PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: February 15, 2022
TIME: 4:05 PM

WSR 22-05-089

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** 20-23-027 **; 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).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) 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 rulemaking petition.

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**
03/25/2022	9:15 a.m.	In response to the coronavirus disease 2019 (COVID-19) pandemic, the Pharmacy Quality Assurance 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 AM 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 telephone or computer mic & speakers (VoIP).	

		UNITED STATES - +1 (631) 992-3221 AUDIO PIN - ATTENDEE-muted - 704-709-411	

Date of intended adoption: 03/25/2022 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Joshua Munroe
Address: PO Box 47852
Olympia, WA 98504-7852
Email: https://fortress.wa.gov/doh/policyreview
Fax: 3602362901
Other: N/A
By (date) 03/11/2022

Assistance for persons with disabilities:

Contact Joshua Munroe
Phone: 3602362987
Fax:
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other:
By (date) 03/18/2022

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% 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% 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 rulemaking 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 DEA completed rulemaking formally de-scheduling Epidiolex federally. Per RCW 69.50.201 the commission has the duty to similarly control Epidiolex as the DEA has, therefore the commission has the duty to remove Epidiolex from the Schedule V list.

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

Statutory authority for adoption: RCW 18.64.005; RCW 69.50.201

Statute being implemented: None

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Washington State Pharmacy Quality Assurance Commission		☐ Private ☐ Public ☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Enforcement:	Margaret Holm	111 Israel Rd SE, Tumwater, WA 98501	360-236-4731

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)(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.

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). 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:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☒ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ 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 .

Explanation of exemptions, if necessary: 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.

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If 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 analysis showing how costs were calculated.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert 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:

Date: 2/15/2022	**Signature:** 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Chair	

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.~~))