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

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.

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

With thanks to Martha Dye Whealan
**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 rulemaking hearing where BOP will receive public comment regarding adoption of a rule.

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

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

- Publish “when, where, and how persons may present their views on the proposed rule”
- Effective date (urgency)
WA BOP Rulemaking: Professional Responsibility

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

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.

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

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.
State vs. Federal Law Preemption Doctrine

- Doctrine applies when it is **impossible to comply with both federal and state law**.

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

Summary

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