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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/27/2012	.	
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The Committee on Health Regulation (Norman) recommended the following:

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

3  
4           Between lines 56 and 57  
5 insert:

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

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

- 12           1. The purchase or other acquisition by a hospital or other



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13 health care entity that is a member of a group purchasing  
14 organization of a prescription drug for its own use from the  
15 group purchasing organization or from other hospitals or health  
16 care entities that are members of that organization.

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

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

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

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



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

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

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

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

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



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71        ~~f.g.~~ In addition to the departmental inspection authority  
72 set forth in s. 499.051, the establishment of the contract  
73 provider and subcontractor and all records pertaining to  
74 prescription drugs subject to this subparagraph shall be subject  
75 to inspection by the agency or entity. All records relating to  
76 prescription drugs of a manufacturer under this subparagraph  
77 shall be subject to audit by the manufacturer of those drugs,  
78 without identifying individual patient information.

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

81 And the directory clause is amended as follows:

82        Delete line 5

83 and insert:

84        Section 1. Subsections (17), (19), (20), and (43), and  
85 paragraph (a) of subsection (54) of

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

88 And the title is amended as follows:

89        Delete lines 267 - 268

90 and insert:

91        "distribution," "drug," "establishment," "prescription  
92 drug," and "wholesale distribution"; amending s.  
93 499.01, F.S.;