

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)

Child Resistant Packaging New Requirements 1/98

- The closures must be tested on children AND senior adults (>50 yrs old)
- 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)

Child Resistant Packaging

- Consumer Product Safety Commission
- Poison Prevention Packaging Act
 - 15 USC 2079
 - 16 CFR 1700.14

CRC Required

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

Child Resistant Packaging

- Exemptions
 - One package sized does not have to comply **IF**
 - All other packages do comply and
 - Noncompliant packages are marked: “For households without children”

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
- *Should* review status periodically

Child Resistant Packaging

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

Child Resistant Packaging

- 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

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 on package

Prescription Marketing Act of 1987 (PDMA)

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

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

- 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 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

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.

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.

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

Prescription Drug Marketing Act

- What finally got FDA moving?
- COUNTERFEITS
 - Counterfeit drugs started showing up in the same distribution channels as other 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
- FINALLY top 3 wholesalers have pledged to stop buying from secondary market.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, & Board inspectors to do inspections
- Certify status to States upon request
- Fees paid by Wholesalers - Save State resources
- Indiana & Oklahoma 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

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

- 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
 - 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
 - RPh would have to exchange syringes - for everybody
 - RPh would have to provide information on Disposal & information on drug treatment

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
- 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)
- Pseudoephedrine law/rule changes

Pharmacy's Role in Bioterrorism Response

Objectives

- 1. To determine what pharmacists need to do to prepare for a bioterrorism event
- 2. To discuss which State laws and rules might apply to bioterrorism response activities
- 3. To assist pharmacists to be better prepared to deal with a bioterrorism incident
- To describe recent bioterrorism planning and demonstration activities

Background

- NPS Planning in WA – 1999 - Present
 - Agencies involved:
 - DOH
 - CDC
 - Fed & State Emergency Management
 - Local Public Health
 - Local Fire Departments
 - PHS Office of Emergency Preparedness
 - WA State Pharmacy Association

National Pharmaceutical Stockpile (NPS)

- Explained by CDC videotape
 - 12 Hour Push Package
 - Initial Drug Supply
 - Now supplemented with Unit of Use drugs
 - Tablet Counters (May not be needed)
 - IV's, other supplies & medical equipment
 - Vendor managed inventory
 - Back up supply
 - Ordered PRN by CDC based upon need

Sea-King 2000 Exercise

- State-Local Communication
- Develop sufficient information for Governor to request NPS
- DOH to receive NPS
- Redistribute to LHJ
- Repackaging exercise?



Repackaging – If needed

- **Why**
 - Financial issue
 - Stock Rotation Issue
- **Personnel**
 - Firefighters
 - Pharmacists
- **Drugs**
 - Acetaminophen 500mg (“Cipro”)
 - Multivitamin (“Doxycycline”)



Repackaging, cont.

- **Methods:**
 - Manual Counting Tray
 - Electronic Counter
 - Volumetric
- **Problems:**
 - Counting to 5
 - Handling drugs
- **Alternatives**
 - Unit of Use
 - Strip-packing
 - Mail Order Pharmacy



Dispensing Sites – Schools?

- Initial treatment for first responders
- May see Large groups of people
- Consistent messages
- Security
- Parking
- Phones
- Utilities
- Support activities



Dispensing sites, cont.

- Develop a template
 - Provide to local public health
 - What is required
 - Layout
 - Personnel
 - Equipment
 - Supplies
 - Where to get health professionals
- Transition to normal Rx distribution system
Wholesalers & Pharmacies

Dispensing sites, cont.

- Examples (2000 & 2001)
 - Tacoma – Restaurant employee with Hepatitis A
 - Immune Globulin Injections for 4,000 patrons
 - Three days of operation
 - Seattle – Meningitis at middle school
 - Rifampin to students & teachers
 - Two days of operation

What do Boards need to think about?

- 1. Who can prescribe in the State?
- 2. Could State or Local Health Officer (MD) write a blanket Rx?
- 3. Could Governor or State Health Officer take control of drugs in pharmacies or wholesalers to reserve for the emergency (e.g. Cipro, etc.)?
- Who can dispense in public health emergencies?
- Do we need legislation?

Law was to be proposed in Virginia 2002 Legislative Session

- **Be it enacted by the General Assembly of Virginia: 1. That § 54.1-3307.3 of the Code of Virginia is enacted as follows:**
- In the event of an occurrence which the Governor of Virginia has declared a disaster or a state of emergency, and where it is necessary to permit the provision of needed drugs, devices, and pharmacy services to the citizens of the Commonwealth, the Board of Pharmacy may waive applicable requirements of this chapter, Chapter 34 of Title 54.1, and of 18 VAC 110-20-10 et seq. as determined by the Board. (*NOTE: Apparently this did not pass.*)

Model State Emergency Health Powers Act

- Proposed by:
 - CDC
 - Georgetown University
 - Johns Hopkins University
 - NOTE: THIS PROPOSED LAW HAS NOT BEEN INTRODUCED OR ENACTED

Model State Emergency Health Powers Act, cont.

- Measures to detect & track potential and existing public health emergencies
 - Increased reporting of cases
 - Pharmacists Report
 - Unusual increase in certain Rx (fever, resp., GI)
 - Unusual increase in antibiotic Rx
 - Unusual increase in OTC (fever, respiratory, GI)
 - Any Rx used to treat uncommon disease with bioterrorism potential.
 - NOTE: WA is starting this reporting - voluntary

Model State Emergency Health Powers Act, cont.

- Mandatory medical examinations
- Mandatory testing
- Health care provider assistance
- Use of providers from other jurisdictions
- Isolation/Quarantine
- Vaccinations & Treatment
- Liability protection

Model State Emergency Health Powers Act, cont.

Control of Property

Take possession of buildings, health care facilities, etc.

Take control of food, drugs, health supplies, etc.

NOTE: We have seen this with flu vaccine

Take control of roads

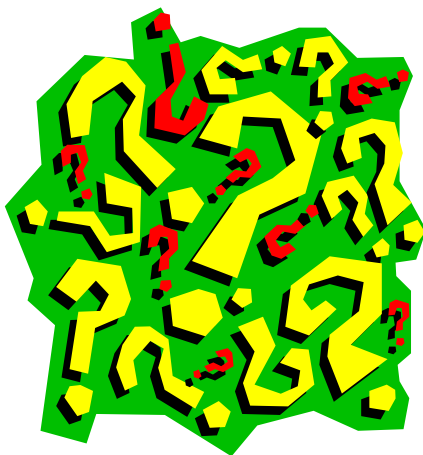
What drugs are already available in our State?

- Pharmacy Survey
 - 88% Response Rate
 - 85% had Cipro/Doxy
 - 180 Cipro
 - 500 Doxy
 - IV Meds 2% to 8% had in stock
 - 15% had injectable Schedule IV drug



Pharmacy Surveys

- **How to survey?**
 - FAX
 - Email
 - Mail
- **What to ask?**
 - Specific drugs
 - Unusual increases
 - OTC drug increases
- **Could CS Monitoring systems help?**



Plans for an exercise

- Exercise planned for September 20-21, 2001 (NYC planned for 9/12)
- Metropolitan Medical Response System meeting (MMRS) (Use as “patients”)
- Would test receipt, repackaging, & dispensing sections of our plan.
- Postponed due to 9/11/2001
- Rescheduled for 1/24/02

Plans for an exercise, cont.

- Receive at Boeing Field – County Owned
- UPS/FedEx availability
- Space available
 - Repackaging & Labeling (5 days supply)
 - Shipment of IV’s & supplies to hospitals
- BOP Pharmacists, DOH Volunteers, Local Public Health, Seattle Firefighters, CDC, PHS/OEP, Local Law Enforcement

Plans for an exercise, cont.

- Dispensing Exercise
 - Triage (exposed?) (Worried but well)
 - Special needs (already ill, language, other)
 - Registration desk
 - Informed consent, Demographic, History, Allergies, CRC Waiver, etc.
 - Forms Complete – Go to Pharmacist
 - Pharmacist
 - Screen Forms to select correct drug (contraindications allergies, etc.)
 - Determine correct drug
 - Pass on to “Pharmacy Technician” for dispensing

Dispensing, cont.

- Pharmacist issues:
- Contraindications
- Drug interactions
- Allergies
- Back up BC method?
- Pregnant/Nursing
- Patient Counseling



Dispensing, cont.

- **Pharmacy Technician**
- **Select pre-labeled container**
- **(Each Tech has access to 1 drug only)**
- **Add patient information (name, date, exp. Date, dispensing location ID)**
- **Maintain records & supply of drugs**



Sample Dispensing Label

Name: _____ Date: _____

Ciprofloxacin Tablets 500 mg #10

Take one tablet twice a day.

It is important to get this prescription refilled to continue treatment for 60 days.

Dr. State Health Officer Expiration Date _____

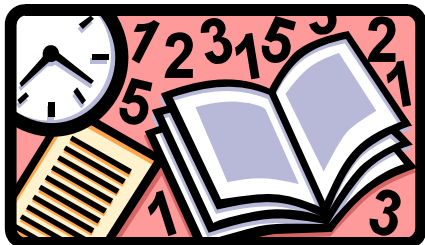
Washington State Department of Health Dispensing Unit # _____

More questions for Boards of Pharmacy

- How much info. Required on label at this time? (e.g., need serial numbers?)
- Can tech complete label after RPh counsels?
- What records must be maintained?
- Can pharmacists etc. from out of State come in to your State to practice?
- Where do you get enough pharmacists for the emergency?
- How do we transfer the CS from CDC to State to Local control? Paperwork? 222's?

What did we learn?

- **Need RPh in Education Sessions**
- **Need Express lane**
- **Need Rx Info at hand**
- **Prepare for questions**
- **Need person to get patients out after RPh finishes**
- **Improve record-keeping**



Summary

- **Discussed Washington bioterrorism efforts**
- **Raised questions**
- **Action**
 - Who is working on this in your community?
 - Share information with other pharmacists



Are there any questions?

