By Senator Leek

	7-00346A-25 2025596
1	A bill to be entitled
2	An act relating to cardiac services providers;
3	amending s. 395.1055, F.S.; revising requirements for
4	licensure of Level I and Level II adult cardiovascular
5	programs; requiring the Agency for Health Care
6	Administration to update specified rules as new
7	applicable industry standards and guidelines are
8	published; providing an effective date.
9	
10	Be It Enacted by the Legislature of the State of Florida:
11	
12	Section 1. Subsections (18) and (19) of section 395.1055,
13	Florida Statutes, are amended to read:
14	395.1055 Rules and enforcement
15	(18) <u>(a)</u> In establishing rules for adult cardiovascular
16	$rac{1}{2}$ services, The agency shall grant licensure $rac{1}{2}$ include provisions
17	that allow for:
18	(a) the establishment of two hospital program licensure
19	levels, a Level I program that authorizes the performance of
20	adult percutaneous cardiac intervention without onsite cardiac
21	surgery, including rotational or other atherectomy devices,
22	electrophysiology, and treatment of chronic total occlusions,
23	and a Level II program that authorizes the performance of
24	percutaneous cardiac intervention with onsite cardiac surgery.
25	(b) 1. For A hospital seeking <u>licensure as</u> a Level I program
26	must:, demonstration that, for the most recent 12-month period
27	as reported to the agency, the hospital has provided a minimum
28	of 300 adult inpatient and outpatient diagnostic cardiac
29	catheterizations or, for the most recent 12-month period, has
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30	discharged or transferred at least 300 patients with the
31	principal diagnosis of ischemic heart disease and that it has
32	1. Have a formalized, written transfer agreement with a
33	hospital that has a Level II program, including written
34	transport protocols to ensure safe and efficient transfer of a
35	patient within 60 minutes.
36	2.a. A hospital located more than 100 road miles from the
37	closest Level II adult cardiovascular services program is not
38	required to meet the diagnostic cardiac catheterization volume
39	and ischemic heart disease diagnosis volume requirements in
40	subparagraph 1. if the hospital demonstrates that it has, for
41	the most recent 12-month period as reported to the agency,
42	provided a minimum of 100 adult inpatient and outpatient
43	diagnostic cardiac catheterizations or that, for the most recent
44	12-month period, it has discharged or transferred at least 300
45	patients with the principal diagnosis of ischemic heart disease.
46	b. For a hospital located more than 100 road miles from the
47	closest Level II adult cardiovascular services program <u>, have</u>
48	does not need to meet the 60-minute transfer time protocol
49	requirement in subparagraph 1. if the hospital demonstrates that
50	it has a formalized, written transfer agreement with a hospital
51	that has a Level II program. The agreement must include written
52	transport protocols to ensure the safe and efficient transfer of
53	a patient, taking into consideration the patient's clinical and
54	physical characteristics, road and weather conditions, and
55	viability of ground and air ambulance service to transfer the

56 patient.

57 3. At a minimum, the rules for adult cardiovascular
58 services must require nursing and technical staff to have

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59	demonstrated experience in handling acutely ill patients
60	requiring intervention, based on the staff member's previous
61	experience in dedicated cardiac interventional laboratories or
62	surgical centers. If a staff member's previous experience is in
63	a dedicated cardiac interventional laboratory at a hospital that
64	does not have an approved adult open heart surgery program, the
65	staff member's previous experience qualifies only if, at the
66	time the staff member acquired his or her experience, the
67	dedicated cardiac interventional laboratory:
68	a. Had an annual volume of 500 or more percutaneous cardiac
69	intervention procedures.
70	b. Achieved a demonstrated success rate of 95 percent or
71	greater for percutaneous cardiac intervention procedures.
72	c.—Experienced a complication rate of less than 5 percent
73	for percutaneous cardiac intervention procedures.
74	d. Performed diverse cardiac procedures, including, but not
75	limited to, balloon angioplasty and stenting, rotational
76	atherectomy, cutting balloon atheroma remodeling, and procedures
77	relating to left ventricular support capability.
78	(c) For A hospital seeking <u>licensure as</u> a Level II program
79	must demonstrate, demonstration that, for the most recent 12-
80	month period as reported to the agency, the hospital has
81	performed a minimum of 1,100 adult inpatient and outpatient
82	cardiac catheterizations, of which at least 400 must be
83	therapeutic catheterizations, or, for the most recent 12-month
84	period, has discharged at least 800 patients with the principal
85	diagnosis of ischemic heart disease.
86	(d) As a condition of licensure as a Level I or Level II
87	program, a hospital must demonstrate all of the following:

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88	<u>1.</u> Compliance with the most recent guidelines of the								
89	American College of Cardiology <u>,</u> and the American Heart								
90	Association, the Society for Cardiovascular Angiography and								
91	Interventions, and, for hospitals providing electrophysiology								
92	services, the Heart Rhythm Society guidelines for staffing,								
93	physician training and experience, operating procedures,								
94	equipment, physical plant, and patient selection criteria, to								
95	ensure patient quality and safety.								
96	2.(e) The establishment of appropriate hours of operation								
97	and protocols to ensure availability and timely referral in the								
98	event of emergencies.								
99	<u>3.(f)</u> The demonstration of A plan to provide services to								
100	Medicaid and charity care patients.								
101	<u>4.(g)</u> For a hospital licensed <u>as a</u> for adult diagnostic								
102	cardiac catheterization that provides Level I or Level II								
103	program for adult cardiovascular services, demonstration that								
104	the hospital is participating in the American College of								
105	Cardiology's National Cardiovascular Data Registry or the								
106	American Heart Association's Get with the Guidelines-Coronary								
107	Artery Disease registry and documentation of an ongoing quality								
108	improvement plan ensuring that the licensed cardiac program								
109	meets or exceeds national quality and outcome benchmarks								
110	reported by the registry in which the hospital participates. A								
111	hospital licensed for Level II adult cardiovascular services								
112	must also participate in the clinical outcome reporting systems								
113	operated by the Society for Thoracic Surgeons.								
114	(19) The agency may adopt rules to administer the								
115	requirements of part II of chapter 408 and shall update such								
116	rules as new applicable industry standards and guidelines are								

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117	publ	ished.										
118		Section	2.	This	act	shall	take	effect	October	1,	2025.	

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