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WSR 23-21-011

PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Classifying wildlife capture drugs as approved legend drugs for the Department of Fish and Wildlife (WDFW). The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-507 to add certain intramammary antibiotic formulations to the list of approved legend drugs in response to a petition from a veterinarian at the Washington Department of Fish and Wildlife (WDFW).

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005; RCW 69.41.075

Reasons why rules on this subject may be needed and what they might accomplish: The commission received a petition on April 25, 2023 from a veterinarian from WDFW to add four antibiotics as WDFW-approved legend drugs in WAC 246-945-507. The request followed a federal regulatory framework decision by the United States Food and Drug Administration (FDA) that took effect on June 11, 2023. On May 4, 2023, the commission voted to approve the request and consider rulemaking. WDFW uses post-capture drugs containing four antibiotics: cephapirin benzathine, penicillin G procaine, ceftiofur hydrochloride, or hetacillin potassium.

Adding post-capture antibiotics to the list of approved legend drugs in WAC 246-945-507 would allow authorized WDFW personnel to acquire necessary antibiotic formulations without each authorized person needing to obtain a prescription. Wildlife capture may introduce pathogens at puncture sites and any delays to the acquisition and administration of post-capture antibiotics increase the risk of infection, morbidity, and mortality.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The Center for Veterinary Medicine (CVM), a branch of the FDA, issues guidance for the industry of veterinary sciences. In Guidance for Industry (GFI) #263, the FDA recommends that drug sponsors—persons or entities responsible for the marketing of a new drug—change the approved conditions of use marketing status for intramammary antibiotics from over-the-counter to that of a prescription medication. As part of a 5-year plan issued by the FDA in 2018, the procurement of intramammary drugs would be enforced in accordance with GFI #263 beginning June 11, 2023. The FDA regulates and enforces the rule.

WDFW regulates environmental policies and environmental impacts of rules. WDFW would be able to provide insight about the impact of GFI #263 on the use of wildlife post-capture drugs. The commission will communicate with WDFW about the regulatory process, invite members of the agency to public meetings, and seek feedback as needed.

Process for developing new rule (check all that apply):

- ☐ Negotiated rule making
- ☐ Pilot rule making
- ☐ Agency study
- ☒ Other (describe) Collaborative rulemaking

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

	(If necessary)
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Web site:	Web site:
Other:	Other:

Additional comments: Rule development takes place in open public meetings prior to a formal rule proposal and comment period. All rulemaking notices are sent via GovDelivery. To receive notices, interested persons may sign up by going to: https://public.govdelivery.com/accounts/WADOH/subscriber/new. After signing up, please click open the box labeled "Health Systems Quality Assurance." Next, click open the box labeled "Health Professions," then check the boxes next to either "Pharmacy Commission Meeting and Agenda" and/or "Pharmacy Commission Newsletter."

Date: 10/5/2023 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:**