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1                   A bill to be entitled  
2           An act relating to medical devices; amending s.  
3           401.2915, F.S.; requiring certain entities to notify  
4           local emergency services medical directors of the  
5           locations of automated external defibrillators;  
6           requiring local emergency medical services medical  
7           directors to maintain registries of certain automated  
8           external defibrillator locations; amending s. 499.01,  
9           F.S.; revising the list of exemptions from the  
10          requirement that certain persons engaged in the  
11          manufacture, repackaging, or assembly of medical  
12          devices hold a device manufacturer permit; amending s.  
13          768.1326, F.S.; directing the State Surgeon General,  
14          with the assistance of the Department of Management  
15          Services, to adopt rules to establish guidelines for  
16          the appropriate placement and deployment of automated  
17          external defibrillators in places of public assembly;  
18          providing a definition; providing exceptions;  
19          providing for construction; providing an effective  
20          date.

21  
22   Be It Enacted by the Legislature of the State of Florida:

23  
24           Section 1. Section 401.2915, Florida Statutes, is amended  
25   to read:

26           401.2915 Automated external defibrillators.—It is the  
27   intent of the Legislature that an automated external  
28   defibrillator may be used by any person for the purpose of  
29   saving the life of another person in cardiac arrest. In order to

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30 achieve that goal, the Legislature intends to encourage training  
31 in lifesaving first aid and set standards for and encourage the  
32 use of automated external defibrillators.

33 (1) As used in this section, the term:

34 (a) "Automated external defibrillator" means a device as  
35 defined in s. 768.1325(2) (b).

36 (b) "Defibrillation" means the administration of a  
37 controlled electrical charge to the heart to restore a viable  
38 cardiac rhythm.

39 (2) In order to promote public health and safety:

40 (a) All persons who use an automated external defibrillator  
41 are encouraged to obtain appropriate training, to include  
42 completion of a course in cardiopulmonary resuscitation or  
43 successful completion of a basic first aid course that includes  
44 cardiopulmonary resuscitation training, and demonstrated  
45 proficiency in the use of an automated external defibrillator.

46 (b) Any person or entity in possession of an automated  
47 external defibrillator is encouraged to notify the local  
48 emergency medical services medical director of the location of  
49 the automated external defibrillator. The owner, operator, or  
50 administrator responsible for a place of public assembly, as  
51 defined in s. 768.1326, shall notify the local emergency medical  
52 services medical director of the location of the automated  
53 external defibrillator. The state agency responsible for a  
54 building or portion of a building owned or leased by the state  
55 shall notify the local emergency medical services medical  
56 director of the location of the automated external  
57 defibrillator. The local emergency medical services medical  
58 director shall maintain a registry of these automated external

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59 defibrillator locations.

60 (c) Any person who uses an automated external defibrillator  
61 shall activate the emergency medical services system as soon as  
62 possible upon use of the automated external defibrillator.

63 (3) Any person who intentionally or willfully:

64 (a) Tamper with or otherwise renders an automated external  
65 defibrillator inoperative, except during such time as the  
66 automated external defibrillator is being serviced, tested,  
67 repaired, recharged, or inspected or except pursuant to court  
68 order; or

69 (b) Obliterates the serial number on an automated external  
70 defibrillator for purposes of falsifying service records,

71  
72 commits a misdemeanor of the first degree, punishable as  
73 provided in s. 775.082 or s. 775.083. Paragraph (a) does not  
74 apply to the owner of the automated external defibrillator or  
75 the owner's authorized representative or agent.

76 (4) Each local and state law enforcement vehicle may carry  
77 an automated external defibrillator.

78 Section 2. Paragraph (q) of subsection (2) of section  
79 499.01, Florida Statutes, is amended to read:

80 499.01 Permits.—

81 (2) The following permits are established:

82 (q) *Device manufacturer permit.*—

83 1. A device manufacturer permit is required for any person  
84 that engages in the manufacture, repackaging, or assembly of  
85 medical devices for human use in this state, except that a  
86 permit is not required if:

87 a. The person is engaged only in manufacturing,

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88 repackaging, or assembling a medical device pursuant to a  
89 practitioner's order for a specific patient; ~~or-~~

90 b. The person does not manufacture, repackage, or assemble  
91 any medical devices or components for such devices, except those  
92 devices or components that are exempt from registration pursuant  
93 to s. 499.015(8).

94 ~~2.1-~~ A manufacturer or repackager of medical devices in  
95 this state must comply with all appropriate state and federal  
96 good manufacturing practices and quality system rules.

97 ~~3.2-~~ The department shall adopt rules related to storage,  
98 handling, and recordkeeping requirements for manufacturers of  
99 medical devices for human use.

100 Section 3. Section 768.1326, Florida Statutes, is amended  
101 to read:

102 768.1326 Placement of automated external defibrillators in  
103 state buildings and places of public assembly; rulemaking  
104 authority.-

105 ~~(1) No later than January 1, 2003,~~ The State Surgeon  
106 General shall adopt rules to establish guidelines on the  
107 appropriate placement of automated external defibrillator  
108 devices in buildings or portions of buildings owned or leased by  
109 the state and in places of public assembly, and shall establish,  
110 by rule, recommendations on procedures for the deployment of  
111 automated external defibrillator devices in such buildings and  
112 places of public assembly in accordance with the guidelines. The  
113 Secretary of Management Services shall assist the State Surgeon  
114 General in the development of the guidelines. The guidelines for  
115 the placement of the automated external defibrillators shall  
116 take into account the typical number of employees and visitors

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117 in the building or place of public assembly ~~buildings~~, the  
118 extent of the need for security measures regarding the building  
119 or place of public assembly ~~buildings~~, special circumstances in  
120 the building or a portion of the building ~~buildings or portions~~  
121 ~~of buildings~~ such as high electrical voltages or extreme heat or  
122 cold, and such other factors as the State Surgeon General and  
123 Secretary of Management Services determine to be appropriate.  
124 For purposes of this section, the term "place of public  
125 assembly" means an educational facility used as an emergency  
126 shelter or a location that has a seating capacity of at least  
127 1,000 people and includes, but is not limited to, any stadium,  
128 ballpark, gymnasium, field house, arena, civic center, or  
129 similar facility used for the conduct of sporting events and any  
130 concert hall, recital hall, theater, indoor or outdoor  
131 amphitheatre, or other auditorium used for the presentation of  
132 musical performances or concerts. The term does not include any  
133 church, synagogue, or other not-for-profit religious  
134 organization or any public association or public library. The  
135 State Surgeon General's recommendations for deployment of  
136 automated external defibrillators in buildings or portions of  
137 buildings owned or leased by the state or in places of public  
138 assembly shall include:

139 (a) ~~(1)~~ A reference list of appropriate training courses in  
140 the use of such devices, including the role of cardiopulmonary  
141 resuscitation;

142 (b) ~~(2)~~ The extent to which such devices may be used by  
143 laypersons;

144 (c) ~~(3)~~ Manufacturer recommended maintenance and testing of  
145 the devices; and

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146 (d)~~(4)~~ Coordination with local emergency medical services  
147 systems regarding registration of automated external  
148 defibrillators and documentation of the incidents of use of the  
149 devices.

150  
151 In formulating these guidelines and recommendations, the State  
152 Surgeon General may consult with all appropriate public and  
153 private entities, including national and local public health  
154 organizations that seek to improve the survival rates of  
155 individuals who experience cardiac arrest.

156 (2) This section may not be construed to:

157 (a) Prohibit a county or municipal government from  
158 enacting, implementing, and enforcing any local ordinance that  
159 expands the requirements of this section for the placement of  
160 automated external defibrillators in a place of public assembly;

161 (b) Mandate the placement of any automated external  
162 defibrillator in any place of public assembly; or

163 (c) Authorize the adoption of rules, guidelines, or  
164 recommendations that would establish any legal standard of care  
165 in civil actions.

166 Section 4. This act shall take effect July 1, 2010.