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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/15/2013	.	
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The Committee on Health Policy (Bean) recommended the following:

1 **Senate Amendment to Amendment (373656) (with title**
2 **amendment)**

3
4 Between lines 737 and 738
5 insert:

6 Section 23. Paragraph (b) of subsection (54) of section
7 499.003, Florida Statutes, is amended to read:

8 499.003 Definitions of terms used in this part.—As used in
9 this part, the term:

10 (54) "Wholesale distribution" means distribution of
11 prescription drugs to persons other than a consumer or patient,
12 but does not include:

13 (b) Any of the following activities, which is not a



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14 violation of s. 499.005(21) if such activity is conducted in
15 accordance with rules established by the department:

16 1. The sale, purchase, or trade of a prescription drug
17 among federal, state, or local government health care entities
18 that are under common control and are authorized to purchase
19 such prescription drug.

20 2. The sale, purchase, or trade of a prescription drug or
21 an offer to sell, purchase, or trade a prescription drug for
22 emergency medical reasons. For purposes of this subparagraph,
23 the term "emergency medical reasons" includes transfers of
24 prescription drugs by a retail pharmacy to another retail
25 pharmacy to alleviate a temporary shortage.

26 3. The transfer of a prescription drug acquired by a
27 medical director on behalf of a licensed emergency medical
28 services provider to that emergency medical services provider
29 and its transport vehicles for use in accordance with the
30 provider's license under chapter 401.

31 4. The revocation of a sale or the return of a prescription
32 drug to the person's prescription drug wholesale supplier.

33 5. The donation of a prescription drug by a health care
34 entity to a charitable organization that has been granted an
35 exemption under s. 501(c)(3) of the Internal Revenue Code of
36 1986, as amended, and that is authorized to possess prescription
37 drugs.

38 6. The transfer of a prescription drug by a person
39 authorized to purchase or receive prescription drugs to a person
40 licensed or permitted to handle reverse distributions or
41 destruction under the laws of the jurisdiction in which the
42 person handling the reverse distribution or destruction receives



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43 the drug.

44 7. The transfer of a prescription drug by a hospital or
45 other health care entity, either directly or through the
46 hospital's or health care entity's supplier, to a person
47 licensed under this part to repackage prescription drugs for the
48 purpose of repackaging the prescription drug for use by that
49 hospital, or other health care entity and other health care
50 entities that are under common control, if ownership of the
51 prescription drugs remains with the hospital or other health
52 care entity at all times. In addition to the recordkeeping
53 requirements of s. 499.0121(6) and the requirements for
54 repackagers in s. 499.01212(2), the hospital or health care
55 entity that transfers prescription drugs pursuant to this
56 subparagraph must reconcile all drugs transferred and returned
57 and resolve any discrepancies in a timely manner.

58 Section 24. Paragraph (b) of subsection (2) of section
59 499.01, Florida Statutes, is amended to read

60 499.01 Permits.—

61 (2) The following permits are established:

62 (b) *Prescription drug repackager permit.*—A prescription
63 drug repackager permit is required for any person that
64 repackages a prescription drug in this state or any person
65 located in another state that repackages and distributes
66 prescription drugs in or into this state that are received in a
67 transfer pursuant to s. 499.003(54) (b)7.

68 1. A person that operates an establishment permitted as a
69 prescription drug repackager may engage in wholesale
70 distribution of prescription drugs repackaged at that
71 establishment and must comply with all the provisions of this



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72 part and the rules adopted under this part that apply to a
73 wholesale distributor.

74 2. A prescription drug repackager must comply with all
75 appropriate state and federal good manufacturing practices.

76 Section 25. Paragraph (a) of subsection (2) of section
77 499.01212, Florida Statutes, is amended to read:

78 499.01212 Pedigree paper.—

79 (2) FORMAT.—A pedigree paper must contain the following
80 information:

81 (a) For the wholesale distribution of a prescription drug
82 within the normal distribution chain or pursuant to a transfer
83 described in s. 499.003(54)(b)7:

84 1. The following statement: "This wholesale distributor
85 purchased the specific unit of the prescription drug directly
86 from the manufacturer."

87 2. The manufacturer's national drug code identifier and the
88 name and address of the wholesale distributor and the purchaser
89 of the prescription drug.

90 3. The name of the prescription drug as it appears on the
91 label.

92 4. The quantity, dosage form, and strength of the
93 prescription drug.

94
95 The wholesale distributor must also maintain and make
96 available to the department, upon request, the point of origin
97 of the prescription drugs, including intracompany transfers, the
98 date of the shipment from the manufacturer to the wholesale
99 distributor, the lot numbers of such drugs, and the invoice
100 numbers from the manufacturer. When a repackager further



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101 distributes prescription drugs to a hospital or other health
102 care entity pursuant to s. 499.003(54)(b)7, the pedigree paper
103 must contain the statement from the wholesale distributor in
104 this subsection, along with the lot numbers of the prescription
105 drugs, the name and address of the repackager and his or her
106 signature, the date of receipt, and the name and address of the
107 person authorized by law to purchase prescription drugs for the
108 purpose of administering or dispensing the drug, as defined in
109 s. 465.003.

110
111 ===== T I T L E A M E N D M E N T =====

112 And the title is amended as follows:

113 Delete line 1024

114 and insert:

115 Rules to develop and implement the program; amending
116 s. 499.003, F.S.; exempting prescription drugs
117 transferred either directly or through a hospital's or
118 health care entity's supplier for the purpose of
119 repackaging from the definition of "wholesale
120 distribution"; amending s. 499.01, F.S.; requiring a
121 permit for prescription drug repackagers located in
122 other states that repackage and distribute drugs for
123 limited purposes into this state; amending s.
124 499.01212, F.S.; requiring pedigree papers for
125 transfers pursuant to s. 499.03(54)(b)7, F.S., to
126 include specified information; amending