WSR 21-07-015
EMERGENCY RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed March 5, 2021, 9:37 a.m., effective March 5, 2021, 9:37 a.m.]

Effective Date of Rule: Immediately upon filing.

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 emergency rule was originally filed on May 20, 2020, under WSR 20-11-078. It was refiled most recently on November 6, 2020, under WSR 20-23-013. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinal (THC). Descheduling 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.

Citation of Rules Affected by this Order: Amending WAC 246-945-056.

Statutory Authority for Adoption: RCW 18.64.005, 69.50.201.

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.

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 United States drug enforcement agency announced that it would be descheduled as a federally controlled substance. 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 rule making to deschedule Epidiolex.

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; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: March 5, 2021.

Tim Lynch, PharmD, MS, FABC, FASHP
Commission 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.