

By Senator Altman

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1                   A bill to be entitled  
2           An act relating to health care facilities; amending s.  
3           395.002, F.S.; redefining the term "accrediting  
4           organization" as used in ch. 395, F.S., relating to  
5           hospitals and other licensed facilities, to include  
6           other accrediting organizations that have been  
7           approved by the Federal Government for purposes of the  
8           Medicare program; amending s. 499.003, F.S.;  
9           redefining the term "wholesale distribution" as it  
10          relates to the sale, purchase, or trade of a  
11          prescription drug from certain eligible entities to a  
12          contract provider or its subcontractor; providing an  
13          effective date.

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15 Be It Enacted by the Legislature of the State of Florida:

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17           Section 1. Subsection (1) of section 395.002, Florida  
18           Statutes, is amended to read:

19           395.002 Definitions.—As used in this chapter:

20           (1) "Accrediting organizations" means the Joint Commission  
21           on Accreditation of Healthcare Organizations, the American  
22           Osteopathic Association, the Commission on Accreditation of  
23           Rehabilitation Facilities, ~~and~~ the Accreditation Association for  
24           Ambulatory Health Care, Inc., and other accrediting  
25           organizations that have been approved by the Federal Government  
26           for purposes of the Medicare program.

27           Section 2. Paragraph (a) of subsection (53) of section  
28           499.003, Florida Statutes, is amended to read:

29           499.003 Definitions of terms used in this part.—As used in

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30 this part, the term:

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

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

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

42 2. The sale, purchase, or trade of a prescription drug or  
43 an offer to sell, purchase, or trade a prescription drug by a  
44 charitable organization described in s. 501(c)(3) of the  
45 Internal Revenue Code of 1986, as amended and revised, to a  
46 nonprofit affiliate of the organization to the extent otherwise  
47 permitted by law.

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

56 4. The sale, purchase, trade, or other transfer of a  
57 prescription drug from or for any federal, state, or local  
58 government agency or any entity eligible to purchase

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59 prescription drugs at public health services prices pursuant to  
60 Pub. L. No. 102-585, s. 602 to a contract provider or its  
61 subcontractor for eligible patients of the agency or entity  
62 under the following conditions:

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

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

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

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

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

86 e.f. The contract provider or subcontractor may administer  
87 or dispense the prescription drugs only to the eligible patients

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88 of the agency or entity or must return the prescription drugs  
89 for or to the agency or entity. The contract provider or  
90 subcontractor must require proof from each person seeking to  
91 fill a prescription or obtain treatment that the person is an  
92 eligible patient of the agency or entity and must, at a minimum,  
93 maintain a copy of this proof as part of the records of the  
94 contractor or subcontractor required under sub-subparagraph d.  
95 ~~e.~~

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

104 Section 3. This act shall take effect July 1, 2010.  
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