

Amendment No. 4

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___	(Y/N)
ADOPTED AS AMENDED	___	(Y/N)
ADOPTED W/O OBJECTION	___	(Y/N)
FAILED TO ADOPT	___	(Y/N)
WITHDRAWN	___	(Y/N)
OTHER	_____	

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee

3 Representative Yarborough offered the following:

4

5 **Amendment (with title amendment)**

6 Remove lines 1785-1799 and insert:

7 Section 1. Paragraphs (f) through (t) of subsection (3) of
8 section 408.036, Florida Statutes are redesignated as paragraphs
9 (e) through (q), respectively, and present paragraphs(e),
10 (m), (n) and (p) of subsection (3) of section 408.036, Florida
11 Statutes, are amended to read:

12 408.036 Projects subject to review; exemptions.—

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

15 ~~(e) For mobile surgical facilities and related health care~~
16 ~~services provided under contract with the Department of~~

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17 ~~Corrections or a private correctional facility operating~~
18 ~~pursuant to chapter 957.~~

19 ~~(m)1. For the provision of adult open-heart services in a~~
20 ~~hospital located within the boundaries of a health service~~
21 ~~planning district, as defined in s. 408.032(5), which has~~
22 ~~experienced an annual net out-migration of at least 600 open-~~
23 ~~heart surgery cases for 3 consecutive years according to the~~
24 ~~most recent data reported to the agency, and the district's~~
25 ~~population per licensed and operational open-heart programs~~
26 ~~exceeds the state average of population per licensed and~~
27 ~~operational open-heart programs by at least 25 percent. All~~
28 ~~hospitals within a health service planning district which meet~~
29 ~~the criteria reference in sub-subparagraphs 2.a.-h. shall be~~
30 ~~eligible for this exemption on July 1, 2004, and shall receive~~
31 ~~the exemption upon filing for it and subject to the following:~~

32 ~~a. A hospital that has received a notice of intent to~~
33 ~~grant a certificate of need or a final order of the agency~~
34 ~~granting a certificate of need for the establishment of an open-~~
35 ~~heart surgery program is entitled to receive a letter of~~
36 ~~exemption for the establishment of an adult open-heart surgery~~
37 ~~program upon filing a request for exemption and complying with~~
38 ~~the criteria enumerated in sub-subparagraphs 2.a.-h., and is~~
39 ~~entitled to immediately commence operation of the program.~~

40 ~~b. An otherwise eligible hospital that has not received a~~
41 ~~notice of intent to grant a certificate of need or a final order~~

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42 ~~of the agency granting a certificate of need for the~~
43 ~~establishment of an open-heart surgery program is entitled to~~
44 ~~immediately receive a letter of exemption for the establishment~~
45 ~~of an adult open-heart surgery program upon filing a request for~~
46 ~~exemption and complying with the criteria enumerated in sub-~~
47 ~~subparagraphs 2.a.-h., but is not entitled to commence operation~~
48 ~~of its program until December 31, 2006.~~

49 ~~2. A hospital shall be exempt from the certificate of need~~
50 ~~review for the establishment of an open-heart surgery program~~
51 ~~when the application for exemption submitted under this~~
52 ~~paragraph complies with the following criteria:~~

53 ~~a. The applicant must certify that it will meet and~~
54 ~~continuously maintain the minimum licensure requirements adopted~~
55 ~~by the agency governing adult open-heart programs, including the~~
56 ~~most current guidelines of the American College of Cardiology~~
57 ~~and American Heart Association Guidelines for Adult Open Heart~~
58 ~~Programs.~~

59 ~~b. The applicant must certify that it will maintain~~
60 ~~sufficient appropriate equipment and health personnel to ensure~~
61 ~~quality and safety.~~

62 ~~e. The applicant must certify that it will maintain~~
63 ~~appropriate times of operation and protocols to ensure~~
64 ~~availability and appropriate referrals in the event of~~
65 ~~emergencies.~~

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

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

72 ~~f. The applicant is performing more than 300 diagnostic~~
73 ~~cardiac catheterization procedures per year, combined inpatient~~
74 ~~and outpatient.~~

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

80 ~~h. If the applicant fails to meet the established criteria~~
81 ~~for open-heart programs or fails to reach 300 surgeries per year~~
82 ~~by the end of its third year of operation, it must show cause~~
83 ~~why its exemption should not be revoked.~~

84 ~~3. By December 31, 2004, and annually thereafter, the~~
85 ~~agency shall submit a report to the Legislature providing~~
86 ~~information concerning the number of requests for exemption it~~
87 ~~has received under this paragraph during the calendar year and~~
88 ~~the number of exemptions it has granted or denied during the~~
89 ~~calendar year.~~

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

96 ~~1. The applicant must certify that it will meet and~~
97 ~~continuously maintain the requirements adopted by the agency for~~
98 ~~the provision of these services. These licensure requirements~~
99 ~~shall be adopted by rule and must be consistent with the~~
100 ~~guidelines published by the American College of Cardiology and~~
101 ~~the American Heart Association for the provision of percutaneous~~
102 ~~coronary interventions in hospitals without adult open-heart~~
103 ~~services. At a minimum, the rules must require the following:~~

104 ~~a. Cardiologists must be experienced interventionalists~~
105 ~~who have performed a minimum of 75 interventions within the~~
106 ~~previous 12 months.~~

107 ~~b. The hospital must provide a minimum of 36 emergency~~
108 ~~interventions annually in order to continue to provide the~~
109 ~~service.~~

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

113 ~~d. Nursing and technical staff must have demonstrated~~
114 ~~experience in handling acutely ill patients requiring~~

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115 ~~intervention based on previous experience in dedicated~~
116 ~~interventional laboratories or surgical centers.~~

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

119 ~~f. Formalized written transfer agreements must be~~
120 ~~developed with a hospital with an adult open-heart surgery~~
121 ~~program, and written transport protocols must be in place to~~
122 ~~ensure safe and efficient transfer of a patient within 60~~
123 ~~minutes. Transfer and transport agreements must be reviewed and~~
124 ~~tested, with appropriate documentation maintained at least every~~
125 ~~3 months. However, a hospital located more than 100 road miles~~
126 ~~from the closest Level II adult cardiovascular services program~~
127 ~~does not need to meet the 60-minute transfer time protocol if~~
128 ~~the hospital demonstrates that it has a formalized, written~~
129 ~~transfer agreement with a hospital that has a Level II program.~~
130 ~~The agreement must include written transport protocols that~~
131 ~~ensure the safe and efficient transfer of a patient, taking into~~
132 ~~consideration the patient's clinical and physical~~
133 ~~characteristics, road and weather conditions, and viability of~~
134 ~~ground and air ambulance service to transfer the patient.~~

135 ~~g. Hospitals implementing the service must first undertake~~
136 ~~a training program of 3 to 6 months' duration, which includes~~
137 ~~establishing standards and testing logistics, creating quality~~
138 ~~assessment and error management practices, and formalizing~~
139 ~~patient-selection criteria.~~

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140 ~~2. The applicant must certify that it will use at all~~
141 ~~times the patient selection criteria for the performance of~~
142 ~~primary angioplasty at hospitals without adult open-heart-~~
143 ~~surgery programs issued by the American College of Cardiology~~
144 ~~and the American Heart Association. At a minimum, these criteria~~
145 ~~would provide for the following:~~

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

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

150 ~~3. The applicant must agree to submit a quarterly report~~
151 ~~to the agency detailing patient characteristics, treatment, and~~
152 ~~outcomes for all patients receiving emergency percutaneous~~
153 ~~coronary interventions pursuant to this paragraph. This report~~
154 ~~must be submitted within 15 days after the close of each~~
155 ~~calendar quarter.~~

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

161 ~~5. Failure of the hospital to continuously comply with the~~
162 ~~requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2.~~
163 ~~and 3. will result in the immediate expiration of this~~
164 ~~exemption.~~

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165 ~~6. Failure of the hospital to meet the volume requirements~~
 166 ~~of sub-subparagraphs 1.a. and b. within 18 months after the~~
 167 ~~program begins offering the service will result in the immediate~~
 168 ~~expiration of the exemption.~~

169
 170 ~~If the exemption for this service expires under subparagraph 5.~~
 171 ~~or subparagraph 6., the agency may not grant another exemption~~
 172 ~~for this service to the same hospital for 2 years and then only~~
 173 ~~upon a showing that the hospital will remain in compliance with~~
 174 ~~the requirements of this paragraph through a demonstration of~~
 175 ~~corrections to the deficiencies that caused expiration of the~~
 176 ~~exemption. Compliance with the requirements of this paragraph~~
 177 ~~includes compliance with the rules adopted pursuant to this~~
 178 ~~paragraph.~~

179 (m) ~~(p)~~ For replacement of a licensed nursing home on the
 180 same site, or within 5 miles of the same site if within the same
 181 subdistrict, if the number of licensed beds does not increase
 182 except as permitted under paragraph (e) ~~(f)~~.

184 -----
 185 **T I T L E A M E N D M E N T**

186 Remove line 127 and insert:
 187 may be valid for up to 2 years; amending s. 408.036, F.S.;
 188 removing exemptions from certificate of need adult for open-
 189 heart services; amending s. 408.0361,