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1                                   A bill to be entitled  
 2           An act relating to certificates of need; amending s.  
 3           408.036, F.S; exempting from review certain projects  
 4           involving percutaneous coronary intervention; providing  
 5           requirements by which certain hospitals may obtain an  
 6           exemption; providing exemption limitations; providing an  
 7           effective date.

8  
 9   Be It Enacted by the Legislature of the State of Florida:

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 11           Section 1. Paragraphs (j), (k), (l), (m), (n), (o), (p),  
 12           (q), (r), (s), and (t) of subsection (3) of section 408.036,  
 13           Florida Statutes, are redesignated as paragraphs (k), (l), (m),  
 14           (n), (o), (p), (q), (r), (s), (t), and (u), respectively, and a  
 15           new paragraph (j) is added to said subsection, to read:

16           408.036 Projects subject to review; exemptions.--

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

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

25           1. The applicant must certify that it will meet and  
 26           continuously maintain the requirements adopted by the agency for  
 27           the provision of these services. These licensure requirements  
 28           shall be adopted by rule pursuant to ss. 120.536(1) and 120.54  
 29           and must be consistent with the guidelines published by the

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30 American College of Cardiology and the American Heart  
 31 Association for the provision of percutaneous coronary  
 32 interventions in hospitals without adult open-heart services. At  
 33 a minimum, the rules shall require the following:

34 a. Cardiologists must be experienced interventionalists  
 35 who have performed a minimum of 75 interventions within the  
 36 previous 12 months.

37 b. The hospital must provide a minimum of 36 emergency  
 38 interventions annually in order to continue to provide the  
 39 service.

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

43 d. Nursing and technical staff must have demonstrated  
 44 experience in handling acutely ill patients requiring  
 45 intervention based on previous experience in dedicated  
 46 interventional laboratories or surgical centers.

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

49 f. Formalized written transfer agreements must be  
 50 developed with a hospital with an adult open-heart-surgery  
 51 program, and written transport protocols must be in place to  
 52 ensure safe and efficient transfer of a patient within 60  
 53 minutes. Transfer and transport agreements must be reviewed and  
 54 tested, with appropriate documentation maintained at least every  
 55 3 months.

56 g. Hospitals implementing the service must first undertake  
 57 a training program of 3 to 6 months, which includes establishing  
 58 standards and testing logistics, creating quality assessment and

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59 error management practices, and formalizing patient-selection  
60 criteria.

61 2. The applicant must certify that it will use at all  
62 times the patient-selection criteria for the performance of  
63 primary angioplasty at hospitals without adult open-heart-  
64 surgery programs issued by the American College of Cardiology  
65 and the American Heart Association. At a minimum, these criteria  
66 would provide for the following:

67 a. Avoidance of interventions in hemodynamically stable  
68 patients who have identified symptoms or medical histories.

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

71 3. The applicant must agree to submit a quarterly report  
72 to the agency detailing patient characteristics, treatment, and  
73 outcomes for all patients receiving emergency percutaneous  
74 coronary interventions pursuant to this paragraph. This report  
75 must be submitted within 15 days after the close of each  
76 calendar quarter.

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

82 5. Failure of the hospital to continuously comply with the  
83 requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2.  
84 and 3. will result in the immediate expiration of this  
85 exemption.

86 6. Failure of the hospital to meet the volume requirements  
87 of sub-subparagraphs 1.a.-b. within 18 months after the program

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88 begins offering the service will result in the immediate  
89 expiration of the exemption.

90  
91 If the exemption for this service expires under subparagraph 5.  
92 or subparagraph 6., the agency may not grant another exemption  
93 for this service to the same hospital for 2 years and then only  
94 upon a showing that the hospital will remain in compliance with  
95 the requirements of this paragraph through a demonstration of  
96 corrections to the deficiencies that caused expiration of the  
97 exemption. Compliance with the requirements of this paragraph  
98 includes compliance with the rules adopted pursuant to this  
99 paragraph.

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