

Committee Substitute for Senate Bill No. 1824

An act relating to veterinary prescription drugs; amending s. 499.003, F.S.; defining the term “veterinary prescription drug wholesaler”; amending s. 499.01, F.S.; requiring a person or establishment to obtain a permit in order to operate as a veterinary prescription drug wholesaler; amending s. 499.012, F.S.; requiring a person to have a veterinary prescription drug wholesaler permit to distribute veterinary prescription drugs in or into this state; requiring a veterinary prescription drug wholesaler that also distributes human prescription drugs that it did not manufacture to obtain a prescription drug wholesaler or out-of-state prescription drug wholesaler permit in lieu of the veterinary prescription drug wholesaler permit; amending s. 499.0121, F.S.; requiring certain prescription wholesalers to use due diligence when purchasing prescription drugs from others; amending s. 499.041, F.S.; requiring an annual fee for a veterinary prescription drug wholesaler’s permit; amending s. 499.065, F.S.; requiring the Department of Health to inspect veterinary prescription drug wholesale establishments; authorizing the department to close such establishment if it creates an imminent danger to the public health; providing an effective date.

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

Section 1. Subsection (40) is added to section 499.003, Florida Statutes, to read:

499.003 Definitions of terms used in ss. 499.001-499.081.—As used in ss. 499.001-499.081, the term:

(40) “Veterinary prescription drug wholesaler” means any person engaged in wholesale distribution of veterinary prescription drugs in or into this state.

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

499.01 Permits; applications; renewal; general requirements.—

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

- (a) A prescription drug manufacturer;
- (b) A prescription drug repackager;
- (c) An over-the-counter drug manufacturer;
- (d) A compressed medical gas manufacturer;
- (e) A device manufacturer;

- (f) A cosmetic manufacturer;
- (g) A prescription drug wholesaler;
- (h) A veterinary prescription drug wholesaler;
- ~~(i)(h)~~ A compressed medical gas wholesaler;
- ~~(j)(i)~~ An out-of-state prescription drug wholesaler;
- ~~(k)(j)~~ A nonresident prescription drug manufacturer;
- ~~(l)(k)~~ A freight forwarder;
- ~~(m)(l)~~ A retail pharmacy drug wholesaler;
- ~~(n)(m)~~ A veterinary legend drug retail establishment;
- ~~(o)(n)~~ A medical oxygen retail establishment;
- ~~(p)(o)~~ A complimentary drug distributor; or
- ~~(q)(p)~~ A restricted prescription drug distributor.

Section 3. Paragraph (g) is added to subsection (2) of section 499.012, Florida Statutes, to read:

499.012 Wholesale distribution; definitions; permits; applications; general requirements.—

(2) The following types of wholesaler permits are established:

(g) A veterinary prescription drug wholesaler permit.—A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler or out-of-state prescription drug wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f).

Section 4. Subsection (12) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(12) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale drug distributor, a prescription drug wholesaler, an out-of-state prescription drug wholesaler, or a prescription drug repackager ~~a wholesale drug distributor~~ must:

(a) Enter an agreement with the selling wholesale drug distributor by which the selling wholesale drug distributor will indemnify the purchasing wholesale drug distributor for any loss caused to the purchasing wholesale drug distributor related to the purchase of drugs from the selling wholesale drug distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale drug distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under ~~pursuant to~~ s. 499.012(3)(g) or \$500,000; however the coverage need not exceed \$2 million.

(c) Obtain information from the selling wholesale drug distributor, including the length of time the selling wholesale drug distributor has been licensed in this state, a copy of the selling wholesale drug distributor's licenses or permits, and background information concerning the ownership of the selling wholesale drug distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale drug distributor's Florida permit is valid.

(e) Inspect the selling wholesale drug distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale drug distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale drug distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale drug distributors in the state in which the establishment is located.

Section 5. Paragraph (g) is added to subsection (2) of section 499.041, Florida Statutes, to read:

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

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

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

Section 6. Section 499.065, Florida Statutes, is amended to read:

499.065 Imminent danger.—

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

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

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an imminent danger to the public health and shall require its immediate closure if the such establishment fails to comply with applicable laws and rules and, because of the such failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

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

Section 7. This act shall take effect July 1, 2004.

Approved by the Governor June 17, 2004.

Filed in Office Secretary of State June 17, 2004.