LEGISLATIVE BILL 1022

Approved by the Governor April 21, 2008

Introduced by Hansen, 42; Christensen, 44.

FOR AN ACT relating to public health and welfare; to adopt the Veterinary Drug Distribution Licensing Act; to provide a penalty; and to provide an operative date.

Be it enacted by the people of the State of Nebraska,

Section 1. Sections 1 to 29 of this act shall be known and may be cited as the Veterinary Drug Distribution Licensing Act.

Sec. 2. The purpose of the Veterinary Drug Distribution Licensing Act is to protect the public health, safety, and welfare by providing for the authorization and licensure of veterinary drug distributors in the State of Nebraska and for the development, establishment, and enforcement of basic standards for such distributors.

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

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

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

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

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

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

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

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

Sec. 10. Veterinary drug order means a lawful order or prescription of a veterinarian licensed to practice in this state, which order or prescription is issued pursuant to a bona fide veterinarian-client-patient relationship.

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

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

Sec. 13. (1) Any person or entity that acts as a veterinary drug

distributor in this state shall obtain a veterinary drug distributor license from the department prior to engaging in distribution of veterinary legend drugs in or into this state.

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

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

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

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

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

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

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

(3) The application shall be signed by:

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

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

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

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

Sec. 14. A veterinary drug distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, storage, security, inventory, and distribution of veterinary legend drugs, including policies and procedures for identifying, recording, and reporting destruction, losses, or thefts of veterinary legend drugs and for correcting all errors and inaccuracies in inventories. The policies shall contain a provision for annual review at which time the policies shall be updated as necessary. A record documenting the review shall be kept with the policies and procedures and shall indicate the date of the review and the signature of the designated representative of the veterinary drug distributor.

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

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

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

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

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

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

(a) Violation of the Veterinary Drug Distribution Licensing Act or

the rules and regulations adopted and promulgated under the act;

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

(c) Unprofessional conduct under the Uniform Credentialing Act;

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

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

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

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

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

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

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

(2) License fees shall include (a) a base fee of fifty dollars and (b) an additional fee of not more than five hundred dollars 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 shall be returned to the applicant, except that the department may retain up to twenty-five dollars as an administrative fee and may retain the entire license fee if an inspection has been completed prior to such denial.

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

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

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

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

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

(3) For applicants not located in this state, 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 under this section.

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

(5) The department may adopt and promulgate rules and regulations which permit the use of alternative methods for assessing a licensee's

compliance with the Veterinary Drug Distribution Licensing Act and the rules and regulations adopted and promulgated under the act.

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

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

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

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

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

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

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

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

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

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

(i) Client name;

(ii) Veterinarian name;

(iii) Veterinary legend drug sold or delivered;

(iv) Quantity of the veterinary legend drug;

(v) Date of issue of veterinary drug order; and

(vi) Expiration date of veterinary drug order;

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

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

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

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

Sec. 23. A veterinary drug distributor shall 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.

Sec. 24. 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 Veterinary Drug Distribution Licensing Act or any rules and regulations adopted and promulgated under the act.

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

(1) Any violation of the Veterinary Drug Distribution Licensing 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) Except for the distribution by manufacturers of a veterinary legend drug that has been delivered into commerce pursuant to an application approved under federal law by the federal Food and Drug Administration, 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;

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

(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 purposes of the Veterinary Drug Distribution Licensing 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, to any paper or electronic records or any premises, facility, area, or location to which access is authorized by the act.

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

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

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

Sec. 27. (1) If the department finds there is a reasonable probability that (a) a veterinary drug distributor has knowingly and intentionally falsified documents relevant to the purchase, sale, or distribution of veterinary legend drugs or has sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit veterinary legend drug and (b) such drug could cause serious, adverse health consequences or death, the department may issue an order to immediately cease distribution of such drug.

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

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

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

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