

# Board of Pharmacy Rules

(Around the Law book in 100 min)

Board rules that are important to  
the practice of pharmacy  
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## Clarification on 1306.11

- (e) A prescription written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription

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- A prescription written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription

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- A prescription written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription

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## WAC 246-858 Internship

- Interns
  - Licensed when accepted to Rx School
  - Intern hours count after 1st Qtr of 1st prof. year
  - 1500 hours are required (will increase to 1740)
  - Board will accept 1200 hours of Rx classes
  - WA Board accepts out of state hours IF other State's Board of Pharmacy accepts them.
  - Must be making academic progress to retain license

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## Internship -cont.

- Preceptor
  - Must have preceptor endorsement or hours  
**WILL NOT BE ACCEPTED!**
  - Advise Board at start of practice experience
  - Reports required
- Special internships
  - Must apply to Board for *prior* approval

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## WAC 246-861 Pharmacy C.E.

- 15 hours required for license renewal
- ACPE accredited or Board approved
- Approval forms in Law book
- Audits performed annually
  - Keep records for 2 years
  - Send certificates ONLY if requested
- Can get credit for instructing BUT not for being a COP faculty member
- CE Waivers available- illness etc

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## WAC 246-861 Pharmacy C.E.

- New pharmacy graduates are EXEMPT from the CE requirement for their First license renewal.
- Note: Somehow, this rule got accidentally deleted when the Board last amended this chapter. However, it remains as a Board policy.
- This policy does NOT apply to newly licensed pharmacists who reciprocated from another state - They are NOT usually "new graduates."

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## Pharmacist Licensing

- Professional Responsibilities
- See list only RPh may perform-below
- RPh Prescriptive Authority
- RPh Drug Therapy monitoring
- AIDS CE requirements
  - 7 hrs
  - one time only

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## Pharmacist Responsibilities

- Receipt of verbal prescriptions
- Consultation with patients
- Consultation with prescribers
- Extemporaneous compounding
  - Bulk compounding from formula by tech &
  - IV admixtures by tech OK

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## Pharmacist Responsibilities, cont.

- Interpretation of patient record data
- Ultimate responsibility for Rx
- Dispensing Rx to patient with consult
- Signing poison registry & C-V book
- Professional communications with MD, RN, other health practitioners
- Using personnel to assist the RPh

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## Pharmacist Responsibilities, cont.

- The responsible pharmacist retains responsibility for any assisted tasks and determine extent to which personnel may be utilized to assist the pharmacist.
- It is OK to delegate to interns & externs
- Interns may do ANYTHING RPh may do UNDER THE SUPERVISION OF RPh.

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## Pharmacist Responsibilities, cont.

- New Rules 2007 - No Refusal to Fill Rx
- See BoP website WAC 246-869-010 & WAC 246-863-095
- Board tried to deal with RPh conscience issue BUT did not consider political realities.
- Primarily deals with OC's & Plan B BUT...
- It is pharmacy's responsibility to meet patient's Rx needs UNLESS certain exceptions apply.

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## Pharmacist Responsibilities, cont.

- Must provide patients with timely alternative to appropriate therapy when Rx is not in stock due to temp. not in stock or not customarily needed by the pharmacy's patients.
- Alternatives: Obtain Rx and deliver to patient
- Contact prescriber for therapeutic equivalent
- Return Rx to patient IF requested
- Transmit Rx to another phcy IF requested
- RPh may NOT refer patient to another pharmacy due to moral or ethical objections.

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## Pharmacist Responsibilities, cont.

- EXCEPTIONS:
- National or State emergencies affecting availability
- Potentially fraudulent prescriptions
- Unavailability of Rx despite a good faith effort to comply with rule concerning "adequate stock."
- Lack of specialized equipment or expertise to safely produce, store, or dispense Rx
- When the pharmacy is not compensated for its usual and customary or contracted charge.

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## Pharmacist Responsibilities, cont.

- What else can you NOT do?
- Destroy unfilled lawful prescriptions
- Refusing to return unfilled lawful prescriptions
- Violating a patient's privacy
- Discriminating against patients as prohibited by law
- Intimidating or harassing a patient

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## Pharmacist Responsibilities, Questions

- What have pharmacists done to cause this reaction?

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## Pharmacist Responsibilities, Answers

- What have pharmacists done to cause this reaction?
- Refused to fill Rx's
- Refused to return Rx's that they refused to fill
- Torn up prescriptions that they refused to fill
- Loudly disparaged the patient for even wanting the drug.
- Calling the patient names (sinner, etc.)
- Refusing to fill prescriptions for AIDS patients

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## Pharmacist Responsibilities

- NOTE: Two pharmacists and a pharmacy have sued the Board and a Court has enjoined the Board from enforcing the provisions of the the Board rule requiring pharmacists to fill ALL prescriptions. This rule will not be in effect unless the Board prevails in the lawsuit scheduled for trial in 2009

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## 246-865 Extended Care Facility

- Emergency kits authorized
  - Owned by Pharmacy
  - Limited contents
  - CS are included in Phcy biennial inventory
- Supplemental dose kits for Unit dose sys.
- See specific rules on drug delivery, storage, record keeping, etc.

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## 246-865 Extended Care Facility

- Question:
- When you perform the pharmacy's DEA inventory do you include controlled substances in the emergency kits of the nursing homes that you serve?

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## 246-867 Impaired Pharmacist

- Treatment preferred to Discipline
- WRAPP program available
- Supported by license fees
- Refusal to participate = Revocation
- Records are confidential

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## 246-869 Pharmacy Licensing

- NOTE: Most of the inspection rules are contained in this chapter- Know them!
- Differential Hours (Pharmacy Dept. is open shorter hours than rest of the store)
  - Physical requirements - Security
  - Patient may leave Rx in locked box
  - No Rx's dispensed if RPh not present
  - Prior Board Inspection & approval required

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## Pharmacy Licensing

- All new pharmacies are inspected prior to opening
- Each pharmacy must have Responsible Pharmacist Manager
- Must require evidence of qualifications

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## Pharmacy Licensing

- Prescription transfers
- Similar to DEA requirements
  - No limit on number of transfers of legend Rx
  - May transfer via FAX

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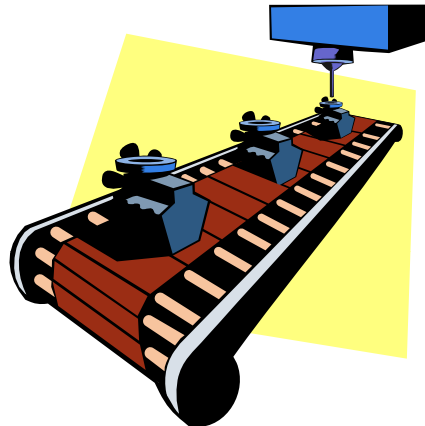
## Prescription Records

- Retain for 2 years -Also see statute of limitations for possible lawsuits
- Injured children 2 yrs from discovery or 18
- Medicaid 7 years, other insurance varies
- Specific information required
- May not refill after ONE year
- PRN refills expire in ONE year
- Rx Copies are “For info only” - Call Doc.
- Emergency Refills OK till prescriber may be contacted - 72 hour limit

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## Automated Devices

- WAC 246-872
- Finally updated 12/06
- Sets general stds.
- Includes Pyxis and similar equipment
- Insure security & accuracy



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## Return or Exchange of Drugs

- Generally prohibited
- Some exceptions -
  - Sealed containers
  - Unit dose
  - Drug was under control of nurse
  - Integrity insured
  - CS return limited by DEA rules

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# Pharmacy Standards

- Adequate Stock (more important now)
- Adequate Facilities
- Physical Standards
- Equipment - Whatever is needed
  - Balance for compounding
  - Laminar hood for IV's
- References - Law book plus current ref. References could be on-line

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# Physical Standards, cont.

- Refrigerator
  - Temp range 36-46 degrees F
  - Clean
  - No food & drug mixing
  - Lock if outside of pharmacy area

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# Conversing with the RPh

- Rule being considered for repeal
- Passed in 1960
- Historical RPh role
- “Don’t bug the pharmacist while he/she is filling a prescription!”



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# Pharmacy Inspections

- Periodic - every 18 to 24 months
- Class A - Score 90-100
- Conditional - Score 80-89
  - Must get A within 60 days
- Unsatisfactory - Score < 80
  - Must get A within 14 days
- Must post inspection certificate

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## Poison Control

- Poison Control Center Phone Number available:
  - Seattle 1-800-732-6985
  - National 1-800-222-1222
- Bottle of ipecac in stock 30 ml
  - Is this still a valid requirement?

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## Rx Labeling WAC 246-869-210

- See also:
  - RCW 18.64.246
  - WAC 246-865-060 Nursing Home
  - WAC 246-871-050 Parenterals
  - WAC 246-873-080 Hospital
- See list of requirements for each type of Rx label (suggest making a chart)

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## Patient Information (Counseling)

- Required for ALL New prescriptions
- Refills as needed - RPh judgment
- Orally if Rx delivered in Pharmacy
- Phone or written if delivered outside of pharmacy
  - Must advise patient how to contact RPh
- Inpatient orders exempt

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## Child Resistant Containers

- Covered in CRC Law discussion

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## Closing a Pharmacy

- Notify Board 15 days before closing
- Provide more info 15 days after closing
- Records, CS, Rx, labels, etc.
- Remove or cover signs - Drugs, Pharmacy, etc.



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## Customized Medication Packages

- May use Med-Packs (Compliance pkg.)
- May put more than one drug in a blister
- Limit supply
- Label with all drugs (see list)

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## 246-871 Parenterals for Home Patients

- See specific standards for this practice
- Equipment, records, personnel, labeling
- Special conditions for antineoplastic Rx
- Quality assurance

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## 246-873 Hospital Pharmacy Std.

- To be discussed in a later lecture

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## 246-875 Pharmacy Patient Record Systems (Patient Profiles)

- Profiles must be maintained **AND** used in filling prescriptions (Recent Lawsuit)
- Note: required content of records
- Manual or computerized systems
- Information is **CONFIDENTIAL**
  - May share with other pharmacies or prescribers who may provide care to patient

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## 246-877 Sales Prohibited

- **NOTE: This chapter was accidentally left out of 2004 Law Book. Obtain from Legislative Website**
- Retail pharmacies may not possess, distribute, or dispense physician's samples. OK for Hosp. Phcy. & Health Care Entities (e.g., Group Health, clinics, etc.)
- Some pharmacies (clinics) have Board permission to distribute samples on Rx
- No one can sell samples!

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## 246-878 Good Compounding

- Discussed by Dr Hazlet in another lecture
- If you comply with these standards should not have a problem with FDA or the Board

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## 246-879 Drug Wholesalers

- Standards expanded due to PDMA of 1987
- Licensing, records, storage, security, returns
- Out of state wholesalers licensed if ship to pharmacies, doctors, etc in WA

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## 246-879 Drug Wholesalers

NABP program to assist States with inspections  
Verified Accredited Wholesaler Program (VAWD)  
Wholesaler submits extensive application & fee.  
NABP surveyor inspects, reports  
NABP evaluates reports & decides

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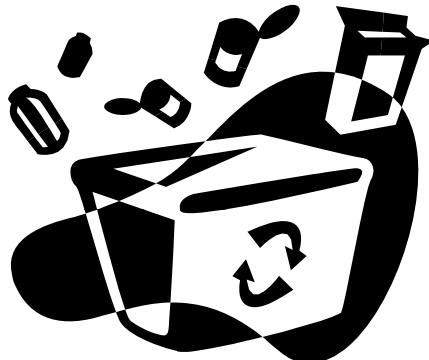
## 246-879 Drug Wholesalers

Indiana was 1st to require VAWD cert.  
North Dakota 2nd  
Other States considering it  
289 Wholesalers have been accredited

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## Salvagers

- Tylenol with odor  
– Pine-sol??
- Outdates/damaged goods purchased by salvager
- Redistributed
- Watch out for “cheap drugs”



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## 246-881 Prescription Advertising

- OK to advertise prices
- Must use generic name if use trade name
- May NOT advertise CS
- MUST disclose prices upon request of **consumer**
- Sharing prices with other pharmacies may be an Anti-trust violation

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## 246-883 Sales Requiring Rx's

- "Blue Book" was used to designate legend Rx Now use "Red Book" (See "Rx" next to drug name)
- Introductory/trade packages OK
- Ephedrine Restrictions
  - Plain Ephedrine = Legend Rx in WA
  - Some Combination products OK for OTC
  - (see list)
  - Ma Huang/Ephedra restricted 25 mg/dose
    - NOTE: Appeals Court upheld FDA ban on ephedra
- Anabolic Steroids - Now CS
- Theophylline formerly OTC now restricted by FDA rules

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## 246-885 Imprints on drugs

- Washington requires imprints on all solid dosage forms (OTC & Legend) to identify drug and manufacturer.
- See RCW 69.41.200 Legend
- See RCW 69.60 OTC
- Now also required by FDA

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## Controlled Substances Law 69.50 RCW

- NOTE: This law covers both licit and illicit drugs. Don't worry about the criminal sections UNLESS you plan to violate this law.

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.101 RCW Definitions
  - (w) Practitioner – includes persons who may prescribe CS instate and out of state
- 69.50.102 RCW Drug Paraphernalia
  - Criminal provisions
- 69.50.201 RCW Enforcement & Scheduling
  - Standards used by Board for scheduling

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.308 RCW Prescriptions
  - Written Rx for II
  - Emergency Rx's
  - Rx's for III-IV
  - Legitimate medical purpose
  - Medical purpose for Schedule V
  - No CS Rxing for self

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.306 RCW Records
  - You gotta keep them
- 69.50.307 RCW Order forms
  - Section repealed – DEA NOW allows electronic ordering of II's
- 69.50.308 RCW Containers
  - Patients must keep CS in Rx container

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.310 RCW Humane Societies  
OK to use Sod. Pentobarbital for euthanasia of animals
- 69.50.311 RCW Triplicate Prescriptions  
Practitioners will consent to use triplicates  
Used in disciplinary cases  
Board may order all Rx's or just certain schedules to be on triplicate forms  
Copy is sent to Board  
Will be replaced by CS Rx Monitoring Program (PMP)

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.311 RCW Electronic Rx Information
  - Same provisions as 69.41.055 RCW

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.402 RCW More Prohibited Acts
  - Obtaining by fraud, deceit etc.
  - Forgery
  - False information to provider
  - Use of > one name to get Rx
  - False information not a privileged communication

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## Controlled Substances Law 69.50 RCW, cont.

- 69.50.402 RCW More Paraphernalia
  - Civil Penalties Provided
  - See 2002 changes regarding syringes
  - Also left out of law book - See RCW 70.115
- 69.50.500 to end
  - Mostly criminal stuff
    - Inspections, searches, seizures, etc.

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## 246-889 Precursor Chemicals

- These are drugs that are used in the manufacture of illicit drugs including Methamphetamine.
- NOTE: THESE RULES HAVE BEEN AMENDED DUE TO LAW CHANGES 2002-2006-SEE LEGISLATIVE WEBSITE
- See also DEA rules 21 CFR 1314.01- .155
- Mostly from the 2006 revisions to the “Patriot Act”.

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## 246-889 Precursor Chemicals

- Pharmacists need to mostly be concerned with ephedrine, pseudoephedrine & phenylpropanolamine (PPA)
- PPA is banned for humans but used in horses
- Behind the counter or locked storage
- Keep log
- Get photo ID
- Train staff & certify training to DEA

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## 246-889 Precursor Chemicals

- Daily personal sale limit = 3.6 gm
- Monthly limit 9 gm
- No sales < 18 years old
- No exemptions for pediatric doses (was in WAC)
- Note: WA law & rules calculate pseudoephedrine content on grams of Salt
- DEA calculates on the grams of Base

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## 246-891 Prophylactics

- Historic responsibility of Board
- Some standards continue in effect
  - Expiration date
  - Packaging
- Did study for FDA to establish new shelf life and testing standards

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## Good Manufacturing Practice Standards WAC 246-895

- Some small manufacturers do not ship products in interstate commerce.
- State needs GMPs comparable to FDA's
- What's the deal with "teat dip"?

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## WAC 246-895 Drug Availability

- Sometimes, people go to the Legislature to get them to allow use of drugs that FDA has not approved
  - Laetrile
  - DMSO (dimethylsulfoxide)
- No one has ever applied to manufacture or distribute these drugs in Washington

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## Drug Product Substitution WAC 246-899

- **NOTE: This chapter was accidentally left out of 2004 Law Book. Obtain from Legislative Website**

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## Drug Product Substitution WAC 246-899

### Dispensing Responsibilities

On oral Rx indicate on the record if substitution is permitted

Indicate mfr or dist of product dispensed (can use NDC, trade name, etc.)

Change info on record if refill is different

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## Drug Product Substitution WAC 246-899

### Labeling

Generic or Trade name of product  
generic names of multiple ingredients or trade name of product

May abbreviate if multiple ingredients at the discretion of the pharmacist.

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## Drug Product Substitution WAC 246-899

For Institutionalized or closed system patients

RPh may identify manufacturer in purchasing records, or packaging records

A published formulary designation may be used on the label

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## Drug Product Substitution WAC 246-899

### Product Selection Responsibilities

Professional responsibility of pharmacist

Use info from federal & state agencies

official compendia, Rx mfr.

Other scientific or professional  
resources including FDA Orange Book

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## Drug Product Substitution WAC 246-899

Prior Authorization (PA) from prescribers

If you fill based on PA, you must keep the  
PA available for review in the pharmacy  
records

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## 246-901 Pharmacy Technicians

- Duties described
- Limits described
- Ratios described BUT Board allowed to change and did so. (1997 law change)
- Specialized functions authorized (tech check tech)
- Training program approval by Board
- Utilization approval by Board

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## Pharmacy Technicians

- Level A = Pharmacy Technicians (1997)
- Level B = Pharmacy Assistants (1997)
- Pharmacy techs may assist with filling Rx EXCEPT for final check

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## Pharmacy Technicians

- Pharmacy Technicians
  - Must have completed Board approved training program and have license posted in pharmacy
- Pharmacy Assistants
  - Must apply to Board within 3 months of hire to allow time to get AIDS CE
  - Must have application on file in pharmacy until then
- AIDS CE required for Techs & Asst - 4 hours one time only

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## 246-903 Nuclear Pharmacy

- Pharmacists must be specially trained
- Pharmacy must meet standards of
  - Board of Pharmacy
  - FDA
  - Nuclear Regulatory Commission
  - State Radiation Agency

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## 246-904 Health Care Entities

- Not to be confused with HCE mentioned in Prescription Drug Marketing Act of 1987 to be discussed later.
- The law and this rule allow ambulatory surgical centers to obtain, administer and dispense drugs.

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## 246-905 Home Dialysis Program

- Medicare approved dialysis programs may provide case lots of certain legend drugs to their patients:
  - Heparin
  - Potassium Chloride
  - Sodium Chloride
  - Dialysate
- Need RPh Consultant, Records, QA

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## Misc. Statutes and Rules

- See pages 255 - 290 in Law book/BoP CD
- Mostly includes laws and rules about prescribing or dispensing authority of other health professionals.
- (may be helpful in the “Who can prescribe exercise?”)BUT ARNP, OD & ND changed since the Law Book was printed.
- Some laws affecting pharmacies
  - Strychnine, Hypodermic devices, Rx sales tax, etc.

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## Summary

- This lecture has discussed the most important rules that are contained in the Washington State Board of Pharmacy Law book
- Students should be able to use this material to practice pharmacy legally during their Initial Pharmacy Practice Experiences (IPPE) and Advanced Pharmacy Practice Experiences (APPE) and be able to pass the law exam upon graduation.

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