



# 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: October 05, 2023

TIME: 2:40 PM

WSR 23-21-010

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

**Subject of possible rule making:** Dialysate and Dialysis Device Manufacturers and Wholesalers in Home Dialysis Programs. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 and creating new sections in chapter 246-945 WAC to include manufacturers and distributors of dialysate and dialysis devices in home dialysis program rules under the commission’s jurisdiction. The amendments under consideration are in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022).

**Statutes authorizing the agency to adopt rules on this subject:** RCW 18.64.257, 69.41.032, and 18.64.005

**Reasons why rules on this subject may be needed and what they might accomplish:** The commission is considering amending WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 and creating new sections in chapter 246-945 WAC to align with statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022). The amendments the commission is considering would increase patient access to dialysis devices and legend drugs used in home dialysis by allowing manufactures and wholesalers to dispense lawfully prescribed dialysis devices and legend drugs for home dialysis directly to the patient, reducing intermediary storage facility use.

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:** None.

**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:**

	(If necessary)
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Other: N/A	Other:

Additional comments: All rulemaking notices will be distributed via GovDelivery. To receive notices, interested persons may sign up by going to: <https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing up, please click

open the box labeled "Health Systems Quality Assurance." Next click open the box labeled "Health Professions," then check the box next to "Pharmacy Quality Assurance Commission."

**Date:** 10/5/2023

**Name:** Kenneth Kenyon, PharmD, BCPS

**Title:** Pharmacy Quality Assurance Commission Chair

**Signature:**

A handwritten signature in black ink that reads "Ken Kenyon". The signature is written in a cursive style with a large, prominent 'K' at the beginning.