



790972

LEGISLATIVE ACTION

Senate

.
. .
. .
. .
. .

House

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

1 **Senate Amendment to Amendment (416374) (with directory and**
2 **title amendments)**

3
4 Between lines 256 and 257
5 insert:

6 (4) A prescription drug repackager permit issued under this
7 part is not required for a restricted prescription drug
8 distributor permitholder that is a health care entity that
9 repackages prescription drugs in this state for its own use or
10 distributes prescription drugs to a hospital or other health
11 care entity in the state for its own use pursuant to s.
12 499.003(54)(a)3. if the restricted prescription drug



790972

13 distributor:

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

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

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

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

30
31 The restricted prescription drug distributor is exempt from the
32 product registration requirements of s. 499.015 with regard to
33 the prescription drugs that it repackages and distributes under
34 this 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 58 - 59

39 and insert:

40 Section 499.01, Florida Statutes, are amended, and
41 subsections (3) and (4) are added to that section, to read:



790972

42
43
44
45
46
47
48
49
50
51
52
53
54

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

And the title is amended as follows:

Delete line 337

and insert:

relating to controlled substances; providing that a
prescription drug repackager permit is not required
for certain restricted prescription drug distributor
permitholders that distribute prescription drugs to
certain hospitals or other health care entities;
exempting certain restricted prescription drug
distributors from product registration requirements;
providing an