



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: 2:02 PM

WSR 24-07-067

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 23-20-119; 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: Removing fenfluramine from the list of Schedule IV substances. The Pharmacy Quality Assurance Commission (commission) is proposing to add a new subsection to WAC 246-945-055 to utilize the commission's authority, under RCW 60.50.201, to delete substances designated as a Schedule IV controlled substance. The commission is also proposing to create a new section, WAC 246-945-05001, to establish a list of exempted substances from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212, including fenfluramine.

Hearing location(s):

Date: 05/02/2024

Time:

10:30 a.m.

Physical Location:

Capital Region ESD Building
6005 Tye Dr. SW
Tumwater, WA 98512

Comment:

Virtual Location: Zoom # [87143495001](#)

Please download and import the following iCalendar (.ics) fields to your calendar system.

https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCtPf

Topic: PQAC Business Meeting 2024

To access the meeting on May 2, 2024 at 9 a.m., go to

<https://zoom.us/join> or
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Date of intended adoption: 05/02/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Julia Katz

Address: PO Box 47852

Assistance for persons with disabilities:

Contact: Julia Katz

Phone: 360-502-5058

Olympia, WA 98504-7852

Email: <https://fortress.wa.gov/doh/policyreview/>

Fax: 360-236-2901

Other: N/A

By (date): 04/18/2024

Fax: 360-236-2901

TTY: 711

Email: PharmacyRules@doh.wa.gov

Other: N/A

By (date): 04/25/2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: RCW 69.50.201(a)[(1)] authorizes the commission to add, delete, or reschedule substances listed in RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212. The commission must consider several factors in doing so, including the scientific evidence of the pharmacological effect of a substance, if known. The statute also allows the commission to consider findings of the U.S. Food and Drug Administration (FDA) or the Drug Enforcement Administration as prima facie evidence relating to one or more of the determinative factors. The commission filed a CR-101 for this rule project on October 3, 2023, under WSR 23-20-119, following a rule petition that was brought forward by an interested individual. The commission is proposing to add a new subsection to WAC 246-945-055 to utilize the commission's authority, under RCW 60.50.201, to delete substances designated as a Schedule IV controlled substance. The commission is also proposing to create a new section, WAC 246-945-05001, to establish a list of exempted substances from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212, including fenfluramine. This new WAC section will clarify and organize substances listed in statute that the commission deletes from a drug schedule via rulemaking.

Reasons supporting proposal: The proposed rules are needed to align the state regulation with a federal law, FR Doc. 2022-27400. The FDA removed fenfluramine from the schedules of the Controlled Substances Act in July 2022. The FDA determined the substance is valuable for individuals ages two and older with Dravet syndrome. Schedule IV substances are described in WAC 246-945-055 but this section does not reference exemptions for substances listed in RCW 69.50.201 that are no longer scheduled. Removing fenfluramine from the list of Schedule IV substances will make it a legend drug which do not have the same administrative and tracking requirements of controlled substances. The U.S. Drug Enforcement Agency (DEA), an agency within the FDA, considered medical and scientific evaluation to determine that fenfluramine has no potential for abuse. For more information, please refer to the Drug Enforcement Administration 21 CFR Part 1308.

Statutory authority for adoption: RCW 18.64.005 and 69.50.201

Statute being implemented: RCW 69.50.201

Is rule necessary because of a:

Federal Law? Yes No

Federal Court Decision? Yes No

State Court Decision? Yes No

If yes, CITATION: 87 FR 78857

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)(iii) exempts rules adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rules. There is no need for fenfluramine to be scheduled differently in the state of Washington than the federal requirement.

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:

- | | |
|---|--|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> 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:

(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



NEW SECTION

WAC 246-945-05001 Identification of substances deleted from RCW 69.50.204, 69.50.206, 69.50.208, 69.50.210, and 69.50.212. The commission, under RCW 69.50.201, deletes the following substance listed in RCW 69.50.210 from Schedule IV in the state of Washington.

Fenfluramine. Any material, compound, mixture, or preparation containing any quantity of the following substance, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine.

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

WAC 246-945-055 Schedule IV. The commission finds that the following substances have a low potential for abuse relative to substances in Schedule III under RCW 69.50.208 and WAC 246-945-054, and have currently accepted medical use in treatment in the United States and that the abuse of the substances may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III. In addition to substances listed in RCW 69.50.210, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule IV.

(1) Narcotic drugs. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set in this subsection: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol).

(2) Depressants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (a) Alfaxalone;
- (b) Fospropofol;
- (c) Suvorexant.

(3) Any material, compound, mixture, or preparation which contains any quantity of Lorcaserin, including its salts, isomers, and salts of such isomers, wherever the existence of such salts, isomers, and salts of isomers is possible.

(4) Stimulants. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (a) Cathine ((+) - norpseudoephedrine);
- (b) SPA ((-)-1-dimethylamino-1,2-diphenylethane).

(5) Other substances. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts: Eluxadoline
(5-[[
(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers.

(6) The commission, under RCW 69.50.201, may delete substances designated as a Schedule IV controlled substance and list them in WAC 246-945-05001.