

WSR 24-18-005
PREPROPOSAL STATEMENT OF INQUIRY
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed August 22, 2024, 8:57 a.m.]

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 of health 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 RCW or WAC.

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 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: Collaborative rule making.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov.

Additional comments: Interested parties can participate in the drafting of the proposed rules. The commission will conduct a series of rules workshops. Rule-making notices will be delivered via the Gov-Delivery 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.

August 21, 2024
Hawkins DeFrance, PharmD, Chair
Pharmacy Quality Assurance Commission