



693974

LEGISLATIVE ACTION

Senate

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House

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Appropriations Subcommittee on Health and Human Services  
(Grimsley) recommended the following:

**Senate Amendment (with directory amendment)**

Delete line 1791

and insert:

~~(m)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the districts~~



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11 ~~population per licensed and operational open heart programs~~  
12 ~~exceeds the state average of population per licensed and~~  
13 ~~operational open heart programs exceeds the state average of~~  
14 ~~population per licensed and operational open heart programs by~~  
15 ~~at least 25 percent. All hospitals within a health service~~  
16 ~~planning district which meet the criteria reference in sub-~~  
17 ~~subparagraphs 2.a. h. shall be eligible for this exemption on~~  
18 ~~July 1, 2004, and shall receive the exemption upon filing for it~~  
19 ~~and subject to the following:~~

20       ~~a. A hospital that has received a notice of intent to grant~~  
21 ~~a certificate of need or a final order of the agency granting a~~  
22 ~~certificate of need for the establishment of an open-heart~~  
23 ~~surgery program is entitled to receive a letter of exemption for~~  
24 ~~the establishment of an adult open-heart-surgery program upon~~  
25 ~~filing a request for exemption and complying with the criteria~~  
26 ~~enumerated in sub-subparagraphs 2.a. h., and is entitled to~~  
27 ~~immediately commence operation of the program.~~

28       ~~b. An otherwise eligible hospital that has not received a~~  
29 ~~notice of intent to grant a certificate of need or a final order~~  
30 ~~of the agency granting a certificate of need for the~~  
31 ~~establishment of an open-heart-surgery program is entitled to~~  
32 ~~immediately receive a letter of exemption for the establishment~~  
33 ~~of an adult open-heart-surgery program upon filing a request for~~  
34 ~~exemption and complying with the criteria enumerated in sub-~~  
35 ~~subparagraphs 2.a. h., but is not entitled to commence operation~~  
36 ~~of its program until December 31, 2006.~~

37       ~~2. A hospital shall be exempt from the certificate-of-need~~  
38 ~~review for the establishment of an open-heart surgery program~~  
39 ~~when the application for exemption submitted under this~~



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40 ~~paragraph complies with the following criteria:~~

41 ~~a. The applicant must certify that it will meet and~~  
42 ~~continuously maintain the minimum licensure requirements adopted~~  
43 ~~by the agency governing adult open heart programs, including the~~  
44 ~~most current guidelines of the American College of Cardiology~~  
45 ~~and American Heart Association Guidelines for Adult Open Heart~~  
46 ~~Programs.~~

47 ~~b. The applicant must certify that it will maintain~~  
48 ~~sufficient appropriate equipment and health personnel to ensure~~  
49 ~~quality and safety.~~

50 ~~e. The applicant must certify that it will maintain~~  
51 ~~appropriate times of operation and protocols to ensure~~  
52 ~~availability and appropriate referrals in the event of~~  
53 ~~emergencies.~~

54 ~~d. The applicant can demonstrate that it has discharged at~~  
55 ~~least 300 inpatients with a principal diagnosis of ischemic~~  
56 ~~heart disease for the most recent 12-month period as reported to~~  
57 ~~the agency.~~

58 ~~e. The applicant is a general acute care hospital that is~~  
59 ~~in operation for 3 years or more.~~

60 ~~f. The applicant is performing more than 300 diagnostic~~  
61 ~~cardiac catheterization procedures per year, combined inpatient~~  
62 ~~and outpatient.~~

63 ~~g. The applicant's payor mix at a minimum reflects the~~  
64 ~~community average for Medicaid, charity care, and self-pay~~  
65 ~~patients or the applicant must certify that it will provide a~~  
66 ~~minimum of 5 percent of Medicaid, charity care, and self-pay to~~  
67 ~~open-heart surgery patients.~~

68 ~~h. If the applicant fails to meet the established criteria~~



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69 ~~for open heart programs or fails to reach 300 surgeries per year~~  
70 ~~by the end of its third year of operation, it must show cause~~  
71 ~~why its exemption should not be revoked.~~

72 ~~3. By December 31, 2004, and annually thereafter, the~~  
73 ~~agency shall submit a report to the Legislature providing~~  
74 ~~information concerning the number of requests for exemption it~~  
75 ~~has received under this paragraph during the calendar year and~~  
76 ~~the number of exemptions it has granted or denied during the~~  
77 ~~calendar year.~~

78 ~~(n) For the provision of percutaneous coronary intervention~~  
79 ~~for patients presenting with emergency myocardial infarctions in~~  
80 ~~a hospital without an approved adult open-heart-surgery program.~~  
81 ~~In addition to any other documentation required by the agency, a~~  
82 ~~request for an exemption submitted under this paragraph must~~  
83 ~~comply with the following:~~

84 ~~1. The applicant must certify that it will meet and~~  
85 ~~continuously maintain the requirements adopted by the agency for~~  
86 ~~the provision of these services. These licensure requirements~~  
87 ~~shall be adopted by rule and must be consistent with the~~  
88 ~~guidelines published by the American College of Cardiology and~~  
89 ~~the American Heart Association for the provision of percutaneous~~  
90 ~~coronary interventions in hospitals without adult open-heart~~  
91 ~~services. At a minimum, the rules must require the following:~~

92 ~~a. Cardiologists must be experienced interventionalists who~~  
93 ~~have performed a minimum of 75 interventions within the previous~~  
94 ~~12 months.~~

95 ~~b. The hospital must provide a minimum of 36 emergency~~  
96 ~~interventions annually in order to continue to provide the~~  
97 ~~service.~~



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98           ~~e. The hospital must offer sufficient physician, nursing,~~  
99 ~~and laboratory staff to provide the services 24 hours a day, 7~~  
100 ~~days a week.~~

101           ~~d. Nursing and technical staff must have demonstrated~~  
102 ~~experience in handling acutely ill patients requiring~~  
103 ~~intervention based on previous experience in dedicated~~  
104 ~~interventional laboratories or surgical centers.~~

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

107           ~~f. Formalized written transfer agreements must be developed~~  
108 ~~with a hospital with an adult open-heart-surgery program, and~~  
109 ~~written transport protocols must be in place to ensure safe and~~  
110 ~~efficient transfer of a patient within 60 minutes. Transfer and~~  
111 ~~transport agreements must be reviewed and tested, with~~  
112 ~~appropriate documentation maintained at least every 3 months.~~  
113 ~~However, a hospital located more than 100 road miles from the~~  
114 ~~closest Level II adult cardiovascular services program does not~~  
115 ~~need to meet the 60-minute transfer time protocol if the~~  
116 ~~hospital demonstrates that it has a formalized, written transfer~~  
117 ~~agreement with a hospital that has a Level II program. The~~  
118 ~~agreement must include written transport protocols that ensure~~  
119 ~~the safe and efficient transfer of a patient, taking into~~  
120 ~~consideration the patient's clinical and physical~~  
121 ~~characteristics, road and weather conditions, and viability of~~  
122 ~~ground and air ambulance service to transfer the patient.~~

123           ~~g. Hospitals implementing the service must first undertake~~  
124 ~~a training program of 3 to 6 months' duration, which includes~~  
125 ~~establishing standards and testing logistics, creating quality~~  
126 ~~assessment and error management practices, and formalizing~~



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127 ~~patient selection criteria.~~

128 ~~2. The applicant must certify that it will use at all times~~  
129 ~~the patient selection criteria for the performance of primary~~  
130 ~~angioplasty at hospitals without adult open heart surgery~~  
131 ~~programs issued by the American College of Cardiology and the~~  
132 ~~American Heart Association. At a minimum, these criteria would~~  
133 ~~provide for the following:~~

134 ~~a. Avoidance of interventions in hemodynamically stable~~  
135 ~~patients who have identified symptoms or medical histories.~~

136 ~~b. Transfer of patients who have a history of coronary~~  
137 ~~disease and clinical presentation of hemodynamic instability.~~

138 ~~3. The applicant must agree to submit a quarterly report to~~  
139 ~~the agency detailing patient characteristics, treatment, and~~  
140 ~~outcomes for all patients receiving emergency percutaneous~~  
141 ~~coronary interventions pursuant to this paragraph. This report~~  
142 ~~must be submitted within 15 days after the close of each~~  
143 ~~calendar quarter.~~

144 ~~4. The exemption provided by this paragraph does not apply~~  
145 ~~unless the agency determines that the hospital has taken all~~  
146 ~~necessary steps to be in compliance with all requirements of~~  
147 ~~this paragraph, including the training program required under~~  
148 ~~sub-subparagraph 1.g.~~

149 ~~5. Failure of the hospital to continuously comply with the~~  
150 ~~requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2.~~  
151 ~~and 3. will result in the immediate expiration of this~~  
152 ~~exemption.~~

153 ~~6. Failure of the hospital to meet the volume requirements~~  
154 ~~of sub-subparagraphs 1.a. and b. within 18 months after the~~  
155 ~~program begins offering the service will result in the immediate~~



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156 ~~expiration of the exemption.~~

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158 ~~If the exemption for this service expires under subparagraph 5.~~  
159 ~~or subparagraph 6., the agency may not grant another exemption~~  
160 ~~for this service to the same hospital for 2 years and then only~~  
161 ~~upon a showing that the hospital will remain in compliance with~~  
162 ~~the requirements of this paragraph through a demonstration of~~  
163 ~~corrections to the deficiencies that caused expiration of the~~  
164 ~~exemption. Compliance with the requirements of this paragraph~~  
165 ~~includes compliance with the rules adopted pursuant to this~~  
166 ~~paragraph.~~

167 ~~(m)-(p)~~ For replacement of a licensed nursing home on the

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169 ===== D I R E C T O R Y C L A U S E A M E N D M E N T =====

170 And the directory clause is amended as follows:

171 Delete lines 1780 - 1783

172 and insert:

173 Section 60. Present paragraphs (f) through (l) of  
174 subsection (3) of section 408.036, Florida Statutes, are  
175 redesignated as paragraphs (e) through (k), respectively,  
176 present paragraphs (o) through (t) of that subsection are  
177 redesignated as paragraphs (l) through (q), respectively, and  
178 present paragraphs (e), (m), (n), and (p) of that subsection are  
179 amended, to read: