



# PROPOSED RULE MAKING

## CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

**Agency:** Department of Health- Board of Pharmacy

- Preproposal Statement of Inquiry was filed as WSR 9-11-049 ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310 or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

**Title of rule and other identifying information:** (Describe Subject)

Chapter 246-886 WAC Animal Control legend drug and WAC 246-887-050, 060, and 070 rules regulating the possession, administration and storage of sodium pentobarbital.

**Hearing location(s):** Department of Health  
Point Plaza East Room 152/153  
310 Israel Rd SE  
Tumwater WA 98501

Date: 08/16/2012

Time: 9:30 a.m.

**Submit written comments to:**

Name: Doreen E. Beebe  
Address: Washington State Board of Pharmacy  
P.O. Box 47852  
Olympia WA 98504-7852

e-mail: <http://www3.doh.wa.gov/policyreview/>  
fax (360)236-2901 by (date) 08/13/2012

**Assistance for persons with disabilities:** Contact

Doreen E. Beebe by 08/13/2012

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 08/16/2012

(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The proposed rules update current requirements for training personnel, and the administration and recordkeeping of legend drugs. In addition, the amended rule will standardize training and recordkeeping requirements for sodium pentobarbital, a controlled substance, mirroring the requirements established for approved legend drugs used in euthanizing animals.

**Reasons supporting proposal:**

The proposed rules are needed in order to establish consistent enforceable standards for training, administration, storage, and recordkeeping for the use of approved drugs. The rules update the minimum training parameters for animal euthanasia training to ensure individuals receive adequate training in the proper techniques and understand the potential hazards associated in administration of approved drugs. Standards established for the storage, recordkeeping, and inventory controls of approved drugs are needed to protect the public from drug diversion and misuse.

**Statutory authority for adoption:**

RCW 18.64.005, RCW 69.41.080 and RCW 69.50.310

**Statute being implemented:**

RCW 69.41.080 and RCW 69.50.310

**Is rule necessary because of a:**

- Federal Law?  Yes  No
  - Federal Court Decision?  Yes  No
  - State Court Decision?  Yes  No
- If yes, CITATION:

**DATE** 07/03/12

**NAME** (type or print)  
Steven Saxe

**SIGNATURE**

**TITLE**  
Acting Executive Director

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

**DATE:** July 03, 2012

**TIME:** 2:33 PM

**WSR** 12-14-105

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

None.

**Name of proponent:** (person or organization) Department of Health, Board of Pharmacy

- Private  
 Public  
 Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Doreen E. Beebe	111 Israel Rd SE, Tumwater WA 98501	(360) 236-4834
Implementation.... Steven Saxe	111 Israel Rd SE, Tumwater WA 98501	(360) 236-2902
Enforcement..... Steven Saxe	111 Israel Rd SE, Tumwater WA 98501	(360) 236-2902

**Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?**

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Doreen E. Beebe

Address: Department of Health

Board of Pharmacy

P.O. Box 47852

Olympia WA 98504-7852

phone (360) 236-4834

fax (360) 236-2901

e-mail [wsbop@doh.wa.gov](mailto:wsbop@doh.wa.gov)

No: Please explain:

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 246-887-050	Sodium pentobarbital for animal euthanasia.
WAC 246-887-060	Sodium pentobarbital administration.
WAC 246-887-070	Sodium pentobarbital records and reports.

## Chapter 246-886 WAC

### ANIMAL CONTROL--LEGEND DRUGS AND CONTROLLED SUBSTANCES

AMENDATORY SECTION (Amending Order 191B, filed 8/30/91, effective 9/30/91)

**WAC 246-886-001 Purpose.** The ~~((purpose of))~~ rules in this chapter ~~((shall be to ensure compliance with the law and rules regarding))~~ establish the use of legend drugs and controlled substances for euthanasia by animal control agencies and humane societies ~~((for the sole purpose of sedating animals prior to euthanasia, when necessary)), and ((for use in))~~ chemical capture programs.

AMENDATORY SECTION (Amending Order 191B, filed 8/30/91, effective 9/30/91)

**WAC 246-886-010 Definitions.** ~~((1) "Board": The Washington state board of pharmacy.~~

~~((2))~~ The following definitions apply throughout this chapter unless the context clearly indicates otherwise:

(1) "Animal control agency"((+)) means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

~~((3))~~ (2) "Approved legend drugs" means any legend drug approved by the board for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(3) "Board" means the Washington state board of pharmacy.

(4) "Chemical capture programs" means wildlife management programs registered under RCW 69.50.320 and 69.41.080 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(5) "Controlled substances" means a drug, substance, or immediate precursor in Schedule I through V of Article II of

chapter 69.50 RCW and Schedule I through V of chapter 246-887 WAC.

(6) "Humane society" (A society incorporated and authorized to act under RCW 16.52.020.

(4)) means a nonprofit organization, association, or corporation, the primary purpose of which is to prevent cruelty to animals, place unwanted animals in homes, provide other services relating to "lost and found" pets, and provide animal care education to the public, as well as sponsoring a neutering program to control the animal population.

(7) "Legend drugs" ("Legend drugs") means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.

((5) "Controlled substances": "Controlled substance" means a drug, substance, or immediate precursor in Schedule I through V of Article II of chapter 69.50 RCW.

(6) "Approved legend drug": Any legend drug approved by the board for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.) (8) "Registered entity" means any humane society or animal control agency registered under RCW 69.50.310.

## **HUMANE SOCIETY AND ANIMAL CONTROL AGENCY**

AMENDATORY SECTION (Amending Order 277B, filed 5/28/92, effective 6/28/92)

**WAC 246-886-020 Registration.** (1) Humane societies and animal control agencies registered with the board under RCW 69.50.310 ((and WAC 246-887-050 to)) may purchase, possess, and administer sodium pentobarbital ((as provided therein may also, under that registration, purchase, possess,)) and ((administer)) approved legend drugs as provided in RCW 69.41.080 ((and herein)).

(2) To apply for registration a humane society or animal control agency shall submit to the board a completed application for registration on forms provided by the board.

(3) A registered humane society or animal control agency shall:

(a) Employ at least one individual who has completed a training program described in WAC 246-886-040;

(b) Designate a responsible person as defined in WAC 246-886-060;

(c) Maintain written policies and procedures available for

inspection by the board that includes processes to:

(i) Require completion of approved training as defined in WAC 246-886-040 by each of the agency's agents or personnel who possess, and administer approved legend drugs or sodium pentobarbital, prior to being approved to administer such drugs;

(ii) Establish a system for the secure storage of all drugs to prevent access by unauthorized personnel to guard against theft and diversion;

(iii) Establish a system for accountability of access, use, and stocking of drug inventory;

(iv) Ensure the proper disposal of all drugs in compliance with state and federal laws and rules; and

(v) Establish a method to investigate and report the theft, loss, or diversion of approved legend drugs and sodium pentobarbital, in compliance with state and federal laws and rules.

AMENDATORY SECTION (Amending WSR 94-02-060, filed 1/3/94, effective 2/3/94)

**WAC 246-886-030 Approved legend drugs.** ~~((+1))~~ The following legend drugs are ~~((hereby))~~ designated as "approved legend drugs" for use by registered humane societies or animal control agencies for ~~((limited purposes))~~ pre-euthanasia sedation:

~~((a))~~ (1) Acetylpromazine.

~~((b) Ketamine))~~ (2) Dexmedetomidine.

(3) Medetomidine.

~~((c))~~ (4) Xylazine.

~~((2) A humane society or animal control agency shall not be permitted to purchase, possess, or administer approved legend drugs unless that society or agency:~~

~~(a) Is registered with the board under RCW 69.50.310 and WAC 246-887-050 to purchase, possess, and administer sodium pentobarbital;~~

~~(b) Submits to the board written policies and procedures ensuring that only those of its agents and employees who have completed a board-approved training program will possess or administer approved legend drugs; and~~

~~(c) Has on its staff at least one individual who has completed a board-approved training program.~~

~~(3) The following legend drugs are hereby designated as "approved legend drugs" only for use by agents and biologists of the Washington state department of wildlife: Naltrexone, detomidine, metdetomidine and yohimbine.))~~

NEW SECTION

**WAC 246-886-035 Sodium pentobarbital--Approved controlled substance.** (1) Registered humane societies and animal control agencies may only use sodium pentobarbital to euthanize injured, sick, homeless or unwanted domestic pets, and domestic or wild animals.

(2) Registered humane societies and animal control agencies shall only possess sodium pentobarbital labeled "For veterinary use only."

AMENDATORY SECTION (Amending Order 191B, filed 8/30/91, effective 9/30/91)

**WAC 246-886-040 Training of personnel.** (1) ~~((Approved legend drugs may only be administered by those personnel who have completed a board-approved training program. Such))~~ Personnel of a registered humane society or animal control agency may administer approved legend drugs and sodium pentobarbital if the individual:

(a) Has been approved by the registered entity to administer these drugs; and

(b) Has completed a board-approved training program or training that is substantially equivalent.

(2) Application for approval of a training program~~((shall))~~ must be submitted to the board ~~((for approval no later than thirty days))~~ prior to the initiation of training.

~~((2) Any))~~ (3) A training program ~~((shall))~~ must:

(a) Use a ~~((text))~~ manual approved by the board~~((The board will make available a list of approved texts. Training programs shall))~~ ;

(b) Be at least four hours in length ~~((and shall))~~ ;

(c) Be taught by a licensed veterinarian or by a person who has completed an approved training program taught by a licensed veterinarian~~((Each program shall require that the trainee participate in))~~ ;

(d) Require both didactic and practical training in the use of ~~((these drugs and shall be required to))~~ both approved legend drugs and sodium pentobarbital;

(e) Require a passing score of no less than seventy-five percent on a final examination~~((Training programs shall))~~ ; and

(f) Include, but not be limited to, the following topics:

~~((a))~~ (i) Anatomy and physiology~~((7))~~ ;

(A) Methods of euthanasia;

(B) Routes of drug administration;

(C) Use of sedatives;

(D) Drug dosing;

(E) Use of restraints; and

(F) Process and verification of death;

~~((b))~~ (ii) Pharmacology of the drugs;  
~~((c))~~ (iii) Indications, contraindications, and adverse effects;  
~~((d))~~ (iv) Human hazards;  
~~((e))~~ (v) Disposal of medical waste (needles, syringes, etc.);  
~~((f))~~ (vi) Recordkeeping and security requirements; and  
(vii) Applicable federal and state laws and rules.  
(4) Training programs shall retain a list of persons who have successfully completed the program for a minimum of two years.  
(5) The board shall maintain a registry of approved training programs and manuals. Interested persons may request a copy of the registry by contacting the board.

AMENDATORY SECTION (Amending Order 277B, filed 5/28/92, effective 6/28/92)

**WAC 246-886-060 Responsible individuals.** (1) ~~((Each agency or))~~ A registered humane society ~~((registered in accordance with WAC 246-887-050))~~ or animal control agency shall name a designated individual as the person who ~~((shall be))~~ is responsible for maintaining all records and submitting all reports required by applicable federal or state law or ~~((regulation, including chapter 246-887 WAC))~~ rule.

(2) ~~((This))~~ The designated individual ~~((shall also be))~~ is responsible for the ordering, possession, safe storage, and ~~((utilization))~~ use of the sodium pentobarbital and approved legend drugs.

AMENDATORY SECTION (Amending Order 191B, filed 8/30/91, effective 9/30/91)

**WAC 246-886-080 Recordkeeping and reports.** (1) A registered humane society or animal control agency must use a bound ~~((log book))~~ logbook with consecutively numbered pages ~~((shall be used))~~ to record the receipt, use, and disposition of approved legend drugs and sodium pentobarbital. ~~((No more than))~~ Only one drug ~~((shall))~~ may be recorded on any single page.

(2) The ~~((record shall be in))~~ logbook must have sufficient detail to allow an audit of the drug usage to be performed and must include:

(a) Date and time of administration;

(b) Route of administration;

(c) Identification number or other identifier assigned to the

animal;

(d) Estimated weight of the animal;

(e) Estimated age and breed of the animal;

(f) Name of drug used;

(g) Dose of drug administered;

(h) Amount of drug wasted; and

(i) Initials of the primary person administering the drug.

(3) The logbook may omit subsections (2)(b), (d), and (e) of this section if the information is recorded in other records cross-referenced by the animal identification number or other assigned identifier.

~~((2) All invoices, record books, disposition records, and other records regarding approved legend drugs shall be maintained in a readily retrievable manner for no less than two years.~~

~~(3) All records shall be available for inspection by the state board of pharmacy or any officer who is authorized to enforce this chapter.)~~

(4) Personnel of the registered entity shall document any errors or discrepancies in the drug inventory in the logbook. He or she shall report the findings to the responsible supervisor for investigation.

(5) The registered entity shall report any unresolved discrepancies in writing to the board within seven days, and to the federal Drug Enforcement Administration if the loss includes a controlled substance.

(6) The designated individual, as defined in WAC 246-886-060, shall perform a physical inventory or count of approved legend drugs ((shall be performed and reconciled with the log book no less frequently than)) and sodium pentobarbital every six months. The physical inventory must be reconciled with the logbook.

~~((5) Any discrepancy in the actual inventory of approved legend drugs shall be documented in the log book and reported immediately to the responsible supervisor who shall investigate the discrepancy. Any discrepancy which has not been corrected within seven days shall be reported to the board of pharmacy in writing.~~

~~(6) Any approved))~~ (7) The supervisor or designated individual shall destroy legend drugs ((which has become)) that are unfit for use due to contamination or having passed its expiration date ((shall be destroyed by a supervisor and another staff member. Record of such destruction shall be made)). A second member of the staff shall witness drugs that are destroyed or wasted. The records of the destruction of drugs are documented in the ((log book which shall be signed and dated by)) logbook with the date of the event and signatures of the individuals involved.

(8) A registered entity shall return all unwanted or unused sodium pentobarbital to the manufacturer or destroy them in accordance with the rules and requirements of the board, the federal Drug Enforcement Administration, and the department of ecology.

(9) A registered entity shall maintain a written list of all authorized personnel who have demonstrated the qualifications to possess and administer approved legend drugs, and sodium pentobarbital.

(10) All records of the registered entity shall be available for inspection by the board or any officer who is authorized to enforce this chapter.

(11) The registered entity shall maintain the logbook and other related records for a minimum of two years.

AMENDATORY SECTION (Amending Order 191B, filed 8/30/91, effective 9/30/91)

**WAC 246-886-090 Drug storage and field use.** (1) The registered humane society and animal control agency must store all approved legend drugs (~~((shall be stored))~~) and sodium pentobarbital in a substantially constructed securely locked cabinet or drawer. Only those persons authorized to administer the drugs shall have keys to the storage area (~~((shall be restricted to those persons authorized to administer the drugs. Specifically designated agents and employees of the registrant may possess a supply of approved legend drugs for emergency field use. Such emergency supply shall be stored in a locked metal box securely attached to the vehicle))~~).

(2) The registered entity may designate only the following agents or personnel to possess and administer approved legend drugs and sodium pentobarbital for locations other than the registered location:

(a) Humane officer;

(b) Animal control enforcement officer;

(c) Animal control authority;

(d) Peace officer authorized by the chief of police, sheriff, or county commissioner.

(3) Specially designated agents of the registered entity may possess a supply of approved legend drugs and sodium pentobarbital for emergency field use. Such emergency supply shall be stored in a locked metal box securely attached to the vehicle. The designated agent is responsible for:

(a) The drug inventory present at the beginning of a shift and is present or accounted for at the end of each shift.

(b) Recording all receipts and use of approved legend drugs and sodium pentobarbital from the emergency supply.

AMENDATORY SECTION (Amending Order 191B, recodified as filed 8/30/91, effective 9/30/91)

**WAC 246-886-100 Violations.** The board may suspend or revoke a registration issued under chapter 69.50 RCW if the board

determines that any agent or employee of a registered humane society or animal control agency has purchased, possessed, or administered legend drugs in violation of RCW 69.41.080 or 69.50.310, or this chapter or has otherwise demonstrated inadequate knowledge in the administration of legend drugs. The board's revocation or suspension of a registration (~~as provided herein~~) would restrict the registered entity's ability to use both approved legend drugs and sodium pentobarbital.

## CHEMICAL CAPTURE PROGRAM

### NEW SECTION

**WAC 246-886-180 Approved legend drugs.** The following legend drugs are designated as "approved legend drugs" for use by agents and biologists of the Washington state department of fish and wildlife chemical capture programs:

- (1) Naltrexone;
- (2) Detomidine;
- (3) Metdetomidine; and
- (4) Yohimbine.

### REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-886-070                      Notification.