

The Washington State Pharmacy Practice Act

- Also:
- Institutional Practice
- Miscellaneous Laws
 - Medicare/Medicaid
 - JCAHO
 - CPSC
 - Tamper-Resistant Pkg
 - Postal Service



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Readings

- RCW 18.64
- RCW 18.64A
- WAC
- 16CFR1700.16

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Objectives

- To review and understand the Pharmacy Practice Act (Chapter 18.64 RCW)
- To discuss Institutional Pharmacy Practice
 - Including Medicare & Medicaid, JCAHO
- To discuss other laws & rules
 - CPSC, PDMA, Robinson-Patman Act, Syringe sales

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Pharmacy Act 18.64 RCW

- 18.64.001 Board of Pharmacy
- Appointed by Governor/Senate Confirm
- 7 members (2 Public & 5 RPh)
- Citizen, Resident of WA, Lic for 5 years
- Public members NOT affiliated with Phcy
- Four Year terms, two term limit

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Pharmacy Act 18.64 RCW cont..

- 18.64.003 Meetings, Chair, Compensation
- Meet PRN (About every 6 weeks)
- Officers - Chair, Vice Chair (Jan to Jan)
- Compensation \$ 50.00/day
- Travel expenses

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Pharmacy Act 18.64 RCW cont...

- 18.64.005 Board Powers & Duties
- 1) Similar to UDA (18.130 RCW discussed earlier)
- 8) Adopt rules for Continuing Education

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Pharmacy Act 18.64 RCW cont...

- 18.64.009 Peace officers
- Board designates enforcement officers
- Declared to be peace officers
- Vested with authority to enforce Drug Laws (see list) and other board rules.

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Pharmacy Act 18.64 RCW cont...

- 18.64.011 Definitions
- 1) Person - broad (individ, corp, etc...)
- 2) Board = Board of Pharmacy
- 3. Drugs
 - a) items in USP & Homeopathic Pharmacopea
 - b) Substances for Dx, Cure, mitigation, TX
 - c) Subs. affect structure/function of body
 - d) Subs. intended as component of above BUT not devices

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Pharmacy Act 18.64 RCW cont...

- 4) Device
- 5) Non-legend = OTC
- 6) Legend = Rx (by Fed/state law or rule)
- 7) Controlled substance see 69.50
- 8) Prescription - order for Rx
- 9) Practitioner - authorized to prescribe
- 10) Pharmacist

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Pharmacy Act 18.64 RCW cont...

- 11) **Practice of Pharmacy**
- Interpreting Rx orders, compounding, dispensing, labeling, **administering**, distributing drugs & devices
- **Monitoring Rx therapy**
- **Initiating or modifying therapy (protocols)**
- **DUR, drug product selection**, Keep records, provide information, (Rx value, hazards & uses)

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Pharmacy Act 18.64 RCW cont..

- 12) Pharmacy. Location Licensed by Board where practice of pharmacy is conducted
- 13) Exclusions from Drug or Device
 - surg. instruments, lab materials, GAS & OXYGEN, Therapy equip, X-ray apparatus. etc.... pesticides, medicated feed
- 14) Poison (NOT include pesticides)
- 15) Deliver/delivery - transfer to another person

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Pharmacy Act 18.64 RCW cont...

- 16) Dispense- Interpretation of drug order, selection, measuring, compounding, labeling, OR packaging necessary to prepare order for delivery.
- 17) Distribute - delivery BUT NOT administering or dispensing
- 18) Compounding - combining ingredients
- 19) Wholesaler - resale to OTHER than consumers

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Pharmacy Act 18.64 RCW cont...

- 20) Manufacture- preparation, compounding, processing of drugs, OR packaging/repackaging, labeling or reliable, NOT include activities of a practitioner who in the course of professional. practice prepares, etc...
- 21) Manufacturer - person who manufactures
- 22) Labeling - process of preparing and affixing label Must include all information

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Pharmacy Act 18.64 RCW cont...

- 23) Administer - direct application of drug by ANY means to body of patient or research subject.
- 24) Master License System - A system in Dept of Licensing to license a variety of persons including Shopkeepers (see 18.64.044)
- 25) Department = Dept of Health
- 26) Secretary = Secretary of Health

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Pharmacy Act 18.64 RCW cont...

- 18.64.020 RCW Licensing required to:
 - Practice Pharmacy
 - Operate a Pharmacy
 - MUST be licensed as a pharmacist or place a pharmacist in charge
- This does NOT apply to manufacturers or wholesalers within the scope of their licenses

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Pharmacy Act 18.64 RCW cont..

- 18.64.040 Examination fee
- Established by Secretary of Health

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Pharmacy Act 18.64 RCW cont..

- Board issued licenses
 - Must submit application
 - Must declare ownership
 - Must pay original & renewal fees
 - Must pay late renewal fee if late
 - Subject to discipline for violations

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Pharmacy Act 18.64 RCW cont..

- 18.64.043 Pharmacy License
- Entitled to operate pharmacy location
- Must notify DoH of change of location or ownership & keep license exhibited in pharmacy

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Pharmacy Act 18.64 RCW cont..

- 18.64.044 RCW Shopkeeper's Registration
- OK to sell OTC's in ORIGINAL PACKAGE
- Fee (not to exceed cost of registration)
- Misdemeanor to sell without registration
 - each day is a separate offense

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Pharmacy Act 18.64 RCW cont..

- 18.64.045 RCW Manufacturer's License
- Authorized to manufacture drugs
- violations = misdemeanor

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Pharmacy Act 18.64 RCW cont..

- 18.64.046 RCW Wholesalers license
- OK to sell legend drugs and OTC or
- OTC only at wholesale
- Wholesale = Sales to other than consumers

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Pharmacy Act 18.64 RCW cont..

- Itinerant Vendor's (Peddler's) Registration
- Sell door to door
 - Watkins products, Fuller Brush, etc...
- Veterinary OTC Drugs
 - Deliver to dairy farms, etc...

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Pharmacy Act 18.64 RCW cont..

- 18.64.050 RCW Duplicate licenses & Certified documents
- Furnish proof of loss (usually notarized statement)
- Pay fee

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Pharmacy Act 18.64 RCW cont..

- 18.64.080 RCW Licensing of Pharmacists
- 18 years old
- Good Moral & Professional Character
- Not unfit - Drugs, Alcohol, CS, physical, mental health issues
- B.S. or Pharm. D. - Accredited Rx school or col.
- Internship
- Pass examinations
- See rules WAC 246-863)

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Pharmacy Act 18.64 RCW cont..

- Exam offered at least 2 times per year (now offered daily!)
- If fail may take two more times in 3yrs
 - Transferring a failed score counts as a failure
- IF 3 failures need additional preparation as directed by the Board.
- Interns
 - Enrolled in an accredited Rx school or college
 - Making timely progress towards degree
 - Board may issue license to those needing it.

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Pharmacy Act 18.64 RCW cont..

- Pharmacy Licensing Rules/Procedures
- NAPLEX & MPJE Computerized
 - Offered daily PearsonVUE computer centers (1/08)
 - Seattle, Renton, Spokane Valley, & Yakima
 - Results in 3 to 5 days
 - Scaled Score of 75 needed to pass
 - May transfer scores to other States
 - (e.g., Oregon & Idaho etc.)
 - May not practice until license in hand

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Pharmacy Act 18.64 RCW cont..

- Pharmacy Licensing Rules/Procedures
- Reciprocity of license
 - Use NABP Procedure
 - Must have a current license in a State where you have a license by EXAMINATION (Some States may allow if active you have licence by reciprocity) Always keep active at least 1 license by exam.
 - Score transfer counts as license by exam
 - FL – NAPLEX within past 12 years
 - CA – Now uses NAPLEX BUT trying to change law to allow reciprocity

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Pharmacy Act 18.64 RCW cont..

- Interns continued
- Practice in pharmacy after registration
- Other locations may be approved by board
- See board rules (WAC 246-858)

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Pharmacy Act 18.64 RCW cont..

- 18.64.140 RCW Annual Renewal RPh Lic.
- Fees determined by Secretary
- May stagger renewals (birthdate)
- Renewal fee plus penalty if late
- Entitled to Pharmacy Lawbook & Updates
- Inactive License Available
- May reactivate (See WAC 246-863-070)
- Be careful about letting license lapse!

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Pharmacy Act 18.64 RCW cont..

- 18.64.160 RCW Refusal, suspension & Revocation of pharmacists& intern licenses (See also 18.130.180 RCW - U.D.A.)
- Covered earlier.

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Pharmacy Act 18.64 RCW cont..

- 18.64.245 Prescription Records
- Records are readily available for two years
- Record of every Rx numbered, dated, filed
- Produce in Court or Grand Jury as required
- Comply with C.S. Record keeping requirements
- Confidential for use in Pharmacy only.
- Open for inspection BoP, Law Enf. Off. with authority to enforce Rx laws.

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Pharmacy Act 18.64 RCW cont..

- 18.64.246 RCW Prescription labels, caps (Revised 2002)
- Name & address of pharmacy Rx no., name of prescriber, directions, name & strength of drug(can omit/MD), name of patient, date, expiration date. Cap shall meet board standards (see WAC 246-869-230) If combo, use generic names or trade name on label. Identify RPh responsible on label or in pharmacy records.
- This section does NOT apply to Hospital inpatients

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Pharmacy Act 18.64 RCW cont..

- Unlawful practices - continued
- 6) Title protection for profession(Phcy only)
- “Drug store”, “Pharmacy”, drugs, show globes, signs etc....
- Misdemeanor - each day separate violation
- (Make sure signs are removed from closed pharmacies)

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Pharmacy Act 18.64 RCW cont..

- 18.64.255 RCW Authorized Practices
- (Keeps Pharmacy Act from controlling other professions)
- 1) Can't restrict other practitioners
- 2) Allows designated RN in HOSPITAL to enter pharmacy in absence of RPh to get Rx in an emergency.(Must leave proper record)
- 3)Can't stop OTC sales by other licensees if properly labeled & original packages.

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Pharmacy Act 18.64 RCW cont..

- 18.64.257 RCW Dialysis Programs (See RCW 69.41.032 also)
- Discussed earlier

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Pharmacy Act 18.64 RCW cont..

- 18.64.270 RCW Responsible for Drug Purity
- Proprietor responsible for quality of drugs
- EXCEPT if sold in original package and patent or proprietary medicines
- Adulteration = misdemeanor
- Forfeiture of the drug products

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Pharmacy Act 18.64 RCW cont..

- 18.64.275 Limitations on Liability for dispensing of prescriptions
- 1) RPh Not liable if dispensed drug was:
 - in form mfg by commercial manufacturer
 - a) strict liability in tort
 - b) Implied warranty provisions
- 2) Must comply with record-keeping rules and related rules

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Pharmacy Act 18.64 RCW cont..

- (See Tacoma DES Case)
- 3) RPh IS liable for injury IF harm was proximately caused by:
 - a) Negligence
 - b) Breach of express warranty made by RPh
 - c) Intentional misrepresentation of facts or intentional concealment of information about the product by the pharmacist

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Pharmacy Act 18.64 RCW cont..

- Is the pharmacist protected from liability under 18.64.275 RCW when he/she compounds a prescription product?

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Pharmacy Act 18.64 RCW cont..

- 18.64.310 RCW Department of Health
- 1) Establish license fees
- 2) Employ Executive Director, with confirmation by board. ED shall be a licensed pharmacist, exempt from civil service rules, employ investigators, etc...
- 3) Investigate & prosecute violations, at direction of board.

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Pharmacy Act 18.64 RCW cont..

- DoH cont.inued
- 4) Make, at direction of board, inspections, investigations, etc... Seize adulterated, misbranded drugs, etc... Provide a written operating agreement with board

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Pharmacy Act 18.64 RCW cont..

- 18.64.350 Nonresident pharmacies
- Legislative intent section
- Pharmacy is patient oriented health service
- There are alternative methods to deliver services
- It is necessary to license out of state pharmacies to protect WA citizens

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Pharmacy Act 18.64 RCW cont..

- Nonresident pharmacy must be licensed IF ships, mails, delivers to an individual CS, legend drugs or devices in WA EXCEPT if delivers in person and shall provide to DoH:
- a) Location, names of owners, list of RPh etc... Report this information annually.
- b) Proof it complies with its home state laws. Must keep valid license, submit insp. report

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Pharmacy Act 18.64 RCW cont..

- c) WA patient records must be readily retrievable.
- 2) Must have toll free number for patients and place this number on Rx labels
- 3) Must comply with WA board rules re: patient medication record systems
- 4) Must comply with WA board rules re: patient information. (Written info is OK BECAUSE Rx is delivered outside of the pharmacy - See patient counseling rule)

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Pharmacy Act 18.64 RCW cont..

- 5) May not dispense in quantity greater than prescribed
 - Some mail order pharmacies were dispensing original and ALL refills at once!
- 6) License fee not to exceed in-state phcy
- 7) Board may grant exemption for isolated transactions (e.g..., border pharmacy)
- 8) Must name resident agent in WA

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Pharmacy Act 18.64 RCW cont..

- 18.64.370 RCW Nonresident Pharmacies
 - 1) No business without license
 - 2) DoH application form
 - 3) Annual renewal
 - penalty fee for late renewal
 - 90 Nonresident pharmacies licensed 9/95
 - 238 nonresident pharmacies licensed 9/02

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Pharmacy Act 18.64 RCW cont..

- 18.64.380 RCW Nonresident Information Required
 - 1) Provide information Re controlled substances
 - 2) Submit to onsite inspection if above is NOT provided to Washington upon request.

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Pharmacy Act 18.64 RCW cont..

- 18.64.370 RCW Nonresident - violations
 - 1) Deny, suspend, revoke or impose fine Not to exceed \$ 1000 per violation for failure to comply with 18.64.350-400 RCW
 - 2) Deny etc... for serious injury to resident IF WA BoP refers case to home state and no action within 45 days or no results WA will investigate

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Pharmacy Act 18.64 RCW cont..

- 18.64.400 RCW Nonresident-Advertising
- It is unlawful:
 - 1) To advertise in WA unless licensed
 - 2) For a resident of WA to advertise services of nonresident pharmacy if it knows is not licensed in WA

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Pharmacy Act 18.64 RCW cont..

- 18.64.410 Nonresident Pharmacy- Rules
- Board may adopt rules to implement these sections
- 18.64.420 RCW Nonresident Confidential Records & Info from (insurers, HMO's etc...) are confidential
- May provide names of licensees and disciplined nonresident pharmacies
- END OF NONRESIDENT Rx Sections

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Pharmacy Act 18.64 RCW cont..

- 18.64.430 Cost Disclosure to Providers
 - Pharmacies must establish procedure to disclose costs of all prescriptions to prescribers upon request related to their prescribing.
- This section was hung on another bill a few years ago and has never been implemented.

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Pharmacy Act 18.64 RCW cont..

- 18.64.430 Health Care Entity
 - Ambulatory surgical centers
 - Provides authority for these centers to purchase, administer and dispense drugs, including controlled substances.

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Pharmacy Technicians 18.64A RCW

- See 1999 Law Revisions
- Technicians licensed since 1977
- Manipulative, Non-discretionary functions
- C & P L & S
- Computer data entry
- 560 Hours of training required
- Now: Ratio 1 RPh to 3 Techs – All pharmacies

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Pharmacy Technicians 18.64A RCW

- Pharmacy Assistants
 - Registered NOT Licensed
- No training required
- Originally typed Rx labels did clerical work
- Now C & P – L & S
- May NOT select drug
- May NOT enter new Rx into computer (refills OK)
- No Ratio of Assistants to RPh

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Institutional Pharmacy Practice

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Objectives

- To discuss the regulation of institutional pharmacy practice in Washington
- To differentiate between federal and state regulation

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Medicare, Medicaid, What's the difference?

- **Medicare**
- Previously very limited pharmacy benefit (until Part D started in 2006)
- Part B Rx drugs that patient can not self administer
- (e.g. injectable anticancer drugs, drugs administered by MD, RN, etc.)
- **Medicaid**
- Rx Drugs are optional but every state provides them
- All drugs included BUT can have limits
- (e.g., prior approval, pref. Rx list, etc. BUT no formulary allowed)

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Medicare, Medicaid, What's the difference?

- **Medicare**
- Federal funds only
- Insurance companies contracting with Medicare set reimbursement.
- Feds may NOT negotiate with drug companies for price concessions.
- **Medicaid**
- State funds then requests Federal matching funds.
- States set reimbursement
- States get rebates from drug companies based on volume of the company's drugs dispensed to Medicaid patients

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Medicare Modernization Act

- Added Rx coverage 05/04 "Discount" cards
- 01/06 Rx coverage (Part D)
- Rx coverage is Optional Penalty for not signing up when eligible
- Monthly Premium
- Co-pays
- Tiered Dispensing Fees
- "Donut Hole"
- Medication Therapy Management (MTM)
- RPh and Others can perform MTM
- Fee based on effort

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Medicare Rules

- Medicare rules are called:
- The Conditions of Participation (CoP)
- Every hospital, nursing home, home health agency, kidney dialysis center, ambulatory surgical center, etc. that wants to treat Medicare patients MUST comply with the Conditions of Participation that are appropriate to that type of facility

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Medicare Rules

- CMS contracts with State agencies to inspect for compliance with CoP.
- Washington State Dept. of Health
 - Hospitals, Hospice, Home Health, Amb. Surg. Ctr, Clinical Laboratories, dialysis centers
- Washington DSHS
 - Nursing Homes (SNF & ICF)
- These agencies also inspect for State Licensing laws/rules compliance.

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Medicare Rules

- Currently there are no CoPs for ambulatory pharmacy services
- BUT pharmacies will need to get accredited to bill certain durable medical equipment to Medicare Part B. NABP has contract for accreditation.
- Pharmacies that are located in or that provide pharmacy services to a Medicare participating facility must meet the facility CoPs

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- 1. Pharmacy Management
 - Must meet needs of patients
 - Pharmacy directed by licensed RPh
 - Drug storage under competent supervision
 - Medical Staff responsible for P & P to minimize errors (may delegate to phcy)

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (a) Pharmacy or Rx storage area must be administered in accordance with accepted professional principles.
 - P & P followed, Records in detail, employees acting within scope of practice, control over drugs, distribution, written reports, minutes of meetings, job descript.

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (2) Adequate personnel to insure quality services, including emergencies
 - Sufficient number & training of staff

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (3) Current & accurate records on receipt & disposition of controlled subs.
 - Records must be readily retrievable, trace movement of CS, RPh is responsible
- (b) Delivery of Services
- Must be consistent with policies, Fed and State laws

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (1) Compounding, dispensing under supervision of RPh
 - (Surveyors interview various staff)
- (2) Drugs in locked storage area
 - Availability of Keys?

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (3) Outdates, mislabeled, unusable Rx not available for patient use.
- (4) Handling of drugs when RPh not available
- (5) Automatic Stop Orders on Drugs
 - Orders get re-written after surgery, transfer, etc.
- (6) ADR, Rx Errors, Administration errors, reported to attending MD & QA program

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (7) Abuses & losses of CS must be reported to RPh, CEO, DEA etc.
- (8) Info on drug interactions, Rx therapy, side effects, etc must be available to professional staff
 - Current drug references are available

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.25
- (9) Formulary system must be established by medical staff

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Medicare Conditions of Participation for Hospitals

- See 42 CFR 482.23 Nursing Services
- These are the drug related responsibilities of nursing but pharmacy retains some responsibility
- (c) Drugs prepared & administered in accordance with laws, prescribers orders, and standards of practice
- (1) Rx administered by nurses

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Joint Commission on Accreditation of Healthcare Organizations

- JCAHO Accreditation means a hospital is *deemed* to meet Medicare COP.
- Choice made by Congress 1965
- JCAHO Standards have changed significantly since 1965 but Medicare's standards have not.
- Should deemed status continue?

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Joint Commission on Accreditation of Healthcare Organizations

- If hospital is JCAHO accredited, State does NOT inspect for Medicare purposes BUT State may inspect for State laws/rules compliance.

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Joint Commission on Accreditation of Healthcare Organizations

- JCAHO focuses heavily on Rx issues
- Now requires elimination of certain abbreviations
- Now requires reconciliation of patient's meds on admission and discharge AND communication with future caregivers
- Community pharmacies should be getting discharge information

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Prescription Writing Abbreviations to avoid JCAHO

- | | |
|--|---|
| ■ U (for unit) <ul style="list-style-type: none">■ Mistaken for 0, 4, cc | ■ MS |
| ■ IU (intl. Unit) <ul style="list-style-type: none">■ μ | ■ MS04 |
| ■ Q.D. or Q.O.D. <ul style="list-style-type: none">■ Mistaken for each other or period = 1 | ■ MgS04 <ul style="list-style-type: none">■ Morphine sulfate or magnesium sulfate |
| ■ Trailing zero 1.0 mg <ul style="list-style-type: none">■ Period is missed | ■ μ g (microgram) <ul style="list-style-type: none">■ Mistaken for milligram use mcg |
| ■ Lack of leading zero <ul style="list-style-type: none">■ .1 mg period gets missed. | |

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Prescription Writing- Abbreviations to avoid

- | | |
|--|---|
| HS – (bedtime or half strength)
Mistaken for each other
q hs mistaken for every hour
T.I.W (3 times per week)
Mistaken for tid, twice/wk | ■ S.C. or S.Q. (for subcutaneous)
mistaken for sublingual or 5 every |
| ■ AS, AD, AU for ears | ■ Write SubQ or full word |
| ■ Mistaken for OS, OD, OU (eyes) | ■ D/C (for discharge) |
| | ■ Mistaken for discontinue |
| | ■ cc (for cubic centimeter)
mistaken for U (units) |

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What is JCAHO going to do about use of prohibited abbr.?

- OK if use of these is “sporadic” (<10%) or if written confirmation of what prescriber meant is in chart.
- Otherwise need plan for improvement to meet requirement in short time period.

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Joint Commission on Accreditation of Healthcare Organizations

- Accreditation is expensive!
- Most small hospitals are NOT accredited
- If not accredited then State inspects for Medicare

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Inspection of Hospitals

- DOH Facilities Staff inspects for
Medicare
State Licensing
- DOH accepts BoP Pharmacy Inspections to determine if hospital meets Rx standards.
DOH spends time in rest of hospital

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BoP Inspection/rules

- WAC 246-873
- All hospitals Must have Rx license
- RPh in charge
- May be consultant
- Adequate staff
- Inspect Rx storage
- RPh responsible for ALL drugs



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WA Hospital Rules, cont.

- RPh shall review original order or a direct copy before administration EXCEPT:
 - In an Emergency
 - In compliance with WAC 246-873-050
 - Absence of a RPh
- Designated RN may obtain Rx from pharmacy leave copy of order & stock bottle or Unit Dose package of drug removed.

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WA Hospital Rules, cont.

- Emergency Outpatient Prescriptions
- Pre-pack meds for ED
- Try to make system as foolproof as possible
- Labels completed by nurse or MD
- Retain order for RPh review
- MD must dispense if CS EXCEPT:
 - 10 Rural hospitals (see 246-873-060)

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WA Hospital Rules, cont.

- Administration of Drugs
- Administered by licensed persons
- Verbal orders limited
- Patient's own drugs
 - Identified by RPh
 - Administered on specific order
 - If not used must be stored
 - May be given back at discharge but could retain if hazardous to patient's health
- Investigational drugs under control of Pharmacy

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WA Hospital Rules, cont.

- Provision of drugs
 - Usually unit dose form in larger hospitals
 - CS usually supplied as floor stock with proof of use sheets
 - Usually stock bottles (floor stock) in rural hospitals
 - Drugs are ordered via chart orders rather than prescriptions
 - Pharmacy should be getting copy of all inpatient Rx orders

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Long Term Care Facilities

- Skilled Nursing Facilities (SNF)
 - Medicare & Medicaid
- Intermediate Care Facilities (ICF) & IMR
 - Medicaid only
- Boarding Homes
 - Medicaid only
- Assisted Living Centers
 - Medicaid only

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Although JCAHO accreditation is available to nursing homes, but very few are accredited AND Unlike hospitals, it does NOT provide deemed status for Medicare purposes - All must be inspected by DOH for Medicare.

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- See 42 CFR 483.60 Pharmacy Services
- SNF may either provide drugs or contract for pharmacy services
- (Washington does not allow SNF to stock drugs except in emergency kit.)
- Therefore, all SNFs contract with RPh's
- May separate Rx provider from consultation service

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Perverse incentives for Reviewing RPh
 - Duty to reduce unnecessary drugs
 - Less drugs = less reimbursement
- Sometimes, consulting is paid separately.
- Rx review reports go to
 - DNS, Administrator, Medical Director

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- Provision of Drugs
 - Dispensed as individual prescriptions but may be Rx or chart order
 - Usually packaged in 30 day blister cards
 - Pharmacies usually provide computerized medication administration records (MAR) for use by nurses
 - Doctors sign off on orders monthly
 - Original Rx required for Schedule II

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- (a) Must meet drug needs of all patients
- (b) must provide services of RPh who
 - Provides consultation on all aspects of Rx services
 - Establishes records system for CS
 - Determines that Rx records are in order

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Medicare Conditions of Participation for Skilled Nursing Facilities (SNF)

- (c) The drug regimen of each resident must be reviewed each month by the pharmacist.
- Rule adopted in 1973
- The first clinical pharmacist service required by Federal rule
- Followed by OBRA 90 and MTM in 2003

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Washington NH Rules

- Rx Services Cte. (same as Medicare)
- RPh consultant
- Rx services
- Controlled Substances
 - II separate from others
 - Except in UD system
- OTC's stock bottles labeled with Patient's names

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Washington NH Rules

- Emergency kit authorized
- Locked drug storage
- Poisons other hazards stored separately
- On site reviews of storage by RPh
- Labeling requirements
 - Different from outpatient label
 - Place CS Schedule number on Rx Label

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Washington NH Rules

- Record books for II & III
 - 24 hour counts for II
 - Weekly counts for III
- Destroy left over CS
 - BoP and Dept. of Ecology working on better disposal methods.
- Continuity of Rx therapy
- OK to provide Rx for patient temp departure from facility.

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Other Long Term Care Facilities

- Institutions for the Mentally Retarded
 - Fircrest School
 - Rainier School
- Usually have full time pharmacy service
- Function like hospital pharmacies but may use combination of floor stock, individual prescriptions or bingo cards

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Other Long Term Care Facilities

- Adult Family Homes/Boarding Homes/Assisted Living
- Theoretically patients need less RN supervision than SNF patients
- Usually supplied by community pharmacy
 - Individual prescriptions
 - Some bingo cards
- Patients may self administer OR non-licensed staff may *assist* them to self administer
- No RPh review of meds required except when filling prescriptions.

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Miscellaneous Laws & Rules

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Misc. Federal and State Laws and Rules Objectives

- The student will be able to discuss a number of Federal and State laws and rules to determine how they affect the practice of pharmacy in WA. These include:
- Child-Resistant Packaging (CRC) with exemptions from these requirements
- PDMA, Robinson-Patman
- Tamper resistant packaging (TRP)

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Child Resistant Packaging Requirements

- The closures must be tested on:
 - children (41 to 52 months) AND
 - adults (50 to 70 years)
- RPh must assure that Rx vials have been certified as meeting both standards (i.e., adults must be able to open closure child must not be able to open closure)
- See CPSC website for list of approved

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Child Resistant Packaging

- Consumer Product Safety Commission
 - Poison Prevention Packaging Act
 - 15 USC 2079
 - 16 CFR 1700.14
- KNOW THE COMMON EXAMPLES OF WHEN CRC ARE REQUIRED AND NOT REQUIRED. THERE MAY BE A TEST!

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CRC Required

- Aspirin,
- methyl salicylate,
- Controlled drugs,
- Rx drugs,
- Iron containing DRUGS & Dietary supplements >250mg,
- Acetaminophen >1 Gm,
- Diphenhydramine >66mg,
- Ibuprofen >1Gm

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Child Resistant Packaging

- Exemptions:
- A manufacturer may distribute multiple package sizes of a drug product
 - One package size does **NOT** have to comply **IF**
 - All other packages do comply and
 - Noncompliant packages are marked: "For households without children"

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Child Resistant Packaging

- Patient **may** request "blanket waiver"
- Prescriber may **NOT** request blanket waiver for one patient or all patients
- Prescriber may request non-complying package
- Patient may request non-complying package
 - WA rule requires patient signature for non-CRC (246-869-210)
 - Federal rule does NOT require signature
- *RPh Should* review patient's status periodically (e.g., new children in household)

103

Child Resistant Packaging

- Exemptions continued:
- Sublingual nitroglycerin
 - MUST dispense in original glass package per FDA
- SL & Chewable Isosorbide dinitrate 10mg/<
- Erythromycin granules 8 Gm erythromycin
- Erythromycin tablets 16 Gm erythromycin
- Cholestyramine powder

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Child Resistant Packaging, exemptions, cont.

- Potassium supplements in unit dose 50mEq/dose
- Sodium Fluoride 264mg/pkg
- Betamethasone in mfg pkg 12.6 mg
- Mebendazole 600mg/pkg
- Methylprednisolone 84 mg
- Colestipol powder 5 Gm
- Pancrelipase tab, cap, powder - no limit

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Child Resistant Packaging

- Oral contraceptives in memory packages
- Prednisone tablets 105 mg/pkg
- Conjugated estrogens mnemonic 26.5mg
- Norethindrone mnemonic 50mg
- Medroxyprogesterone acetate

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Child Resistant Packaging

- CRC Rx containers may NOT be refilled
 - Throw away if plastic
 - Use NEW cap if glass
- Dual closure packages OK BUT dispense in CRC position
- Don't need CRC's for inpatients (hospital, nursing home, boarding homes, etc.)

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Child Resistant Packaging

- Iron Products
- 1997 FDA Rule
 - 30mg or > of elemental iron
 - Blister packaging & TRP

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Child Resistant Packaging

- Case: Army officer who traveled to areas where malaria was present so was ordered to take Chloroquin to prevent infection. Madigan Army Hospital pharmacy filled Rx using CRC container. Officer's grandchild found container in unsafe place, opened it and ingested several tablets resulting in brain damage and permanent vegetative state.

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Child Resistant Packaging

- Case continued: Family sued US Government saying that Officer should have been warned about extreme danger/toxicity to children associated with the drug.
- The federal judge found in favor of whom?
 - Government?
 - Family?

110

U.S. Postal Service

- Formerly only VA could mail narcotics
- Rule was silent on other controlled subs.
- Now any pharmacy may mail any controlled substance
 - Inner container properly labeled
 - Outer container plain wrapper
 - May not indicate nature of contents

111

FDA rules

- Expiration dates
 - All Rx drugs have expiration dates
 - Most OTC drugs have expiration dates
 - Drug expires on...
 - Misbranding to sell after expiration date
- Watch out when Rx computer system sets arbitrary one year exp. date. Will confuse and/or anger patient if differs from date printed on the package by the manufacturer.

112

Prescription Marketing Act of 1987 (PDMA)

- In 1970s & 80s Diversion of legend drugs was rampant!
- Rx Detail persons & doctors sold or traded samples to pharmacies who used them to fill prescriptions.
- Small hospitals purchased, at a discount, well in excess of their own needs then resold at a profit.
- There was an underground Rx economy

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Prescription Marketing Act of 1987 (PDMA)

- Pharmacists would remove the imprints that identified the drug as a “sample” so it could be resold. Using Acetone, abrasives, etc.
- The engine that made the system work was differential pricing by the drug manufacturers.
- Hospitals, NH pharmacies, Governments got much cheaper prices than community pharmacies.

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Prescription Drug Marketing Act of 1987

- States must license wholesaler distributors
- Prescription drugs may not be re-imported EXCEPT by Manufacturer or in emergency
- Bans sale, trade or purchase of Rx samples
- Mandate storage, handling, records-samples
- Bans trafficking or counterfeiting Rx coupons
- Prohibit resale drugs by hospitals, & other Health Care Entities

115

Prescription Drug Marketing Act of 1987

- We thought this fixed the problem
 - Hospitals stopped selling excess to retail
 - Samples were prohibited in retail pharmacies
 - Drug companies tightened up on sample distribution even hired outside auditors to verify that detail persons are in compliance

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Prescription Drug Marketing Act of 1987

UNFORTUNATELY, people found loopholes in the law.

The PDMA did NOT prohibit manufacturers or wholesalers from selling to nursing home pharmacies at low contract prices.

All the pharmacy had to do is sign a form stating that the drugs were intended to be used ONLY for nursing home patients.

No one checked to see if this was really the case.

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Prescription Drug Marketing Act of 1987

All over the Country people were opening up "Closed Door Pharmacies" alleging they were supplying nursing homes.

The same folks also obtained a license to operate a wholesale drug company - usually in the same building.

Drugs bought by the pharmacy were diverted to the wholesale operation and then resold at a profit in the secondary wholesale market. Frequently these drugs ended up being sold to the major wholesalers.

118

Prescription Drug Marketing Act

- FDA was supposed to require pedigree to show where drug came from & who held it. BUT rule has been opposed by wholesalers for 20 YEARS!
- Authorized Distributors
- Unauthorized distributors
- FINALLY, FDA issued pedigree rules 2004
- FDA MAY soon require RFID technology for pedigree
- BUT part of rules have been enjoined by secondary wholesaler group lawsuit.

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Prescription Drug Marketing Act

- What finally got FDA moving?
- COUNTERFEITS
 - Counterfeit drugs started showing up in the same distribution channels as diverted drugs.
 - Counterfeit Procrit, Serostim, Lipitor, etc. were distributed from the secondary wholesale distributors either directly to pharmacies and hospitals or through major wholesalers.

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Prescription Drug Marketing Act

- New FDA rules on pedigree RFID
- Lots of arguments on what information should be contained in the chip.
- Start with most susceptible products
 - (See NABP Listing)

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Prescription Drug Marketing Act

- Wholesale distribution now out of control AGAIN
- Florida had 1,400 Rx wholesalers- now has strong wholesaler rules & less wholesalers
- WA has about 300 licensed (in & out of state)
- Secondary wholesale market
 - Has fed into major wholesalers due to price differential
- FINALLY top 3 wholesalers have pledged to stop buying from secondary market as of 2005

122

Susceptible to Counterfeit, NABP list

- | | |
|--------------------|-------------|
| ■ Crixivan | ■ Resperdol |
| ■ Diflucan | ■ Rocephin |
| ■ Epogen & Procrit | ■ Serostim |
| ■ Globulin, Immune | ■ Viagra |
| ■ Lamisil | ■ Viracept |
| ■ Lipitor | ■ Zocor |
| ■ Neupogen | ■ Zyprexa |
| ■ Neutropin | ■ Etc. |
| ■ Retrovir | |

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Susceptible to Counterfeit, NABP list

- | | |
|--------------------------|--|
| ■ Mostly expensive drugs | ■ As with currency counterfeiting, you don't counterfeit one dollar bills! |
| ■ High demand | |
| ■ Brand name | |

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Prescription Drug Marketing Act

- NABP Activities
- Developed new model law & rules
- Developed Verified Accredited Wholesale Distributor Program (VAWD)
- Contracts with former DEA, FDA, & State Board inspectors to do inspections
- Certify status to States upon request
- Fees paid by Wholesalers - Save State resources
- Indiana, Oklahoma, Wisconsin North Dakota & Illinois have adopted VAWD
- Other states are strengthening their laws & rules

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PDMA

- To whom a may hospital or health care entity* sell drugs?
 - To its own patients on prescription
 - To non-profit affiliates
 - Among hospitals/health care entities under common control
 - In an emergency or shortage to retail pharmacy
- *health care entity is an organization that provides health care in addition to pharmacy services (e.g., Group Health, UW Med Ctr, Spokane Heart Inst.)
- A Retail pharmacy is **NOT** a H.C. Entity
- *The health care entity in this law is NOT the same one found in RCW 18.64

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Robinson-Patman Act

- Passed in the 1930's
- Allowed lower Rx prices for hospitals
- As hospitals developed outpatient services by filling outpatient Rx's etc.
- Some pharmacists thought hospital pharmacies were unfairly competing with community pharmacies SO THEY SUED!

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Robinson-Patman Act

- Abbott Labs et al v. Portland Retail Druggists Assn. 425 US 1 (1976) US Supreme Court defined what "Own use" means regarding Rx sales
 - Inpatients for use in hospital
 - Emergency room patients
 - Outpatient for use on the premises
 - Take home for continuation of therapy
 - Hospital employee or dependent Rx's
 - Staff physician for personal use or dependents

128

Tamper Resistant Pkgs.

- NO TRP prior to 1982
- 10/82 Tylenol Extra Str. Chicago 7 deaths
- 2/86 Tylenol Caps, New York, 1 death
- 3/86 Contac Capsules, Extortion
- 6/86 Excedrin Extra Str, WA, 2 deaths
- 3/91 Sudafed 12 hour caps, WA 2 deaths

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Tamper Resistant Pkgs.

- 21CFR211.132
- Required for ALL OTC's EXCEPT
- dermatological, dentifrice, insulin or throat lozenge product
- One tamper resistant feature
- Two piece capsules - Two tamper resistant features (Now these capsules have disappeared from OTC products)
- Label advises of what feature(s) used

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Needles & Syringes

- Chapter 70.115 RCW
- Retailer must be satisfied that syringe to be used for a "legal" purpose
- Retailer is NOT required to sell syringes
- Chapter 69.50.412(5) Drug paraphernalia
- It is lawful for any person over 18 to possess sterile syringes & needles for the purpose of reducing blood-borne diseases.

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Needles & Syringes, cont.

- Background
- Needle exchange program proposed in Spokane by local health dept.
- Prosecutor threatened to arrest participants
- Health district sued - BOP Amicus Brief
- WA Supreme Court decided that disease prevention trumped drug abuse prevention
- This legalized needle Exchange in WA

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Needles & Syringes, cont.

- Background, cont.
- 2001 Legislator tried to expand use of sterile syringes for disease prevention
- Bill withdrawn after opposition surfaced
- 2002 tried again but opponents placed crippling amendments on bill
 - Pharmacies would have to exchange syringes - for everybody
 - RPh would have to provide information on Disposal & information on drug treatment

133

Needles & Syringes, cont.

- Governor used line item veto to remove these amendments (Gov can veto whole sections of a bill but not anything smaller.) (See Chapter 218 Laws of 2002 on Code Reviser website)
- See also:
 - RCW 70.115 Syringes
 - RCW 69.50.412 Criminal Drug Paraphernalia
 - RCW 69.50.4121 Civil Drug Paraphernalia

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Misc. Federal Laws and Rules Summary

- We have discussed a number of federal laws and rules to determine how they affect the practice of pharmacy in WA. These included:
 - Child-Resistant Packaging (CRC) with exemptions from these requirements
 - PDMA, Robinson-Patman
 - Tamper resistant packaging (TRP)

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Are there any questions?



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