WSR 22-05-089
PROPOSED RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed February 15, 2022, 4:05 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-23-027.

Title of Rule and Other Identifying Information: WAC 246-945-056 Schedule V. The pharmacy quality assurance commission (commission) is proposing to amend WAC 246-945-056 to delete Epidiolex from Schedule V controlled substances in Washington state in line with changes in Uniform Controlled Substances Act and in response to a rule-making petition.

Hearing Location(s): On March 25, 2022, at 9:15 a.m. In response to the coronavirus disease 2019 (COVID-19) pandemic, the commission will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead.

To access the meeting, please register for this meeting and join from your computer, tablet, or smartphone. Please register for the PQAC business meeting on March 25, 2022, 9:00 a.m. PST, at https://attendee.gotowebinar.com/register/4623500690320973325. After registering, you will receive a confirmation email containing information about joining the webinar.

Participants can use their phone or computer mic and speakers (VoIP). United States +1-631-992-3221, Audio Pin - Attendee - muted 704-709-411.

Date of Intended Adoption: March 25, 2022.

Submit Written Comments to: Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, email https://fortress.wa.gov/doh/policyreview, fax 360-236-2901, by March 11, 2022.

Assistance for Persons with Disabilities: Contact Joshua Munroe, phone 360-236-2987, TTY 711, email PharmacyRules@doh.wa.gov, by March 18, 2022.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: Epidiolex is an FDA-approved cannabidiol with less than 0.3 percent tetrahydrocannabinal (THC), used to help treat some seizure disorders. The Uniform Controlled Substances Act (chapter 69.50 RCW) declassifies hemp products with less than 0.3 percent THC from the definition of a controlled substance because hemp was removed from the definition of marijuana per RCW 15.140.030(6). The commission received a petition from interested parties to update the rules to reflect changes caused by the Uniform Controlled Substances Act. In response to the rule-making petition and the goal of reducing superfluous pressure on the health system during the ongoing coronavirus disease 2019 (COVID-19) pandemic, the commission implemented emergency rules to delete Epidiolex from the list of Schedule V controlled substances beginning May 20, 2020, under WSR 20-11-078, and has retained the emergency rule since then. This proposal is intended to permanently delete Epidiolex from the list of Schedule V controlled substances in WAC 246-945-056 consistent with the emergency rule. The current emergency rule under WSR 21-22-065 was filed on October 29, 2021.

Reasons Supporting Proposal: In August 2020, the Drug Enforcement Administration (DEA) completed rule making formally descheduling Epi-

diolex federally. Per RCW 69.50.201, the commission has the duty to similarly control Epidiolex as DEA has, therefore the commission has the duty to remove Epidiolex from the Schedule V list.

This proposal is in response to a rule-making petition, but it also aligns Washington state rule with the federal change.

Statutory Authority for Adoption: RCW 18.64.005, 69.50.201.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Washington state pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Joshua Munroe, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2987; Enforcement: Margaret Holm, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4731.

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)(v) exempts rules, the content of which is explicitly and specifically dictated by statute. RCW 69.50.201 requires the commission to deschedule Epidiolex the same as was done federally.

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(3) as the rule content is explicitly and specifically dictated by statute.

Explanation of exemptions: Epidiolex is no longer considered a controlled substance by the federal government. Per RCW 69.50.201, the commission has the duty to deschedule Epidiolex in Washington state as well.

February 15, 2022
Teri Ferreira, RPh
Pharmacy Quality Assurance Chair

OTS-2392.1

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

WAC 246-945-056 Schedule V. The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, 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 V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having

a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

((~~(3) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.~~))

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-056, filed 6/1/20, effective 7/1/20.]

Reviser's note: The brackets and enclosed material in the text of the above section occurred in the copy filed by the agency.

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.