

WSR 24-07-067

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed March 15, 2024, 2:02 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-20-119.

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): 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?pwd=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 <https://us02web.zoom.us/j/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/j/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, by April 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 United States 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 rule making.

Reasons Supporting Proposal: The proposed rules are needed to align the state regulation with a federal law, F.R. 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 United States Drug Enforcement Agency, 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 C.F.R. Part 1308.

Statutory Authority for Adoption: RCW 18.64.005 and 69.50.201.

Statute Being Implemented: RCW 69.50.201.

Rule is necessary because of federal law, 87 F.R. 78857.

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)(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.

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(4).

Scope of exemption for rule proposal:

Is fully exempt.

March 5, 2024
Kenneth Kenyon, PharmD, BCPS, Chair
Pharmacy Quality Assurance Commission

OTS-5139.1

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 prepara-

tion 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.

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency and appear in the Register pursuant to the requirements of RCW 34.08.040.