**The Florida Senate**

# BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Community Affairs Committee

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| BILL: | CS/CS/SB 2556 |
| INTRODUCER: | Community Affairs and Health Regulation Committees and Senator Altman |
| SUBJECT: | Medical Devices |
| DATE: | April 20, 2010 REVISED: |

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Harper | Wilson | HR | **Fav/CS** |
| 2. | Gizzi | Yeatman | CA | **Fav/CS** |
| 3. | | | JU | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |

## Please see Section VIII. for Additional Information:

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| A. COMMITTEE SUBSTITUTE..... | X | Statement of Substantial Changes |
| B. AMENDMENTS..... | | Technical amendments were recommended |
| | | Amendments were recommended |
| | | Significant amendments were recommended |

## I. Summary:

This committee substitute (CS) requires an owner, operator, or administrator responsible for a place of public assembly and the state agency responsible for a state building to notify the local emergency medical services (EMS) medical director of the location of an Automated External Defibrillator (AED), if an AED is located at the place of public assembly or in the state building. The local EMS medical directors must maintain registries of the locations of these AEDs. The CS requires the State Surgeon General to establish guidelines and recommendations for the placement and deployment of AEDs in places of public assembly as defined in the CS.

The CS also exempts medical device manufacturing facilities that are registered with the federal Food and Drug Administration, from the requirement to get a device manufacturer permit from the Department of Health.

This CS substantially amends sections 401.2915 and 768.1326 of the Florida Statutes.

## II. Present Situation:

**Automated External Defibrillators (AEDs), Cardiac Arrest**
An AED device is defined under the Cardiac Arrest Survival Act, s. 768.1325, F.S., to mean a lifesaving device that:

- Is commercially distributed in accordance with the Federal Food, Drug, and Cosmetic Act;
- Is capable of recognizing the presence or absence of ventricular fibrillation, and is capable of determining without intervention by the user of the device whether defibrillation should be performed; and
- Upon determining that defibrillation should be performed, is able to deliver an electrical shock to an individual.

Section 401.2915, F.S., provides that the Legislature's intent is for an AED to be used by any person for the purpose of saving the life of another person in cardiac arrest.

The American Heart Association provides the following description of cardiac arrest: "Cardiac arrest is the sudden, abrupt loss of heart function. The victim may or may not have diagnosed heart disease... Sudden death (also called sudden cardiac death) occurs within minutes after symptoms appear."[1]

According to the American Heart Association, cardiac arrest can be reversed if it is treated within a few minutes with an electric shock to the heart to restore a normal heartbeat—a procedure known as *defibrillation*. The American Heart Association reports that a victim's chances of survival are reduced by 7 to 10 percent with every minute that passes without defibrillation, and few attempts at resuscitation succeed after 10 minutes have elapsed.[2]

**Placement of AEDs in State Buildings**
In order to promote public health and safety, any person or entity in possession of an AED is encouraged to register the existence and location of the AED with the local EMS medical director.[3]

Section 768.1326, F.S., provides that the State Surgeon General shall adopt rules to establish guidelines on the appropriate placement of AEDs in buildings or portions of buildings owned or leased by the state, and shall establish recommendations on procedures for the deployment of AEDs in such buildings in accordance with these guidelines. The Secretary of Management Services is required to assist the State Surgeon General in the development of the guidelines.

The placement guidelines for automated external defibrillators must take into account:

- The typical number of employees and visitors in the buildings,
- The extent of the need for security measures regarding the buildings,

[1] See definition of "cardiac arrest" at <http://www.americanheart.org/presenter.jhtml?identifier=4481> (Last visited on April 6, 2010).
[2] See the American Heart Association's website at : <http://www.americanheart.org/presenter.jhtml?identifier=4481> (Last visited on April 6, 2010).
[3] s. 401.2915(2), F.S.

- Special circumstances in buildings or portions of buildings such as high electrical voltages or extreme heat or cold, and
- Such other factors as the State Surgeon General and the Secretary of Management Services determine to be appropriate.

The State Surgeon General's recommendations for deployment of AEDs in buildings or portions of buildings owned or leased by the state shall include:

- A reference list of appropriate training courses in the use of such devices, including the role of cardiopulmonary resuscitation;
- The extent to which such devices may be used by laypersons;
- Manufacturer recommended maintenance and testing of the devices; and
- Coordination with local emergency medical services systems regarding the incidents of use of the devices.

These guidelines have been promulgated in Rule 64E-2.039, Florida Administrative Code.[4]

**Medical Device Manufacturer**

The Florida Drug and Cosmetic Act is located in part I of ch. 499, F.S. The purpose of this Act is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[5] The Department of Health is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[6] Administrative and criminal penalties may result for failure to comply with the statutory requirements in the act or administrative rules prescribed by the Department.[7]

Section 499.01(f), F.S., requires any individual who engages in the "manufacture, repackaging, or assembly of medical devices for human use", to obtain a device manufacturer permit from the Department of Health,[8] unless it is for the manufacture, repackage, or assemble of a medical device in response to a practitioner's order for a specific patient.[9]

The term medical *manufacturer* is defined in s. 499.003(31), F.S., as:

(a) A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;
(b) The holder or holders of an approved or effective application of:
    a. A New Drug Application (NDA),
    b. An Abbreviated New Drug Application (ANDA),
    c. A Biologics License Application (BLA), or

[4] Department of Health, Guidelines for Automated External Defibrillators (AED) in State Owned or Leased Facilities, found at <http://www.doh.state.fl.us/Family/Heart/PDF/Admin_Code64E2_039.pdf> (Last visited on April 6, 2010).
[5] The Federal Food, Drug and Cosmetic Act, 21 United States Code, beginning at section 301, forms the basis for the Act and also protects Floridians from dangerous drugs, devices, and cosmetics.
[6] Section 449.002, Florida Statutes.
[7] Chapter 64F-12, Florida Administrative Code, contains the rules adopted under the Act's authority.
[8] Florida Department of Health, Application for Permit under chapter 499, Florida Statutes, available online at http://www.doh.state.fl.us/MQA/DDC/Applications/ap-Manufacturer.pdf (last visited on April 19, 2010).
[9] Section 499.01(q), F.S. *See* s. 499.02(15) and (31), F.S., for the statutory definition of "device" and "manufacturer".

d. A New Animal Drug Application (NADA);

(c) A private label distributor whose prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d) A person described in paragraphs (a)-(c), who is registered under the federal act as a prescription drug manufacturer, and who has entered into an agreement with another prescription drug manufacturer for the distribution of the prescription drug as the manufacturer in consistency with the federal act and its implementing regulations;

(e) A member of an affiliated group[10], including but not limited persons in paragraphs (a)-(d), that distributes prescription drugs only for the manufacturer of the drugs who is also a member of the affiliated group, whether or not the distributor has obtained title to the drugs; or

(f) A person permitted as a third party logistics provider- only while providing warehousing, distribution, or other logistic services on behalf of a person described in paragraphs (a)-(e).[11]

The term medical device manufacturer does *not* include pharmacies operating under the pharmacy practice standards provided in ch. 465, F.S., or any rules promulgated therein.[12]

To date, there are 376 medical device manufacturers permitted by the Florida Department of Health.[13] According to the Medical Device Industry Education Consortium, Florida ranks second in the U.S. for the largest number of FDA registered medical device facilities, employing approximately 20,700 employees throughout the state of Florida.[14]

***Florida Department of Health Regulations***

Pursuant to subsection (2) of s. 499.01, F.S., a medical device manufacturer is required to comply with all state *and* federal good manufacturing practices and quality system rules. Rules 64F-12.018 and 64F-12.019, of the Florida Administrative Code, currently require medical device manufacturers to pay a biennial fee of $1,200 and be subject to inspections by the Department of Health every two years. These state requirements duplicate the federal requirements prescribed by the U.S. Food Drug and Administration (FDA).

***Federal FDA Regulations***

The Federal Food, Drug and Cosmetic Act, requires owners and operators of a facility that is involved in the production or distribution of medical devices to also register annually with the FDA. Under federal requirements, the manufacturer is required to pay an annual establishment registration fee and deliver a list of the devices used by that facility. [15] In addition to state

[10] This paragraph defines the term "affiliated group" to man an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The manufacturer is required to disclose the names of all of its affiliated group members to the department.

[11] Section 499.003(31), F.S.

[12] Paragraph (f) of s. 499.003(31), F.S.

[13] Florida Department of Health, License Verification, available online at http://ww2.doh.state.fl.us/IRM00PRAES/PRASLIST.ASP#theBottom (last visited on April 19, 2010).

[14] Sullivan, Michael, Medical Device Industry Education Consortium, National Science Foundation Presentation August 2006, available online at http://www.spcollege.edu/nsf/mdiec/files/MDIEC%20Overview%2008-2006.pdf (last visited on April 19, 2010).

[15] *See* 21 CFR parts 807 and 820. The Division of Compliance Risk Management and Surveillance is responsible for overseeing the Drug Registration and Listing System (DRLS & eDRLS).

inspections by the Florida Department of Health, medical device manufacturers are also subject to FDA inspections every two years.[16]

According to the FDA, the federal medical device establishment registration fee schedule for the 2010-2012 Fiscal Years are:

| Year | FY 2010 | FY 2011 | FY 2012 |
|---|---|---|---|
| Fee | $2,008 | $2,179 | $2,364 |

[17]

## III. Effect of Proposed Changes:

**Section 1** amends s. 401.2915, F.S., to require an owner, operator, or administrator who is responsible for a place of public assembly, to notify the local EMS medical director of the location of the AED. The CS also requires a state agency responsible for a building or portion of a building that is owned or leased by the state, to notify the local EMS medical director of the location of the AED. In response to such notification, the local EMS medical director is required to maintain a registry of the AED locations.

**Section 2** amends s. 499.01, F.S., to exempt medical device manufacturing facilities registered with the federal Food and Drug Administration from the requirement to get a device manufacturer permit from the department.

**Section 3** amends s. 768.1326, F.S., to include placement of AED devices *in places of public assembly*[18] in the guidelines developed by the State Surgeon General on placement of AEDs in state buildings.

The CS defines the term "place of public assembly" to mean: a location with a seating capacity of at least 1,000 people, which includes, but is not limited to:

- Any stadium, ballpark, gymnasium, field house, arena, civic center, or similar facility used for the conduct of sporting events; and
- Any concert hall, recital hall, theater, indoor or outdoor amphitheatre, or other auditorium used for the presentation of musical performances or concerts.

The term does not include any church, synagogue, or other not-for-profit religious organization or any public association or public library.

The CS also requires the State Surgeon General to establish by rule: guidelines on the appropriate placement of AED devices *in places of public assembly*, and recommendations on procedures for the deployment of AED devices *in places of public assembly* in accordance with the guidelines.

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[16] *See* 21 CFR parts 807 and 820.

[17] FDA, U.S. Food and Drug Administration, Medical Devices: Device Registration and Listing, available online at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm#reg (last visited on April 19, 2010).

[18] **Note**: words in italics indicate changes to current statutory language.

In conformance to existing law, the guidelines for the placement of the AEDs must take into account:

- The typical number of employees and visitors in a *building owned or leased by the state or place of public assembly*,
- The extent of the need for security measures regarding the *building or place of public assembly*,
- Special circumstances in the building or portion of the building, and
- Such other factors as the State Surgeon General and the Secretary of Management Services determine to be appropriate.

The State Surgeon General's recommendations for deployment of AEDs in *places of public assembly* shall include:

- A reference list of appropriate training courses in the use of AED devices, including the role of cardiopulmonary resuscitation;
- The extent to which AED devices may be used by laypersons;
- Manufacturer recommended maintenance and testing of the devices; and
- Coordination with local EMS systems regarding *registration of automated external defibrillators and documentation* of the incidents of use of the devices.

The CS specifies that it does not prohibit a county or municipal government from enacting, implementing, and enforcing any local ordinance that expands the requirements of this section for the placement of AEDs in a place of public assembly. The CS further specifies that the language in this section shall not be construed as a mandate for the placement of any AED in any place of public assembly.

**Section 4** provides an effective date of July 1, 2010.

## IV. Constitutional Issues:

### A. Municipality/County Mandates Restrictions:

This CS requires local emergency medical services medical directors to also maintain a registry of automated external defibrillator locations for places of public assembly. These provisions fall under subsection (a) of section 18 of Article VII, State Constitution, which prohibits counties and municipalities from being bound by general laws that require them to spend funds or to take actions requiring the expenditure of funds unless certain exemptions or exceptions are met.[19]

Subsection (d) of section 18 of Article VII, State Constitution grants an exemption to subsection (a) if the law is determined to have an insignificant fiscal impact. An insignificant fiscal impact means an amount not greater than the average statewide population for the applicable fiscal year times ten cents (FY 2009-2010 $1.88 million). A fiscal estimate is currently not available.

[19] FLA. CONST. art. VII, s. 18(a).

Under current law, any person or entity that is in possession of an automated external defibrillator is encouraged to notify the local emergency medical services medical director of its location. Since the provisions of this CS only add places of public assembly to existing registry requirements, it is not likely to have a significant fiscal impact. However, if it is determined that this CS has more than an insignificant fiscal impact, it would require a finding of an important state interest and a two-thirds vote of the membership of each house of the Legislature in order to effectively bind cities and counties.[20]

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

## V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Owners, operators and administrators that are responsible for a place of public assembly may incur additional expenses in order to meet the provisions of this CS.

Beginning on July 1, 2010, medical device manufacturing facilities that are registered with the federal Food and Drug Administration will be exempt from the permit requirements prescribed by the Florida Department of Health.

C. Government Sector Impact:

The Division of Emergency Management within the Department of Health has indicated that the provisions of this CS will not have a fiscal impact on their operations.[21]

## VI. Technical Deficiencies:

None.

## VII. Related Issues:

None.

[20] FLA. CONST. art. VII, s. 18(d).
[21] Email from Michael Forrester, Florida Department of Health: Office of Legislative Planning, *SB 2556 Fiscal Analysis* (March 31, 2010) (on file with the Senate Committee on Health Regulation).

## VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS/CS by Community Affairs on April 20, 2010:**
This Committee Substitute to the Committee Substitute (CS/CS) exempts Florida medical device manufacturing facilities that are regulated by the federal Food and Drug Administration from the permit requirements under the Florida Department of Health.

**CS by Health Regulation on April 13, 2010:**
The Committee Substitute (CS) clarifies that the bill is not to be construed as a mandate for the placement of AEDs in places of public assembly.

The CS removes the requirement for an owner, operator, or administrator responsible for a place of public assembly to have at least one employee or volunteer who is trained in the operation and use of an AED present whenever a place of public assembly is used for publicly or privately sponsored events or activities.

The CS also removes immunity from liability for the use of an AED by an employee or volunteer as provided in the original bill.

B. Amendments:

None.