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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/21/2019 3:11 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Revises Animal Euthanasia Drug Outlet requirements, adds sedatives and analgesic medications and expectations.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2019 4:30 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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Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

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

DATE: 11/26/2019

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Portland State Office

Building - Conf. Rm 1A

800 NE Oregon St.

Portland, OR 97232

NEED FOR THE RULE(S):

Revisions to Division 080 – Controlled Substances are provided to address directives of 2019 SB 71, which add sedatives and analgesic medications for use by a humane society or animal control agency personnel to humanely euthanize injured, sick, homeless or unwanted domestic pets and other animals. Registration with the Board as an Animal Euthanasia Drug Outlet will permits the utilization of a limited number of sedative and analgesic drugs for these purposes. Drug outlet expectations for drugs being administered on-site include: (1) Proper acquisition of drugs, from Oregon registered distributors; (2) Proper and secure drug storage; and (3) Documentation. Record keeping requirements related to controlled substances must comply with all related federal and state regulations and are subject to state and federal regulatory oversight. Many sedative and analgesic drugs have a high abuse potential therefore an outlet's record keeping must be robust.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 SB 71

FISCAL AND ECONOMIC IMPACT:

Any humane society or animal control agency that euthanizes animals must be registered by the Board of Pharmacy as a

drug outlet and comply with requirements, including: drug storage, record keeping, completion of self inspection report and reporting all controlled substance drug losses.

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).

There are currently 28 local animal control agencies or humane societies registered with the Board. Some are public entities and some may be considered small business.

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

Small businesses were not involved in the development of these rules.

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

The Board worked with the Oregon State Veterinary Medical Examining Board and the Oregon Veterinary Medical Association to incorporate the changes in 2019 SB 71.

AMEND: 855-080-0100

RULE SUMMARY: Rules are revised to incorporate 2019 SB 71 which adds sedatives and analgesic medications for use by a humane society or animal control agency personnel to humanely euthanize injured, sick, homeless or unwanted domestic pets and other animals.

CHANGES TO RULE:

855-080-0100

Animal Euthanasia ¶

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or registration renewed to allow the purchase, possession and administration of sodium pentobarbital and sedative and analgesic medications for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:¶

(a) ~~Storage. All supplies of sodium pentobarbital shall be~~ Registration. Registration as an animal euthanasia drug outlet is limited to animal control agencies and humane societies for the purpose of purchasing, possessing, or administering sodium pentobarbital and sedative and analgesic medications to euthanize animals. The outlet must identify and provide to the Oregon Board of Pharmacy via application, a designated representative who will serve as the primary contact person responsible for managing the outlet operations. The outlet shall notify the Board within 15 days of any change in designated representative. Registration requires submission of an application and a certificate of registration will be issued upon approval. All registrations and renewals shall be accompanied by an annual fee defined in Division 110 of this Chapter. ¶

(b) Drug Storage. All supplies of sodium pentobarbital and sedative and analgesic medications shall be acquired from an Oregon registered distributor, and kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital and sedative and analgesic medications. Such designated person shall allow access to and withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital and sedative and analgesic medications; ¶

(~~b~~c) Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:¶

- (A) A record of the withdrawal of sodium pentobarbital and sedative and analgesic medications, signed by the person who takes possession of the sodium pentobarbital and sedative and analgesic medications for administration;¶
- (B) A record of the weight, species of animal and dosage of each drug administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;¶
- (C) A record of all wastage of each drug signed by the person administering ~~the~~each drug and the designated person responsible for security; and¶
- (D) A weekly record of verification of the ~~stock~~amount of each drug on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;¶
- (E) A record of disposal of any expired or unwanted sodium pentobarbital and sedative and analgesic medications. Disposal shall be in a-conformance with ~~21 CFR 1307.21~~federal regulations.¶
- ~~(F) Complete the annual Self-Inspection Report by February 1 each year, and retain for Board inspection.¶~~
- ~~(ed) Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the State Board of Pharmacy or its agents.¶~~
- ~~(2) The fee for registration shall be paid as specified in division 110 of this chapter of rules Drug Enforcement Administration (DEA), and Board of Pharmacy or its agents.¶~~
- ~~(2) The outlet shall notify the Board of Pharmacy in the event of a significant drug loss or violation related to drug theft within one (1) business day.¶~~
- ~~(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to the DEA, a copy shall be sent to the Board of Pharmacy.¶~~
- ~~(34) The Board of Pharmacy will suspend or revoke the registration of any humane society or animal control agency animal euthanasia drug outlet which allows a person to administer sodium pentobarbital and sedative or analgesic medications who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.~~

Statutory/Other Authority: ORS 475.095, ORS 475.190, ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, 2019 OL Ch. 126