

By Senator Peaden

2-00956B-09

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1                   A bill to be entitled  
 2           An act relating to manufacturers and purchasers of  
 3           prescription drugs; amending s. 499.003, F.S.;  
 4           redefining the term "manufacturer" as it relates to  
 5           the Florida Drug and Cosmetic Act; amending s. 499.01,  
 6           F.S.; revising the business entities that are eligible  
 7           for a permit as a health care clinic establishment in  
 8           order to purchase prescription drugs; providing an  
 9           effective date.

10  
 11 Be It Enacted by the Legislature of the State of Florida:

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 13           Section 1. Subsection (31) of section 499.003, Florida  
 14           Statutes, is amended to read:

15           499.003 Definitions of terms used in this part.—As used in  
 16           this part, the term:

17           (31) "Manufacturer" means:

18           (a) A person who prepares, derives, manufactures, or  
 19           produces a drug, device, or cosmetic.

20           (b) The holder or holders of a New Drug Application (NDA),  
 21           an Abbreviated New Drug Application (ANDA), a Biologics License  
 22           Application (BLA), or a New Animal Drug Application (NADA),  
 23           provided such application has become effective or is otherwise  
 24           approved consistent with s. 499.023.~~†~~

25           (c) A co-licensee who has entered into an agreement with a  
 26           co-licensed partner to manufacture or market a product  
 27           consistent with the federal act.

28           (d) A private label distributor for whom the private label  
 29           distributor's prescription drugs are originally manufactured and

2-00956B-09

20091144

30 labeled for the distributor and have not been repackaged. ~~or~~

31 (e) The distribution point for one of the persons  
32 identified in paragraph (a), paragraph (b), paragraph (c), or  
33 paragraph (d) if the distribution point is:

34 1. A member of the affiliated group of one of the persons  
35 identified in paragraph (a), paragraph (b), paragraph (c), or  
36 paragraph (d) who distributes prescription drugs manufactured by  
37 affiliated group members only. The distribution point that is an  
38 affiliated group member may acquire title to a prescription drug  
39 before distributing the prescription drug, is exempt from s.  
40 499.01(2)(c)1., and is a manufacturer for purposes of s.  
41 499.01212. As used in this subparagraph, the term "affiliated  
42 group" means an affiliated group as defined in 26 U.S.C. s.  
43 1504, as amended.

44 2. A person under contract with one of the persons  
45 identified in paragraph (a), paragraph (b), paragraph (c), or  
46 paragraph (d) to distribute their prescription drugs, who may  
47 not take title to the prescription drugs, and who is permitted  
48 as a third-party logistics provider under s. 499.01 ~~the~~  
49 manufacturer, contract manufacturer, or private label  
50 distributor whether the establishment is a member of the  
51 manufacturer's affiliated group or is a contract distribution  
52 site.

53  
54 The term excludes pharmacies that are operating in compliance  
55 with pharmacy practice standards as defined in chapter 465 and  
56 rules adopted under that chapter.

57 Section 2. Paragraph (t) of subsection (2) of section  
58 499.01, Florida Statutes, is amended to read:

2-00956B-09

20091144

59 499.01 Permits.—

60 (2) The following permits are established:

61 (t) *Health care clinic establishment permit.*—Effective  
62 January 1, 2009, a health care clinic establishment permit is  
63 required for the purchase of a prescription drug by a place of  
64 business at one general physical location owned and operated by  
65 a professional corporation or professional limited liability  
66 company described in chapter 621, any other legal entity through  
67 which qualified practitioners may practice their profession  
68 under state law, or a corporation that employs a veterinarian as  
69 a qualifying practitioner. For the purpose of this paragraph,  
70 the term “qualifying practitioner” means a licensed health care  
71 practitioner defined in s. 456.001 or a veterinarian licensed  
72 under chapter 474, who is authorized under the appropriate  
73 practice act to prescribe and administer a prescription drug.

74 1. An establishment must provide, as part of the  
75 application required under s. 499.012, designation of a  
76 qualifying practitioner who will be responsible for complying  
77 with all legal and regulatory requirements related to the  
78 purchase, recordkeeping, storage, and handling of the  
79 prescription drugs. In addition, the designated qualifying  
80 practitioner shall be the practitioner whose name, establishment  
81 address, and license number is used on all distribution  
82 documents for prescription drugs purchased or returned by the  
83 health care clinic establishment. Upon initial appointment of a  
84 qualifying practitioner, the qualifying practitioner and the  
85 health care clinic establishment shall notify the department on  
86 a form furnished by the department within 10 days after such  
87 employment. In addition, the qualifying practitioner and health

2-00956B-09

20091144\_\_

88 care clinic establishment shall notify the department within 10  
89 days after any subsequent change.

90 2. The health care clinic establishment must employ a  
91 qualifying practitioner at each establishment.

92 3. In addition to the remedies and penalties provided in  
93 this part, a violation of this chapter by the health care clinic  
94 establishment or qualifying practitioner constitutes grounds for  
95 discipline of the qualifying practitioner by the appropriate  
96 regulatory board.

97 4. The purchase of prescription drugs by the health care  
98 clinic establishment is prohibited during any period of time  
99 when the establishment does not comply with this paragraph.

100 5. A health care clinic establishment permit is not a  
101 pharmacy permit or otherwise subject to chapter 465. A health  
102 care clinic establishment that meets the criteria of a modified  
103 Class II institutional pharmacy under s. 465.019 is not eligible  
104 to be permitted under this paragraph.

105 6. This paragraph does not prohibit a qualifying  
106 practitioner from purchasing prescription drugs.

107 Section 3. This act shall take effect upon becoming a law.