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# NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 875
VETERINARY MEDICAL EXAMINING BOARD

**FILED**
05/04/2021 11:21 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Minimum Standards for Veterinary Drugs

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 08/20/2021 3:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Portland,OR 97232

Filed By:
Brenda Biggs
Rules Coordinator

HEARING(S)

*Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 08/20/2021
TIME: 10:30 AM
OFFICER: Brenda Biggs
ADDRESS: Oregon Veterinary Medical Examining Board
800 NE Oregon Street
NE Oregon Street
Portland, OR 97232
SPECIAL INSTRUCTIONS:
Per Governor Kate Brown's Executive Order 20-12, the Portland State Office Building remains closed to the public. The public hearing will be held virtually via zoom meeting only.
Please contact the Hearings Officer for details on attending the public hearing or to register to speak at the public hearing.

NEED FOR THE RULE(S):

Amending to clarify "Pharmacy" self-inspection checklist; Amending to require pharmacy inspection checklist as part of registration; Amended to include all prescription labeling requirements here; Amended separating facility and managing veterinarian responsibilities from responsibilities of all licensees; Amended to include that it is the Managing Veterinarian responsibility to ensure that all agents, licensees, and employees of the facility are in compliance with this rule.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

OAR 875
Available on the Oregon Veterinary Board Website: https://www.oregon.gov/ovmeb/Pages/practice-act.aspx
Available on the Oregon Secretary of State Website:
https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=875

FISCAL AND ECONOMIC IMPACT:

No fiscal or economic impact as changes are only to clarify and organize the existing rules.

COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

No fiscal or economic impact as changes are only to clarify and organize the existing rules.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

None - No fiscal or economic impact as changes are only to clarify and organize the existing rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

No fiscal or economic impact as changes are only to clarify and organize the existing rules.

AMEND: 875-015-0040

RULE SUMMARY: Amending to clarify “Pharmacy” self-inspection checklist; Amending to require pharmacy inspection checklist as part of registration; Amended to include all prescription labeling requirements; Amended separating facility and managing veterinarian responsibilities from responsibilities of all licensees; Amended to include that it is the Managing Veterinarian responsibility to ensure that all agents, licensees, and employees of the facility are in compliance with this rule.

CHANGES TO RULE:

875-015-0040
Minimum Standards for Veterinary Drugs
(1) Definitions:¶
(a) Administer' means the direct application of a drug or device whether by injection, inhalation, ingestion or any other means, to the body of an animal patient by:¶
(A) A veterinarian, Certified Veterinary Technician or employee under the veterinarian's supervision; or¶
(B) A client or their authorized agent at the direction of the veterinarian.¶
(b) Dispense' or Dispensing' means, under a lawful prescription of a veterinarian, the preparation and delivery of a prescription drug, in a suitable container appropriately labeled for subsequent veterinary patient administration, to a client or other individual entitled to receive the prescription drug. Controlled substances and legend drugs shall be dispensed, ordered or prescribed based on a VCPR.~~¶~~
~~(2) Policies and Procedures. The veterinary facility¶~~
(c) "Pharmacy Self-Inspection Form": The Oregon Veterinary Medical Examining Board Dispensing Practitioner Drug Outlet Self-Inspection form. The pharmacy self-inspection form will be available from the Board on its website or upon request.¶
(2) Policies and Procedures, Acquisition and Inspection: The veterinary facility and managing veterinarian must:~~¶~~

(a) Maintain written policies and procedures for drug procurement and management, including storage, security, integrity, access, dispensing, disposal, record-keeping and accountability; and¶
(b) Comply with all federal and state laws regarding veterinary drugs.¶
(3) Drug Security and Storage: ¶
(b) All records of receipt and disposal of drugs must be retained for a minimum of three years;¶
(c) All records required by these rules or by other state or federal law must be readily retrievable and available for inspection by the Board's inspector or inspectors from other agencies having jurisdiction;¶
(d) The veterinary facility and managing veterinarian must verify that prescription drugs are acquired from a source registered with the Board of Pharmacy;¶
(e) Inspection: Veterinary facilities will be periodically inspected to ensure compliance with these rules. The Managing Veterinarian of a veterinary facility must annually complete the pharmacy self-inspection form. The completed pharmacy self-inspection form shall be submitted with the application for a veterinary facility license and with the annual application to renew a veterinary facility license. All drug records and storage areas shall be made available for inspection.¶
(f) Managing veterinarians are responsible for ensuring that all licensees, agents and employees of the facility, and the facility as applicable, maintain compliance with the rules and regulations set forth in section (3) or this rule.¶
(3) Drug Dispensing, Security, Storage and Recordkeeping: All licensees, managing veterinarians and faciltiies must:¶
(a) Comply with all federal and state laws regarding veterinary drugs.¶
(ab) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. Controlled drugs must be kept in a locked cabinet with access limited to persons authorized by the Managing Veterinarian.;¶
(bc) In accordance with 21 CFR 1301.75, controlled substances listed in Schedule I, II III, IV and IV shall be stored in a securely locked, substantially constructed cabinet.¶
(4d) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to the supplier;¶
(e) All drugs, including drug samples, must be stored according to manufacturer's published guidelines and in appropriate conditions of temperature, light, humidity, sanitation, ventilation and space.¶
(5f) Prescription Labeling. A prescription must be labeled with the following information:¶
(aA) Name of patclient;¶
(bB) Name of prescriber;-¶
(cC) Name, address, and phone number of the facility;¶
(dD) Identification of the animal, herd or flock, (if appropriate);¶
(E) Date of dispensing;¶
(eF) Name and strength of the drug;¶
(fG) Quantity dispensed;¶
(g)H) Dosage and frequency;¶
(I) Withdrawal time, (if appropriate);¶
(J) Any other Directions for use;¶
(hK) Manufacturer's expiration date, or an earlier date if preferable, after which the drug should not be administered to the patient; and¶
(iL) Cautionary information as required for patient safety and required precautionary information regarding controlled substances:-In accordance with 21 CFR 290.5, the label of any drug listed as a 'controlled substance' in Schedule II, III or IV of the Federal Controlled Substances Act must, when dispensed to or for a patient, contain the following warning:-"Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are 'blind.'¶
(6g) Dispensing and Drug Delivery:¶
(aA) The veterinarian or their representative must orally counsel the client concerning all new drugs prescribed,

unless circumstances would render oral counseling ineffective.¶
(~~b~~B) If requested, a prescription shall be provided to a client for drugs and medications prescribed by the veterinarian under a valid VCPR.¶
(~~c~~C) Rabies vaccine shall be administered only by an Oregon-licensed veterinarian, a Certified Veterinary Technician under direct supervision of an Oregon-licensed veterinarian, or a person authorized by the Oregon Public Health Veterinarian pursuant to OAR 333-019-0017.¶
(~~d~~D) Drugs must be dispensed in a new container that complies with the current provisions of the Federal Consumer Packaging Act (~~Public Law 91-601, 91st Congress, S. 216~~216 CFR 500) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.¶
(~~7~~E) Disposal of Drugs: Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to the supplier. At the discretion of the veterinarian, outdated drugs may be dispensed as long as the client is informed and there is no fee charged for the drugs.¶
(~~8~~h) Record Keeping~~¶~~
: (a) For all drugs, a dispensing record must be maintained separately from the patient chart and retained for a minimum of three years. The record must show, at a minimum, the following:¶
(A) Name of patient;¶
(B) Dose, dosage form, quantity dispensed;¶
(C) Directions for use;¶
(D) Date of dispensing; and¶
(E) Name of person dispensing the prescription.~~¶~~
~~(b) All records of receipt and disposal of drugs must be retained for a minimum of three years.¶~~
~~(c) All records required by these rules or by other state or federal law must be readily retrievable and available for inspection by the Board's inspector or inspectors from other agencies having jurisdiction.¶~~
~~(9) Drug Acquisition: The veterinary facility must verify that prescription drugs are acquired from a source registered with the Board of Pharmacy.¶~~
~~(10) Inspection: Veterinary facilities will be periodically inspected to ensure compliance with these rules. The Managing Veterinarian of a veterinary facility must annually complete and maintain the self-inspection form prior to inspection, and must make all drug records and storage available for inspection. The self-inspection form will be available from the Board on its website or upon request.~~
Statutory/Other Authority: ORS ~~686.210,~~ 686.040, ORS 686.370, ors 686.130
Statutes/Other Implemented: ORS 686.~~210,~~120, ORS 686.040, ORS 686.370, ors 686.130