

By the Committees on Community Affairs; and Health Regulation;
and Senator Altman

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20102556c2

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

578-05287-10

20102556c2

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

578-05287-10

20102556c2

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,

578-05287-10

20102556c2

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

578-05287-10

20102556c2

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 a location with a seating capacity of at least
126 1,000 people and includes, but is not limited to, any stadium,
127 ballpark, gymnasium, field house, arena, civic center, or
128 similar facility used for the conduct of sporting events and any
129 concert hall, recital hall, theater, indoor or outdoor
130 amphitheatre, or other auditorium used for the presentation of
131 musical performances or concerts. The term does not include any
132 church, synagogue, or other not-for-profit religious
133 organization or any public association or public library. The
134 State Surgeon General's recommendations for deployment of
135 automated external defibrillators in buildings or portions of
136 buildings owned or leased by the state or in places of public
137 assembly shall include:

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

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

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

145 (d) ~~(4)~~ Coordination with local emergency medical services

578-05287-10

20102556c2

146 systems regarding registration of automated external
147 defibrillators and documentation of the incidents of use of the
148 devices.

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

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

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

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

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