

Board of Pharmacy Rules (Around the Law book in 90 min)

Board rules that are important to the practice of pharmacy
(Not to mention passing the class)

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BoP Rules - Objectives

- ◆ The student will be able to follow the rules that are important to pharmacy practice in Washington.
- ◆ The student will be able to discuss and apply the legal concepts contained in WAC 246-858 through 905

Hint:
It is worth reading the WACs in the Salmon Book!

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WAC 246-858 Internship

- ◆ Interns
 - Licensed after 1st Qtr of 1st prof. year
 - 1500 hours are required
 - 1200 hours may be in classes
 - Board accepts out of state hours IF that Board accepts
 - Must be making progress to retain license

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Internship -cont.

- ◆ Preceptor
 - Must be approved or hours WILL NOT BE ACCEPTED!
 - Advise Board at start of internship
 - Reports required
- ◆ Special internships
 - Must apply to Board for 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

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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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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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246-867 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
 - Board approval required

Pharmacy Licensing

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

Pharmacy Licensing

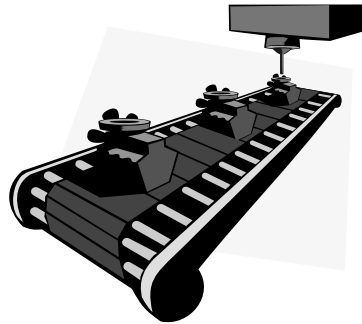
- ◆ Prescription transfers
- ◆ Similar to DEA requirements
 - No limit on number of transfers of legend Rx
 - May transfer via FAX

Prescription Records

- ◆ Retain for 2 years -Also see statute of limitations for possible lawsuits
- ◆ 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

Mechanical devices in Hospitals

- ◆ Outdated 1965 rule
- ◆ Now handle new applications on case by case basis
- ◆ New rule due soon



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Return or Exchange of Drugs

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

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Pharmacy Standards

- ◆ Adequate Stock
- ◆ 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 repealed
- ◆ Passed in 1960
- ◆ "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

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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 outside of pharmacy
 - Must advise patient how to contact RPh
- ◆ Inpatient orders exempt

Child Resistant Containers

- ◆ Covered in CRC Law discussion

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.



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)

246-871 Parenterals for Home Patients

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

246-873 Hospital Pharmacy Std.

- ◆ To be discussed in a later lecture

246-875 Pharmacy Patient Record Systems (Patient Profiles)

- ◆ Profiles must be maintained **AND** used in filling prescriptions
- ◆ Note: required content of records
- ◆ Manual or computerized systems
 - All Washington pharmacies have computer now.
- ◆ Information is **CONFIDENTIAL**
 - May share with other pharmacies or prescribers who may provide care to patient

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.)
- ◆ No one can sell samples!

246-878 Good Compounding

- ◆ To be discussed in another lecture
- ◆ If you comply with these standards should not have a problem with FDA

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, etc in WA
- ◆ Salvager's have presented a problem

Salvagers

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



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

246-883 Sales Requiring Rx's

- ◆ "Blue Book" was used to designate legend Rx Now "Red Book"
- ◆ 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
- ◆ Anabolic Steroids - Now CS
- ◆ Theophylline now restricted

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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 may allow 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

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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 Prohibited Acts
 - Limits on prescribing Sched II stimulants
 - ◆ Narcolepsy
 - ◆ Hyperkinesis (ADHD)
 - ◆ Drug-induced brain dysfunction
 - ◆ Epilepsy
 - ◆ Differential diagnosis of depression
 - ◆ Refractory depression
 - MD or RPh Should place diagnosis on Rx
 - Board may add other conditions by rule

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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
 - 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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246-887 Controlled Substances

- ◆ Adopted DEA rules by reference with **some** exceptions
- ◆ Some state rules more stringent than DEA
 - CS transfers only made in EMERGENCIES
 - Schedule II records must be separate
 - Schedule V sales – Several differences from DEA
 - Non-narcotic Schedule II restrictions
 - ◆ ADHD, Narcolepsy, Epilepsy, etc (See 69.50.402 RCW)

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Controlled Substances

- ◆ Board collects information on CS samples sent to practitioners

246-889 Precursor Chemicals

- ◆ These are drugs that are used in the manufacture of illicit Methamphetamine
- ◆ Should not involve pharmacy practice EXCEPT when a pharmacy sells large quantities of ephedrine or pseudoephedrine products that may be used illegally.
- ◆ Now they are shoplifting pseudoephedrine due to sales restrictions

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

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"?

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

Drug Product Substitution WAC 246-899

- ◆ **NOTE: This chapter was accidentally left out of 2003 Law Book. Obtain from Legislative Website**

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

Pharmacy Technicians

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

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
- ◆ 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.

Summary

- ◆ This lecture has discussed the most important rules that are contained in the Washington State Board of Pharmacy Law book (Salmon - 2003)
- ◆ Students should be able to use this material to practice pharmacy legally during their internship and externship and be able to pass the law exam upon graduation.