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LEGISLATIVE ACTION

Senate

House

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Floor: WD

03/09/2012 05:46 PM

Senator Bogdanoff moved the following:

Senate Amendment (with title amendment)

Delete lines 223 - 247

and insert:

Section 5. Paragraph (n) of subsection (3) of section
408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

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

(n) For the provision of percutaneous coronary intervention
for patients presenting with emergency myocardial infarctions in
a hospital without an approved adult open-heart-surgery program.
In addition to any other documentation required by the agency, a



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14 request for an exemption submitted under this paragraph must
15 comply with the following:

16 1. The applicant must certify that it will meet and
17 continuously maintain the requirements adopted by the agency for
18 the provision of these services. These licensure requirements
19 shall be adopted by rule pursuant to ss. 120.536(1) and 120.54
20 and must be consistent with the guidelines published by the
21 American College of Cardiology and the American Heart
22 Association for the provision of percutaneous coronary
23 interventions in hospitals without adult open-heart services. At
24 a minimum, the rules shall require the following:

25 a. Cardiologists must be experienced interventionalists who
26 have performed a minimum of 75 interventions within the previous
27 12 months.

28 b. The hospital must provide a minimum of 36 emergency
29 interventions annually in order to continue to provide the
30 service.

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

34 d. Nursing and technical staff must have demonstrated
35 experience in handling acutely ill patients requiring
36 intervention based on previous experience in dedicated
37 interventional laboratories or surgical centers.

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

40 f. Formalized written transfer agreements must be developed
41 with a hospital with an adult open-heart-surgery program, and
42 written transport protocols must be in place to ensure safe and



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43 efficient transfer of a patient within 60 minutes. Transfer and
44 transport agreements must be reviewed and tested, with
45 appropriate documentation maintained at least every 3 months.
46 However, a hospital located more than 100 road miles from the
47 closest Level II adult cardiovascular services program does not
48 need to meet the 60-minute transfer time protocol if the
49 hospital demonstrates that it has a formalized, written transfer
50 agreement with a hospital that has a Level II program. The
51 agreement must include written transport protocols to ensure the
52 safe and efficient transfer of a patient, taking into
53 consideration the patient's clinical and physical
54 characteristics, road and weather conditions, and viability of
55 ground and air ambulance service to transfer the patient.

56 g. Hospitals implementing the service must first undertake
57 a training program of 3 to 6 months' duration, which includes
58 establishing standards and testing logistics, creating quality
59 assessment and error management practices, and formalizing
60 patient-selection criteria.

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



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72 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. and b. within 18 months after the
88 program 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 6. Paragraph (b) of subsection (3) of section



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101 408.0361, Florida Statutes, is amended to read:

102 408.0361 Cardiovascular services and burn unit licensure.-

103 (3) In establishing rules for adult cardiovascular
104 services, the agency shall include provisions that allow for:

105 (b) For a hospital seeking a Level I program, demonstration
106 that, for the most recent 12-month period as reported to the
107 agency, it has provided a minimum of 300 adult inpatient and
108 outpatient diagnostic cardiac catheterizations or, for the most
109 recent 12-month period, has discharged or transferred at least
110 300 inpatients with the principal diagnosis of ischemic heart
111 disease and that it has a formalized, written transfer agreement
112 with a hospital that has a Level II program, including written
113 transport protocols to ensure safe and efficient transfer of a
114 patient within 60 minutes. However, a hospital located more than
115 100 road miles from the closest Level II adult cardiovascular
116 services program does not need to meet the 60-minute transfer
117 time protocol if the hospital demonstrates that it has a
118 formalized, written transfer agreement with a hospital that has
119 a Level II program. The agreement must include written transport
120 protocols to ensure the safe and efficient transfer of a
121 patient, taking into consideration the patient's clinical and
122 physical characteristics, road and weather conditions, and
123 viability of ground and air ambulance service to transfer the
124 patient.

125
126 ===== T I T L E A M E N D M E N T =====

127 And the title is amended as follows:

128 Delete lines 20 - 27

129 and insert:



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130 services; amending s. 408.036, F.S.; providing an
131 exception from certain requirements for exemption from
132 certificate-of-need review for hospitals providing
133 percutaneous coronary intervention for certain
134 patients; amending s. 408.0361, F.S.; providing an
135 exception from certain requirements for exemption from
136 certificate-of-need review for hospitals providing
137 cardiovascular services and burn unit services;
138 amending s.