

By Senator Atwater

25-112-04

1                                   A bill to be entitled  
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; providing an effective  
10          date.

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

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14           Section 1. Present paragraphs (j), (k), (l), (m), (n),  
15           (o), (p), (q), (r), (s), and (t) of subsection (3) of section  
16           408.036, Florida Statutes, are redesignated as paragraphs (k),  
17           (l), (m), (n), (o), (p), (q), (r), (s), (t), and (u),  
18           respectively, and a new paragraph (j) is added to that  
19           subsection, to read:

20           408.036 Projects subject to review; exemptions.--

21           (3) EXEMPTIONS.--Upon request, the following projects  
22           are subject to exemption from the provisions of subsection  
23           (1):

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

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1           1. The applicant must certify that it will meet and  
2 continuously maintain the requirements adopted by the agency  
3 for the provision of these services. These licensure  
4 requirements shall be adopted by rule pursuant to ss.  
5 120.536(1) and 120.54 and must be consistent with the  
6 guidelines published by the American College of Cardiology and  
7 the American Heart Association for the provision of  
8 percutaneous coronary interventions in hospitals without adult  
9 open-heart services. At a minimum, the rules shall require the  
10 following:

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

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

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

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

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

27           f. Formalized written transfer agreements must be  
28 developed with a hospital with an adult open-heart-surgery  
29 program, and written transport protocols must be in place to  
30 ensure safe and efficient transfer of a patient within 60  
31 minutes. Transfer and transport agreements must be reviewed

1 and tested, with appropriate documentation maintained at least  
2 every 3 months.

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

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

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

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

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

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

30 5. Failure of the hospital to continuously comply with  
31 the requirements of sub-subparagraphs 1.c.-f. and

1 subparagraphs 2. and 3. will result in the immediate  
2 expiration of this exemption.  
3 6. Failure of the hospital to meet the volume  
4 requirements of sub-subparagraphs 1.a.-b. within 18 months  
5 after the program begins offering the service will result in  
6 the immediate expiration of the exemption.  
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8 If the exemption for this service expires under subparagraph  
9 5. or subparagraph 6., the agency may not grant another  
10 exemption for this service to the same hospital for 2 years  
11 and then only upon a showing that the hospital will remain in  
12 compliance with the requirements of this paragraph through a  
13 demonstration of corrections to the deficiencies that caused  
14 expiration of the exemption. Compliance with the requirements  
15 of this paragraph includes compliance with the rules adopted  
16 pursuant to this paragraph.

17 Section 2. This act shall take effect July 1, 2004.

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20 SENATE SUMMARY

21 Provides an exemption from certificate-of-need review for  
22 the provision of percutaneous coronary intervention to  
23 patients who have emergency myocardial infarctions in a  
24 hospital without an approved adult open-heart-surgery  
25 program.  
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