

# The Legend Drug Act And Electronic Prescriptions

Chapter 69.41 RCW

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## Readings

- 69.41.010 RCW thru 69.41.350 RCW

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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 understand the requirements for electronic prescriptions.

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## Why have a State Legend Drug Act?

- Without a state law to determine which drugs require a prescription, we would have to rely on federal prosecutions for prescription drug violations that occurred within the state.
- It provides a convenient way for the law to cover all professions rather than having to change each profession's practice act when some provision would apply to all prescribers dispensers, etc.

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## 69.41.010 Definitions

- Essentially the same as 18.64 RCW BUT NOTE: (16) Practitioner: this lists **most but not all** of the persons who may legally prescribe, OR administer legend drugs.
- Also includes which out of state persons may legally prescribe legend drugs.
- Note: Other restrictions & info. may be in the individual practitioner's practice acts.
- (Also see 69.50.101 RCW for controlled substance prescribing authority-instate and out of state.)

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## 69.41.010 Definitions

- (13) "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.
- A prescription must be hand printed, typewritten, or electronically generated.
- NOTE: No penalty for non-compliance!

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## 69.41.020 Prohibited Acts

- Legend drugs may only be purchased, dispensed, administered in accordance with this chapter!
- Violations of Legend drug Act
- Obtain, procure, etc by:
  - a. Fraud, deceit, misrepresentation
  - b. Forgery, alteration of Rx or written order
  - c. Concealment of material fact
  - d. 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.
  - Similar prohibitions as Controlled Substances Act

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## 69.41.020 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

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## 69.41.030 RCW

- Unlawful to sell, deliver, possess legend drug EXCEPT on order or Rx of MD, DO, etc.
- Note: Includes out of State prescriber list
- 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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## 69.41.032 RCW

- Permits Medicare certified kidney dialysis programs to dispense case lots of certain drugs to their patients if prescribed by MD or DO.
- Board has authority to determine which drugs by rule. (See WAC 246-905-020)
  - Heparin, KCl, NaCl, dialysate

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## 69.41.040 RCW

- Prescription Requirements:
- Legitimate medical purpose incl. research
- Authorized prescriber
- NOT valid 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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## 69.41.040 RCW

- Violation if RPh fills & knows or should have known it was not valid Rx. Examples:
  - Rx with typist's white out covering "Ampicillin" now says "Percodan"
  - Forged Morphine Rx's hidden in pharmacy drawer not in Rx file
  - RPh who allowed forger to "practice" writing Rx's in the Pharmacy until they were good enough to pass.
  - Note on back of forged Rx: "It's OK for Jim to have 900 ml of Tussionex - he has a very bad cough."
  - "I see dead people!"

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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

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## 69.41.044 RCW Confidentiality

- Certain records are exempt from public disclosure law (42.56 RCW)
- Info. Received from Mfr., rep of mfr, whl, phcy, practitioner
- This section does not restrict investigations or proceedings of board. But, board must comply with 42.56 RCW (Public Disclosure Law.)

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## Chapter 42.56 RCW public disclosure of records

- Formerly chapter 42.17 RCW
- Most public records possessed by the State are available upon request.
- However there are over 56 separate EXEMPTIONS that prevent many disclosures.
- A Committee is now examining all of these exemptions possible changes in 2009 Legislature.

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## Chapter 42.56 RCW Exemption from public disclosure of records

- Specific intelligence information of law enforcement & disciplinary boards
- Test questions
- *Library records*
- SSN, & residence phone of DOH licensees
- Info. Obtained by BOP 69.45.090 drug samples info. From drug mfrs.

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## Chapter 42.56 RCW Exemption from public disclosure of records

- 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 42.56 RCW more Exemptions from public disclosure of records

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

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## 69.41.055 RCW Electronic Prescriptions

- Electronic Rx's are acceptable
- Must comply with laws & rules
- Board must approve the system & keep list of systems approved (See Board Website)
- Must include choice brand/generic
- System must have adequate security
- RPh professional judgement - validity
- Board can issue rules

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## Electronic Rx, cont.

### **No intervening person may have access to the prescription order**

- Concern -PBM's, payers, others might change order AFTER prescriber transmitted it and before RPh received it.
- MD, RPh, patient might not know about change.
- (NOTE: Medicare Modernization Act preempts this provision also SureScripts needs to have access to get Rx to Pharmacy)

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## DEA's Position on Electronic

- DEA is working on rules for electronic Rx's.
- Current DEA proposal is very complex and will not fly!
- Currently electronic Rx's are NOT OK with DEA - RPh must call prescriber to verify any electronic Rx and treat as a verbal Rx.

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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



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## Rx Samples Labeling by a practitioner

- Original Package
- FDA approved label
- Need only add
- Practitioner Name
- Name of Patient



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## Question

- Have you EVER seen a drug, dispensed by a practitioner that has been properly labeled in compliance with this law?

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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 is needed 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 - Drugs include:
  - Acetylpromazine, Ketamine, Xylazine
- BUT note that Ketamine is now a CS
- See also WAC 246-887-050 for rules re: use of Pentobarbital for euthanasia.

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## 69.41.085 RCW Medication Assistance

- See also definition 69.41.010(14)
- Allows a non-practitioner to **assist** a person in AFH or BH or own home to self-administer a medication.
- May not assist with IV or injectables EXCEPT pre-filled insulin syringes
- Helps keep people out of nursing homes

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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
- (FDA reviews and approves brand and generic names to avoid look-alike and sound-alike drug names)

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## 69.41.110 RCW Substitution

- Substitute to dispense drug with prescriber's 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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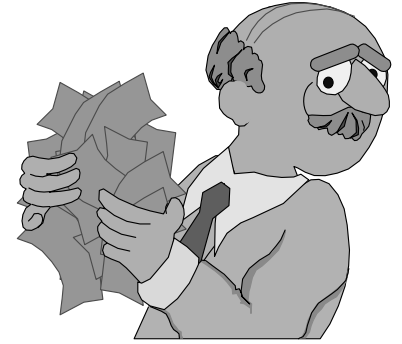
## 69.41.120 RCW Substitution

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

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## 69.41.130 RCW Savings pass on

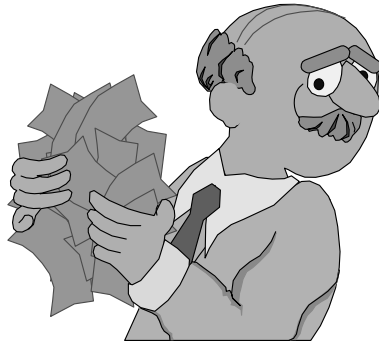
- Patient may request Brand name drug otherwise RPh MUST substitute if prescriber signs on “substitution permitted” line
- If doc signs DAW can't honor patient request for generic unless authorized by prescriber



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## 69.41.130 RCW Savings pass on, cont.

- 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 BUT if imports are allowed into US, this could be an issue again!

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## 69.41.150 RCW Liability Generic or Preferred drug list Prescriber or Pharmacist

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



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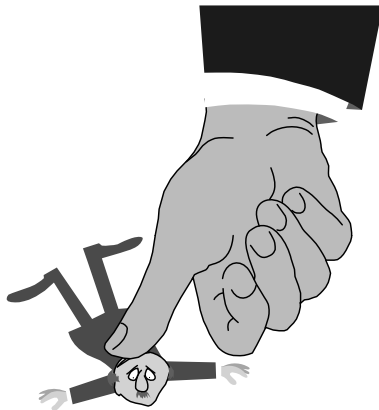
## 69.41.160 RCW Signs

- 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
- BOP has never had such a case



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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 (not in lawbook go to legislative website)

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## 69.41.190 RCW Preferred drug substitution

- Amended in 2003
- Establishes Preferred Drug List (PDL) for state sponsored Rx programs (Medicaid, L&I, Uniform Medical Plan (State employees health plan))
- Pharmacists are performing therapeutic interchange (substitution) for selected drugs on the PDL
- Program started 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, immunosuppressive drug, or an immunomodulator/antiviral treatment for Hepatitis C.
  - If so, RPh must dispense non-preferred Rx
- If substitute from PDL, must notify prescriber

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Here's how each PDL program works if a **non**-endorsing practitioner prescribes a non preferred drug in one of the PDL classes and indicates "dispense as written" (DAW):

**Uniform Medical Plan (PPO):** Higher co-pay for non-preferred drug

**L&I:** A non-endorsing practitioner does not qualify for the "dispense as written" exemption and the non preferred drug would not be payable unless the pharmacist or practitioner calls with medical justification.

**Medicaid:** The pharmacist is required to contact DSHS to request a non preferred drug and show medical justification.

**NOTE:** Each program's rules are fairly complex see HCA or program websites.

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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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## More Information

- See Washington Health Care Authority Website
- [www.rx.wa.gov](http://www.rx.wa.gov)

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## RCW 69.41.200 to 260 Imprinting Rx

- Discussed in previous lecture

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## 69.41.300 to 350 RCW Anabolic Steroids

- NOTE: these drugs are now controlled substances so most prosecutions would be under UCSA
- Anabolic steroids are defined
- Board may make rules
- Practitioners are restricted from prescribing, administering etc.
- Must keep good records if do prescribe

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## 69.41.300 to 350 RCW Anabolic Steroids

- Supt. Of Public Instruction must distribute warning signs to school districts and districts are to post signs
- Penalties for students who violate law regarding use of these drugs.
- Restrictions apply to high school and college athletes
- Penalties for possession

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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.