PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

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DATE: October 03, 2023
TIME: 5:28 PM

WSR 23-20-119

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Removing fenfluramine from the list of Schedule IV substances. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-055 to remove fenfluramine from the list of Schedule IV substances and adding a new section to chapter 246-945 WAC to establish a list of schedule IV exemptions.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005 and 69.50.201

Reasons why rules on this subject may be needed and what they might accomplish: The commission received a petition on March 28, 2023 requesting to remove fenfluramine from the list of schedule IV substances following the Drug Enforcement Administration's (DEA) removal of the substance from the federal Controlled Substances Act (CSA) in December of 2022. Fenfluramine is a medication used in the treatment of seizures associated with certain syndromes and as an appetite suppressant.

The commission voted to approve the petition and consider rulemaking at their May 4, 2023 business meeting. Schedule IV substances are described in WAC 246-945-055 but this section does not reference exemptions for substances listed in RCW 69.50.210 that are no longer scheduled. Removing fenfluramine from the list of Schedule IV substances will make it a legend drug which does not have the administrative and tracking requirements of controlled substances.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The federal CSA of 1970 regulates and schedules narcotics and other substances. Section 1308 of the CSA classified fenfluramine as a schedule IV substance in 1973. Fenfluramine was de-scheduled by the DEA, the federal agency responsible for updating CSA regulations, in 2022 following a formal request. The request was made by a pharmaceutical company that manufactures a seizure medication containing fenfluramine and recently approved by the Food and Drug Administration. While the commission has independent authority to schedule, amend the schedules, or remove drugs from a schedule, licensees must also acquire registrations from the DEA. Matching the drug schedules to that of the DEA will streamline licensee regulations.

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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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: October 3, 2023 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:**