The Washington State Pharmacy Practice Act

Also:

Miscellaneous Laws
  - CPSC
  - Tamper-Resistant Pkg
  - Postal Service

IMPORTANT NOTE:

In scheduling our lectures this year, we accidentally scheduled two of my lectures for the Veteran’s Day holiday. This left us short of an opportunity to deal with some important issues. I will not attempt to deal with 139 slides in this 100 minute block. I will hit the highlights and skip over many of these slides. I suggest that you read all of them and mark any that you may have questions on so if I skip one, you can ask me to cover it in more detail. Note further that you are responsible for the content on the exam and on MPJE.

Readings

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

Objectives

- To review and understand the Pharmacy Practice Act (Chapter 18.64 RCW)
- To discuss other laws & rules
  - CPSC, PDMA, Robinson-Patman Act, Syringe sales
Clarification:

- Prescribe
- Order
- Administer
- Dispense

Who can prescribe Clarification

- Prescribe - authority related to prescription drugs USUALLY a written or verbal prescription.
- Order - Same as prescribe but USUALLY the patient is in a prescriber’s office or a hospital, nursing home, etc.
- Administer - get the drug into the patient
- Dispense - interpret prescriber’s Rx or order package & label the drug and give to the patient

Examples

- A health professional “prescribes” a drug for a patient either on a written Rx or calls the pharmacy.
- A health professional “orders” a nurse to administer a drug or vaccine to a patient.
- In either of the above cases, the HP must have the authority to prescribe that drug or vaccine before the pharmacist may fill the Rx or the nurse may fulfill the order.

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
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

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

Pharmacy Act 18.64 RCW cont...

- 10) Suggest strategies for preventing, reducing, and eliminating Rx misuse, diversion & abuse. Including prof & public education and treatment of persons misusing and abusing drugs.
- 11) Conduct or encourage Educational programs for Lic. Health Practitioners & Licensed Health care facilities

Pharmacy Act 18.64 RCW cont...

- 12) Monitor trends of Rx abuse, etc.... & Report to disciplinary boards, educational, treatment, law enforcement regarding trends
- 13) Enter into written agreements with other state & federal agencies. Referral by other agencies to DoH (DSHS, L&I, Other Boards) Encourage referral from HMO’s & insurers
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.

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 Pharmacopeia
     b) Substances for Dx, Cure, mitigation, TX
     c) Subs. affect structure/function of body
     d) Subs. intended as component of above BUT not devices

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

Pharmacy Act 18.64 RCW cont...

- 11) Practice of Pharmacy
  a) Interpreting Rx orders, compounding, dispensing, labeling, administering, distributing drugs & devices
  b) Monitoring Rx therapy
  c) Initiating or modifying therapy (protocols)
  d) DUR, drug product selection, Keep records, provide information, (Rx value, hazards & uses)
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 (does NOT include pesticides)

15) Deliver/delivery - transfer to another person

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

20) Manufacture- preparation, compounding, processing of drugs, OR packaging/repackaging, labeling or reliable, NOT include activities of a practitioner who in the course of prof. practice prepares, etc...

21) Manufacturer - person who mfrs

22) Labeling - process of preparing and affixing label Must include all information

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
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

Pharmacy Act 18.64 RCW cont..

18.64.040 Examination fee
- Established by Secretary of Health

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

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
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

Pharmacy Act 18.64 RCW cont..

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

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

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...
Pharmacy Act 18.64 RCW cont..

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

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
  - B.S. or Pharm. D. - Accredited Rx school or col.
  - Internship
  - Pass examinations
  - See rules WAC 246-863)

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
- 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.

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
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 license 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
  - Have to take the law exam of state you are entering

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)

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!

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.
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.

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

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)

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.
Pharmacy Act 18.64 RCW cont..

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

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

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

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

DoH cont. continued

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

18.64.300 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
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:

- Location, names of owners, list of RPh etc... Report this information annually.
- Proof it complies with its home state laws. Must keep valid license, submit insp. report.

WA patient records must be readily retrievable.

- Must have toll free number for patients and place this number on Rx labels.
- Must comply with WA board rules re: patient medication record systems.
- 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).

May not dispense in quantity greater than prescribed:

- Some mail order pharmacies were dispensing original and ALL refills at once!

License fee not to exceed in-state pharmacy.

Board may grant exemption for isolated transactions (e.g., border pharmacy).

Must name resident agent in WA.

18.64.370 RCW Nonresident Pharmacies:

- No business without license
- DoH application form
- Annual renewal
- Penalty fee for late renewal

90 Nonresident pharmacies licensed 9/95
238 nonresident pharmacies licensed 9/02
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.

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

Pharmacy Act 18.64 RCW cont..

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

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
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.

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.

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

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
Miscellaneous Laws & Rules

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)

Child Resistant Packaging Requirements changed 1/98

- 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

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!
**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**

- Aspirin,
- Acetaminophen >1 Gm,
- Diphenhydramine >66mg,
- Ibuprofen >1Gm

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**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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**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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**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)
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

Child Resistant Packaging

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

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.)

Child Resistant Packaging

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

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?

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

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.
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

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

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.

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
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.

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.

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.
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)

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

Susceptible to Counterfeit, NABP list

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

Susceptible to Counterfeit, NABP list

- Mostly expensive drugs
- High demand
- Brand name
- As with currency counterfeiting, you don’t counterfeit one dollar bills!
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 & Illinois have adopted VAWD
  - Other states are strengthening their laws & rules

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

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!

Robinson-Patman Act

  - 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
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

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

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.

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
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

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

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)

Are there any questions?