



# 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: August 22, 2024

TIME: 8:57 AM

WSR 24-18-005

**Agency:** Department of Health – Pharmacy Quality Assurance Commission

**Subject of possible rule making:** Considering adding kratom to the list of Schedule I substances. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-051 and adding new sections to chapter 246-945 WAC to add kratom and its active compounds to the list of Schedule I substances in response to a petition request to do so.

**Statutes authorizing the agency to adopt rules on this subject:** RCW 18.64.005, 69.50.201 and 69.50.203

**Reasons why rules on this subject may be needed and what they might accomplish:** The department received a petition from an interested party on June 15, 2024, requesting that the commission classify kratom and its two active alkaloid compounds, mitragynine and 7-hydroxymitragynine, as Schedule I substances. The petition claimed the potential for abuse, lack of accepted medical use, and public health risks associated with use of kratom as justifications for listing kratom as a Schedule I substance.

Kratom (*Mitragyna speciosa*) is a substance derived from a tree of the same name and can reportedly give users a stimulant or sedative effect. It is not included in the list of controlled substances at the federal level, though the Drug Enforcement Administration (DEA) lists kratom as a “Drug and Chemical of Concern.” As of December 2023, sixteen states regulate the sale of kratom products to varying degrees.

Kratom is not currently listed as a controlled substance in either the Revised Code of Washington (RCW) or the Washington Administrative Code (WAC).

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:** Both the Federal Drug Administration (FDA) and the DEA have regulatory authority over kratom and kratom projects. The commission would not rely on coordination with either the FDA or DEA for the placement of kratom on the list of Schedule I substances in the WAC but would inform both agencies should it schedule kratom as a Schedule I controlled substance.

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

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

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

|   |                         |
|---|-------------------------|
| Name: Joshua Munroe                           | (If necessary)<br>Name: |
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Web site:

Web site:

Other:

Other:

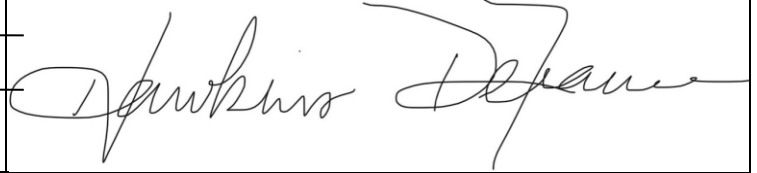
Additional comments: Interested parties can participate in the drafting of the proposed rules. The commission will conduct a series of rules workshops. Rulemaking notices will be delivered via the GovDelivery list. To receive notices, please go to: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing in, please click open the box labeled "Health Systems Quality Assurance." Next click open the box labeled "Health Professions" and then click again on "Pharmacy Commission Newsletter." You may also check the box next to one or more of the other professions or facilities listed to receive information related to that specific topic.

**Date:** 8/21/2024

**Signature:**

**Name:** Hawkins DeFrance, PharmD

**Title:** Pharmacy Quality Assurance Commission Chair

A handwritten signature in black ink, appearing to read "Hawkins DeFrance", written over a horizontal line.