

By Senator Fasano

11-1047-04

1                                   A bill to be entitled  
2           An act relating to veterinary prescription  
3           drugs; amending s. 499.003, F.S.; defining the  
4           term "veterinary prescription drug wholesaler";  
5           amending s. 499.01, F.S.; requiring a person or  
6           establishment to obtain a permit in order to  
7           operate as a veterinary prescription drug  
8           wholesaler; amending s. 499.012, F.S.;  
9           providing that the distribution of veterinary  
10          prescription drugs is not included within the  
11          meaning of the terms "wholesale distribution"  
12          or "wholesale distributor" of prescription  
13          drugs; amending s. 499.041, F.S.; requiring an  
14          annual fee for a veterinary prescription drug  
15          wholesaler's permit; amending s. 499.065, F.S.;  
16          requiring the Department of Health to inspect  
17          veterinary prescription drug wholesale  
18          establishments; authorizing the department to  
19          close such establishment if it creates an  
20          imminent danger to the public health; providing  
21          an effective date.

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

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25           Section 1. Subsection (40) is added to section  
26   499.003, Florida Statutes, to read:  
27           499.003 Definitions of terms used in ss.  
28   499.001-499.081.--As used in ss. 499.001-499.081, the term:  
29           (40) "Veterinary prescription drug wholesaler" means  
30   any person engaged in wholesale distribution of veterinary  
31   prescription drugs in or into this state. A veterinary

1 prescription drug wholesaler may not sell any veterinary  
2 prescription drugs to any person or entity other than an  
3 animal health entity.

4 Section 2. Subsection (1) of section 499.01, Florida  
5 Statutes, is amended to read:

6 499.01 Permits; applications; renewal; general  
7 requirements.--

8 (1) Prior to operating, a permit is required for each  
9 person and establishment that intends to operate as:

- 10 (a) A prescription drug manufacturer;  
11 (b) A prescription drug repackager;  
12 (c) An over-the-counter drug manufacturer;  
13 (d) A compressed medical gas manufacturer;  
14 (e) A device manufacturer;  
15 (f) A cosmetic manufacturer;  
16 (g) A prescription drug wholesaler;  
17 (h) A compressed medical gas wholesaler;  
18 (i) An out-of-state prescription drug wholesaler;  
19 (j) A nonresident prescription drug manufacturer;  
20 (k) A freight forwarder;  
21 (l) A retail pharmacy drug wholesaler;  
22 (m) A veterinary legend drug retail establishment;  
23 (n) A medical oxygen retail establishment;  
24 (o) A complimentary drug distributor; ~~or~~  
25 (p) A restricted prescription drug distributor; or-  
26 (q) Veterinary prescription drug wholesaler.

27 Section 3. Paragraphs (a) and (b) of subsection (1) of  
28 section 499.012, Florida Statutes, are amended to read:

29 499.012 Wholesale distribution; definitions; permits;  
30 applications; general requirements.--

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

1 (a) "Wholesale distribution" means distribution of  
2 prescription drugs to persons other than a consumer or  
3 patient, but does not include:

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

7 a. The purchase or other acquisition by a hospital or  
8 other health care entity that is a member of a group  
9 purchasing organization of a prescription drug for its own use  
10 from the group purchasing organization or from other hospitals  
11 or health care entities that are members of that organization.

12 b. The sale, purchase, or trade of a prescription drug  
13 or an offer to sell, purchase, or trade a prescription drug by  
14 a charitable organization described in s. 501(c)(3) of the  
15 Internal Revenue Code of 1986, as amended and revised, to a  
16 nonprofit affiliate of the organization to the extent  
17 otherwise permitted by law.

18 c. The sale, purchase, or trade of a prescription drug  
19 or an offer to sell, purchase, or trade a prescription drug  
20 among hospitals or other health care entities that are under  
21 common control. For purposes of this section, "common control"  
22 means the power to direct or cause the direction of the  
23 management and policies of a person or an organization,  
24 whether by ownership of stock, by voting rights, by contract,  
25 or otherwise.

26 d. The sale, purchase, trade, or other transfer of a  
27 prescription drug from or for any federal, state, or local  
28 government agency or any entity eligible to purchase  
29 prescription drugs at public health services prices pursuant  
30 to Pub. L. No. 102-585, s. 602 to a contract provider or its  
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1 subcontractor for eligible patients of the agency or entity  
2 under the following conditions:

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

7 (II) The contract provider or subcontractor must be  
8 authorized by law to administer or dispense prescription  
9 drugs.

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

12 (IV) A contract provider or subcontractor must  
13 maintain separate and apart from other prescription drug  
14 inventory any prescription drugs of the agency or entity in  
15 its possession.

16 (V) The contract provider and subcontractor must  
17 maintain and produce immediately for inspection all records of  
18 movement or transfer of all the prescription drugs belonging  
19 to the agency or entity, including, but not limited to, the  
20 records of receipt and disposition of prescription drugs. Each  
21 contractor and subcontractor dispensing or administering these  
22 drugs must maintain and produce records documenting the  
23 dispensing or administration. Records that are required to be  
24 maintained include, but are not limited to, a perpetual  
25 inventory itemizing drugs received and drugs dispensed by  
26 prescription number or administered by patient identifier,  
27 which must be submitted to the agency or entity quarterly.

28 (VI) The contract provider or subcontractor may  
29 administer or dispense the prescription drugs only to the  
30 eligible patients of the agency or entity or must return the  
31 prescription drugs for or to the agency or entity. The

1 contract provider or subcontractor must require proof from  
2 each person seeking to fill a prescription or obtain treatment  
3 that the person is an eligible patient of the agency or entity  
4 and must, at a minimum, maintain a copy of this proof as part  
5 of the records of the contractor or subcontractor required  
6 under sub-sub-subparagraph (V).

7 (VII) In addition to the departmental inspection  
8 authority set forth in s. 499.051, the establishment of the  
9 contract provider and subcontractor and all records pertaining  
10 to prescription drugs subject to this sub-subparagraph shall  
11 be subject to inspection by the agency or entity. All records  
12 relating to prescription drugs of a manufacturer under this  
13 sub-subparagraph shall be subject to audit by the manufacturer  
14 of those drugs, without identifying individual patient  
15 information.

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

19 a. The sale, purchase, or trade of a prescription drug  
20 among federal, state, or local government health care entities  
21 that are under common control and are authorized to purchase  
22 such prescription drug.

23 b. The sale, purchase, or trade of a prescription drug  
24 or an offer to sell, purchase, or trade a prescription drug  
25 for emergency medical reasons. For purposes of this  
26 sub-subparagraph, the term "emergency medical reasons"  
27 includes transfers of prescription drugs by a retail pharmacy  
28 to another retail pharmacy to alleviate a temporary shortage.

29 c. The transfer of a prescription drug acquired by a  
30 medical director on behalf of a licensed emergency medical  
31 services provider to that emergency medical services provider

1 and its transport vehicles for use in accordance with the  
2 provider's license under chapter 401.

3 d. The revocation of a sale or the return of a  
4 prescription drug to the person's prescription drug wholesale  
5 supplier.

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

11 f. The transfer of a prescription drug by a person  
12 authorized to purchase or receive prescription drugs to a  
13 person licensed or permitted to handle reverse distributions  
14 or destruction under the laws of the jurisdiction in which the  
15 person handling the reverse distribution or destruction  
16 receives the drug.

17 g. The transfer of a prescription drug by a hospital  
18 or other health care entity to a person licensed under this  
19 chapter to repackage prescription drugs for the purpose of  
20 repackaging the prescription drug for use by that hospital, or  
21 other health care entity and other health care entities that  
22 are under common control, if ownership of the prescription  
23 drugs remains with the hospital or other health care entity at  
24 all times. In addition to the recordkeeping requirements of  
25 s. 499.0121(6), the hospital or health care entity that  
26 transfers prescription drugs pursuant to this sub-subparagraph  
27 must reconcile all drugs transferred and returned and resolve  
28 any discrepancies in a timely manner.

29 3. The distribution of prescription drug samples by  
30 manufacturers' representatives or distributors'  
31 representatives conducted in accordance with s. 499.028.

1           4. The sale, purchase, or trade of blood and blood  
2 components intended for transfusion. As used in this  
3 subparagraph, the term "blood" means whole blood collected  
4 from a single donor and processed either for transfusion or  
5 further manufacturing, and the term "blood components" means  
6 that part of the blood separated by physical or mechanical  
7 means.

8           5. The lawful dispensing of a prescription drug in  
9 accordance with chapter 465.

10           6. Distribution of veterinary prescription drugs.

11           (b) "Wholesale distributor" means any person engaged  
12 in wholesale distribution of prescription drugs, other than  
13 veterinary prescription drugs, in or into this state,  
14 including, but not limited to, manufacturers; repackagers;  
15 own-label distributors; jobbers; private-label distributors;  
16 brokers; warehouses, including manufacturers' and  
17 distributors' warehouses, chain drug warehouses, and wholesale  
18 drug warehouses; independent wholesale drug traders;  
19 exporters; retail pharmacies; and the agents thereof that  
20 conduct wholesale distributions.

21           Section 4. Paragraph (h) is added to subsection (1) of  
22 section 499.041, Florida Statutes, to read:

23           499.041 Schedule of fees for drug, device, and  
24 cosmetic applications and permits, product registrations, and  
25 free-sale certificates.--

26           (1) The department shall assess applicants requiring a  
27 manufacturing permit an annual fee within the ranges  
28 established in this section for the specific type of  
29 manufacturer.

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1           (h) The fee for a veterinary prescription drug  
2 wholesaler's permit may not be less than \$300 or more than  
3 \$500 annually.

4           Section 5. Section 499.065, Florida Statutes, is  
5 amended to read:

6           499.065 Imminent danger.--

7           (1) Notwithstanding s. 499.051, the department shall  
8 inspect each prescription drug wholesale establishment,  
9 prescription drug repackager establishment, veterinary  
10 prescription drug wholesale establishment, and retail pharmacy  
11 drug wholesaler establishment that is required to be permitted  
12 under this chapter as often as necessary to ensure compliance  
13 with applicable laws and rules. The department shall have the  
14 right of entry and access to these facilities at any  
15 reasonable time.

16           (2) To protect the public from prescription drugs that  
17 are adulterated or otherwise unfit for human or animal  
18 consumption, the department may examine, sample, seize, and  
19 stop the sale or use of prescription drugs to determine the  
20 condition of those drugs. The department may immediately seize  
21 and remove any prescription drugs if the Secretary of Health  
22 or his or her designee determines that such prescription drugs  
23 represent a threat to the public health. The owner of any  
24 property seized under this section may, within 10 days after  
25 the seizure, apply to a court of competent jurisdiction for  
26 whatever relief is appropriate. At any time after 10 days, the  
27 department may destroy the drugs as contraband.

28           (3) The department may determine that a prescription  
29 drug wholesale establishment, prescription drug repackager  
30 establishment, veterinary prescription drug wholesale  
31 establishment, or retail pharmacy drug wholesaler



1 establishment that is required to be permitted under this  
2 chapter is an imminent danger to the public health and require  
3 its immediate closure if such establishment fails to comply  
4 with applicable laws and rules and, because of such failure,  
5 presents an imminent threat to the public's health, safety, or  
6 welfare. Any establishment so deemed and closed shall remain  
7 closed until allowed by the department or by judicial order to  
8 reopen.

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10 For purposes of this section, a refusal to allow entry to the  
11 department for inspection at reasonable times, or a failure or  
12 refusal to provide the department with required documentation  
13 for purposes of inspection, constitutes an imminent danger to  
14 the public health.

15 Section 6. This act shall take effect July 1, 2004.

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18 SENATE SUMMARY

19 Requires a permit to operate as a veterinary prescription  
20 drug wholesaler. Provides that the distribution of  
21 veterinary prescription drugs is not within the meaning  
22 of the terms "wholesale distribution" or "wholesale  
23 distributor." Requires an annual fee for veterinary  
24 prescription drug wholesaler permit. Requires the  
25 Department of Health to inspect veterinary prescription  
26 drug wholesale establishments and to close such an  
27 establishment if it creates an imminent danger to the  
28 public health.

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