

WSR 24-07-066

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed March 15, 2024, 1:58 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-21-011.

Title of Rule and Other Identifying Information: Classifying wildlife capture drugs as approved legend drugs for the Washington state department of fish and wildlife (WDFW). The pharmacy quality assurance commission (commission) is proposing to amend WAC 246-945-507 to add four intramammary antibiotics to the list of approved legend drugs in chapter 246-945 WAC in response to a petition request from a veterinarian at WDFW to do so.

Hearing Location(s): On May 2, 2024, at 9:30 a.m., at Capital Region ESD Building, 6005 Tye Drive S.W., Tumwater, WA 98512; or via Zoom # 871 4349 5001. Please download and import the following iCalendar (.ics) fields to your calendar system <https://us02web.zoom.us/join/88256001236> and use the Webinar ID 861 1495 8466. The access options include one-tap mobile US +12532158782,,86114958466# or +16699009128,,86114958466#; or telephone. Dial (for higher quality, dial a number based on your current location) US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799, Webinar ID 861 1495 8466. International numbers available <https://us02web.zoom.us/join/88256001236>

Date of Intended Adoption: May 2, 2024.

Submit Written Comments to: Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview/>, fax 360-236-2901, by April 18, 2024.

Assistance for Persons with Disabilities: Contact Julia Katz, phone 360-502-5058, fax 360-236-2901, TTY 711, email [PharmacyRules@doh.wa.gov](mailto:PharmacyRules@doh.wa.gov), by April 25, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: RCW 69.41.080 authorizes the commission to adopt rules to regulate the purchase, possession, and administration of legend drugs by agencies required to register with the commission under chapter 69.50 RCW for the purpose of chemical capture programs. The commission has designated certain drugs as approved legend drugs for use by WDFW chemical capture programs to uphold the safety and welfare of wildlife. The commission filed a CR-101 for this rule project, on October 5, 2023, under WSR 23-21-011, following a rule petition that was brought forward by a WDFW veterinarian, which cited a United States Food and Drug Administration (FDA) Guidance for Industry (GFI) - GFI #263 - as a forthcoming challenge for WDFW chemical capture programs. GFI #263 changed the approved marketing status for post-capture antibiotics from over-the-counter to prescription.

The commission is proposing to add four drugs to WAC 246-945-507(1) and alphabetize the lists of drugs and substances in WAC 246-945-507(1) and 246-945-507(2). The four added drugs are cephapirin benzathine, penicillin G procaine, ceftiofur hydrochloride, and

hetacillin potassium. Two of the four drugs, ceftiofur hydrochloride and hetacillin potassium, were excluded in the final list of drugs affected by GFI #263. The commission approved draft language including all four drugs on December 14, 2023. The proposed rules will allow authorized WDFW employees to use the four legend drugs without each authorized person needing to obtain a prescription.

Reasons Supporting Proposal: The goal of adding the four drugs to the approved legend drug list for WDFW capture programs is to increase access to the drugs in the treatment of captured wildlife. The WDFW capture program staff have found timely use of the drugs to be valuable for preventing morbidity and mortality from puncture wounds. Placing the drugs in a legend drug list for WDFW capture program staff will allow them to be distributed in a timely fashion by not requiring each authorized person to obtain a prescription.

Statutory Authority for Adoption: RCW 18.64.005, 69.41.075, 69.41.080, and 69.50.320.

Statute Being Implemented: RCW 69.41.080.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Julia Katz, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058; and Enforcement: Marlee O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. The commission did not complete a cost-benefit analysis under RCW 34.05.328. RCW 34.05.328 (5)(b)(ii) exempts rules relating only to internal governmental operations that are not subject to violation by a nongovernment party. WAC 246-945-507 regulates legend drugs solely for the WDFW.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules relate only to internal governmental operations that are not subject to violation by a nongovernment party.

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: RCW 34.05.310 (4)(b) exempts rules relating only to internal governmental operations that are not subject to violation by a nongovernment party. WAC 246-945-507 regulates legend drugs solely for the WDFW

Scope of exemption for rule proposal:

Is fully exempt.

March 5, 2024

Kenneth Kenyon, PharmD, BCPS, Chair  
Pharmacy Quality Assurance Commission

**OTS-5140.1**

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-507 Department of fish and wildlife chemical capture programs—Approved legend drugs and approved controlled substances.**

(1) The following legend drugs are designated as "approved legend drugs" for use by registered department of fish and wildlife chemical capture programs:

- (a) Acetylpromazine;
- (b) Atipamezole;
- (c) Azaperone;
- (d) Ceftiofur hydrochloride;
- (e) Cephapirin benzathine;
- (f) Detomidine;
- ~~((e))~~ (g) Dexmedetomidine;
- ~~((f))~~ (h) Hetacillin potassium;
- (i) Isoflurane;
- ~~((g))~~ (j) Medetomidine;
- ~~((h))~~ (k) Naltrexone;
- ~~((i))~~ (l) Penicillin G procaine;
- (m) Tolazoline;
- ~~((j))~~ (n) Xylazine; and
- ~~((k))~~ (o) Yohimbine.

(2) The following controlled substances are controlled substances approved for use by registered department of fish and wildlife chemical capture programs:

- (a) Butorphanol;
- (b) Carfentanil;
- (c) Diazepam;
- ~~((e))~~ (d) Diprenorphine;
- ~~((d) Carfentanil;))~~
- (e) Fentanyl;
- (f) Ketamine;
- (g) Midazolam;
- (h) Tiletamine; and
- (i) Zolazepam.

(3) Staff of registered department of fish and wildlife chemical capture programs may administer legend drugs and controlled substances which have been prescribed by a licensed veterinarian for a specific animal or management group of animals, which have been dispensed by a pharmacy or a veterinarian and are properly labeled in accordance with either RCW 18.64.246 or 69.41.050 and WAC 246-945-015 through 246-945-017 or 246-933-340 (5) (a) and (b).