospitals; amending s.

3           395.003, F.S.; revising provisions designating

4           classes of disease; exempting certain cancer

5           center hospitals from licensure restrictions;

6           amending s. 408.0361, F.S.; revising provisions

7           relating to licensing standards for adult

8           cardiovascular services; revising the period of

9           validity for certain licenses authorized under

10          a grandfather provision; revising the criteria

11          for the adoption of rules by the Agency for

12          Health Care Administration; requiring certain

13          hospitals to participate in clinical

14          outcome-reporting systems operated by the

15          American College of Cardiology and the Society

16          for Thoracic Surgeons for purposes of such rule

17          criteria; removing a requirement that the

18          agency include specified data in rules;

19          providing an effective date.

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

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

25           395.003 Licensure; issuance, renewal, denial,  
26 modification, suspension, and revocation.--

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

28           (a) The diagnosis-related groups for 65 percent or

29           more of the discharges from the hospital, in the most recent

30           year for which data is available to the Agency for Health Care

31           Administration pursuant to s. 408.061, are for diagnosis,

588-2456-07

1 care, and treatment of patients who have:

2 1. Cardiac-related diseases and disorders classified  
3 as diagnosis-related groups in major diagnostic category 5  
4 ~~103-145, 478-479, 514-518, or 525-527~~;

5 2. Orthopedic-related diseases and disorders  
6 classified as diagnosis-related groups in major diagnostic  
7 category 8 ~~209-256, 471, 491, 496-503, or 519-520~~;

8 3. Cancer-related diseases and disorders classified as  
9 discharges in which the principal diagnosis is neoplasm or  
10 carcinoma or is for an admission for radiotherapy or  
11 antineoplastic chemotherapy or immunotherapy ~~diagnosis-related~~  
12 ~~groups 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275,~~  
13 ~~303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367,~~  
14 ~~400-414, 473, or 492~~; or

15 4. Any combination of the above discharges. Any  
16 hospital classified as an exempt cancer center hospital  
17 pursuant to 42 C.F.R. s. 412.23(f) as of December 31, 2005, is  
18 exempt from the licensure restrictions of this subsection.

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

22 Section 2. Section 408.0361, Florida Statutes, is  
23 amended to read:

24 408.0361 Cardiovascular ~~Cardiology~~ services and burn  
25 unit licensure.--

26 (1) Each provider of diagnostic cardiac  
27 catheterization services shall comply with rules adopted by  
28 the agency that establish licensure standards governing the  
29 operation of adult inpatient diagnostic cardiac  
30 catheterization programs. The rules shall ensure that such  
31 programs:

Bill No. SB 760

Barcode 081070

588-2456-07

1           (a) Comply with the most recent guidelines of the  
2 American College of Cardiology and American Heart Association  
3 Guidelines for Cardiac Catheterization and Cardiac  
4 Catheterization Laboratories.

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

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

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

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

15           (2) Each provider of adult cardiovascular  
16 ~~interventional cardiology~~ services or operator of a burn unit  
17 shall comply with rules adopted by the agency that establish  
18 licensure standards that govern the provision of adult  
19 cardiovascular ~~interventional cardiology~~ services or the  
20 operation of a burn unit. Such rules shall consider, at a  
21 minimum, staffing, equipment, physical plant, operating  
22 protocols, the provision of services to Medicaid and charity  
23 care patients, accreditation, licensure period and fees, and  
24 enforcement of minimum standards. The certificate-of-need  
25 rules for adult cardiovascular ~~interventional cardiology~~  
26 services and burn units in effect on June 30, 2004, are  
27 authorized pursuant to this subsection and shall remain in  
28 effect and shall be enforceable by the agency until the  
29 licensure rules are adopted. Existing providers and any  
30 provider with a notice of intent to grant a certificate of  
31 need or a final order of the agency granting a certificate of

Bill No. SB 760

Barcode 081070

588-2456-07

1 need for adult cardiovascular ~~interventional cardiology~~  
2 services or burn units shall be considered grandfathered and  
3 receive a license for their programs effective on the  
4 effective date of this act. The grandfathered licensure shall  
5 be for at least 3 years or until July 1, 2008 ~~a period~~  
6 ~~specified in the rule~~, whichever is longer, but shall be  
7 required to meet licensure standards applicable to existing  
8 programs for every subsequent licensure period.

9 (3) In establishing rules for adult cardiovascular  
10 ~~interventional cardiology~~ services, the agency shall include  
11 provisions that allow for:

12 (a) Establishment of two hospital program licensure  
13 levels: a Level I program authorizing the performance of adult  
14 percutaneous cardiac intervention without onsite cardiac  
15 surgery and a Level II program authorizing the performance of  
16 percutaneous cardiac intervention with onsite cardiac surgery.

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

28 (c) For a hospital seeking a Level II program,  
29 demonstration that, for the most recent 12-month period as  
30 reported to the agency, it has performed a minimum of 1,100  
31 adult inpatient and outpatient cardiac catheterizations, of

Bill No. SB 760

Barcode 081070

588-2456-07

1 which at least 400 must be therapeutic catheterizations, or,  
2 for the most recent 12-month period, has discharged at least  
3 800 patients with the principal diagnosis of ischemic heart  
4 disease.

5 (d) Compliance with the most recent guidelines of the  
6 American College of Cardiology and American Heart Association  
7 guidelines for staffing, physician training and experience,  
8 operating procedures, equipment, physical plant, and patient  
9 selection criteria to ensure patient quality and safety.

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

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

15 (4)(a) The agency shall establish a technical advisory  
16 panel to develop procedures and standards for measuring  
17 outcomes of adult cardiovascular services ~~interventional~~  
18 ~~cardiac programs~~. Members of the panel shall include  
19 representatives of the Florida Hospital Association, the  
20 Florida Society of Thoracic and Cardiovascular Surgeons, the  
21 Florida Chapter of the American College of Cardiology, and the  
22 Florida Chapter of the American Heart Association and others  
23 with experience in statistics and outcome measurement. Based  
24 on recommendations from the panel, the agency shall develop  
25 and adopt rules for the adult cardiovascular services which  
26 ~~interventional cardiac programs~~ that include at least the  
27 following:

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

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

Bill No. SB 760

Barcode 081070

588-2456-07

1 this state.

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

8 ~~3.(d)~~ Specific steps to be taken by the agency and  
9 licensed hospitals that do not meet the outcome standards  
10 within specified time periods, including time periods for  
11 detailed case reviews and development and implementation of  
12 corrective action plans.

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

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

588-2456-07

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

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

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

13  
14 The workgroup shall submit a report by January 1, 2005, to the  
15 secretary and the Legislature identifying specific problem  
16 areas and recommending needed changes in statutes or rules.

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

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