

LEGISLATURE OF NEBRASKA  
ONE HUNDREDTH LEGISLATURE  
SECOND SESSION  
**LEGISLATIVE BILL 1022**

FINAL READING

(SECOND)

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 the
- 2           Veterinary Drug Distribution Licensing Act; to provide a
- 3           penalty; and to provide an operative date.
- 4 Be it enacted by the people of the State of Nebraska,

1           Section 1. Sections 1 to 29 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  
5 welfare by providing for the authorization and licensure of  
6 veterinary drug distributors in the State of Nebraska and for  
7 the development, establishment, and enforcement of basic standards  
8 for such distributors.

9           Sec. 3. For purposes of the Veterinary Drug Distribution  
10 Licensing Act, the definitions found in sections 4 to 11 of this  
11 act shall apply.

12           Sec. 4. Controlled substance has the definition found in  
13 section 28-401.

14           Sec. 5. Department means the Division of Public Health of  
15 the Department of Health and Human Services.

16           Sec. 6. (1) Distribution means the act of receiving  
17 orders, possessing, warehousing, and record keeping related to the  
18 sale and delivery of veterinary legend drugs.

19           (2) Distribution does not include (a) intracompany sales  
20 of veterinary legend drugs, including any transaction or transfer  
21 between any division, subsidiary, or parent company and an  
22 affiliated or related company under common ownership or common  
23 control or (b) the delivery of or the offer to deliver veterinary  
24 legend drugs by a common carrier solely in the usual course of  
25 business of transporting such drugs as a common carrier if the

1 common carrier does not store, warehouse, or take legal ownership  
2 of such drugs.

3           Sec. 7. Human legend drug means any drug labeled for  
4 human use and required by federal law or regulation to be dispensed  
5 pursuant to a prescription, including finished dosage forms and  
6 active ingredients. Human legend drug does not include a device or  
7 a device component, part, or accessory.

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

22           Sec. 9. Veterinary drug distributor means any person or  
23 entity, other than a pharmacy, that engages in the distribution of  
24 veterinary legend drugs in the State of Nebraska.

25           Sec. 10. Veterinary drug order means a lawful order or

1 prescription of a veterinarian licensed to practice in this state,  
2 which order or prescription is issued pursuant to a bona fide  
3 veterinarian-client-patient relationship.

4       Sec. 11. Veterinary legend drug means a drug which under  
5 federal law is required, prior to being distributed, to be labeled  
6 with the following statement: "Caution: Federal law restricts this  
7 drug to use by or on the order of a licensed veterinarian."

8       Sec. 12. No person or entity shall distribute, sell,  
9 or offer for sale any veterinary legend drug in this state  
10 without first obtaining a license issued by the department under  
11 the Veterinary Drug Distribution Licensing Act, except that a  
12 veterinarian licensed under the Veterinary Medicine and Surgery  
13 Practice Act acting within the scope of practice of his or  
14 her profession shall not be required to be licensed under the  
15 Veterinary Drug Distribution Licensing Act.

16       Sec. 13. (1) Any person or entity that acts as a  
17 veterinary drug distributor in this state shall obtain a veterinary  
18 drug distributor license from the department prior to engaging in  
19 distribution of veterinary legend drugs in or into this state.

20       (2) An applicant for an initial or renewal license as a  
21 veterinary drug distributor shall file a written application with  
22 the department. The application shall be accompanied by the fee  
23 established by the department pursuant to section 18 of this act  
24 and shall include the following information:

25       (a) The applicant's name, business address, type of

1 business entity, and telephone number. If the applicant is a  
2 partnership, the application shall include the name of each partner  
3 and the name of the partnership. If the applicant is a corporation,  
4 the application shall include the name and title of each corporate  
5 officer and director, all corporate names of the applicant, and  
6 the applicant's state of incorporation. If the applicant is a sole  
7 proprietorship, the application shall include the name of the sole  
8 proprietor, the name of the proprietorship, and the proprietor's  
9 social security number. The social security number shall not be  
10 a public record and may only be used by the department for  
11 administrative purposes;

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

13 (c) The addresses and telephone numbers of all facilities  
14 to be used by the applicant for the storage, handling, and  
15 distribution of veterinary legend drugs and the names of persons  
16 to be in charge of such facilities. A separate license shall be  
17 obtained for each such facility;

18 (d) A listing of all licenses, permits, or other  
19 similar documentation issued to the applicant in any other state  
20 authorizing the applicant to purchase, possess, and distribute  
21 veterinary legend drugs;

22 (e) The names and addresses of the owner of the  
23 applicant's veterinary legend drug distribution facilities, a  
24 designated representative at each such facility, and all managerial  
25 employees at each such facility; and

1           (f) Other information as required by the department,  
2 including affirmative evidence of the applicant's ability to comply  
3 with the Veterinary Drug Distribution Licensing Act and the rules  
4 and regulations adopted under the act.

5           (3) The application shall be signed by:

6           (a) The owner, if the applicant is an individual or  
7 partnership;

8           (b) The member, if the applicant is a limited liability  
9 company with only one member, or two of its members, if the  
10 applicant is a limited liability company with two or more members;  
11 or

12           (c) Two of its officers, if the applicant is a  
13 corporation.

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

18           Sec. 14. A veterinary drug distributor shall establish,  
19 maintain, and adhere to written policies and procedures for  
20 the receipt, storage, security, inventory, and distribution of  
21 veterinary legend drugs, including policies and procedures for  
22 identifying, recording, and reporting destruction, losses, or  
23 thefts of veterinary legend drugs and for correcting all errors and  
24 inaccuracies in inventories. The policies shall contain a provision  
25 for annual review at which time the policies shall be updated

1 as necessary. A record documenting the review shall be kept with  
2 the policies and procedures and shall indicate the date of the  
3 review and the signature of the designated representative of the  
4 veterinary drug distributor.

5           Sec. 15. To enable the establishment of distribution of  
6 veterinary legend drugs in this state, the department may issue a  
7 provisional license on or before July 1, 2009, to any applicant who  
8 meets the following conditions:

9           (1) The applicant has not been found to have committed  
10 any of the acts or offenses described in section 17 of this act;

11           (2) The applicant has established written policies and  
12 procedures as required by section 14 of this act; and

13           (3) The applicant has paid a fee of five hundred dollars.

14           Sec. 16. The department may waive requirements under  
15 sections 12 to 15 of this act upon proof satisfactory to  
16 the department that such requirements are duplicative of other  
17 requirements of Nebraska laws, rules, or regulations and that the  
18 granting of such waiver will not endanger the public safety.

19           Sec. 17. (1) A veterinary drug distributor license may  
20 be denied, refused renewal, suspended, limited, or revoked by the  
21 Director of Public Health if he or she finds that the applicant  
22 or licensee; the designated representative; the owner if a sole  
23 proprietorship; or any person having an interest in the applicant  
24 or licensee of more than ten percent has been found to have  
25 committed any of the following acts or offenses:

1           (a) Violation of the Veterinary Drug Distribution  
2 Licensing Act or the rules and regulations adopted and promulgated  
3 under the act;

4           (b) Conviction of a misdemeanor or felony under state  
5 law, federal law, or the law of another jurisdiction which, if  
6 committed within this state, would have constituted a misdemeanor  
7 or felony under state law and which has a rational connection with  
8 the person's capacity to distribute veterinary legend drugs;

9           (c) Unprofessional conduct under the Uniform  
10 Credentialing Act;

11           (d) Active addiction as defined in section 38-106;

12           (e) Permitting, aiding, or abetting veterinary drug  
13 distribution or the performance of activities requiring a license  
14 under the Veterinary Drug Distribution Licensing Act by a person  
15 not licensed under the Veterinary Drug Distribution Licensing Act;

16           (f) Having had his or her credential denied, refused  
17 renewal, limited, suspended, or revoked or having had such  
18 credential disciplined in any other manner by another jurisdiction  
19 relating to the performance of veterinary drug distribution;

20           (g) Performing veterinary drug distribution without a  
21 valid license or in contravention of any limitation placed upon the  
22 license; or

23           (h) Fraud, forgery, or misrepresentation of material  
24 facts in procuring or attempting to procure a license under the  
25 Veterinary Drug Distribution Licensing Act.



1           (2) The department shall issue or renew a license to any  
2 applicant that satisfies the requirements for licensure or license  
3 renewal under the Veterinary Drug Distribution Licensing Act.

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

7           (2) License fees shall include (a) a base fee of fifty  
8 dollars and (b) an additional fee of not more than five hundred  
9 dollars based on variable costs to the department of inspections  
10 and of receiving and investigating complaints, other similar direct  
11 and indirect costs, and other costs of administering the act as  
12 determined by the department. If an application under the act is  
13 denied, the license fee shall be returned to the applicant, except  
14 that the department may retain up to twenty-five dollars as an  
15 administrative fee and may retain the entire license fee if an  
16 inspection has been completed prior to such denial.

17           (3) The department shall also collect a fee established  
18 by the department, not to exceed the actual cost to the department,  
19 for reinstatement of a license that has lapsed or has been  
20 suspended or revoked. The department shall collect a fee of ten  
21 dollars for a duplicate original license.

22           (4) The department shall remit all license fees collected  
23 under the act to the State Treasurer for credit to the Health and  
24 Human Services Cash Fund. License fees collected under this section  
25 shall only be used for activities related to the licensure of

1 veterinary drug distributors.

2           Sec. 19. A veterinary drug distributor license shall  
3 expire on July 1 of each odd-numbered year and may be renewed.  
4 The license shall not be transferable. The department shall mail  
5 an application for renewal to each licensee not later than May 15  
6 of the year the license expires. If an application for renewal is  
7 received from the licensee after July 1, the department may impose  
8 a late fee and shall refuse to issue the license until such late  
9 fee and renewal fee are paid. Failure to receive an application for  
10 renewal shall not relieve the licensee from the late fee imposed by  
11 this section.

12           Sec. 20. (1) Except as otherwise provided in section 15  
13 of this act, each veterinary drug distributor transacting commerce  
14 in this state shall be inspected by the department prior to the  
15 issuance of an initial or renewal license by the department under  
16 the Veterinary Drug Distribution Licensing Act.

17           (2) The department may provide in rules and regulations  
18 for the inspection of any veterinary drug distributor licensed in  
19 this state in such manner and at such times as the department  
20 determines. As part of any such inspection, the department may  
21 require an analysis of suspected veterinary legend drugs to  
22 determine authenticity.

23           (3) For applicants not located in this state, the  
24 department may accept an inspection which was accepted for  
25 licensure by another state in which the applicant is licensed

1 or by a nationally-recognized accreditation program in lieu of an  
2 inspection by the department under this section.

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

7 (5) The department may adopt and promulgate rules  
8 and regulations which permit the use of alternative methods  
9 for assessing a licensee's compliance with the Veterinary Drug  
10 Distribution Licensing Act and the rules and regulations adopted  
11 and promulgated under the act.

12 Sec. 21. (1) A veterinary drug distributor transacting  
13 commerce in this state shall establish and maintain accurate  
14 records of all transactions regarding the receipt and distribution  
15 or other disposition of veterinary legend drugs as provided in the  
16 Veterinary Drug Distribution Licensing Act.

17 (2) All records of receipt, distribution, or other  
18 disposal of veterinary legend drugs shall be available to the  
19 department upon request for inspection, copying, verifying, or  
20 other proper use.

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

25 (4) Records kept at a central location that can be

1 retrieved by computer or other electronic means shall be readily  
2 available for authorized inspection during the inspection period.

3           Sec. 22. A veterinary drug distributor may distribute  
4 veterinary legend drugs to:

5           (1) A licensed veterinarian or to another veterinary drug  
6 distributor subject to the requirements of section 21 of this act;  
7 and

8           (2) A layperson responsible for the control of an animal  
9 if:

10           (a) A licensed veterinarian has issued, prior  
11 to such distribution, a veterinary drug order for the  
12 veterinary legend drug in the course of an existing, valid  
13 veterinarian-client-patient relationship;

14           (b) At the time the veterinary legend drug leaves the  
15 licensed location of the veterinary drug distributor, those in the  
16 employ of the veterinary drug distributor possess a copy of the  
17 veterinary drug order for the veterinary legend drug;

18           (c) The original veterinary drug order is retained on  
19 the premises of the veterinary drug distributor or an authorized  
20 central location for three years after the date of the last  
21 transaction affecting the veterinary drug order and includes the  
22 following information:

23           (i) Client name;

24           (ii) Veterinarian name;

25           (iii) Veterinary legend drug sold or delivered;

- 1           (iv) Quantity of the veterinary legend drug;  
2           (v) Date of issue of veterinary drug order; and  
3           (vi) Expiration date of veterinary drug order;

4           (d) All veterinary legend drugs distributed on the  
5 veterinary drug order of a licensed veterinarian are sold in  
6 the original, unbroken manufacturer's containers; and

7           (e) The veterinary legend drugs, once distributed, are  
8 not returned to the veterinary drug distributor for resale or  
9 redistribution.

10           Nothing contained in Nebraska statutes governing the  
11 practice of pharmacy shall be construed to prohibit a veterinary  
12 drug distributor from selling or otherwise distributing a  
13 veterinary legend drug pursuant to a veterinary drug order  
14 by a veterinarian licensed in this state and, when a valid  
15 veterinarian-client-patient relationship exists, to the layperson  
16 responsible for the control of the animal.

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

21           Sec. 23. A veterinary drug distributor shall not:

22           (1) Operate from a place of residence;

23           (2) Possess, sell, purchase, trade, or otherwise furnish  
24 controlled substances; and

25           (3) Possess, sell, purchase, trade, or otherwise furnish

1 human legend drugs.

2           Sec. 24. The department, the Attorney General, or any  
3 county attorney may institute an action in the name of the state  
4 for an injunction or other process against any person to restrain  
5 or prevent any violation of the Veterinary Drug Distribution  
6 Licensing Act or any rules and regulations adopted and promulgated  
7 under the act.

8           Sec. 25. It is unlawful for any person to commit or to  
9 permit, cause, aid, or abet the commission of any of the following  
10 acts in this state:

11           (1) Any violation of the Veterinary Drug Distribution  
12 Licensing Act or rules and regulations adopted and promulgated  
13 under the act;

14           (2) Providing the department, any of its representatives,  
15 or any federal official with false or fraudulent records or making  
16 false or fraudulent statements regarding any matter under the act;

17           (3) Obtaining or attempting to obtain a veterinary legend  
18 drug by fraud, deceit, or misrepresentation or engaging in the  
19 intentional misrepresentation or fraud in the distribution of a  
20 veterinary legend drug;

21           (4) Except for the distribution by manufacturers of  
22 a veterinary legend drug that has been delivered into commerce  
23 pursuant to an application approved under federal law by the  
24 federal Food and Drug Administration, the manufacture, repackaging,  
25 sale, transfer, delivery, holding, or offering for sale of

1 any veterinary legend drug that is adulterated, misbranded,  
2 counterfeit, suspected of being counterfeit, or otherwise rendered  
3 unfit for distribution;

4 (5) Except for the wholesale distribution by  
5 manufacturers of a veterinary legend drug that has been  
6 delivered into commerce pursuant to an application approved under  
7 federal law by the federal Food and Drug Administration, the  
8 adulteration, misbranding, or counterfeiting of any veterinary  
9 legend drug;

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

14 (7) The alteration, mutilation, destruction,  
15 obliteration, or removal of the whole or any part of the labeling  
16 of a veterinary legend drug or the commission of any other act with  
17 respect to a veterinary legend drug that results in the veterinary  
18 legend drug being misbranded;

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

23 (9) Prohibiting or otherwise impeding access, during  
24 normal business hours, to any paper or electronic records or any  
25 premises, facility, area, or location to which access is authorized

1 by the act.

2           Sec. 26. (1) Upon issuance of a final disciplinary action  
3 against a person who knowingly and intentionally violates any  
4 provision of section 25 of this act other than as provided in  
5 subsection (2) of this section, the department shall assess a fine  
6 of one thousand dollars against such person. For each subsequent  
7 final disciplinary action for violation of such section issued by  
8 the department against such person, the department shall assess a  
9 fine of one thousand dollars plus one thousand dollars for each  
10 final disciplinary action for violation of such section previously  
11 issued against such person, not to exceed ten thousand dollars.

12           (2) Upon issuance of a final disciplinary action against  
13 a person who fails to provide an authorized person the right of  
14 entry provided in section 25 of this act, the department shall  
15 assess a fine of five hundred dollars against such person. For  
16 each subsequent final disciplinary action for such failure issued  
17 against such person, the department shall assess a fine equal to  
18 one thousand dollars times the number of such disciplinary actions,  
19 not to exceed ten thousand dollars.

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

23           Sec. 27. (1) If the department finds there is a  
24 reasonable probability that (a) a veterinary drug distributor  
25 has knowingly and intentionally falsified documents relevant to the



1 purchase, sale, or distribution of veterinary legend drugs or has  
2 sold, distributed, transferred, manufactured, repackaged, handled,  
3 or held a counterfeit veterinary legend drug and (b) such drug  
4 could cause serious, adverse health consequences or death, the  
5 department may issue an order to immediately cease distribution of  
6 such drug.

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

13 Sec. 28. The department may adopt and promulgate rules  
14 and regulations to carry out the Veterinary Drug Distribution  
15 Licensing Act.

16 Sec. 29. Any person who knowingly and intentionally  
17 engages in distribution of veterinary legend drugs in this state  
18 in violation of the Veterinary Drug Distribution Licensing Act is  
19 guilty of a Class III felony.

20 Sec. 30. This act becomes operative on December 1, 2008.