



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017)
(Implements RCW 34.05.310)

Do **NOT** use for expedited rule making

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FILED

DATE: November 10, 2020

TIME: 8:29 AM

WSR 20-23-027

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: The Pharmacy Quality Assurance Commission (commission) is opening WAC 246-945-056 Schedule V, to consider deleting Epidiolex from the list of Schedule V controlled substance in Washington state in line with changes to federal regulation and in response to a stakeholder petition to do so.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005; RCW 69.50.201

Reasons why rules on this subject may be needed and what they might accomplish: Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC, used to help treat some seizure disorders. The 2018 Agricultural Improvement Act (2018 Farm Bill) amended the Controlled Substances Act and declassified hemp products with less than 0.3% THC from Schedule I and excluded hemp from the definition of marijuana. Epidiolex remained on Schedule V until April 6, 2020 when the United States drug enforcement agency (DEA) announced that it would no longer be a federally controlled substance. Following this statement and decision from the 2018 Farm Bill, the commission received a petition from stakeholders to update their rules to reflect the change. In response to the federal change, stakeholder petition, and in support of the COVID-19 pandemic response, the commission implemented emergency rules to delete Epidiolex from the list of Schedule V controlled substances on July 10, 2020 under WSR 20-15-059. This proposal is opening WAC 246-945-056 to consider making the emergency rule permanent and align Washington regulation with the federal decision.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: The DEA stated in April, 2020 that Epidiolex is no longer subject to the Controlled Substances Act nor considered a controlled substance. Although changes have not yet been codified in CFR, hemp was excluded from the definition of marijuana by the 2018 Farm Bill and is no longer considered a controlled substance.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative


Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

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(If necessary)

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Additional comments: Interested parties can sign up for notifications regarding the rulemaking process by signing up for GovDelivery at the following address: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>

Date: 11/09/2020	Signature: 
Name: Tim Lynch, PharmD, MS, FABC, FASH	
Title: Pharmacy Quality Assurance Commission Chair	