

The Washington State Pharmacy Practice Act



1

Objectives

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

2

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

3

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

4

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

5

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

6

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.

7

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

8

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

9

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.

10

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

11

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

12

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)

13

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

14

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

15

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

16

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

17

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

18

Pharmacy Act 18.64 RCW cont..

- ⌘ 18.64.040 Examination fee
- ⌘ Established by Secretary of Health

19

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

20

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

21

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

22

Pharmacy Act 18.64 RCW cont..

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

23

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

24

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...

25

Pharmacy Act 18.64 RCW cont..

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

26

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)

27

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.

28

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

29

Pharmacy Act 18.64 RCW cont..

- ⌘ Pharmacy Licensing Rules/Procedures
- ⌘ 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

30

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)

31

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!

32

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

33

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

34

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

35

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

36

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

37

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

38

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.

39

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

40

Pharmacy Act 18.64 RCW cont..

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

41

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

42

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)

43

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.

44

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

45

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

46

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

47

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

48

Pharmacy Act 18.64 RCW cont..

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

49

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.

50

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

51

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

52

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

53

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 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)

54

Pharmacy Act 18.64 RCW cont..

- ⌘ 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

55

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

56

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

57

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

58

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 who is not licensed in WA

59

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

60

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

61

Pharmacy Act 18.64 RCW cont..

⌘18.64.430 Health Care Entity

- ☒ Ambulatory surgical centers
- ☒ Provides availability of drugs

62

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

63

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

64



65