

By Senator Brodeur

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1                   A bill to be entitled  
2           An act relating to adult cardiovascular care  
3           standards; amending s. 395.1055, F.S.; deleting the  
4           requirement for the Agency for Health Care  
5           Administration to adopt certain rules for adult  
6           inpatient diagnostic cardiac catheterization programs;  
7           revising standards for rules relating to adult  
8           cardiovascular services; requiring the agency to  
9           update its rules as often as necessary to remain  
10          consistent with new standards and guidelines published  
11          by certain entities; providing an effective date.

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

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15           Section 1. Subsections (16), (18), and (19) of section  
16   395.1055, Florida Statutes, are amended to read:

17           395.1055 Rules and enforcement.—

18           ~~(16) Each provider of diagnostic cardiac catheterization~~  
19   ~~services shall comply with rules adopted by the agency which~~  
20   ~~establish licensure standards governing the operation of adult~~  
21   ~~inpatient diagnostic cardiac catheterization programs. The rules~~  
22   ~~must ensure that such programs:~~

23           ~~(a) Comply with the most recent guidelines of the American~~  
24   ~~College of Cardiology and American Heart Association Guidelines~~  
25   ~~for Cardiac Catheterization and Cardiac Catheterization~~  
26   ~~Laboratories.~~

27           ~~(b) Perform only adult inpatient diagnostic cardiac~~  
28   ~~catheterization services and will not provide therapeutic~~  
29   ~~cardiac catheterization or any other cardiology services.~~

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30 ~~(c) Maintain sufficient appropriate equipment and health~~  
31 ~~care personnel to ensure quality and safety.~~

32 ~~(d) Maintain appropriate times of operation and protocols~~  
33 ~~to ensure availability and appropriate referrals in the event of~~  
34 ~~emergencies.~~

35 ~~(e) Demonstrate a plan to provide services to Medicaid and~~  
36 ~~charity care patients.~~

37 (18) In establishing rules for adult cardiovascular  
38 services, the agency shall include provisions that provide allow  
39 for all of the following:

40 (a) The establishment of two hospital program licensure  
41 levels, a Level I program that authorizes the performance of  
42 adult percutaneous cardiac intervention without onsite cardiac  
43 surgery, including rotational or other atherectomy devices,  
44 electrophysiology, and treatment of chronic total occlusions,  
45 and a Level II program that authorizes the performance of  
46 percutaneous cardiac intervention with onsite cardiac surgery.

47 (b)1. ~~For~~ A hospital seeking a Level I program must have a  
48 ~~demonstration that, for the most recent 12-month period as~~  
49 ~~reported to the agency, the hospital has provided a minimum of~~  
50 ~~300 adult inpatient and outpatient diagnostic cardiac~~  
51 ~~catheterizations or, for the most recent 12-month period, has~~  
52 ~~discharged or transferred at least 300 patients with the~~  
53 ~~principal diagnosis of ischemic heart disease and that it has a~~  
54 ~~formalized,~~ written transfer agreement with a hospital that has  
55 a Level II program, including written transport protocols to  
56 ensure safe and efficient transfer of a patient ~~within 60~~  
57 ~~minutes.~~

58 ~~2.a. A hospital located more than 100 road miles from the~~

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59 ~~closest Level II adult cardiovascular services program is not~~  
60 ~~required to meet the diagnostic cardiac catheterization volume~~  
61 ~~and ischemic heart disease diagnosis volume requirements in~~  
62 ~~subparagraph 1. if the hospital demonstrates that it has, for~~  
63 ~~the most recent 12-month period as reported to the agency,~~  
64 ~~provided a minimum of 100 adult inpatient and outpatient~~  
65 ~~diagnostic cardiac catheterizations or that, for the most recent~~  
66 ~~12-month period, it has discharged or transferred at least 300~~  
67 ~~patients with the principal diagnosis of ischemic heart disease.~~

68 2.b. ~~A hospital located more than 100 road miles from the~~  
69 ~~closest Level II adult cardiovascular services program must have~~  
70 ~~a does not need to meet the 60-minute transfer time protocol~~  
71 ~~requirement in subparagraph 1. if the hospital demonstrates that~~  
72 ~~it has a formalized, written transfer agreement with a hospital~~  
73 ~~that has a Level II program which includes. The agreement must~~  
74 ~~include~~ written transport protocols to ensure the safe and  
75 efficient transfer of a patient, taking into consideration the  
76 patient's clinical and physical characteristics, road and  
77 weather conditions, and viability of ground and air ambulance  
78 service to transfer the patient.

79 ~~3. At a minimum, the rules for adult cardiovascular~~  
80 ~~services must require nursing and technical staff to have~~  
81 ~~demonstrated experience in handling acutely ill patients~~  
82 ~~requiring intervention, based on the staff member's previous~~  
83 ~~experience in dedicated cardiac interventional laboratories or~~  
84 ~~surgical centers. If a staff member's previous experience is in~~  
85 ~~a dedicated cardiac interventional laboratory at a hospital that~~  
86 ~~does not have an approved adult open heart surgery program, the~~  
87 ~~staff member's previous experience qualifies only if, at the~~

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88 ~~time the staff member acquired his or her experience, the~~  
89 ~~dedicated cardiac interventional laboratory:~~

90 ~~a. Had an annual volume of 500 or more percutaneous cardiac~~  
91 ~~intervention procedures.~~

92 ~~b. Achieved a demonstrated success rate of 95 percent or~~  
93 ~~greater for percutaneous cardiac intervention procedures.~~

94 ~~c. Experienced a complication rate of less than 5 percent~~  
95 ~~for percutaneous cardiac intervention procedures.~~

96 ~~d. Performed diverse cardiac procedures, including, but not~~  
97 ~~limited to, balloon angioplasty and stenting, rotational~~  
98 ~~atherectomy, cutting balloon atheroma remodeling, and procedures~~  
99 ~~relating to left ventricular support capability.~~

100 (c) For a hospital seeking a Level II program,  
101 demonstration that, for the most recent 12-month period as  
102 reported to the agency, the hospital has performed a minimum of  
103 1,100 adult inpatient and outpatient cardiac catheterizations,  
104 of which at least 400 must be therapeutic catheterizations, or,  
105 for the most recent 12-month period, has discharged at least 800  
106 patients with the principal diagnosis of ischemic heart disease.

107 (d) Compliance with the most recent guidelines of the  
108 American College of Cardiology, ~~and~~ the American Heart  
109 Association, and the Society for Cardiac Angiography and  
110 Intervention guidelines for staffing, physician training and  
111 experience, operating procedures, equipment, physical plant, and  
112 patient selection criteria, to ensure patient quality and  
113 safety.

114 (e) The establishment of appropriate hours of operation and  
115 protocols to ensure availability and timely referral in the  
116 event of emergencies.

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117 (f) The demonstration of a plan to provide services to  
118 Medicaid and charity care patients.

119 (g) For a hospital licensed for adult diagnostic cardiac  
120 catheterization that provides Level I or Level II adult  
121 cardiovascular services, demonstration that the hospital is  
122 participating in the American College of Cardiology's National  
123 Cardiovascular Data Registry or the American Heart Association's  
124 Get with the Guidelines-Coronary Artery Disease registry and  
125 documentation of an ongoing quality improvement plan ensuring  
126 that the licensed cardiac program meets or exceeds national  
127 quality and outcome benchmarks reported by the registry in which  
128 the hospital participates. A hospital licensed for Level II  
129 adult cardiovascular services must also participate in the  
130 clinical outcome reporting systems operated by the Society for  
131 Thoracic Surgeons.

132 (19) The agency may adopt rules to administer the  
133 requirements of part II of chapter 408 and shall update agency  
134 rules as often as necessary to remain consistent with new  
135 standards and guidelines published by federal health agencies  
136 and nationally recognized medical organizations.

137 Section 2. This act shall take effect July 1, 2024.