The Washington State Pharmacy Practice Act

Objectives

To review and understand the Pharmacy Practice Act (Chapter 18.64 RCW)

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
- 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) Regulate Practice & Enforce Laws assign
  2) Examinations
  3) Establish qualifications for RPh & Interns
  4. Conduct Hearings (may use ALJ)
  5) Issue subpoenas & administer oaths
  6) Assist law enforcement agencies Re: RX

**Pharmacy Act 18.64 cont..**

- **7) Promulgate Rules** - dispensing, distribution, wholesaling, manufacturing of Rx/Devices for Protection of Public health & safety. Violation of these rules shall constitute grounds for refusal, suspension, revocation of licenses or any other authority granted by the board.

- **8) Adopt rules for Continuing Education**

**Pharmacy Act 18.64 RCW cont...**

- **9) Be immune collectively & individually from suit in any action based upon disciplinary proceedings or other official acts performed as members.**
- **Employees immune also acting RE: disciplinary proceedings.**

**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 prog. 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 laws.

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

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**
  - 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)

**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**

**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

**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 prof. practice prepares, etc...
- **21) Manufacturer** - person who mfrs
- **22) Labeling** - process of preparing and affixing label Must include all information
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

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

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
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
  - New requirements in 2004 & 2005 related to pseudoephedrine sales limits & reports

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 - Prometric Centers (Sylvan)
- 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..

Reciprocity of license
- Use NABP Procedure
- Must have current license in State where you have license by EXAMINATION (State may allow lic by rec)
- 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

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.)
‧ 1) Got license by fraud, misrepresentation or deceit.
‧ 2) Found mentally incompetent - Automatic
‧ 3) Knowingly violated OR permitted viol. of state or federal drug law or rule

Pharmacy Act 18.64 RCW
cont..

‧ 4) Knowingly allowed unlicensed person to take charge of pharmacy or practice pharmacy - Except Intern or PhA.
‧ 5) Compounded, dispensed drug which contains more or less than ordered BUT pharmacist may exercise professional judgment

Pharmacy Act 18.64 RCW
cont..

‧ 18.64.163 Uniform Disciplinary Act
‧ UDA 18.130 RCW governs pharmacy and All other health care professions
‧ (We will discuss in Discipline Lecture)
‧ Licenses of pharmacists and interns
‧ Discipline of pharmacists and interns

Pharmacy Act 18.64 RCW
cont..

‧ 18.64.165 RCW Refusal etc... of Other Licenses.
‧ 1) Fraud, misrepresentation, deceit
‧ 2) Violate or permit violation of state or federal law or rule related to drugs, C.S., cosmetics or non-prescription drugs or rules of the board, OR convicted of a felony.
‧ Note: Currently, Board may NOT fine firms for violations
Pharmacy Act 18.64 RCW cont..

18.64.200 RCW Appeal Procedure other Licenses
Appeal may be taken in accordance with Administrative Procedure Act 34.05 RCW
- Mark vs Williams et al
- Jones vs BoP, et al

Pharmacy Act 18.64 RCW cont..

18.64.205 RCW Retired Active License
- Board MAY adopt rules to allow:
- Emergency or Intermittent practice
- Must meet CE
- Reduced fee
- Can’t have if forced to retire

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 require.
- 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..

- 18.64.247 RCW Penalty for Violations of 18.64.245 (Records) and 246 (Labeling)
- Violations are misdemeanor

Pharmacy Act 18.64 RCW cont..

- 18.64.250 RCW Unlawful practices-Viol.
  - 1) Unlicensed practice of Pharmacy
  - 2) Permit dispensing etc... not under supervision of RPh.
  - 3) RPh or Shopkeeper who fails to renew lic
  - 4) Making false representations to get lic. for himself or other person
  - 5) Knowing or willful violation of 18.64

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)
- Medicare approved Dialysis Center may:
  - Sell, possess, dispense in full case lots drugs prescribed by a physician
  - List of drugs approved by board (246-905)
  - Heparin, NaCl, KCl, & Dialysate

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
- RPh Not liable if dispensed Rx was:
  - in form mfg by commercial mfr
  - 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.inued

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

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.

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
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

- a) WA patient records must be readily retrievable.
- 2) Must have toll free number for patients and place this no. 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)

- 5) May not dispense in quantity greater than prescribed
  - Some pharmacies dispensed 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

- 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
**Pharmacy Act 18.64 RCW cont..**

- 18.64.380 RCW Nonresident Information Required
  - 1) Information Re controlled substances
  - 2) Submit to onsite inspection if (1) is NOT provided to state

**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 we refer 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 to:
    - 1) Advertise in WA unless licensed
    - 2) Resident of WA to advertise services of nonresident 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
Pharmacy Act 18.64 RCW
cont..

18.64.430 Cost Disclosure to Providers
Must establish procedure to disclose costs of all prescriptions to prescribers upon request related to their prescribing
This section has not been implemented

Pharmacy Act 18.64 RCW
cont..

18.64.430 Health Care Entity
Ambulatory surgical centers
Provides availability of drugs

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
No training required
Originally typed labels + clerical
Now C & P – L & S
May NOT select drug
May NOT enter new Rx into computer
No Ratio