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LEGISLATIVE ACTION

Senate

House

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Floor: 16/AD/2R
04/29/2010 11:56 AM

Senator Negron moved the following:

Senate Amendment (with title amendment)

Between lines 648 and 649
insert:

Section 17. Present subsections (32) through (54) of
section 499.003, Florida Statutes, are renumbered as subsections
(33) through (55), respectively, and a new subsection (32) is
added to that section, to read:

499.003 Definitions of terms used in this part.—As used in
this part, the term:

(32) "Medical convenience kit" means packages or units that
contain combination products as defined in 21 C.F.R. s.
3.2(e)(2).



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14 Section 18. Paragraph (i) is added to subsection (3) of
15 section 499.01212, Florida Statutes, to read:

16 499.01212 Pedigree paper.—

17 (3) EXCEPTIONS.—A pedigree paper is not required for:

18 (i) The wholesale distribution of prescription drugs
19 contained within a medical convenience kit if:

20 1. The medical convenience kit is assembled in an
21 establishment that is registered as a medical device
22 manufacturer with the United States Food and Drug
23 Administration;

24 2. The medical convenience kit manufacturer purchased the
25 prescription drug directly from the manufacturer or from a
26 wholesaler that purchased the prescription drug directly from
27 the manufacturer;

28 3. The medical convenience kit manufacturer complies with
29 federal law for the distribution of the prescription drugs
30 within the kit; and

31 4. The drugs contained in the medical convenience kit are:

32 a. Intravenous solutions intended for the replenishment of
33 fluids and electrolytes;

34 b. Products intended to maintain the equilibrium of water
35 and minerals in the body;

36 c. Products intended for irrigation or reconstitution;

37 d. Anesthetics; or

38 e. Anticoagulants.

39
40 ===== T I T L E A M E N D M E N T =====

41 And the title is amended as follows:

42 Delete line 91



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43 and insert:
44 employee; amending s. 499.003, F.S.; defining the term
45 "medical convenience kit"; amending s. 499.01212,
46 F.S.; providing that a pedigree paper is not required
47 for wholesale distribution of prescription drugs
48 contained within a medical convenience kit under
49 certain circumstances; providing appropriations from
50 the General