



# PROPOSED RULE MAKING

**CR-102 (July 2022)**  
**(Implements RCW 34.05.320)**  
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON  
FILED

DATE: March 15, 2024

TIME: 1:58 PM

**WSR 24-07-066**

**Agency:** Department of Health – Pharmacy Quality Assurance Commission

**Original Notice**

**Supplemental Notice to WSR**

**Continuance of WSR**

**Preproposal Statement of Inquiry was filed as WSR 23-21-011; or**

**Expedited Rule Making--Proposed notice was filed as WSR \_\_\_\_\_; or**

**Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

**Proposal is exempt under RCW \_\_\_\_\_.**

**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):**

| Date:      | Time:     | Physical Location:  | Comment: |
|------------|-----------|---|----------|
| 05/02/2024 | 9:30 a.m. | <p data-bbox="487 79 893 170">Capital Region ESD Building<br/>6005 Tye Dr. SW<br/>Tumwater, WA 98512</p> <p data-bbox="487 210 893 273"><b>Virtual Location:</b> Zoom # <a href="#">87143495001</a></p> <p data-bbox="487 304 893 399">Please download and import the following iCalendar (.ics) fields to your calendar system.</p> <p data-bbox="487 430 893 651"> <a href="https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf">https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf</a> </p> <p data-bbox="487 682 893 745">Topic: PQAC Business Meeting 2024</p> <p data-bbox="487 777 893 840">To access the meeting on May 2, 2024 at 9 a.m., go to</p> <p data-bbox="487 871 893 997"> <a href="https://zoom.us/join">https://zoom.us/join</a> or<br/> <a href="https://us02web.zoom.us/j/88256001236">https://us02web.zoom.us/j/88256001236</a> and use the Webinar ID 861 1495 8466         </p> <p data-bbox="487 1029 893 1186">           The access options include one tap mobile: US:<br/>           +12532158782,,86114958466#<br/>           or<br/>           +16699009128,,86114958466#         </p> <p data-bbox="487 1218 893 1617">           Or Telephone: Dial (for higher quality, dial a number based on your current location):<br/>           US: +1 253 215 8782 or<br/>           +1 669 900 9128 or<br/>           +1 346 248 7799 or<br/>           +1 669 444 9171 or<br/>           +1 386 347 5053 or<br/>           +1 564 217 2000 or<br/>           +1 646 558 8656 or<br/>           +1 646 931 3860 or<br/>           +1 301 715 8592 or<br/>           +1 312 626 6799         </p> <p data-bbox="487 1648 893 1690">Webinar ID: 861 1495 8466</p> |          |

**Date of intended adoption:** 05/02/2024 (Note: This is **NOT** the **effective** date)

| Submit written comments to:   | Assistance for persons with disabilities:  |
|---|--|
| <p data-bbox="74 1787 812 1822">Name: Julia Katz</p> <p data-bbox="74 1822 812 1896">Address: PO Box 47852<br/>Olympia, WA 98504-7852</p> <p data-bbox="74 1896 812 1932">Email: <a href="https://fortress.wa.gov/doh/policyreview/">https://fortress.wa.gov/doh/policyreview/</a></p> <p data-bbox="74 1932 812 1967">Fax: 360-236-2901</p> <p data-bbox="74 1967 812 2003">Other: N/A</p> | <p data-bbox="812 1787 1549 1822">Contact: Julia Katz</p> <p data-bbox="812 1822 1549 1858">Phone: 360-502-5058</p> <p data-bbox="812 1858 1549 1894">Fax: 360-236-2901</p> <p data-bbox="812 1894 1549 1929">TTY: 711</p> <p data-bbox="812 1929 1549 2003">Email: PharmacyRules@doh.wa.gov</p> |

By (date): 04/18/2024

Other: N/A

By (date): 04/25/2024

**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 U.S. 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 WAC 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

**Is rule necessary because of a:**

- Federal Law?  Yes  No
- Federal Court Decision?  Yes  No
- State Court Decision?  Yes  No

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** None

**Type of proponent:**  Private  Public  Governmental

**Name of proponent:** Pharmacy Quality Assurance Commission

**Name of agency personnel responsible for:**

|                 | Name           | Office Location                      | Phone        |
|-----------------|----------------|--------------------------------------|--------------|
| Drafting:       | Julia Katz     | 111 Israel Rd SE, Tumwater, WA 98501 | 360-502-5058 |
| Implementation: | Julia Katz     | 111 Israel Rd SE, Tumwater, WA 98501 | 360-502-5058 |
| Enforcement:    | Marlee O’Neill | 111 Israel Rd SE, Tumwater, WA 98501 | 360-502-5058 |

**Is a school district fiscal impact statement required under [RCW 28A.305.135](#)?**  Yes  No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

**Is a cost-benefit analysis required under [RCW 34.05.328](#)?**

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

Name:

Address:  
Phone:  
Fax:  
TTY:  
Email:  
Other:

No: Please explain: 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.

### Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

#### (1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

[RCW 34.05.310](#) (4)(b)  
(Internal government operations)

[RCW 34.05.310](#) (4)(e)  
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)  
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)  
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)  
(Correct or clarify language)

[RCW 34.05.310](#) (4)(g)  
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW \_\_\_\_\_.

Explanation of how the above exemption(s) applies to the proposed rule: 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.

#### (2) Scope of exemptions: *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

#### (3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

**Signature:**

**Date:** 03/05/2024

**Name:** Kenneth Kenyon, PharmD, BCPS

**Title:** Pharmacy Quality Assurance Commission Chair

A handwritten signature in black ink that reads "Ken Kenyon". The signature is written in a cursive style with a horizontal red line underneath it.

**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).