

## The Legend Drug Act

Chapter 69.41 RCW  
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## BOP Rulemaking Authority

- Question from one of the class groups?
- BOP must identify the authority they are using when they adopt a rule. Look at fine print at end of each WAC section - Statutory Authority.
- RCW 18.64.005 (may or may not cite § (7))
- 96-02-006 = Where published in WA State Register
- Filed date and Effective date

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## BOP Rulemaking Authority, cont.

- Legend Drug Act 69.41.075
- Uniform Controlled Substances Act 69.50.301
- Precursor Drugs 69.43.050
- Etc.

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## Legend Drug Act Objectives

- The student shall be able to discuss the State Legend Drug Act that determines how prescription drugs may be prescribed, distributed, and dispensed in WA.
- The student shall be able to recognize who may legally prescribe and dispense drugs

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## Legend Drug Act Objectives

- The student shall be able to determine the requirements for drug product substitution
- The student shall be able to understand the requirements of the preferred drug list for State sponsored Rx programs
- The student shall be able to determine if a product is properly imprinted for identification purposes

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## Legend Rx vs OTC vs CS vs Nutritional

- OTC - no prescription required
- Legend - prescription required
- Controlled Substances
  - Mostly legend drugs
  - Registration with DEA plus prescriptions required
  - Some Schedule V require prescriptions
  - Some Schedule V OTC
    - Only in pharmacies, must sign for them
- Nutritional Supplements including Vitamins are NOT drugs

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## 69.41.010 Definitions

- Essentially the same as 18.64 RCW BUT  
NOTE: (11) Practitioner: this lists **most** of the persons who may legally prescribe OR administer legend drugs.
- Also includes which out of state persons may legally prescribe. See also 69.41.030

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## 69.41.020 Prohibited Acts

- Legend drugs may only be dispensed etc in accordance with this chapter!
- Violations of Legend drug Act
- Obtain, procure, etc by:
  - Oa. Fraud, deceit, misrepresentation
  - Ob. Forgery, alteration of Rx or written order
  - Oc. Concealment of material fact
  - Od. False name or address

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### 69.41.020 RCW cont.

- 2. False information to practitioner to obtain drug is not a “privileged communication”.
- 3. No willful false statement in Rx, order, report, or record.
- 4. A person may not falsely assume title of Mfr, Whl or Practitioner to get drugs
- 5. Can't make or utter false or forged Rx or other written order.

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### 69.42.020 RCW cont.

- 6. No false or forged label on legend drug
- 7. May not willfully fail to maintain records required by:
  - Sec 042 - Mfr, Whl, Phcy, Practitioner
  - Sec 270 - Duplicate requirement

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### 69.41.030 RCW

- Unlawful to sell, deliver, possess legend drug EXCEPT on order or Rx of MD, DO, etc.
- Possession etc. OK for Mfr., Whl. or their employees or Practitioner in course of profession or common carrier in course of employment
- Family planning clinic may dispense commercially packaged OC's prescribed by practitioner

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### 69.41.040 RCW

- Prescription Requirements:
- Legitimate medical purpose incl. research
- Authorized prescriber
- NOT Rx if issued to Rx abuser or NOT in course of professional treatment
- Violation if RPh fills & knows or should have known it was not valid Rx

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## 69.41.042 RCW Records

- All licensees must maintain records to account for receipt and disposition of legend drugs.
- Records must be available for inspections by the board or representatives
- Records must be maintained for 2 years
- NOTE: 69.41.270 duplicates this section

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## 69.41.044 RCW Confidentiality

- Certain records are exempt from public disclosure law (42.17 RCW)
- Mfr., rep of mfr, whl, phcy, practitioner
- This section does not restrict investigations or proceedings of board. But, board must comply with 42.17 RCW.

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## Chapter 42.17 RCW Public Disclosure of Records (NOT in Board Law Book)

- Most public records possessed by the State are available upon request.
- However there are over 56 separate EXEMPTIONS (See 42.17.313(a) thru (ddd))

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## Chapter 42.17.301 RCW Exemption from public disclosure of records

- (d) Specific intelligence information of law enforcement & disciplinary boards
- (f) Test questions
- (l) Library records
- (w) SSN, residence, & residence phone of DOH licensees
- (x) Info. Obtained by BOP 69.45.090 drug samples info. From drug mfrs.

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### Chapter 42.17.301 RCW Exemption from public disclosure of records

- (y) Records, reports, info obtained by BOP under:
  - 69.41.044 – Mfr, wholesaler, phcy, practitioner
  - 69.41.280 – refers to above records
  - 18.64.420 – records from nonresident pharmacies

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### Chapter 42.17.301 RCW Exemption from public disclosure of records

- (hh) Information & documents created by/for quality improvement committees of hospitals and Peer Review Committees under 4.24.250 RCW

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### 69.41.050 RCW Labeling by a practitioner

- Prescriber#
- Directions for use
- Name of drug\* (brand or generic)
- Strength\*
- Name of Patient#
- Date
- \*May omit
- #Required on Samples



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### 69.41.070 RCW Penalties

- Penalties range - misdemeanor to felony
- 1. Obtain by fraud etc. = felony
- 2. Sale, delivery, intent to deliver = felony
- 3. Possession only = misdemeanor
- 4. Filling false Rx = felony
- 5. Practitioner labeling = misdemeanor
- 6. Practitioner - Steroids = Disciplinary action

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## 69.41.070 RCW Penalties cont.

- 8. Anabolic Steroids
  - Possession < 200 tabs or 8 x 2 cc = misdemeanor
  - Possession > 200 tabs or 8 x 2cc = felony
- NOTE: Now steroids are controlled substances so this subsection should be repealed. Prosecutions will be under 69.50 RCW.

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## 69.41.075 RCW Rules & List

- Board of pharmacy to make rules
- Board to identify legend drugs - consider:
  - Toxicity
  - Potential for harmful effects
  - Method of use
  - Collateral safeguards necessary for safe use
- MUST classify as legend IF need practitioner supervision for safe use
- May use commercial list (see 246-883-020)

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## 69.41.080 RCW Animal Control

- Humane Societies & Animal Control Agencies may be permitted to use certain legend drugs to sedate animals prior to euthanasia or for chemical capture.
- See WAC 246-886 for rules & list of Rx BUT note that Ketamine is now a CS – will be deleted from the rules shortly
- See also WAC 246-887-050 for rules re: use of Pentobarbital for euthanasia of animals.

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## 69.41.100 RCW Substitution

- Legislative intent section
- Patients should receive safe, therapeutically effective drugs at most reasonable cost consistent with high quality drug standards.
- 1977 Legislative Session

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## 69.41.110 RCW Substitution

- Definitions:
- 1. Brand name = proprietary or trade name
- 2. Generic name = official title in USP or a formulary (See USAN a USP-FDA function)

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## 69.41.110 RCW Substitution

- Substitute to dispense drug with prescribers authorization
- Therapeutically equivalent drug to that Rx'd
  - MUST be identical base or salt
- BUT with *prior consent* of prescriber need NOT be identical (Therapeutic Substitution)
- Therapeutically equivalent = same efficacy & toxicity when administered in same dosage regimen

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## 69.41.120 RCW Substitution

- Instructions re: Substitution, Form of Rx
- All Rx's must contain instructions re: sub.
- If written then two line Rx form
  - Dispense as Written on Right side
  - Substitution Permitted on Left side
- If out of state Rx follow Rx'er instructions
- If oral Rx must tell RPh sub or no sub
- If substitute RPh must ID on Rx file copy

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## 69.41.130 RCW Savings pass on

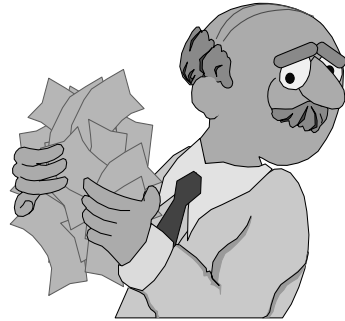
- Patient may request Brand name drug otherwise RPh MUST substitute if prescriber signs on substitution permitted line
- If doc signs DAW can't honor patient request for generic



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### 69.41.130 RCW Savings pass on

- If substitute must use product that has less wholesale cost than brand and pass on 60% of the savings to the purchaser.



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### 69.41.140 RCW Min. Mfg. Standards.

- May NOT substitute a company's drug unless manufacturer meets minimum standards
  - FDA Quality Control Standards
  - Comply with FDA rules
- In 1970's some generics were problematic – no longer seen as a problem

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### 69.41.150 RCW Liability Generic or PDL Prescribing or dispensing

- Prescriber NOT liable for side effects or adverse effects related to DPS
- Pharmacist assumes NO greater liability than for brand product



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### 69.41.160 RCW Signs

- Pharmacy must post VISIBLE sign
- Under WA law an equivalent but less expensive drug may in some cases be substituted for the drug prescribed by your doctor...
- only with consent of doctor
- consult your doctor or pharmacist for info.

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## 69.41.170 RCW Coercion of RPh

- Unlawful for employer to coerce (see 9A36.070 RCW) a pharmacist to substitute or dispense a generic drug.
- Violation is misdemeanor



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## 69.41.180 RCW Rules

- Board of Pharmacy to adopt rules
- may include list of
  - Therapeutically equivalent or
  - Non-therapeutically equivalent drugs
- i.e., Positive or Negative Formulary
- NOTE: Neither has been adopted
- See also WAC 246-899

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## WAC 246-899 Drug Product Substitution

- Dispensing responsibilities
  - Oral Rx - note on Rx if substituted
  - ALL Rx's note what product was dispensed
- Criteria for DPS
  - Federal Agencies, Compendia, Rx Mfrs.
  - Scientific resources, "Orange Book"

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## Drug Product Substitution rules, cont.

- Products must meet federal standards (Problem- substandard generics in 1970's)
- Out of state prescriptions
  - Honor instructions of prescriber
  - If not clear - may only substitute if
  - familiar with that states laws, or get information on state subs. laws, or call prescriber for permission to substitute

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### 69.41.190 RCW Preferred drug substitution

- **New law chapter 29 laws of 2003**
- **Establishes Preferred Drug List (PDL) for state sponsored Rx programs (Medicaid, L&I, Uniform Medical Plan (State employees health plan))**
- **Pharmacists will be doing therapeutic interchange (substitution) for selected drugs on the PDL**
- **Program starts on 3/01/2004**

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### 69.41.190 RCW Preferred drug substitution

- Any RPh filling a Rx under state program shall substitute a preferred drug for a non-preferred drug unless the *endorsing practitioner* has indicated DAW or if the Rx is for a refill of:
  - Antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug
- If so, RPh must dispense non-preferred
- If substitute from PDL, must notify prescriber

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### 69.41.190 RCW Preferred drug substitution

- Whenever a prescriber indicates DAW for a non-preferred drug the following will happen:
  - Medicaid – Prior Authorization required
  - UMP – Higher co-pay required
  - L & I - Unknown

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### 69.41.190 RCW Preferred drug substitution

- What is an endorsing practitioner?
- A prescriber who has endorsed the PDL
  - **Has reviewed the PDL**
  - **Agrees that it is OK to substitute preferred Rx**
  - **Will indicate DAW when does NOT want to substitute therapeutically**
  - **Prescribers will sign up with HCA on-line or in writing**

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## 69.41.190 RCW Preferred drug substitution

- Drugs Classes on 11/03 PDL
- ACE Inhibitors
- Calcium Channel Blockers
- Oral Hypoglycemic Agents
- Proton Pump Inhibitors
- Estrogens (tabs & cream only)
- Long acting opioids
- Triptan oral formulations
- Skeletal muscle relaxants
- Statins
- Urinary Incontinence
- NSAIDS/COX-II

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## Examples of PDL

- ACE Inhibitors
  - Captopril
  - Enalapril
  - Lisinopril
  - Ramipril
  - NOTE: No generics yet.
  - (when generics are available they will be preferred drugs)

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## 69.41.190 RCW Preferred drug substitution

- **Interesting questions for pharmacists**
- **What do I dispense when there are several preferred drugs on the PDL?**
- **Will drug companies re-orient their marketing activities towards pharmacists?**

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## 69.41.200 RCW Imprinting Rx

- All solid dosage legend drugs must be imprinted with code etc. to identify:
  - The drug
  - The manufacturer or distributor
- 1. Can't mfr or distribute within state
- 2. Labeling
- 3. Names of BOTH Mfr and Distributor on label

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## 69.41 RCW Imprinting

- 69.41.210 Definitions
- 69.41.220 Publish list of imprints
  - (Board never got funds to do this)
  - See Micromedex, Poison centers, other references.
- 69.41.230 Violations = Contraband
- 69.41.240 Board rules (WAC 246-885)

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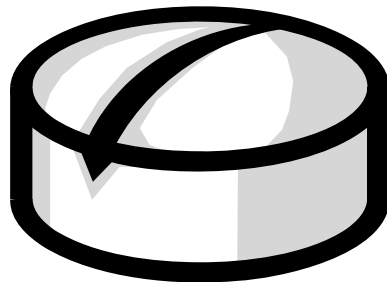
## 69.41 RCW Imprinting

- 69.41.250 Exemptions
- 1) Board may exempt IF infeasible to print
  - e.g., NTG, HT's, TT's, etc.
- 2. Rules do not apply to legend drug mfg or compounded by pharmacy for retail sale BUT not for resale (i.e. to another phcy etc.)
- 69.41.260 Effective Date 12/12/81
- FDA rule requires imprints 9/13/95!!!

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## Imprints on Legend Drugs WAC 246-885

- Per 69.41.200-280
- All solid dosage forms must be imprinted to ID"
  - Drug
  - Distributor
- Per 69.60 RCW
- All OTC drugs must be imprinted



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## 69.41.300 Steroids

- Anabolic steroids & human growth hormone defined
- 69.41.310 Board rules list steroids
  - See WAC 246-883-040
- 69.41.320 Practitioners Use, Records
- No steroids, auto-transfusion to increase athletic ability
- Maintain records of Rxing, dispensing including Diagnosis and basis for Dx

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## Legible prescription

- "Legible prescription means a prescription or medication order issued by a practitioner that is capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order."

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## Legend Drug Act Summary

- We have discussed the State Legend Drug Act that determines how prescription drugs may be prescribed, distributed, and dispensed in WA. Including who may prescribe prescription drugs in this state and specific requirements regarding drug product substitution.

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