RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 29, 2021
TIME: 8:20 AM

WSR 21-22-065

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-056 Schedule V. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to remove Epidiolex from the list of Schedule V controlled substances in Washington state. This adopted emergency rule will extend WSR 21-14-061 filed on July 2, 2021. The emergency which was originally filed on May 20, 2020 under WSR 20-11-078. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinal (THC). De-scheduling the drug from Schedule V will maintain the emergency rule. It also aligns Washington state rule with the federal decision to exclude all hemp products with less than 0.3% THC from the definition of marijuana and the United States drug enforcement agency's (DEA) rulemaking to remove Epidiolex from Schedule V, completed on August 21, 2020.

Citation of rules affected by this order:

New: None
Repealed: None
Amended: WAC 246-945-056
Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.50.201

Other authority: 21 U.S.C. Ã‚Â§ 811

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☒ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC used to help treat some seizure disorders. The 2018 Agricultural Improvement Act amended the Controlled Substances Act and declassified hemp products with less than 0.3% THC from Schedule I; however, Epidiolex was placed on Schedule V until April 6, 2020 when the DEA announced that it would be de-scheduled as a federally controlled substance. The DEA finalized rulemaking to remove Epidiolex from Schedule V on August 21, 2020. This emergency rule will maintain the emergency rule already in effect and update Washington rule to align with the federal decision. Emergency rules are necessary to reduce burdens on practitioners prescribing Epidiolex and allow patients easier access to the care they need. This rule may also help reduce pressure on the health system during the ongoing COVID-19 pandemic. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. The commission has initiated permanent rulemaking. The CR-101 to permanently de-schedule Epidiolex (WSR 20-23-027) was filed on November 10, 2020.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	1	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

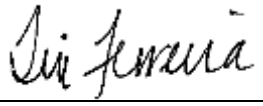
	New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: 9/2/2021	**Signature:** 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Commission 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.~~))