



165656

LEGISLATIVE ACTION

Senate

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House

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The Committee on Budget (Fasano) recommended the following:

**Senate Amendment (with title amendment)**

Delete lines 2714 - 2718

and insert:

3. For a prescribed drug billed as a 340B prescribed medication rendered to all Medicaid-eligible individuals, including claims for cost sharing for which the agency is responsible, the claim must meet the requirements of the Deficit Reduction Act of 2005 and the federal 340B program, and contain a national drug code.

Delete lines 4006 - 4018

and insert:



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14 Section 104. Subsection (23) and paragraph (a) of  
15 subsection (54) of section 499.003, Florida Statutes, are  
16 amended to read:

17 499.003 Definitions of terms used in this part.—As used in  
18 this part, the term:

19 (23) "Health care entity" means a closed pharmacy or any  
20 person, organization, or business entity that provides  
21 diagnostic, medical, surgical, or dental treatment or care, or  
22 chronic or rehabilitative care, but does not include any  
23 wholesale distributor or retail pharmacy licensed under state  
24 law to deal in prescription drugs. However, a blood  
25 establishment is a health care entity that may engage in the  
26 wholesale distribution of prescription drugs under s.  
27 499.01(2)(g)1.c.

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

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

34 1. The purchase or other acquisition by a hospital or other  
35 health care entity that is a member of a group purchasing  
36 organization of a prescription drug for its own use from the  
37 group purchasing organization or from other hospitals or health  
38 care entities that are members of that organization.

39 2. The sale, purchase, or trade of a prescription drug or  
40 an offer to sell, purchase, or trade a prescription drug by a  
41 charitable organization described in s. 501(c)(3) of the  
42 Internal Revenue Code of 1986, as amended and revised, to a



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43 nonprofit affiliate of the organization to the extent otherwise  
44 permitted by law.

45 3. The sale, purchase, or trade of a prescription drug or  
46 an offer to sell, purchase, or trade a prescription drug among  
47 hospitals or other health care entities that are under common  
48 control. For purposes of this subparagraph, "common control"  
49 means the power to direct or cause the direction of the  
50 management and policies of a person or an organization, whether  
51 by ownership of stock, by voting rights, by contract, or  
52 otherwise.

53 4. The sale, purchase, trade, or other transfer of a  
54 prescription drug from or for any federal, state, or local  
55 government agency or any entity eligible to purchase  
56 prescription drugs at public health services prices pursuant to  
57 Pub. L. No. 102-585, s. 602 to a contract provider or its  
58 subcontractor for eligible patients of the agency or entity  
59 under the following conditions:

60 a. The agency or entity must obtain written authorization  
61 for the sale, purchase, trade, or other transfer of a  
62 prescription drug under this subparagraph from the State Surgeon  
63 General or his or her designee.

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

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

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

71 ~~d.e.~~ The contract provider and subcontractor must maintain



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72 and produce immediately for inspection all records of movement  
73 or transfer of all the prescription drugs belonging to the  
74 agency or entity, including, but not limited to, the records of  
75 receipt and disposition of prescription drugs. Each contractor  
76 and subcontractor dispensing or administering these drugs must  
77 maintain and produce records documenting the dispensing or  
78 administration. Records that are required to be maintained  
79 include, but are not limited to, a perpetual inventory itemizing  
80 drugs received and drugs dispensed by prescription number or  
81 administered by patient identifier, which must be submitted to  
82 the agency or entity quarterly.

83 ~~e.f.~~ The contract provider or subcontractor may administer  
84 or dispense the prescription drugs only to the eligible patients  
85 of the agency or entity or must return the prescription drugs  
86 for or to the agency or entity. The contract provider or  
87 subcontractor must require proof from each person seeking to  
88 fill a prescription or obtain treatment that the person is an  
89 eligible patient of the agency or entity and must, at a minimum,  
90 maintain a copy of this proof as part of the records of the  
91 contractor or subcontractor required under sub-subparagraph e.

92 ~~f.g.~~ In addition to the departmental inspection authority  
93 set forth in s. 499.051, the establishment of the contract  
94 provider and subcontractor and all records pertaining to  
95 prescription drugs subject to this subparagraph shall be subject  
96 to inspection by the agency or entity. All records relating to  
97 prescription drugs of a manufacturer under this subparagraph  
98 shall be subject to audit by the manufacturer of those drugs,  
99 without identifying individual patient information.

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

102 And the title is amended as follows:

103       Delete line 360

104 and insert:

105       activities; redefining the term "wholesale  
106       distribution" to delete a provision requiring certain  
107       entities to keep prescription drugs of the agency  
108       separate from other drugs in their inventory; amending  
109       s. 499.005, F.S.; clarifying