



PREPROPOSAL STATEMENT OF INQUIRY

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

Agency: Department of Health- Board of Pharmacy

Subject of possible rule making: Chapter 246-878 WAC Good Compounding Practices; Chapter 246-871 WAC Pharmaceutical -- Parenteral Products for Non-Hospitalized Patients; Chapter 246-903 WAC Nuclear Pharmacies and Pharmacists; and Chapter 246-873 WAC Hospital Pharmacy Standards. The Board of Pharmacy will evaluate nationally recognized compounding standards to update and set enforceable practice and quality standards for the compounding of sterile and non-sterile preparation in all practice settings.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005 State Board of Pharmacy -- Powers and duties; RCW 18.64A.030 Rules -- Duties of technicians, assistants; RCW 18.64.410 Nonresident pharmacies -- Rules; and HB 1800 (Chapter 146, Laws of 2013)

Reasons why rules on this subject may be needed and what they might accomplish: In 2008, US Pharmacopeia Convention, a nonprofit organization that sets guidelines for drug standards, adopted minimum practice and quality standards for sterile compounding known as USP 797 and later USP 795 for non-sterile compounding. Washington State rules on compounding practices for pharmacies were last adopted in 1994. Updated rules will ensure that standards are appropriate, clear, and enforceable to protect the public's health and safety from hazardous practices similar to recent events involving hundreds of cases of fungal meningitis and other infections due to the administration of contaminated medications produced using unsafe compounding techniques.

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) The Board of Pharmacy will use a collaborative rule-making process to develop new and amended rules.

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.)

Interested parties will receive notice of rulemaking and stakeholder workshops, and will have the opportunity to submit written comments on the proposed rules. The Board of Pharmacy will use listservs to notify interested parties. Interested parties will have the opportunity to comment and the Board of Pharmacy will take public testimony during the official public rules hearing. For more information, please contact: Doreen Beebe, Program Manager with the Washington State Department of Health, Board of Pharmacy, PO Box 47852, Olympia WA 98504; by phone 360-236-4834; by email: wsbop@doh.wa.gov.

DATE 5/20/2013
NAME (TYPE OR PRINT) Chris Humberson, R.Ph
SIGNATURE
TITLE Executive Director, Board of Pharmacy

CODE REVISER USE ONLY
OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED
DATE: May 20, 2013
TIME: 10:41 AM
WSR 13-11-096