

**ONE HUNDREDTH LEGISLATURE - SECOND SESSION -
2008**

COMMITTEE STATEMENT

LB1022

Hearing Date: February 22, 2008

Committee On: Health and Human Services

Introducer(s): (Hansen)

Title: Adopt the Veterinary Drug Distribution Licensing Act

Roll Call Vote - Final Committee Action:

Placed on General File with Amendments

Vote Results:

7 Yes	Senators Erdman, Gay, Hansen, Howard, Johnson, Pankonin, Stuthman
0 No	
0 Absent	
0 Present, not voting	

Proponents:

Duane Gangwish
Larry L. Williams
Elaine Lust
Ryan Loseke

Representing:

Nebraska Cattlemen
Nebraska Veterinary Medical Association
Professional Veterinary Products Ltd.
Nebraska Cattlemen

Opponents:

Representing:

Neutral:

Dan Upson
Richard Hedrick
Joni Cover

Representing:

Self and Nebraska Cattlemen
Self
Nebraska Pharmacists Association

Summary of purpose and/or change:

LB 1022 adopts the Veterinary Drug Distribution Licensing Act (act). The bill defines terms (sections 1-12).

Licensure (sections 13-20)

The bill requires licensure by the Department of Health and Human Services (department) before any person or entity may distribute, sell, or offer for sale any veterinary legend drug in the State of Nebraska.

Any person, partnership, corporation, business entity, or other entity located in Nebraska or any other location that acts as a veterinary drug distributor is required to obtain a veterinary drug distributor license from the department prior to engaging in distribution of veterinary legend drugs in or into Nebraska.

An application for licensure must be filed with the department and accompanied by a fee established by the department. Information required on the application is prescribed. The department is required to issue or renew a license to any applicant that satisfies the requirements for licensure or license renewal. A veterinary drug distributor license expires on July 1 of each odd-numbered year, may be renewed, and is not transferable.

License fees include (a) a base fee of \$50 and (b) an additional fee of not more than \$500 based on variable costs to the department of inspections and of receiving and investigating complaints, other similar direct and indirect costs, and other costs of administering the act as determined by the department. If an application under the act is denied, the license fee must be returned to the applicant, but the department may retain up to \$25 as an administrative fee and may retain the entire license fee if an inspection has been completed prior to the denial. The department must also collect a fee for reinstatement of a license that has lapsed or has been suspended or revoked, and a fee of \$10 for a duplicate original license.

A licensed veterinary drug distributor may purchase, possess, or otherwise acquire veterinary legend drugs.

A veterinary drug distributor must establish, maintain, and adhere to written policies and procedures for the receipt, storage, security, inventory, and distribution of veterinary legend drugs. The policies must also provide for an annual review, and a record documenting such review must be kept and signed by the licensee.

The department may issue a temporary veterinary drug distributor license upon conditions and for periods of time as the department determines to be in the public interest. The department must establish a temporary license fee at an amount not to exceed the annual fee for renewal of a license as a veterinary drug distributor.

The department may waive licensure requirements upon proof satisfactory to the department that the requirements duplicate other requirements of Nebraska laws, rules, or regulations and that the granting of the waiver will not endanger the public safety.

The bill provides for discipline of a veterinary drug distributor license by the Director of Public Health if he or she finds that the applicant or licensee has violated any provisions of the act or rules and regulations adopted under the act.

The department may deny or restrict the application for a veterinary drug distributor license if the applicant has been convicted of a criminal violation of the act, Nebraska statutes governing the practice of pharmacy, or the federal Food, Drug, and Cosmetic Act.

The department may deny or restrict the application for a veterinary drug distributor license if the applicant has been convicted in another state of a criminal violation of the laws of the other state governing veterinary drug distribution or the practice of pharmacy or the federal Food, Drug, and Cosmetic Act.

Inspections (section 21)

The bill requires every veterinary drug distributor transacting commerce in Nebraska to be inspected by the department prior to the issuance of an initial or renewal license. The department may provide for other inspections of licensed veterinary drug distributors in rules and regulations. As part of any such inspection, the department may require an analysis of suspected veterinary legend drugs to determine authenticity. For applicants not located in Nebraska, the department may accept an inspection which was accepted for licensure by another state in which the applicant is licensed or by a nationally-recognized accreditation program in lieu of an inspection by the department. The department may establish and collect fees for inspection activities, which may not exceed the department's actual cost for such activities.

The department may adopt and promulgate rules and regulations to permit the use of alternative methods for assessing a licensee's compliance with the act.

Records (section 22)

A veterinary drug distributor transacting commerce in Nebraska must establish and maintain accurate records of all transactions regarding the receipt and distribution or other disposition of veterinary legend drugs as provided in the act. All records of receipt, distribution, or other disposal of veterinary legend drugs must be available to the department upon request for inspection, copying, verifying, or other proper use. If a veterinary drug distributor is authorized by the department to maintain records at a central location, such records must be made available for authorized inspections within forty-eight hours. Records kept at a central location that can be retrieved by computer or other electronic means must be readily available for authorized inspection during the inspection period.

Distribution of veterinary legend drugs (section 23)

A veterinary drug distributor may distribute veterinary legend drugs to: (1) a licensed veterinarian or to another veterinary drug distributor; and (2) a layperson responsible for the control of an animal, under prescribed conditions.

If all federal labeling requirements are met, labeling provisions of Nebraska laws governing the practice of pharmacy will not apply to veterinary legend drugs distributed pursuant to the act.

Prohibited acts (sections 24, 26)

A veterinary drug distributor may not: (1) operate from a place of residence; (2) possess, sell, purchase, trade, or otherwise furnish controlled substances; and (3) possess, sell, purchase, trade, or otherwise furnish human legend drugs (section 24).

The bill makes it unlawful for any person to commit or to permit, cause, aid, or abet the commission of any of the following acts (section 26): (1) any violation of the act or rules and regulations adopted and promulgated under the act;

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

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

(4) the manufacture, repackaging, sale, transfer, delivery, holding, or offering for sale of any veterinary legend drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or otherwise rendered unfit for distribution, with exceptions;

(5) the adulteration, misbranding, or counterfeiting of any veterinary legend drug, with exceptions;

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

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

(8) for the purposes of the act, the manufacture, repackaging, sale, transfer, delivery, holding, possessing or offering for sale, trade, or any other form of dissemination, any controlled substance; and

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

Injunction, fines (sections 25, 27)

The department, the Attorney General, or any county attorney may institute an action in the name of the state for an injunction or other process against any person to restrain or prevent any violation of the act or any rules and regulations adopted and promulgated under the act.

The department must assess a fine of \$1,000 upon the issuance of a final disciplinary action against a person who knowingly and intentionally violates any of the provisions of section 26, except for subsection (9). The department must assess a fine of \$1,000, for each subsequent violation, plus \$1,000 for each previous action for a violation, not to exceed \$10,000.

The department must assess a fine of \$500 upon the issuance of a final disciplinary action against a person who fails to provide an authorized right of entry as provided in subsection (9) of section 26. For each subsequent action for such failure,

the department must assess a fine equal to \$1,000 times the number of such actions, not to exceed \$10,000.

The bill permits the department to issue an order to immediately cease distribution of a drug and provides condition under which such an order may be issued. Notice and an opportunity for hearing must be provided. The department must vacate the order if it determines, after the hearing, that inadequate grounds exist to support the actions required by the order.

Rules and regulations (section 29)

The department may adopt and promulgate rules and regulations to carry out the act.

Criminal penalties (section 30)

Any person who knowingly and intentionally engages in distribution of veterinary legend drugs in Nebraska in violation of the act is guilty of a Class III felony.

Explanation of amendments, if any:

The committee amendment (AM 2085) makes technical changes and rewrites two sections of the bill. The amendment rewrites section 16 of the bill relating to provisional licensure, and section 18 relating to the denial, refusal to renew, suspension, limitation, or revocation of a veterinary drug distributor license, and grounds for such action. The amendment also clarifies that a veterinarian licensed under the Veterinary Medicine and Surgery Practice Act acting within his or her scope of practice is not required to be licensed under the Veterinary Drug Distribution Act.

Senator Joel Johnson, Chairperson