



# PREPROPOSAL STATEMENT OF INQUIRY

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

**Agency:** Department of Health

**Subject of possible rule making:** Chapter 246-XXX WAC--Blood establishments. The Department of Health (department) is adding a new chapter to Title 246 WAC to establish requirements related to a public registry to ensure the transparency of blood establishments pursuant to Substitute House Bill (SHB) 2580 (Chapter 47, Laws of 2016).

**Statutes authorizing the agency to adopt rules on this subject:** SHB 2580 (Chapter 47, Laws of 2016)

**Reasons why rules on this subject may be needed and what they might accomplish:** SHB 2580 was enacted by the 2016 Washington State Legislature requiring the department to: (1) establish and administer a registration process for blood-collecting or blood-distributing establishments that collect or distribute blood for allogeneic transfusion in Washington state that are licensed by the US Food and Drug Administration (FDA); (2) create and maintain an online public registry of all registered blood establishments that supply blood products for transfusion in Washington state; and (3) set fees for applying for or renewing a registration. The purpose of the registry is to ensure the safety and transparency of Washington's blood supply.

**Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies:**  
U.S. Food and Drug Administration. The department will coordinate the rule with the FDA as necessary and appropriate.

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

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

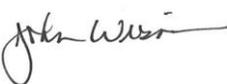
**How interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication:**

(List names, addresses, telephone, fax numbers, and e-mail of persons to contact; describe meetings, other exchanges of information, etc.)

Interested parties may participate in the development of draft rules prior to a formal proposal or may receive information on how to participate in rulemaking by contacting Susan Walker, Lab Quality Assurance Supervisor, 20425 72nd Ave S., Suite 310, Kent, WA 98032; email: susan.walker@doh.wa.gov; telephone: 253.395.6745; fax: 253.395.6365.

**DATE**  
07/07/2016

**NAME (TYPE OR PRINT)**  
John Wiesman, DrPH, MPH

**SIGNATURE**  
  
, DrPH, MPH

**TITLE**  
Secretary of Health

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FILED

**DATE: July 07, 2016**

**TIME: 2:18 PM**

**WSR 16-15-009**