441062

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/20/2010	.	
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The Committee on Community Affairs (Bennett) recommended the following:

Senate Amendment (with title amendment)

Between lines 73 and 74
insert:

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

499.01 Permits.—

(2) The following permits are established:

(q) *Device manufacturer permit.*—

1. A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a

441062

permit is not required if:

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or.

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

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

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

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete lines 2 - 8

and insert:

An act relating to medical devices; amending s. 401.2915, F.S.; requiring certain entities to notify local emergency services medical directors of the locations of automated external defibrillators; requiring local emergency medical services medical directors to maintain registries of certain automated external defibrillator locations; amending s. 499.01, F.S.; revising the list of exemptions from the requirement that certain persons engaged in the manufacture, repackaging, or assembly of medical

441062

devices hold a device manufacturer permit; amending s.