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LEGISLATIVE ACTION

Senate

House

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Floor: 4/AD/2R

03/08/2012 02:17 PM

Senator Hays moved the following:

Senate Amendment (with directory and title amendments)

Between lines 907 and 908

insert:

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

(a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the



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14 group purchasing organization or from other hospitals or health
15 care entities that are members of that organization.

16 2. The sale, purchase, or trade of a prescription drug or
17 an offer to sell, purchase, or trade a prescription drug by a
18 charitable organization described in s. 501(c)(3) of the
19 Internal Revenue Code of 1986, as amended and revised, to a
20 nonprofit affiliate of the organization to the extent otherwise
21 permitted by law.

22 3. The sale, purchase, or trade of a prescription drug or
23 an offer to sell, purchase, or trade a prescription drug among
24 hospitals or other health care entities that are under common
25 control. For purposes of this subparagraph, "common control"
26 means the power to direct or cause the direction of the
27 management and policies of a person or an organization, whether
28 by ownership of stock, by voting rights, by contract, or
29 otherwise.

30 4. The sale, purchase, trade, or other transfer of a
31 prescription drug from or for any federal, state, or local
32 government agency or any entity eligible to purchase
33 prescription drugs at public health services prices pursuant to
34 Pub. L. No. 102-585, s. 602 to a contract provider or its
35 subcontractor for eligible patients of the agency or entity
36 under the following conditions:

37 a. The agency or entity must obtain written authorization
38 for the sale, purchase, trade, or other transfer of a
39 prescription drug under this subparagraph from the State Surgeon
40 General or his or her designee.

41 b. The contract provider or subcontractor must be
42 authorized by law to administer or dispense prescription drugs.



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43 c. In the case of a subcontractor, the agency or entity
44 must be a party to and execute the subcontract.

45 ~~d. A contract provider or subcontractor must maintain~~
46 ~~separate and apart from other prescription drug inventory any~~
47 ~~prescription drugs of the agency or entity in its possession.~~

48 d.e. The contract provider and subcontractor must maintain
49 and produce immediately for inspection all records of movement
50 or transfer of all the prescription drugs belonging to the
51 agency or entity, including, but not limited to, the records of
52 receipt and disposition of prescription drugs. Each contractor
53 and subcontractor dispensing or administering these drugs must
54 maintain and produce records documenting the dispensing or
55 administration. Records that are required to be maintained
56 include, but are not limited to, a perpetual inventory itemizing
57 drugs received and drugs dispensed by prescription number or
58 administered by patient identifier, which must be submitted to
59 the agency or entity quarterly.

60 ~~e.f.~~ The contract provider or subcontractor may administer
61 or dispense the prescription drugs only to the eligible patients
62 of the agency or entity or must return the prescription drugs
63 for or to the agency or entity. The contract provider or
64 subcontractor must require proof from each person seeking to
65 fill a prescription or obtain treatment that the person is an
66 eligible patient of the agency or entity and must, at a minimum,
67 maintain a copy of this proof as part of the records of the
68 contractor or subcontractor required under sub-subparagraph d
69 ~~sub-subparagraph e.~~

70 f.g. In addition to the departmental inspection authority
71 set forth in s. 499.051, the establishment of the contract



72 provider and subcontractor and all records pertaining to
73 prescription drugs subject to this subparagraph shall be subject
74 to inspection by the agency or entity. All records relating to
75 prescription drugs of a manufacturer under this subparagraph
76 shall be subject to audit by the manufacturer of those drugs,
77 without identifying individual patient information.

78
79 ===== D I R E C T O R Y C L A U S E A M E N D M E N T =====

80 And the directory clause is amended as follows:

81 Delete line 856

82 and insert:

83 Section 35. Subsections (17), (19), (20), and (43), and
84 paragraph (a) of subsection (54) of

85
86 ===== T I T L E A M E N D M E N T =====

87 And the title is amended as follows:

88 Delete line 76

89 and insert:

90 "establishment," "prescription drug," and "wholesale
91 distribution"; amending s.