PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (June 2004)
(Implements RCW 34.05.310)
Do **NOT** use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

Subject of possible rule making: Chapter 246-873A WAC (new) and Chapter 246-873 WAC Pharmacy Hospital Standards- The Pharmacy Quality Assurance Commission (commission) is considering establishing standards supporting the regulatory, inspection, and investigation of pharmacy services provided in individual practitioner offices and multi-practitioner clinics owned and operated by a hospital based on the level of risk and the type of pharmacy services provided at a particular location.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.043 as amended by SSB6558 (chapter 118, Laws 2016), and RCW 18.64.005

Reasons why rules on this subject may be needed and what they might accomplish: Currently, RCW 18.64.043 allows hospital pharmacy licenses to include any individual practitioner's office or multi-practitioner clinics owned and operated by a hospital, and identified by the hospital on the pharmacy application or renewal, but no supporting rules providing specific information regarding the licensing process were ever implemented. Substitute Senate Bill 6558 (SSB 6558) directs the commission to provide clear and specific standards supporting the regulatory, inspection and investigation of these associated licensed clinic locations based on the level of risk and the type of pharmacy services provided at a particular location.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:
The Drug Enforcement Administration (DEA) enforces the controlled substances laws and regulations of the United States. The potential exists that controlled substances could be transferred and stored at these hospital pharmacy associated clinics. The commission will need to coordinate information with the DEA to keep them informed of clinic sites in possession of controlled substances for DEA registration purposes. Other regulator bodies that provide guidance and oversight for drug handling and compounding practices include the Center for Disease Control (CDC), the Food and Drug Administration (FDA) and the United States Pharmacopeia (USP) will be valuable resources for these new rules.

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

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

How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:
(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Stakeholders will be invited to participate in rule-writing workshops and provide input throughout the rule making process. Interested parties can sign-up to receive information, updates, or provide comments to the commission at WSPQAC@doh.wa.gov or by contacting Rich Cieslinski R. Ph., Rules Coordinator, at the Department of Health, Pharmacy Quality Assurance Commission, P.O. Box 47852, Olympia WA 98504-7852.

DATE
July 22, 2016

NAME (TYPE OR PRINT)
Steven Saxe, R.Ph., FACHE

SIGNATURE

TITLE
Executive Director, Pharmacy Quality Assurance Commission

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