

Bill No. CS for SB 1108

Amendment No.      Barcode 444154

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| <u>Senate</u> | CHAMBER ACTION | <u>House</u> |
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11 Senator Silver moved the following amendment:

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13 **Senate Amendment (with title amendment)**

14 On page 43, between lines 14 and 15,

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16 insert:

17 Section 8. Paragraph (a) of subsection (1) of section  
18 499.012, Florida Statutes, is amended to read:

19 499.012 Wholesale distribution; definitions; permits;  
20 general requirements.--

21 (1) As used in this section, the term:

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

25 1. Any of the following activities, which is not a  
26 violation of s. 499.005(21) if such activity is conducted in  
27 accordance with s. 499.014:

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

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1 or health care entities that are members of that organization.

2 b. The sale, purchase, or trade of a prescription drug  
3 or an offer to sell, purchase, or trade a prescription drug by  
4 a charitable organization described in s. 501(c)(3) of the  
5 Internal Revenue Code of 1986, as amended and revised, to a  
6 nonprofit affiliate of the organization to the extent  
7 otherwise permitted by law.

8 c. The sale, purchase, or trade of a prescription drug  
9 or an offer to sell, purchase, or trade a prescription drug  
10 among hospitals or other health care entities that are under  
11 common control. For purposes of this section, "common control"  
12 means the power to direct or cause the direction of the  
13 management and policies of a person or an organization,  
14 whether by ownership of stock, by voting rights, by contract,  
15 or otherwise.

16 d. The sale, purchase, trade, or other transfer of a  
17 prescription drug from or for any federal, state, or local  
18 government agency or any entity eligible to purchase  
19 prescription drugs at public health services prices pursuant  
20 to Pub. L. No. 102-585, s. 602 to a contract provider or its  
21 subcontractor for eligible patients of the agency or entity  
22 under the following conditions:

23 (I) The agency or entity must obtain written  
24 authorization for the sale, purchase, trade, or other transfer  
25 of a prescription drug under this sub-subparagraph from the  
26 Secretary of Health or his or her designee.

27 (II) The contract provider or subcontractor must be  
28 authorized by law to administer or dispense prescription  
29 drugs.

30 (III) In the case of a subcontractor, the agency or  
31 entity must be a party to and execute the subcontract.

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1 (IV) A contract provider or subcontractor must  
2 maintain separate and apart from other prescription drug  
3 inventory any prescription drugs of the agency or entity in  
4 its possession.

5 (V) The contract provider and subcontractor must  
6 maintain and produce immediately for inspection all records of  
7 movement or transfer of all the prescription drugs belonging  
8 to the agency or entity, including, but not limited to, the  
9 records of receipt and disposition of prescription drugs. Each  
10 contractor and subcontractor dispensing or administering these  
11 drugs must maintain and produce records documenting the  
12 dispensing or administration. Records that are required to be  
13 maintained include, but are not limited to, a perpetual  
14 inventory itemizing drugs received and drugs dispensed by  
15 prescription number or administered by patient identifier,  
16 which must be submitted to the agency or entity quarterly.

17 (VI) The contract provider or subcontractor may  
18 administer or dispense the prescription drugs only to the  
19 eligible patients of the agency or entity or must return the  
20 prescription drugs for or to the agency or entity. The  
21 contract provider or subcontractor must require proof from  
22 each person seeking to fill a prescription or obtain treatment  
23 that the person is an eligible patient of the agency or entity  
24 and must, at a minimum, maintain a copy of this proof as part  
25 of the records of the contractor or subcontractor required  
26 under sub-sub-subparagraph (V).

27 ~~(VII) The prescription drugs transferred pursuant to~~  
28 ~~this sub-subparagraph may not be billed to Medicaid.~~

29 (VII)~~(VIII)~~ In addition to the departmental inspection  
30 authority set forth in s. 499.051, the establishment of the  
31 contract provider and subcontractor and all records pertaining

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1 to prescription drugs subject to this sub-subparagraph shall  
2 be subject to inspection by the agency or entity. All records  
3 relating to prescription drugs of a manufacturer under this  
4 sub-subparagraph shall be subject to audit by the manufacturer  
5 of those drugs, without identifying individual patient  
6 information.

7 2. Any of the following activities, which is not a  
8 violation of s. 499.005(21) if such activity is conducted in  
9 accordance with rules established by the department:

10 a. The sale, purchase, or trade of a prescription drug  
11 among federal, state, or local government health care entities  
12 that are under common control and are authorized to purchase  
13 such prescription drug.

14 b. The sale, purchase, or trade of a prescription drug  
15 or an offer to sell, purchase, or trade a prescription drug  
16 for emergency medical reasons. For purposes of this  
17 sub-subparagraph, the term "emergency medical reasons"  
18 includes transfers of prescription drugs by a retail pharmacy  
19 to another retail pharmacy to alleviate a temporary shortage.

20 c. The transfer of a prescription drug acquired by a  
21 medical director on behalf of a licensed emergency medical  
22 services provider to that emergency medical services provider  
23 and its transport vehicles for use in accordance with the  
24 provider's license under chapter 401.

25 d. The revocation of a sale or the return of a  
26 prescription drug to the person's prescription drug wholesale  
27 supplier.

28 e. The donation of a prescription drug by a health  
29 care entity to a charitable organization that has been granted  
30 an exemption under s. 501(c)(3) of the Internal Revenue Code  
31 of 1986, as amended, and that is authorized to possess

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1 prescription drugs.

2 f. The transfer of a prescription drug by a person  
3 authorized to purchase or receive prescription drugs to a  
4 person licensed or permitted to handle reverse distributions  
5 or destruction under the laws of the jurisdiction in which the  
6 person handling the reverse distribution or destruction  
7 receives the drug.

8 3. The distribution of prescription drug samples by  
9 manufacturers' representatives or distributors'  
10 representatives conducted in accordance with s. 499.028.

11 4. The sale, purchase, or trade of blood and blood  
12 components intended for transfusion. As used in this  
13 subparagraph, the term "blood" means whole blood collected  
14 from a single donor and processed either for transfusion or  
15 further manufacturing, and the term "blood components" means  
16 that part of the blood separated by physical or mechanical  
17 means.

18 5. The lawful dispensing of a prescription drug in  
19 accordance with chapter 465.

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21 (Redesignate subsequent sections.)

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

25 And the title is amended as follows:

26 On page 1, line 24, following the semicolon

27

28 insert:

29 amending s. 499.012, F.S.; redefining the term

30 "wholesale distribution" with respect to

31 regulation of distribution of prescription

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