



576758

LEGISLATIVE ACTION

Senate

.
. .
. .
. .
. .

House

The Committee on Health Regulation (Diaz de la Portilla)
recommended the following:

Senate Amendment (with directory and title amendments)

Between lines 64 and 65
insert:

(3) 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 that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use pursuant to s. 499.003(54)(a)3. if the restricted prescription drug distributor:



576758

13 (a) Notifies the department in writing of its intention to
14 engage in repackaging under this exemption 30 days before
15 actually engaging in the repackaging of prescription drugs at
16 the permitted establishment;

17 (b) Is under common control with the hospital or other
18 health care entity to which the restricted prescription drug
19 distributor distributes prescription drugs. For purposes of this
20 paragraph, the term "common control" means the power to direct
21 or cause the direction of the management and policies of a
22 person or an organization, whether by ownership of stock, by
23 voting rights, by contract, or otherwise;

24 (c) Repackages the prescription drugs in accordance with
25 proper manufacturing practices and current state and federal
26 laws and rules; and

27 (d) Labels the prescription drugs in accordance with state
28 and federal laws and rules.

29
30 The restricted prescription drug distributor is exempt from the
31 product registration requirements of s. 499.015 with regard to
32 the prescription drugs that it repackages and distributes under
33 this subsection.

34
35 ===== D I R E C T O R Y C L A U S E A M E N D M E N T =====

36 And the directory clause is amended as follows:

37 Delete line 15

38 and insert:

39 499.01, Florida Statutes, is amended, and subsection (3) is
40 added to that section, to read:

41



576758

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

43 And the title is amended as follows:

44 Delete line 9

45 and insert:

46 that permit until its expiration; providing that a
47 prescription drug repackager permit is not required
48 for certain restricted prescription drug distributor
49 permitholders that distribute prescription drugs to
50 certain hospitals or other health care entities;
51 exempting certain restricted prescription drug
52 distributors from product registration requirements;
53 providing an