



# PROPOSED RULE MAKING

## CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

**Agency:** Department of Health- Board of Pharmacy

- Preproposal Statement of Inquiry was filed as WSR 09-15-061 ; or
- Expedited Rule Making--Proposed notice was filed as WSR \_ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

**Title of rule and other identifying information:** (Describe Subject)  
WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW.

**Hearing location(s):** Green River Community College  
12401 SE 320th Street  
Lindbloom Student Center - 1st floor  
Glacier Room  
Auburn, WA 98092-3622

Date: 12/10/2009 Time: 9:00 a.m.

**Submit written comments to:**

Name: Doreen E. Beebe  
Address: Washington State Board of Pharmacy  
PO Box 47863  
Olympia WA 98504-7863  
Website: <http://www3.doh.wa.gov/policyreview/>  
fax 360.236.2901 by (date) 12/04/2009

**Assistance for persons with disabilities:** Contact

Doreen E. Beebe by 12/07/2009

TTY (800) 833-6388 or () 711

**Date of intended adoption:** 12/10/2009

(Note: This is NOT the effective date)

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:**

The purpose of the proposal is to provide an up-to-date reference in rule to the 2009 edition of the commercial pharmaceutical publication, Drug Topics Red Book (Red Book) per RCW 69.41.075. The Red Book is the reference used by the State Board of Pharmacy (Board) to identify federally-classified drugs. The proposal also corrects the address for the Board of Pharmacy administrative office, and provides a more efficient way to obtain the Red Book through the Board.

**Reasons supporting proposal:**

The Board is charged with classifying drugs as legend or prescription only. It is necessary that the Board use current references when classifying drugs in rule. The Red Book is an industry-recognized resource for healthcare professionals with the latest information on prescription and over-the-counter products. The reference includes drug package information: dosage forms, route of administration, etc. The proposal also amends language to provide a more efficient way to obtain the book. Access to a current and trusted drug information resource will help ensure safe and optimal use of drugs.

**Statutory authority for adoption:**  
RCW 18.64.005 and RCW 69.41.075

**Statute being implemented:**  
RCW 69.41.075

**Is rule necessary because of a:**

- Federal Law?  Yes  No
  - Federal Court Decision?  Yes  No
  - State Court Decision?  Yes  No
- If yes, CITATION:

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER  
STATE OF WASHINGTON  
FILED

DATE: November 03, 2009

TIME: 3:08 PM

**WSR 09-22-083**

**DATE** 11/03/09

**NAME** (type or print)  
Susan Teil Boyer

**SIGNATURE** *Susan Teil Boyer*

**TITLE**  
Executive Director, WA State Board of Pharmacy

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:**

None.

**Name of proponent:** (person or organization) Washington State Board of Pharmacy

- Private
- Public
- Governmental

**Name of agency personnel responsible for:**

Name	Office Location	Phone
Drafting..... Doreen E. Beebe	310 Israel Rd SE, Tumwater WA 98501	360.236.4834
Implementation.... Doreen E. Beebe	310 Israel Rd SE, Tumwater WA 98501	360.236.4834
Enforcement..... Grant Chester	310 Israel Rd SE, Tumwater WA 98501	360.236.4817

**Has a small business economic impact statement been prepared under chapter 19.85 RCW?**

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

**Is a cost-benefit analysis required under RCW 34.05.328?**

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No: Please explain: The Board has determined this rule does not qualify as a significant rule under RCW

34.05.328(5)(c)(iii).

AMENDATORY SECTION (Amending WSR 02-14-049, filed 6/27/02, effective 7/28/02)

**WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW.** (1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the ((2002)) 2009 edition of the *Drug Topics Red Book*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the State Board of Pharmacy, ((1300 Quince Street)) 310 Israel Road S.E., P.O. BOX 47863, Olympia, Washington 98504-7863. To obtain copies of this list from the department, interested persons must submit a written request, indicating which format they wish to receive, and payment of ((seventy-six dollars for each copy to the board)) the actual cost of the text or CD, including shipping and handling charges from the publisher. Requestors may also contact the publisher directly to obtain copies. The department takes no responsibility for periodic updates or on-line access. Arrangements for periodic updates or on-line access must be made directly with the publisher.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.