

Administrative Law

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Objectives

- ◆ Understand where the Board of Pharmacy gets power to regulate the practice of pharmacy
- ◆ Understand the process of rulemaking
- ◆ Understand issues involved in recent changes in pharmacy/pharmacist professional responsibility
- ◆ Understand the hierarchy of federal vs. state powers and preemption

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Administrative Law

- ◆ Body of law created by administrative agencies.
 - Federal: CFR
 - WA: WAC
- ◆ Administrative agencies
 - Created by legislatures, who delegate rulemaking power to these agencies
 - Part of the executive branch of the federal government or individual states.

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Administrative Law

- ◆ Examples of Administrative Agencies
 - Federal:
 - Food and Drug Administration (in Dept of HHS) administers the Federal Food, Drug, and Cosmetic Act;
 - Drug Enforcement Administration (in Dept of Justice) administers the federal Controlled Substances Act
 - State:
 - Board(s) of Pharmacy/Department of Health

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WA Board of Pharmacy: Powers (RCW 18.64)

- ◆ Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare
- ◆ Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses
- ◆ Conduct hearings for the revocation or suspension of licenses or any other authority to practice granted by the board

Board of Pharmacy: APA Procedural Requirements

- ◆ The Washington Administrative Procedure Act (RCW 34.05) decrees how administrative agencies in Washington (including the BoP) shall do the following:
 - Make rules (regulations)
 - Provide public access to agency rules, rulemaking proceedings

APA (cont'd)

- ◆ Conduct adjudicative proceedings: e.g. how the Board of Pharmacy would conduct a disciplinary proceeding against a pharmacist
- ◆ Have decisions from adjudicative proceedings appealed: judicial review by Superior Court
- ◆ Enforce penalties
- ◆ Have rules reviewed by the state legislature

Washington State Superior Courts and Administrative Agencies

- ◆ Superior Courts are the courts of *general jurisdiction*
- ◆ Washington Superior Courts also hear appeals from courts of limited jurisdiction, including administrative agencies
- ◆ Discretionary enforcement

How does the Board of Pharmacy conduct rulemaking?

- ◆ Board must solicit public comment on the subject of the possible rulemaking at least 30 days before proposed rule is filed/published.
- ◆ Proposed rule must be published in State Register at least twenty days before the rule-making hearing where BOP will receive public comment regarding adoption of a rule.

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Format of Publication of Proposed Rule: RCW 34.04.320

- ◆ Cite statutory authority to make rule
- ◆ Give a “short explanation of the rule”
 - purpose
 - anticipated effects of new rule or modification
 - short description of the changes the proposal would make
 - statement of the reasons supporting the proposed action

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Format of Publication of Proposed Rule: RCW 34.04.320 (cont'd)

- ◆ Publish name(s) of individual(s) proposing rule and of agency personnel administering rulemaking
- ◆ State whether rule is necessary as a result of federal or state court action, and, if so, cite the court case involved

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Format of Publication of Proposed Rule: RCW 34.04.320 (cont'd)

- ◆ Publish “when, where, and how persons may present their views on the proposed rule”
- ◆ Effective date (urgency)

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WA BOP Rulemaking: Professional Responsibility

- ◆ See BOP web site
- ◆ WAC 246-869-010 Pharmacies' Responsibility
- ◆ WAC 246-863-095 Pharmacist's Professional Responsibilities

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FINAL RULE: WAC 246-863-095: RPh's professional responsibilities

- ◆ Main thrust: pharmacist or ancillary personnel can be disciplined by the Board for the following conduct: destroying or taking away a prescription, violating patient's privacy, violating state or federal discrimination law, behavior that could be interpreted as intimidation or harassment.

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WAC 246-863-095; WAC 246-869-010

- ◆ Other important obligation emphasized by rulemaking: the pharmacist may not delegate the decision to refuse to dispense a legally prescribed drug or device to support personnel
- ◆ Inventory concerns: addressed in WAC 246-869-010, Pharmacies' responsibilities

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State vs. Federal Law

- ◆ Supremacy Clause (Article VI, Clause 2 of the U.S. Constitution) makes federal constitutional law the supreme law
 - enables Congress to displace state statutory and constitutional laws
 - makes explicit that federal law binds state judges.

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State vs. Federal Law Preemption Doctrine

- ◆ Doctrine applies when it is **impossible to comply with both federal and state law**.
 - Ex.: Federal Food and Drug Act of 1906 imposed labeling requirements that conflicted with state labeling requirements at the time, McDermott v. Wisconsin (1913).

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Conditional Preemption: HIPAA; DEA Schedules

- ◆ Federal statute/regulations can expressly describe how statutory schemes can co-exist:
 - HIPAA: preempts state law to the extent that it is more protective of health information than state law.
 - If state law provides *greater* protection of “protected health information” than HIPAA, then HIPAA Privacy Rule allows state law to prevail.
- ◆ States may have more restrictive schemes: CS

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Summary

- ◆ Rulemaking process; public comment
- ◆ Agency adjudicative powers; referral to courts
- ◆ Changes in pharmacy/pharmacist professional responsibilities
- ◆ Preemption

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