

Amendment No.

CHAMBER ACTION

Senate

House

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1 Representative Patronis offered the following:

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3 **Amendment (with title amendment)**

4 Between lines 1228 and 1229, insert:

5 Section 14. Subsections (32) through (54) of section
6 499.003, Florida Statutes, are renumbered as subsections (33)
7 through (55), respectively, present subsection (42) and
8 paragraph (a) of present subsection (53) are amended, and a new
9 subsection (32) is added to that subsection, to read:

10 499.003 Definitions of terms used in this part.—As used in
11 this part, the term:

12 (32) "Medical convenience kit" means packages or units
13 that contain combination products as defined in 21 C.F.R. s.
14 3.2(e)(2).

15 (43)-(42) "Prescription drug" means a prescription,
16 medicinal, or legend drug, including, but not limited to,
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17 finished dosage forms or active ingredients subject to, defined
18 by, or described by s. 503(b) of the Federal Food, Drug, and
19 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
20 (11), subsection (46) ~~(45)~~, or subsection (53) ~~(52)~~.

21 (54) ~~(53)~~ "Wholesale distribution" means distribution of
22 prescription drugs to persons other than a consumer or patient,
23 but does not include:

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

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

32 2. The sale, purchase, or trade of a prescription drug or
33 an offer to sell, purchase, or trade a prescription drug by a
34 charitable organization described in s. 501(c)(3) of the
35 Internal Revenue Code of 1986, as amended and revised, to a
36 nonprofit affiliate of the organization to the extent otherwise
37 permitted by law.

38 3. The sale, purchase, or trade of a prescription drug or
39 an offer to sell, purchase, or trade a prescription drug among
40 hospitals or other health care entities that are under common
41 control. For purposes of this subparagraph, "common control"
42 means the power to direct or cause the direction of the
43 management and policies of a person or an organization, whether

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44 by ownership of stock, by voting rights, by contract, or
45 otherwise.

46 4. The sale, purchase, trade, or other transfer of a
47 prescription drug from or for any federal, state, or local
48 government agency or any entity eligible to purchase
49 prescription drugs at public health services prices pursuant to
50 Pub. L. No. 102-585, s. 602 to a contract provider or its
51 subcontractor for eligible patients of the agency or entity
52 under the following conditions:

53 a. The agency or entity must obtain written authorization
54 for the sale, purchase, trade, or other transfer of a
55 prescription drug under this subparagraph from the State Surgeon
56 General or his or her designee.

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

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

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

64 d.e. The contract provider and subcontractor must maintain
65 and produce immediately for inspection all records of movement
66 or transfer of all the prescription drugs belonging to the
67 agency or entity, including, but not limited to, the records of
68 receipt and disposition of prescription drugs. Each contractor
69 and subcontractor dispensing or administering these drugs must
70 maintain and produce records documenting the dispensing or
71 administration. Records that are required to be maintained

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72 include, but are not limited to, a perpetual inventory itemizing
73 drugs received and drugs dispensed by prescription number or
74 administered by patient identifier, which must be submitted to
75 the agency or entity quarterly.

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

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

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

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98 Remove line 63 and insert:

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99 to the Governor and Legislature; amending s. 499.003,
100 F.S.; defining the term "medical convenience kit" for
101 purposes of pt. I of ch. 499, F.S.; conforming cross-
102 references; amending s. 499.01, F.S.;

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