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LEGISLATIVE ACTION

Senate

House

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Floor: 8/AD/2R

03/08/2012 02:23 PM

Senator Hays moved the following:

Senate Amendment (with directory and title amendments)

Between lines 1107 and 1108

insert:

(4) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(54)(a)3., if:

(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in



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14 repackaging under this exemption, 30 days before engaging in the
15 repackaging of prescription drugs at the permitted
16 establishment;

17 (b) The prescription drug distributor is under common
18 control with the hospitals or other health care entities to
19 which the prescription drug distributor is distributing
20 prescription drugs. As used in this paragraph, "common control"
21 means the power to direct or cause the direction of the
22 management and policies of a person or an organization, whether
23 by ownership of stock, voting rights, contract, or otherwise;

24 (c) The prescription drug distributor repackages the
25 prescription drugs in accordance with current state and federal
26 good manufacturing practices; and

27 (d) The prescription drug distributor labels the
28 prescription drug it repackages in accordance with state and
29 federal laws and rules.

30
31 The prescription drug distributor is exempt from the product
32 registration requirements of s. 499.015, with regard to the
33 prescription drugs that it repackages and distributes under this
34 subsection.

35
36 ===== D I R E C T O R Y C L A U S E A M E N D M E N T =====

37 And the directory clause is amended as follows:

38 Delete lines 908 - 910

39 and insert:

40 Section 36. Paragraphs (c) and (e) of subsection (2) of
41 section 499.01, Florida Statutes, are amended, and subsections
42 (3) and (4) are added to that section, to read:



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

And the title is amended as follows:

Delete line 146

and insert:

controlled substances; exempting certain prescription
drug repackagers from permit requirements if they
repackage prescription drugs for their own use or for
certain related entities; providing notification
requirements; exempting such repackagers from product
registration requirements; providing an effective
date.