

LEGISLATURE OF NEBRASKA
ONE HUNDREDTH LEGISLATURE
SECOND SESSION

LEGISLATIVE BILL 1022

Introduced by Hansen, 42; Christensen, 44.

Read first time January 17, 2008

Committee: Health and Human Services

A BILL

1 FOR AN ACT relating to public health and welfare; to adopt
2 the Veterinary Drug Distribution Licensing Act; and to
3 provide a penalty.
4 Be it enacted by the people of the State of Nebraska,

1 Section 1. Sections 1 to 30 of this act shall be known
2 and may be cited as the Veterinary Drug Distribution Licensing Act.

3 Sec. 2. The purpose of the Veterinary Drug Distribution
4 Licensing Act is to protect the public health, safety, and welfare
5 by providing for the authorization and licensure of facilities and
6 persons to distribute, under specific conditions, veterinary legend
7 drugs to the public in the State of Nebraska.

8 Sec. 3. For purposes of the Veterinary Drug Distribution
9 Licensing Act, the definitions found in sections 4 to 13 of this
10 act shall apply.

11 Sec. 4. Animal means any animal other than man.

12 Sec. 5. Controlled substance has the definition found in
13 section 28-401.

14 Sec. 6. Department means the Division of Public Health of
15 the Department of Health and Human Services.

16 Sec. 7. Distribution means the act of receiving orders,
17 possessing, warehousing, and record keeping relevant to veterinary
18 legend drug sales and delivery. Distribution does not include:
19 (1) Intracompany sales of veterinary legend drugs, including any
20 transaction or transfer between any division, subsidiary, or parent
21 company and an affiliated or related company under common ownership
22 or common control; or (2) the delivery of or the offer to deliver
23 a veterinary legend drug by a common carrier solely in the usual
24 course of business of transporting such drugs as a common carrier
25 if the common carrier does not store, warehouse, or take legal

1 ownership of such drugs.

2 Sec. 8. Human legend drug means any drug labeled for
3 human use and required by federal law or regulation to be dispensed
4 pursuant to a prescription, including finished dosage forms and
5 active ingredients. Human legend drug does not include a device or
6 a device component, part, or accessory.

7 Sec. 9. Veterinarian-client-patient relationship means a
8 relationship pursuant to which (1) a veterinarian has assumed the
9 responsibility for making clinical judgments regarding the health
10 of an animal and the need for medical treatment, and the client
11 has agreed to follow the veterinarian's instructions, (2) the
12 veterinarian has sufficient knowledge of the animal to initiate at
13 least a general or preliminary diagnosis of the medical condition
14 of the animal, meaning that the veterinarian has recently seen
15 and is personally acquainted with the keeping and care of the
16 animal by virtue of an examination of the animal or by medically
17 appropriate and timely visits to the premises where the animal is
18 kept, and (3) the veterinarian is readily available or has arranged
19 for emergency coverage and for followup evaluation in the event of
20 adverse reactions or the failure of the treatment regimen.

21 Sec. 10. Veterinary drug distributor means any premises,
22 other than a pharmacy, that holds a valid license issued by
23 the department under the Veterinary Drug Distribution Licensing
24 Act. Veterinary drug distributor includes, but is not limited to,
25 any premises described in a license issued by the department in

1 which veterinary legend drugs are stored, possessed, or warehoused
2 and from which veterinary legend drugs are furnished, sold, or
3 otherwise disseminated pursuant to a veterinary drug order from a
4 veterinarian licensed to practice in Nebraska.

5 Sec. 11. Veterinary drug order means a lawful order or
6 prescription of a veterinarian licensed to practice in this state,
7 which order or prescription is issued pursuant to the establishment
8 of a bona fide veterinarian-client-patient relationship. For the
9 purposes of the Veterinary Drug Distribution Licensing Act, a
10 veterinary drug order shall expire and become void one hundred
11 eighty days after the date of issue.

12 Sec. 12. Veterinary legend drug means a drug which under
13 federal law is required, prior to being distributed, to be labeled
14 with the following statement: "Caution: Federal law restricts this
15 drug to use by or on the order of a licensed veterinarian."

16 Sec. 13. No person or entity shall distribute, sell, or
17 offer for sale any veterinary legend drug in this state without
18 first obtaining a license issued by the department under the
19 Veterinary Drug Distribution Licensing Act.

20 Sec. 14. (1) Any person, partnership, corporation,
21 business entity, or other entity located in this state or any other
22 location that acts as a veterinary drug distributor shall obtain
23 a veterinary drug distributor license from the department prior
24 to engaging in distribution of veterinary legend drugs in or into
25 this state.

1 (2) An applicant for an initial or renewal license as a
2 veterinary drug distributor shall file a written application with
3 the department. The application shall be accompanied by the fee
4 established by the department pursuant to section 19 of this act
5 and shall include the following information:

6 (a) The applicant's name, business address, type of
7 business entity, and telephone number. If the applicant is a
8 partnership, the application shall include the name of each partner
9 and the name of the partnership. If the applicant is a corporation,
10 the application shall include the name and title of each corporate
11 officer and director, all corporate names of the applicant, and
12 the applicant's state of incorporation. If the applicant is a sole
13 proprietorship, the application shall include the name of the sole
14 proprietor, the name of the proprietorship, and the proprietor's
15 social security number. The social security number shall not be
16 a public record and may only be used by the department for
17 administrative purposes;

18 (b) All trade or business names used by the applicant;

19 (c) The addresses and telephone numbers of all facilities
20 to be used by the applicant for the storage, handling, and
21 distribution of veterinary legend drugs and the names of persons
22 to be in charge of such facilities. A separate license shall be
23 obtained for each such facility;

24 (d) A listing of all licenses, permits, or other
25 similar documentation issued to the applicant in any other state

1 authorizing the applicant to purchase, possess, and distribute
2 veterinary legend drugs;

3 (e) The names and addresses of the owner of the
4 applicant's veterinary legend drug distribution facilities, a
5 designated manager at each such facility, and all managerial
6 employees at each such facility; and

7 (f) Other information as required by the department,
8 including affirmative evidence of the applicant's ability to comply
9 with the Veterinary Drug Distributor Licensing Act and the rules
10 and regulations adopted under the act.

11 (3) The application shall be signed by:

12 (a) The owner, if the applicant is an individual or
13 partnership;

14 (b) The member, if the applicant is a limited liability
15 company with only one member, or two of its members, if the
16 applicant is a limited liability company with two or more members;
17 or

18 (c) Two of its officers, if the applicant is a
19 corporation.

20 (4) A veterinary drug distributor holding a valid license
21 issued pursuant to the Veterinary Drug Distribution Licensing Act
22 shall have the authority to purchase, possess, or otherwise acquire
23 veterinary legend drugs.

24 Sec. 15. A veterinary drug distributor shall establish,
25 maintain, and adhere to written policies and procedures for

1 the receipt, storage, security, inventory, and distribution of
2 veterinary legend drugs, including policies and procedures for
3 identifying, recording, and reporting destruction, losses, or
4 thefts of veterinary legend drugs and for correcting all errors and
5 inaccuracies in inventories. The policies shall contain a provision
6 for annual review at which time the policies shall be updated
7 as necessary. A record documenting the review shall be kept with
8 the policies and procedures and shall indicate the date of the
9 review and the signature of the designated representative of the
10 veterinary drug distributor.

11 Sec. 16. The department may issue a temporary veterinary
12 drug distributor license upon conditions and for periods of time as
13 the department determines to be in the public interest. A temporary
14 license fee shall be fixed by the department at an amount not to
15 exceed the annual fee for renewal of a license as a veterinary drug
16 distributor.

17 Sec. 17. The department may waive requirements under
18 sections 13 to 16 of this act upon proof satisfactory to
19 the department that such requirements are duplicative of other
20 requirements of Nebraska laws, rules, or regulations and that the
21 granting of such waiver will not endanger the public safety.

22 Sec. 18. (1) A veterinary drug distributor license may
23 be denied, refused renewal, suspended, limited, or revoked by the
24 Director of Public Health if he or she finds that the applicant
25 or licensee has violated any provisions of the Veterinary Drug

1 Distribution Licensing Act or of the rules and regulations adopted
2 under the act.

3 (2) The department shall issue or renew a license to any
4 applicant that satisfies the requirements for licensure or license
5 renewal under the act.

6 (3) The department may deny or restrict the application
7 for a veterinary drug distributor license if the applicant
8 has been convicted of a criminal violation of the Veterinary
9 Drug Distribution Licensing Act, Nebraska statutes governing the
10 practice of pharmacy, the Federal Food, Drug, and Cosmetic Act, 21
11 U.S.C. 301 et seq., as such act existed on January 1, 2008.

12 (4) The department may deny or restrict the application
13 for a veterinary drug distributor license if the applicant has been
14 convicted in another state of a criminal violation of the laws of
15 such state governing veterinary drug distribution or the practice
16 of pharmacy or of the Federal Food, Drug, and Cosmetic Act, 21
17 U.S.C. 301 et seq., as such act existed on January 1, 2008.

18 Sec. 19. (1) An applicant for an initial or renewal
19 license under the Veterinary Drug Distribution Licensing Act shall
20 pay a license fee as provided in this section.

21 (2) License fees shall include (a) a base fee of fifty
22 dollars and (b) an additional fee of not more than five hundred
23 dollars based on variable costs to the department of inspections
24 and of receiving and investigating complaints, other similar direct
25 and indirect costs, and other costs of administering the act as

1 determined by the department. If an application under the act is
2 denied, the license fee shall be returned to the applicant, except
3 that the department may retain up to twenty-five dollars as an
4 administrative fee and may retain the entire license fee if an
5 inspection has been completed prior to such denial.

6 (3) The department shall also collect a fee established
7 by the department, not to exceed the actual cost to the department,
8 for reinstatement of a license that has lapsed or has been
9 suspended or revoked. The department shall collect a fee of ten
10 dollars for a duplicate original license.

11 (4) The department shall remit all license fees collected
12 under the act to the State Treasurer for credit to the Health and
13 Human Services Cash Fund. License fees collected under this section
14 shall only be used for activities related to the licensure of
15 veterinary drug distributors.

16 Sec. 20. A veterinary drug distributor license shall
17 expire on July 1 of each odd-numbered year and may be renewed.
18 The license shall not be transferable. The department shall mail
19 an application for renewal to each licensee not later than May 15
20 of the year the license expires. If an application for renewal is
21 received from the licensee after July 1, the department may impose
22 a late fee and shall refuse to issue the license until such late
23 fee and renewal fee are paid. Failure to receive an application for
24 renewal shall not relieve the licensee from the late fee imposed by
25 this section.

1 Sec. 21. (1) Each veterinary drug distributor transacting
2 commerce in this state shall be inspected by the department prior
3 to the issuance of an initial or renewal license by the department
4 under the Veterinary Drug Distribution Licensing Act.

5 (2) The department may provide in rules and regulations
6 for the inspection of any veterinary drug distributor licensed in
7 this state in such manner and at such times as the department
8 determines. As part of any such inspection, the department may
9 require an analysis of suspected veterinary legend drugs to
10 determine authenticity.

11 (3) For applicants not located in this state, the
12 department may accept an inspection which was accepted for
13 licensure by another state in which the applicant is licensed
14 or by a nationally-recognized accreditation program in lieu of an
15 inspection by the department under this section.

16 (4) The department may establish and collect fees for
17 inspection activities conducted under this section. Such fees
18 shall not exceed the department's actual cost for such inspection
19 activities.

20 (5) The department may adopt and promulgate rules
21 and regulations which permit the use of alternative methods
22 for assessing a licensee's compliance with the Veterinary Drug
23 Distribution Licensing Act and the rules and regulations by a
24 veterinary drug distributor.

25 Sec. 22. (1) A veterinary drug distributor transacting

1 commerce in this state shall establish and maintain accurate
2 records of all transactions regarding the receipt and distribution
3 or other disposition of veterinary legend drugs as provided in the
4 Veterinary Drug Distribution Licensing Act.

5 (2) All records of receipt, distribution, or other
6 disposal of veterinary legend drugs shall be available to the
7 department upon request for inspection, copying, verifying, or
8 other proper use.

9 (3) If a veterinary drug distributor is authorized by
10 the department to maintain records at a central location, such
11 records shall be made available for authorized inspections within
12 forty-eight hours.

13 (4) Records kept at a central location that can be
14 retrieved by computer or other electronic means shall be readily
15 available for authorized inspection during the inspection period.

16 Sec. 23. A veterinary drug distributor may distribute
17 veterinary legend drugs to:

18 (1) A licensed veterinarian or to another veterinary drug
19 distributor subject to the requirements of section 22 of this act;
20 and

21 (2) A layperson responsible for the control of an animal
22 if:

23 (a) A licensed veterinarian has issued, prior to such
24 distribution, a veterinary drug order for the drug in the course of
25 an existing, valid veterinarian-client-patient relationship;

1 (b) At the time the veterinary legend drug leaves
2 the licensed location of the veterinary drug distributor, the
3 distributor possesses a copy of the veterinary drug order for the
4 veterinary legend drug;

5 (c) The original order is retained on the premises of the
6 veterinary drug distributor or an authorized central location for
7 three years after the date of the last transaction affecting the
8 order and includes the following information:

9 (i) Client name;

10 (ii) Veterinarian name;

11 (iii) Drug sold or delivered;

12 (iv) Quantity of the drug;

13 (v) Date of issue of order; and

14 (vi) Expiration date of order;

15 (d) All veterinary legend drugs distributed on the order
16 of a licensed veterinarian are sold in the original, unbroken
17 manufacturer's containers; and

18 (e) The drugs, once distributed, are not returned to the
19 veterinary drug distributor for resale or redistribution.

20 Nothing contained in Nebraska statutes governing the
21 practice of pharmacy shall be construed to prohibit a veterinary
22 drug distributor from selling or otherwise distributing a
23 veterinary legend drug pursuant to a veterinary drug order
24 by a veterinarian licensed in this state and, when a valid
25 veterinarian-client-patient relationship exists, to the layman

1 responsible for the control of the animal.

2 (3) If all federal labeling requirements are met,
3 labeling provisions of Nebraska laws governing the practice of
4 pharmacy shall not apply to veterinary legend drugs distributed
5 pursuant to the Veterinary Drug Distribution Licensing Act.

6 Sec. 24. A veterinary drug distributor shall not:

7 (1) Operate from a place of residence;

8 (2) Possess, sell, purchase, trade, or otherwise furnish
9 controlled substances; and

10 (3) Possess, sell, purchase, trade, or otherwise furnish
11 human legend drugs.

12 Sec. 25. The department, the Attorney General, or any
13 county attorney may institute an action in the name of the state
14 for an injunction or other process against any person to restrain
15 or prevent any violation of the Veterinary Drug Distribution
16 Licensing Act or any rules and regulations adopted and promulgated
17 under the act.

18 Sec. 26. It is unlawful for any person to commit or to
19 permit, cause, aid, or abet the commission of any of the following
20 acts in this state:

21 (1) Any violation of the Veterinary Drug Distribution
22 Licensing Act or rules and regulations adopted and promulgated
23 under the act;

24 (2) Providing the department, any of its representatives,
25 or any federal official with false or fraudulent records or making

1 false or fraudulent statements regarding any matter under the act;

2 (3) Obtaining or attempting to obtain a veterinary legend
3 drug by fraud, deceit, or misrepresentation or engaging in the
4 intentional misrepresentation or fraud in the distribution of a
5 veterinary legend drug;

6 (4) Except for the distribution by manufacturers of
7 a veterinary legend drug that has been delivered into commerce
8 pursuant to an application approved under federal law by the
9 federal Food and Drug Administration, the manufacture, repackaging,
10 sale, transfer, delivery, holding, or offering for sale of
11 any veterinary legend drug that is adulterated, misbranded,
12 counterfeit, suspected of being counterfeit, or otherwise rendered
13 unfit for distribution;

14 (5) Except for the wholesale distribution by
15 manufacturers of a veterinary legend drug that has been
16 delivered into commerce pursuant to an application approved under
17 federal law by the federal Food and Drug Administration, the
18 adulteration, misbranding, or counterfeiting of any veterinary
19 legend drug;

20 (6) The deliberate receipt of any veterinary legend drug
21 that is adulterated, misbranded, stolen, obtained by fraud or
22 deceit, counterfeit, or suspected of being counterfeit and the
23 delivery or proffered delivery of such drug for pay or otherwise;

24 (7) The alteration, mutilation, destruction,
25 obliteration, or removal of the whole or any part of the labeling

1 of a veterinary legend drug or the commission of any other act with
2 respect to a veterinary legend drug that results in the veterinary
3 legend drug being misbranded;

4 (8) For the purposes of the Veterinary Drug Distribution
5 Licensing Act, the manufacture, repackaging, sale, transfer,
6 delivery, holding, possessing or offering for sale, trade, or any
7 other form of dissemination, any controlled substance; and

8 (9) Prohibiting or otherwise impeding access, during
9 normal business hours and with at least forty-eight hours notice,
10 to any paper or electronic records or any premises, facility, area,
11 or location to which access is authorized by the act.

12 Sec. 27. (1) Upon issuance of a final disciplinary action
13 against a person who knowingly and intentionally violates any
14 provision of section 26 of this act other than as provided in
15 subsection (2) of this section, the department shall assess a fine
16 of one thousand dollars against such person. For each subsequent
17 final disciplinary action for violation of such section issued by
18 the department against such person, the department shall assess a
19 fine of one thousand dollars plus one thousand dollars for each
20 final disciplinary action for violation of such section previously
21 issued against such person, not to exceed ten thousand dollars.

22 (2) Upon issuance of a final disciplinary action against
23 a person who fails to provide an authorized person the right of
24 entry provided in section 26 of this act, the department shall
25 assess a fine of five hundred dollars against such person. For

1 each subsequent final disciplinary action for such failure issued
2 against such person, the department shall assess a fine equal to
3 one thousand dollars times the number of such disciplinary actions,
4 not to exceed ten thousand dollars.

5 (3) All fines collected under this section shall be
6 remitted to the State Treasurer for distribution in accordance with
7 Article VII, section 5, of the Constitution of Nebraska.

8 Sec. 28. (1) If the department finds there is a
9 reasonable probability that (a) a veterinary drug distributor
10 has knowingly and intentionally falsified documents relevant to the
11 purchase, sale, or distribution of veterinary legend drugs or has
12 sold, distributed, transferred, manufactured, repackaged, handled,
13 or held a counterfeit veterinary legend drug and (b) such drug
14 could cause serious, adverse health consequences or death, the
15 department may issue an order to immediately cease distribution of
16 such drug.

17 (2) Persons subject to any order issued by the department
18 under this section shall be provided with notice and an opportunity
19 for an informal hearing to be held not later than thirty days after
20 the date the order was issued. If the department determines, after
21 such hearing, that inadequate grounds exist to support the actions
22 required by the order, the department shall vacate the order.

23 Sec. 29. The department may adopt and promulgate rules
24 and regulations to carry out the Veterinary Drug Distribution
25 Licensing Act.

1 Sec. 30. Any person who knowingly and intentionally
2 engages in distribution of veterinary legend drugs in this state
3 in violation of the Veterinary Drug Distribution Licensing Act is
4 guilty of a Class III felony.