



1 Administration pursuant to s. 408.061, are for diagnosis,  
2 care, and treatment of patients who have:

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

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

9 3. Cancer-related diseases and disorders classified as  
10 discharges in which the principal diagnosis is neoplasm or  
11 carcinoma or is for an admission for radiotherapy or  
12 antineoplastic chemotherapy or immunotherapy ~~diagnosis related~~  
13 ~~groups 64, 82, 172, 173, 199, 200, 203, 257 260, 274, 275,~~  
14 ~~303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367,~~  
15 ~~400 414, 473, or 492; or~~

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

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

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

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

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

1 catheterization programs. The rules shall ensure that such  
2 programs:

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

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

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

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

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

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

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

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

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

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

30 (c) For a hospital seeking a Level II program,  
31 demonstration that, for the most recent 12-month period as

1 reported to the agency, it has performed a minimum of 1,100  
2 adult inpatient and outpatient cardiac catheterizations, of  
3 which at least 400 must be therapeutic catheterizations, or,  
4 for the most recent 12-month period, has discharged at least  
5 800 patients with the principal diagnosis of ischemic heart  
6 disease.

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

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

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

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

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

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

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

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

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

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

1 | programs in a report due to the secretary and the Legislature  
2 | by July 1, 2005.

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

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

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

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

19 |           Section 3. This act shall take effect July 1, 2007.  
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1                   STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN  
2                   COMMITTEE SUBSTITUTE FOR  
3                   Senate Bill 760

4 The committee substitute revises the definition of the types  
5 of specialty hospitals that may not be licensed by the Agency  
6 for Health Care Administration (AHCA or agency).

6 The committee substitute changes the terms cardiology and  
7 cardiovascular services throughout s. 408.0361, F.S., which  
8 relates to licensure of hospital cardiology services and burn  
9 units. The grandfathered licensure status of certain hospitals  
10 with adult interventional cardiology services and or burn  
11 units is changed from a period specified in rule to until July  
12 1, 2008.

10 The committee substitute deletes the inclusion in rules of a  
11 standard data set consisting of data elements reported to the  
12 AHCA in accordance with s. 408.061, F.S. It also requires  
13 Level I and Level II hospitals to participate in clinical  
14 outcome-reporting systems operated by the American College of  
15 Cardiology and the Society for Thoracic Surgeons.

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