

PHARM 543 MIDTERM REVIEW SHEET

*** Note that you are responsible for all course materials. This is no attempt to reproduce the PowerPoint slides which are available on the course webpage. In case of any inconsistency between this review sheet and the PowerPoint slides, the slides prevail.***

I. INTRODUCTION

- Academic honesty is expected. Recognize what constitutes plagiarism.
- Know what to do in case there is a fire or earthquake in the classroom.
- Know course goals.
- Understand the process of law making in both Washington state and federally.

II. NATURE OF THE LAW

Sources of U.S. Law

- US constitution and each State constitution
- Statutory law (laws made by state and federal legislatures)
- Common law (laws made when courts interpret constitution(s) and statutes.
- Administrative law (executive agency regulations)

US Constitution

- Whenever you are trying to determine the source or law-making power of a particular branch of gov't or gov't agency, remember that the source of all lawmaking authority is the U.S. Constitution. Thus, all power to do things legally must emerge from the U.S. Constitution. Some of this power is "enumerated" or written down in the text of the Constitution and some of it has emerged from judicial interpretation.
- The framers of the Constitution (the Founding Fathers) were primarily concerned with protecting the people against gov't tyranny eg. British style oppression of American colonies, so they gave the federal gov't only limited/enumerated powers, and the state gov'ts/courts more general powers. The Framers wanted to balance power between the federal gov't, state gov't and the courts so to limit federal gov't power and prevent tyranny. This is called *separation of powers*.
- This balance of power between federal gov't and state gov'ts is known as "**federalism**" and is alive and well today:
 - eg. *Oregon v. Gonzales*;
 - eg., Who determines drug scheduling? The federal DEA under the federal Controlled Substances Act or the state legislatures?
- The concept of "preemption" touches up against "federalism". (Preemption will be discussed below)

- Some of the **enumerated federal powers** that are written down in the U.S. Constitution are found in the Articles:
 - **Article I:** Powers of Congress
 - **Article II:** Powers of the Executive Branch
 - **Article III:** Powers of the Judiciary.
 - **Article IV:** Governs state-state relations, and state-federal gov't relations
 - **Article V:** How US Constitution can be changed or amended (2/3 vote by both houses of Congress to propose amendment, and 3/4 of legislatures of each state to ratify amendment).
 - **Article VI, cl. 2:** This Constitution, ..., shall be the supreme Law of the Land; ...". This is known as the "Supremacy Clause" and is the Constitutional basis (source of power) for the hierarchy of laws/preemption doctrine. As the "plain text" of the Constitution says, the federal Constitution as federal law supercedes all other laws. The preemption doctrine flows from this Supremacy clause.
- Know how states are empowered to make laws (Amendment X of Bill of Rights) and what laws they can make.
- Common law is law made by the courts. Understand the terms "*Stare decisis*" and "**precedent.**"

III. ADMINISTRATIVE LAW

- Administrative law is the body of law regulating administrative agencies
- This body of law in Washington state is the WAC. Federally, it is the CFR.
- Administrative agencies are created by legislatures, who delegate law-making power on particular subjects to these agencies through statutes
 - Know how the Board of Pharmacy in particular **promulgates** rules
- Federal and state administrative agencies also usually have judicial power to hold hearings and render decisions in order to enforce regulations they promulgate
- Examples:
 - Federal: Food and Drug Administration (in Dept of HHS) administers the *Federal Food, Drug, and Cosmetic Act*; DEA: Drug Enforcement Administration (in Dept of Justice) administers the federal *Controlled Substances Act*
 - State: Board(s) of Pharmacy/Department of Health administers the state equivalent, e.g. the state-monitored practice of pharmacy in Washington State.
- Administrative action is initiated by an agency; e.g. Board of Pharmacy begins investigation against a pharmacist for alleged violation of a statute or regulation. Administrative sanctions by BoP include:
 - Warnings
 - Fines
 - License suspension or revocation
 - Probationary period

Federal Preemption, Express or Field:

- The Supremacy Clause (Article VI of the Constitution) makes the federal law supreme law and thus enables Congress to displace state statutory and constitutional law. The **preemption doctrine** flows from this Supremacy Clause
- Preemption can take three different forms:
 - Express preemption: intent to supercede state law is declared within the body of the (federal) legislation. Eg. we intend to preempt state law...”
 - Field preemption: not expressed in statute, but courts subsequently look at the federal law and determine that Congress by implication intended to “occupy the field”.
 - Conflict preemption: courts determine that an actual conflict exists between the two bodies of law, because either:
 - It is impossible to comply with both federal and state law. Example: Federal Food and Drug Act of 1906 imposed labeling requirements that conflicted with state labeling requirements at the time, *McDermott v. Wisconsin* (1913).
OR
 - State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Example: Supreme Court held that the Employee Retirement Income Security Act of 1974 (ERISA), which allows patients to sue for reimbursement of denied benefits, but not for damages stemming from the denial, preempts state statutory schemes that allowed patients to sue HMO’s for damages/injuries resulting from the refusal of the HMO to cover treatment that a doctor has deemed “medically necessary.” The Texas law conflicts with Federal ERISA law and is therefore, preempted.

IV. ETHICS INTRODUCTION

- The law informs you about what you must or must not do. Ethics helps you decide what you ought to do when the law is silent. Knowledge of ethics is therefore a tool in your “toolbox” for approaching “dilemmas”.
- The study of ethics is a moving target: always ask yourself-whose ethics? (ethics reflects personal and societal and cultural values and what these values are changes with time as well as “cultural diversity”)
- **Some ethics tools for your ethics “toolbox”** include:
 - The 4 principles of the “Georgetown mantra”
 - Nonmaleficence, beneficence, autonomy and justice. Know what each one of these principles means.
 - The virtues approach
 - Very old (eg., Hippocratic oath) and focuses on virtues and intent of the provider
 - The 4 box method of Jonsen et al.’s Clinical ethics
 - Prof. Hazlet’s “root cause” analysis
 - The utilitarian argument for “cost-benefit” and the “greatest good for the most people” (focus on ends more than means).

When approaching a dilemma and/or ethics case:

- First ask-whose ethics? (Whose perspective? Who are the stakeholders?)
- Then ask-what are the issues (clinical, ethical, legal).
- Then consider what different ethics approaches would say about the dilemma.
- Is there a specific issue of law you need to consider?
- The “7 things” for the class approach are:
 - Perspective
 - Beneficence
 - Nonmaleficence
 - Autonomy
 - Justice
 - Virtue
 - Root cause analysis

V. FEDERAL AGENCIES

Statutory authority (Title 21 United States Code) to promulgate regulations (Title 21 Code of Federal Regulations) (Revised Code of Washington-WAC)

- Know the various agencies that affect pharmacy practice in Washington and why they do.
 - Federal agencies:
 - DEA
 - HHS → CMS (previously HCFA)
 - CPSC
 - EPA
 - OSHA
 - FTC
 - State agencies:
 - DOH
 - DSHS
 - MAA
 - DOE
 - HCA

VI. CONTROLLED SUBSTANCES / DEA

- **21CFR1300**
 - Controlled Substances in 5 schedules - Know all 5 schedules and some examples of drugs in each, know prescribing rules (quantities, refills, prescription requirements, etc.) for each schedule and when exceptions are permitted.

Registration 1301

- Must register with DEA for ALL activities related to controlled substances, separate registration for EACH location.

- Exemptions: Medical residents often don't have their own DEA number, they use the hospital DEA number with a hospital assigned 3 digit suffix. Residents may use this DEA number only for treating hospital patients.
- Military exemptions- Must use service ID number on Rx.
- Commercial ocean vessel exemptions- Ocean vessels may obtain controlled substances. If MD on board, MD must have DEA registration. If no MD on board, captain of ship may obtain CS. Pharmacy should advise DEA of sales to ocean vessels.

****KNOW THE FORMULA FOR IDENTIFYING LEGITIMATE DEA NUMBERS!**

- DEA will register somebody IF the state will authorize the person.
- DEA requires that CS be secure—know what constitutes secure versus non- secure storage.
- Other security controls:
 - Employers must have screening procedures
 - May NOT employ person convicted of felony related to CS or if DEA registration was previously denied, revoked, surrendered for cause.
 - Must notify DEA of theft or “significant loss” of CS.
 - Employees must report drug diversion by other employees.
- **Records 1304**
 - Everyone who handles CS must keep records of receipt and disposition. Schedule I and II records must be kept separate from all others.
 - Know record retention times, and drug inventory schedules.
- **DEA Requirements for CS Prescription 1306.05**
 - Know what is required and what is NOT required on CS prescription. What info can a pharmacist change and what may NOT be changed?
- **Schedule II Emergency Dispensing (emergency defined under 21CFR 290.10)**
 - “Immediate administration necessary,” “no alternative treatment available”
 - Dispense only to cover period of emergency
 - Need to obtain signed Rx within 7 days
 - Must notify DEA if you do not receive signed Rx within 7 days

VII. COMPOUNDING

- Distinctions between “compounding” and “manufacturing”
- FDA Compliance Policy Guide “9 points of light” (remember, this is a guideline and is not legally enforceable)
- State BOPs have jurisdiction over pharmacy compounding, NOT FDA
- **Good Compounding Practices (WAC 246-878, RCW 18.64.011(18))**

- These are described in your lecture slides- review these and be familiar with them.

VIII. RESEARCH ETHICS

- Ethical conduct of research involving human subjects, critical issue in realm of ethics
- The **Belmont Report** was written in response to horrible lapses in research ethics. Report speaks of 3 principles:
 - Respect for persons (informed consent, comprehension, voluntariness)
 - Beneficence (risk/benefit assessment)
 - Justice (who gets to participate in clinical trials?)
- Whether or not a treatment is a medical experiment depends upon the INTENT of the researcher.
- Institutional Review Boards- “the common rule” (reflects principles of Belmont Report)
- 45CFR Section 46.111 requires that human subjects research procedures include:
 - Equitable selection of subjects
 - Informed consent be sought as per regulations
 - Informed consent be documented
 - Adequate provision for data monitoring to ensure subject safety
 - Adequate provisions for privacy protection
 - If relevant, additional safeguards for “vulnerable” populations

IX. CONFIDENTIALITY

- Legal requirements for protecting patient confidentiality come from recently enacted federal law HIPAA as well as WA State privacy statutes. HIPAA, as a federal statute, specifically addresses the “federalism” issue (federal preemption) in the language of the statute. The language of the statute addresses “conflict preemption” by specifically stating HIPAA pre-empts state law to the extent that it is more protective but not if state law is more protective.
- Other sources of Duty of Confidentiality in addition to state and federal law include JCAHO and institutional policies.
- Confidentiality provisions of HIPAA are also known as “Privacy Rule” and it protects “individually identifiable health information” that is transmitted or maintained in any medium, created or received by covered entity or employer that relates to past, present or future physical or mental health/condition, provision of health care to an individual, or SSN
- Covered entity may not use or disclose personal health information except:
 - As Privacy Rule permits or requires
 - As individual who is the subject of the information authorizes in writing
 - “Disclosure”: a release, transfer, provision

Required Disclosures

- Covered entity must disclose personal health information in 2 situations:
 - To individuals specifically when they request access
 - For the purpose of treatment, payment, and health care operations
- Treatment= providing health care and related services
- Payment= activities of a health care provider to obtain premiums, determine or fulfill responsibilities for coverage or provision of benefits, and furnish or obtain reimbursement for an individual
- Also refers to activities of health care provider to obtain payment or be reimbursed for provision of health care to an individual
- A covered entity may also rely on informal permission to disclose to individual's family, friends, or to other persons designated by patient to be directly relevant to patient's care or payment for care (e.g. pharmacist dispensing prescription to a person acting on behalf of the patient)
- **Incidental use and disclosure is protected under HIPAA**
- A use or disclosure of personal health information that occurs "incident to" an otherwise permitted use or disclosure is allowed as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information shared was limited to the "minimum necessary."

Public interest and benefit activities:

- As required by law (e.g. domestic violence)
- For essential gov't functions (e.g. military, intelligence gathering)
- Worker's compensation
- **"Need to know principle"**: Access only the specific information necessary to perform a particular function in the exercise of his or her duties.
- **Privacy practice notice**: Patient must be provided with a notice of the practices of the covered entity, including notice of its information practices and how it uses and discloses patient information.
- **RCW 70.02: Uniform Health Care Information Act**
 - Except as authorized by Act, health care information cannot be disclosed to any other person without patient's written authorization.