

Bill No. SB 182

Amendment No. \_\_\_\_ Barcode 830962

CHAMBER ACTION

Senate

House

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Senator Atwater moved the following amendment:

**Senate Amendment (with title amendment)**

On page 4, between lines 16 and 17,

insert:

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

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1 Association Guidelines for Cardiac Catheterization and Cardiac  
2 Catheterization Laboratories.

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

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

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

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

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

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1 act. The grandfathered licensure shall be for at least 2 years  
2 or a period specified in the rule, whichever is longer, but  
3 shall be required to meet licensure standards applicable to  
4 existing programs for every subsequent licensure period.

5 (3) In establishing rules for adult interventional  
6 cardiology services, the agency shall include provisions that  
7 allow for:

8 (a) Establishment of two hospital program licensure  
9 levels: a Level I program authorizing the performance of adult  
10 percutaneous cardiac intervention without onsite cardiac  
11 surgery and a Level II program authorizing the performance of  
12 percutaneous cardiac intervention with onsite cardiac surgery.

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

24 (c) For a hospital seeking a Level II program,  
25 demonstration that, for the most recent 12-month period as  
26 reported to the agency, it has performed a minimum of 1,100  
27 adult inpatient and outpatient cardiac catheterizations, of  
28 which at least 400 must be therapeutic catheterizations, or,  
29 for the most recent 12-month period, has discharged at least  
30 800 patients with the principal diagnosis of ischemic heart  
31 disease.

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

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

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

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

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

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

28        (c) Outcome standards specifying expected levels of  
29 performance in Level I and Level II adult interventional  
30 cardiology services. Such standards may include, but shall not  
31 be limited to, in-hospital mortality, infection rates,

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1 nonfatal myocardial infarctions, length of stay, postoperative  
2 bleeds, and returns to surgery.

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

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

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

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

31 (b) Additional factors that should be considered,

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1 including the viability of safety net services, the extent of  
2 market competition, and the accessibility of hospital  
3 services.

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

8  
9 (Redesignate subsequent sections.)

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12 ===== T I T L E A M E N D M E N T =====

13 And the title is amended as follows:

14 On page 1, line 9, after the semicolon,

15

16 insert:

17 amending s. 408.0361, F.S.; requiring the  
18 agency to adopt rules to develop licensing  
19 standards for cardiology services and burn  
20 units; providing criteria for such rules;  
21 requiring certain providers to comply with such  
22 rules; requiring the agency to include certain  
23 provisions in establishing the rules; requiring  
24 the agency to establish a technical advisory  
25 panel and adopt rules based on the panel's  
26 recommendations; requiring the secretary of the  
27 agency to appoint an advisory group; providing  
28 membership criteria for such group; requiring  
29 the group to make certain recommendations;  
30 requiring the secretary to appoint a workgroup;  
31 providing the components of such workgroup's

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