Pharmacy 543 Course Outline[1]

There will be no attempt to reproduce the power point slides which are available on the course webpage.

I. Introduction.

- Academic honesty is expected. Recognize that "phrase attribution" can be evaluated with online sources and lack of attribution is now the commonest form of plagiarism.
- Know what to do in case there is a fire or earthquake in the classroom.
- Know course goals.
- Know the process of law making in both Washington state and federally. Understand the Federal Register, the federal equivalents of the WAC, and RCW.

II. Library Resources

- Understand Boolean searching and understand positional operators.
- Recognize the different truncation symbols used in PubMed (asterix) and LexisNexis (exclamation mark).
- To get to the official website for Washington state: Go to Health links and type in "access Washington"
- Databases for pharmacy ethics questions:
    - PubMed,
    - Drugs and Pharmacology,
    - IPA (International Pharmaceutical Abstracts)
- to find cited articles –remember Web of Science

III. Using Law Resources

- A bill gets a number and it is "codified" which is the process by which it becomes a law and ends up in a "code" (eg. U.S.C. or R.C.W.)
- U.S.C. is the United States Code
- R.C.W. is the Revised Code of Washington
- Once a bill has become a law (part of the federal code or state code-it is a piece of "statute") it still needs implementing regulations. The bill will authorize an implementing agency to "promulgate regulations" (make rules for implementation). For example, the implementing regulations for the RCW are found in the WAC, the Washington administrative Code. The federal equivalent is the Code of Federal Regulations (the "CFR").
- www.leg.wa.gov is a source for RCW, WAC, AG opinions and the state Register.
- The process of promulgating regulations requires publication and opportunity for public comment in the Federal or state Register. At the federal level, in the Federal Register, and at the state level, in the state

[1] Note: Where power point notes are extensive-I will provide you with study Qs to guide your way….

Register, an agency needs to inform the public about the proposed rule and the agency assembles all of that public comment and publish this in the Registers.

- The Board of Pharmacy website has preceptor forms as well as information on licensed pharmacists' credentials.

IV. Ethics Introduction

- Ethics helps you decide what you *ought* to do when the law is silent. The attitude of the Board of Pharmacy is to support good clinical care of pts by pharmacists.
- the law informs you about what you *must* or *must not* do
- knowledge of ethics are Tools 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")
- **when evaluating the ethics cases for class**-make your **implicit** assumptions **explicit**-ask yourselves-would my conclusions be different-at a different time or in a different social context? (eg. which perspective are you implicitly adopting?)
- **Some ethics tools for your ethics "toolbox"** include the 1) 4 principles of the "Georgetown mantra"; 2)the virtues approach, 3) the 4 box method of Jonsen et al.'s Clinical ethics, 4) Prof. Hazlet's "root cause" analysis, 5) research ethics from the Belmont report and 6) lurking in the background-the utilitarian argument for "cost-benefit" and the "greatest good for the most people" (focus on ends more than means).
  - The Georgetown mantra is nonmaleficence, beneficence, autonomy and justice. Know what each one of these principles means.
  - Virtue ethics is very old (eg., Hippocratic oath) and focuses on virtues and intent of the provider.
  - 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

- Different ethics approachs can be compared. For example the Principles approach (the "Georgetown mantra") can be compared to a virtues ethics approach:

Principle	**Virtue**
Nonmaleficence	Nonmalevolence, compassion
Beneficence	Benevolence, altruism
Justice	Fairness, empathy
Autonomy	Respectfulness for other persons, compassion

V. Nature of the Law/Aministrative 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 (cts) interpret constitution(s) and statutes.
  - Administrative law (executive agency reg'ns)

- **US Constitution**
  - N.B. 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 federal constitutional right to privacy that has emerged in cases mentioned in class- *Griswold, Roe v. Wade, Casey*).
  - 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/cts 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. Schiavo series of ct cases;
    - 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 basi s(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.
- **Article X Gives states the right to make laws (legislate)** in all areas except those specifically prohibited or given to Congress by the US Constitution.
  - Prohibited: states can't make treaties, raise armies,coin money. They also can't regulate interstate commerce. (the federal gov't has enumerated powers; the rest of the powers are delegated to the states,
  - eg., traditional areas of state lawmaking include civil wrongs (torts), family law, medical malpractice and personal injury (a branch of tort law); trusts and estates; regulation of pharmacy and medicine/licensing; education etc.

Comments on the US Constitution: Know the Amendments, esp. the Bill of Rights. (The 14th Amendment Due Process Clause is where the judicially created "constitutional right to privacy" comes from).

- **Federal Preemption, Express or Field**:
  - Congress can displace, or preempt, state law when it intends to and is acting within the scope of its constitutional powers:
    - **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*. Davila (**N.**B. FYI: ERISA Preemption is the primary reason pts have difficulty suing their HMOs! State laws that attempt to regulate health care regularly bump up against **the federal preemption problem**…notice how concepts of "federalism" and "federal preemption" affect your personal rights and your practice as a pharmacist today!)

- **Possible to resolve preemption issue** by drafting Federal statute/regulations that expressly describe how federal and state statutory schemes can co-exist: Example, 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.

- Remember that the power of the federal law to preempt state law comes from Article VI, cl.2, the "Supremacy clause".

- **Common law** is law made by the courts:
  - Governed by precedent or stare decisis.
  - Eg. *Roe v. Wade is* "superprecedent" for *Planned Parenthood v. Casey.*
  - *Griswold v. Connecticut (1965)* found a "penumbra" of rights from the US Constitution that make up (judicially created through Constitutional interpretation) a Federal Constitutional right of privacy. This right of privacy was important to the Court's rationale in the subsequent *Roe v. Wade* decision as well as the later Supreme Court decision in *Casey*. This right of privacy is hotly argued- right now- as the reason to protect physician-assisted suicide; it is also the reason the Supreme Court has recognized a Constitutional right to refuse medical treatment (coming up later…but *Schiavo* was about this right, in that Terri's husband,acting as her surrogate, exercised her right for her, to refuse food and water-these actions are all legal -based on right of privacy).

- **Administrative Law**
  - **is body of law created by administrative agencies.**
  - Usually regulations.
    - This body of law in Washington state is the WAC; federally it is the CFR

	Statute	Regulation
Federal	USC	CFR
WA	RCW	WAC

- Administrative agencies are created by legislatures, who delegate law making power to these agencies,
- Federal and state administrative agencies also have judicial power to hold hearings and render decisions in order to enforce regulations **they promulgate.**
  - 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, eg. 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 include:
    - Warnings
    - Fines
    - License suspension or revocation
    - Probationary period

VI. Drug Laws-Pharmacy Practice I

- The **Board of Pharmacy's legal powers and duties** arise from the **Pharmacy Act 18.64 RCW** and include:
    - Appointment of 7 members by the governor
    - (2 members of public and 5 RPh's).
    - Regulate Practice (of Pharmacy) and enforce laws assigned to it
    - Examinations
    - Establish qualifications
    - Conduct Hearings (may use ALJ)
    - Issue subpoenas and administer oaths
    - Assist law enforcement agencies RE: Rx
    - Promulgate Rules for dispensing, distribution, wholesaling, manufacturing of Rx/Devices.Violation of these rules shall constitute grounds for refusal, suspension, revocation of licenses or any other authority granted by the board.
    - Adopt rules for Continuing Education
    - be immune collectively and individually from suit in any action based upon disciplinary proceedings or other official acts performed as members. E''ees immune also acting RE: disciplinary proceedings.
    - suggest strategies for preventing, reducing, and eliminating Rx misuse, diversion and abuse.
    - monitoring trends of Rx abuse
    - written agreements with DEA
- Under the Washington state Pharmacy Act section 18.64.011 "Definitions" the "**Practice of pharmacy"** includes
    - interpreting Rx orders, compounding, dispensing, labeling, administering, distributing drugs and devices
    - monitoring Rx therapy
    - initiating or modifying therapy (protocols)
    - drug product selection, keep records, provide information,(Rx value, hazards and uses)
    - Note that **Medicare approved dialysis programs have limited pharmacy practice rights: "** may sell..dispense heparin, NaCl, KCl, and Dialysate" under RCW 18.64.257
- A Shopkeeper's Registration and license permits gift shops in hospitals, supermarkets, to sell OTCs.
- Know the requirements for pharmacy licensure in Washington state (18.64.080 RCW) and procedures required for relicensure.
- Know potential disciplinary actions facing a pharmacist under the Washington State Uniform Disciplinary Act.

- Know how long Prescription records (and what information needs to be retained) need to be kept under Washington state law and the DEA. How are the **Medicaid** rules on this issue different? *(important practice point).

- RCW 18.64.246 Prescription labels, caps (revised 2002) has very specific requirements for what needs to be one prescription labels-**what are these requirements?**

- **Some of the Unlawful practices under 18.64.250 RCW include:**
    - Unlicensed practice.
    - Permitting dispensing not under supervision of RPh.
    - RPh or Shopkeeper who fails to renew license.
    - Making false representations to get license.

VII. Drug Laws-Pharmacy Practice II

- The Washington State Board of Pharmacy (BOP) must identify the authority used when a rule is adopted (Note that their ultimate, ultimate authority arises from the US. Constitution-specific rights are enumerated and are powers given to the feds; all other powers are given to the states under Article X). Look at fine print at end of each WAC section to identify the Statutory Authority.
- **Washington State Legend Drug Act Chpt. 69.41 RCW**
    - determines how Rx may be prescribed, distributed, and dispensed in WA. (note the similarity to the federal CSA, the federal DEA and the lurking issues of "federalism" and Federal preemption…)
    - know requirements for drug product substitution
    - understand the requirements of the preferred drug list for State sponsored Rx programs
    - determine what proper imprinting is
    - OTC-no prescription required
    - Legend-prescription required
    - Controlled substances

        Mostly legend drugs
        - Registration with DEA
        - prescriptions required

    - Some schedule V require prescriptions
    - Some Schedule V OTC
    - Nutritional supplements are NOT drugs
    - Definitions section under "Practitioner" lists most of the persons who may legally prescribe OR administer legend drugs.
    - Prohibited Acts (similar to fed. DEA)
    - Legend drugs may only be dispensed etc in accordance with this chapter!
    - Violations of Legend drug Act include
        - Obtain, procure, legend drugs by:

            a. Fraud, deceit, misrepresentation
            b. Forgery, alteration of Rx or written order
            c. Concealment of material fact
            d. False name or address

- The who can prescribe section of the Legend Drug act is RCW 69.41.030
  - Unlawful to sell, deliver, possess legend drug EXCEPT on order or Rx of MD, DO, etc.
  - Could a properly licensed family planning clinic, open up a packaged OTC and hand you a couple for emergency contraception? NO. Can they dispense commercially available plan B?

69.41.040 RCW **Prescription** Requirements:
  - **Legitimate medical purpose** incl. research
  - Authorized prescriber
  - Violation of Washington State Legend Drug Act if RPh **fills & knows or should have known it was not valid Rx**
  - **Not a Rx if issued to a prescription drug abuser or not in course of treatment!**

Records must be maintained for **2 years**

69.41.050 RCW **Labeling Requirements**
  - Prescriber #
  - Directions for use
  - Name of drug* (brand or generic)
  - Strength*
  - Name of Patient (required on samples)
  - Date
  - *May omit

69.41.070 RCW governs **Penalties**
  - Obtain by fraud etc. = felony
  - **Sale, delivery, intent to deliver = felony**
  - Possession only = misdemeanor
  - Filling false Rx = felony

69.41.110 RCW governs **Drug Substitution**
  - Definitions:
    - Brand name = proprietary or trade name
    - Generic name = official title
    - Need prescriber's authorization

  Therapeutically equivalent drug to that Rx'd
  MUST be identical base or salt
  BUT with prior consent of Rx'er need NOT be identical (Therapeutic Substitution)
  (Therapeutically equivalent = same efficacy & toxicity when administered in same dosage regimen)
    - If substitute must use product that has less wholesale cost than

brand and **pass on 60% of the savings to the purchaser.**

69.41.200 RCW **Imprinting** Rx

- All solid dosage legend drugs must be imprinted with code etc. to identify:

VIII. Ethics-Autonomy

- The class approach to a ethics case is to:
  -choose and then state the perspective (or stakeholder) you wish to represent
- Then consider ethical principle of Beneficence
- Then consider the ethical principle of nonmaleficence
- Then consider the ethical principle of Autonomy
- Then consider the ethical principle of Justice
- Then consider virtue ethics
- Then consider a root cause analysis

IX. Drug Laws-FDA

- Statutory authority (Title 21 United States Code) to promulgate regulations (Title 21 Code of Federal Regulations) (Revised Code of Washington-WAC)
- **What are the 4 elements of a "drug"?**
  - **Recognition i**n an official compendium USP/NF or Homepathic Pharmacopeia
  - "**intended for** use in Dx, cure, mitigation, treatment or prevention of disease in man or other animals",
  - **intended to affect** the structure or function of the body of man or other animals, but not food.
  - **components** (of any of the above, is a drug-anything that is used in making the drug, even if it isn't showing up in the final product).

  - **Device:** same as "drug" except "does not achieve any of its principal intended purposes through chemical action…and is not dependent upon being metabolized…"
  - **Cosmetics:** intended…for cleaning, beautifying, promoting attractiveness, altering appearance-components,
  - NOTE: What **differentiates a cosmetic from a drug** is INTENT of use-is it for cleaning and beautifying or for treatment of disease?
- What about FDA's reach of practice of medicine into the state… (Look-another "federalism" concern…) Limited by an approved application. (Note: the very limited reach of the FDA's jurisdiction: can only interfere with the practice of medicine/pharmacy in states when there has been a violation of an approved application)

- **FDA has two big sticks**
  - **Adulteration**
    - making it from bad stuff
    - making it in a way that it could become bad….
    - Putting it into a container/closure system where it could become bad…
    - Strength/quality differs from claim; official compendium or otherwise
    - Parrot in the pharmacy….
  - **Misbranding**
    - Labeling is false or misleading
    - Understandability by ordinary person under customary conditions of purchase/use
    - Warning for habit-forming
    - Size of type
    - Active ingredients specified; inactives in (descending order of predominance) alpha order; alcohol
    - Established name (USAN)
    - Adequate directions for use and warnings
    - Packaging
    - Following labeling could result in health hazard
    - If subject to deterioration; packaging precautions in labeling
    - Adequate information for use (MedGuide)

The FDA Orange Book: used for therapeutic substitution

- Electronic Orange Book-Approved Products with Therapeutic Equivalence Evaluations. http://www.fda.gov/cder/orange/default.htm

Expiration Dates: last day of the month for the product, except for a couple of OTCs that don't have one-it is misbranding to sell an expired date

FDA Recalls:

- virtually always a voluntary recall.
- Product is subject to FDA legal action
  - Threat or potential threat to humans or animals
    - Adulteration
    - Misbranding
    - Or material misleading

X. Drug Laws-Compounding.

FDA recognizes that the traditional role of compounding is not manufacturing FDCA 21 USC 360 (g)(1)

- o FDA Compliance Policy Guide-aka "9 points of light".
- o FDA Compliance Policy Guide is guideline (and not legally enforceable)
  - Reissued Compliance Policy Guide: www.fda.gov/cder/pharmcomp/default/htm.
  - Products typically subpotent
  - Does the FDA have any **jurisdiction** over pharmacist compounding?
  - Who else?
  - State Boards of Pharmacy have jurisdiction not the FDA
  - Examples of Violations of the "9 pts of light" include: CPG 460.200
    - compounding of drugs in advance of receiving prescriptions
    - compounding of drugs removed from market for safety!
    - compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance…
    - Compounding commercially available drugs etc.

WAC 246-878 Good Compounding Practices

- "Compounding" in WA: RCW 18.64.011(18)
  Compounding shall be the act of combining of two or more…
  - o allows compounding of a commercially available product if prescriber authorizes in writing or verbally and pt agrees.
  - presumption of prescriber-pharmacist-patient relationship. (otherwise it might seem like it is manufacturing) and you also need to make sure that it is not causing harm…
  - eg. remember need for **Patient counseling** (eg. what are you going to do to make sure the product is sterile and remains that way?)

XI. Medicare, Medicaid, OBRA90

- Fraud is the deliberate deception for unfair and unlawful gain.
- **Purposeful fraud** includes
    - Dispensing of generics while billing for brand Rx
    - Dispense one strength and bill for another
    - Misrepresentations on applications for licensure.
    - Charging for pts that don't exist
    - Price-fixing antitrust activities
    - Kickbacks
    - Upcoding
    - Unbundling
- **Unwitting Fraud** includes
    - prescriptions billed for but not picked up by pt.
    - medicare pts paying for services
    - incorrect provider numbers
    - undocumented services.
- Medicare Part D has expanded requirements for monitoring and reporting fraud.
- **False Claims Act** and Qui Tam action
    - A growing area of law enforcement.
    - HIPAA penalities include criminal fines and/or imprisonment up to 10 years
    - Debarment, exclusion, loss of licensure
    - Damages severe: 3x the amount of damage suffered by gov't plus a mandatory civil penalty

XII. Research Ethics

- The Ethical Conduct of Research Involving Human subjects.
    - Critical issue in the realm of ethics.
    - NIH (OHRP) www.hhs.gov/ohrp/
    - UW Human Subjects Division www.washington.edu/research/hsd/index.php
    - UW is one of the largest recipients of US research money and the grantgiving authorities take money away for violations of research ethics!!!
    - Remember-protocol stays open during stages of manuscript preparation
    - The **Belmont Report** was written in response to some horrible lapses in research ethics…(eg Nuremberg trials of the Nazis who experimented on their captives; Willowbrook State School NY Hep.B vaccine 'trial"; Tuskegee Syphilis "study" which withheld Pen G from pts with tertiary syphilis so they progressed to untreatable brain damage/dementia!)
    - Whether or not a treatment is a medical experiment depends upon the INTENT of the researcher/provider!
        - "medical experiment" means: (a) use…in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject…
        - if the INTENT is to provide treatment for Dx, or to "improve the health" it is medical treatment, not medical experiment.
        - The Belmont Report speaks of three principles:
            - **respect for persons** (application: informed consent-information, comprehension, voluntariness)
            - **Beneficence** (application: risk/benefit assessment)
            - **Justice**-(application: who gets to participate in the clinical trial

Institutional Review Boards (IRB) look **to the common rule** which is codified in 45 CFR§ 46.111 for detailed (fed) reg'ns for conducting human subjects research.

- "the common rule" reflects the principles of the Belmont Report.
- **45 CFR § 46.111** requires that human subjects research procedures include:
    - selection of subjects is equitable
    - Informed consent must be sought as per the regulations
    - Informed consent must be documented
    - Adequate provision for data monitoring to ensure subject safety
    - Adequate provisions for privacy protection
    - If relevant, additional safeguards for "vulnerable" populations.
    - Following these research rules is a big deal. If you don't you open your institution up to a ban on all federally funded research. You also create all sorts of bad press and maybe other legal liabilities.

XIII. DEA Drug Laws

- 21 C.F.R. 1300
  - **Controlled Substances in 5 Schedules** from **the Controlled Substances Act**
  - Schedule 1. no medical use. Heroin, marijuana, LSD
  - Schedule II. medical use high abuse potential-Morphine, codeine, oxycontin, percodan, percocet, Ritalin
  - Schedule III. less abuse potential-Codeine combo, hydrocodone combo, marinol
  - Schedule IV less abuse potential-Librium, valium, other benzos
  - Schedule V some abuse potential
    - Some Rx only some OTC –eg.Codeine cough syrups, Tylenol elixir with codeine, antidiarrheals

  - Schedule I not prescribed (may Rx if investigational drug)
  - Schedule II written Rx or emergency NO refills
  - Schedule III Verbal Rx OK refillable 5/6 months
  - Schedule IV same as III
  - Schedule V Verbal Rx OK refill per MD up to 12 months (the 6 month limit does not apply to V scripts); Some are OTC
  - (NOTE: from the date of issuance of a Schedule III drug, a Rx can be filled for up to 6 months after date; but a Schedule II drug can be filled up to 12 months! DEA drafting glitch?)

Must register for ALL activities related to Controlled Substances

- Separate registration for EACH location
  - MD with 2 offices if Rx only= 1 registration if dispense/administer at both then 2 registrations.

Registration -1301

- Exemptions: agents/E'ees as residents often don't have their own DEA numbers, but they use the UW DEA number, and the hospital assigns the resident a 3 digit suffix. They can only use this DEA number while they are treating hospital pts.
- Hospital keeps list of suffixes and makes available to other registrants and law enforcements
- If they are moonlighting, they have to get their own DEA number
- Military exemptions
  - Army, navy, public health service, etc
  - Must use service ID no. (ie. SSN) on Rx
  - Ocean Vessels (commercial)
    - May obtain C.S.
    - If MD, must have registration
    - If no MD, Captain of the ship may obtain Controlled Substances

- Pharmacy advises DEA then OK to sell

NOTE: Please memorize and practice the formula for Identifying a real from a forged DEA number!

- DEA will register somebody IF the state will authorize the person.
  - DEA can removed registration with
    - Order to show cause
    - Hearing could be held
    - Applications=your burden of proof
    - Suspend/revoke=DEA's burden of proof

The DEA requires that Controlled Substances be **SECURE**

- Practioners/Pharmacy Security-Securely locked in a substantially constructed cabinet. A Pharmacy also can dispense CS amongst other Rx drugs in place of a substantially constructed cabinet.
- Other security controls
  - E'ers must have screening procedures
  - May NOT employ person convicted of felony related to CS or if had DEA registration denied, revoked, surrendered for cause.
  - Must notify DEA and Board of Pharmacy of any theft or "significant loss" of CS.
  - E'ees MUST report drug diversion by other E'ees.
  - Must include symbol for schedule on label. Eg …C-I,

Records 1304

- Everybody who handles CS must keep records of receipt and disposition
- Types of records vary by Registrant
- Records must be "readily retrievable" eg. Pharmacies Must maintain ALL records of receipt and disposition (invoices, 222s, Rx, Returns, Loss Reports, Sales invoices)
- MDs must keep these records IF
  - Dispense CS to pts for use at home
  - Regularly dispense or administer And
    - Charge fee for CS or
    - Charge higher office fees

Schedule I and II records must be kept separate from all others (incl. inventories, Rx,)

When do you have to do Drug Inventories?

- originally taken on 5/1/71 (when CSA became effective law)
- Then every 2 years
- New pharmacies on opening (even if zero)

Perpetual Inventories:

- Some pharmacies maintain a perpetual inventory of all CS
- Some have perpetual inventory of II's only
- These do NOT meet the requirement for a biennial inventory.
- (eg. nursing home pharmacies have to count the pills in the ER kits in the homes, plus DEA number of pharmacy, durg strength, quantity, form etc.
- eg. newly controlled substances.eg. Ketamine, Midrin. (inventory on the day it is controlled by DEA).
- Must keep inventory at location for 2 years.
- You have to do an exact count for I and II
- Estimated count for III, IV and V EXCEPT for bottles over 1000 then exact count!

- N.B. Fiorinal is a CS, Fioricet is NOT a CS.

DEA Requirements for Prescriptions 1306.05(a) Format - Issuance of Rx

- Dated address of Patient
- Directions for use
- Name, address, DEA number of prescriber
- Manually signed by prescriber (like check)
- Sched. II in ink, indelible pencil or typed
- Can be prepared by clerk SIGNED by MD on date of issue
- Can NOT write post-dated Rx
- If Rx unsigned must send back to doctor
- If Wrote patient name "John Smith" but meant "Jim Smith" must return for new Rx
- If strength ordered is not in stock
- OK to change and change directions & quantity.
- Must document changes
- THINGS NOT NEEDED ON Rx LABELS
  Pharmacy DEA number
  Prescriber DEA number
  Patient address
  Prescriber address
- How do you handle if 30 day limit by insurance company but visits every 90 days?
  - Date 3 prescriptions with today's date.
  - Write "Do not fill before **_____**"
  - Each Rx may then be filled at 30 day intervals. (but not S.II)

(Note: Prescriptions for Schedule III, IV and V can be partially dispensed up to amount authorized on Rx within 6 months)

Schedule II limitations: NEW RULES

- NOW DEA says the following:

For a physician to prepare multiple prescriptions for a schedule II controlled substance on the same day with instructions to fill on different dates **is tantamount to writing a prescription authorizing refills of a schedule II controlled substance -To do so conflicts with the provisions of the CS Act which provides: "No prescription for a controlled substance in schedule II may be refilled**."

Who may fill CS prescriptions?

- Only a pharmacist or pharmacy intern in a registered location

Prescriptions-Emergency Dispensing:

- Schedule II Emergency oral Prescriptions
  - Emergency defined under 21 CFR 290.10 as
    - "immediate administration necessary"
    - "no alternative treatement available"
    - "not reasonably possible for prescriber to get written Rx to dispenser
    - covers period of ER only
    - needs signed Rx in 7 days
    - must notify DEA if you do not get signed Rx in 7 days

XIV. Confidentiality.

- The legal requirements for protecting pt confidentiality come from the recently enacted federal law HIPAA, as well as Washington State privacy statutes. HIPAA, as a federal statute, specifically addresses the "federalism" issue (of 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 the Duty of Confidentiality in addition to state and fed. Law are JCAHO and institutional policies.

- Fact sheet about HIPAA: www.privacyrights.org/fs/fs8-med.htm

- The Confidentiality provisions of HIPAA are also known as the "**Privacy Rule"** and it protects "Individually identifiable health information" that is transmitted or maintained in any medium…created or received by covered entity or E'er that relates to the:
  - Past, present, or future physical or mental health/condition
  - Provision of health care to an individual
  - SSN
  - A covered entity may not use or disclose PHI, except
    - As the Privacy rules permits or requires
    - As the individual who is the subject of the information authorizes in writing.
    - "disclosure": a release, transfer, provision.

Required Disclosures:

a covered entity MUST disclose PHI in only 2 situations:

- to individuals (or their PR) specifically when they request access
- for the purposes of treatment, payment, and health care operations
  - "treatment" providing health care and related services is treatment
  - "payment"-activities of a HCP 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 (RPh to insurance plans)
  - QA another permitted d/c

- Uses and disclosures with opportunity to agree or object – informal permission may be obtained from individual by asking the individual outright, or by circumstances that give I. opportunity to object…
- For notification and other purposes: a covered entity may also rely on informal permission to disclose to individual's family, friends, or to other persons whom the I. identifies, PHI directly relevant to that person's involvement in the I's care or payment for care.
    - Eg. pharmacist dispensing of a filled prescription to a person acting on behalf or the patient.

Incidental use and disclosure is protected under HIPAA:

A use or disclosure of PHI 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 (statute, reg'n eg., abused children, domestic violence)
- For essential gov't functions eg. military missions, intelligence gathering, Secret service,
- Worker's compensaton, Washington L& I.

"Need to know" principle: access **only the specific information necessary to perform a particular function in the exercise of his or her duties**.

- If you are talking to another HCP for treatment purposes
- d/c to individual, or individual's PR
- use or disclosure made pursuant to a (written) authorization
- d/c required by law(including to HHS for compliance investigation or review)

Privacy practice notice: pt must be provided with a notice of the practices of the covered entity.

- Must give notice of its information practices, including how it uses and discloses info: uwmedicine.org/Global/Legal/privacy.htm

- Access: pt may inspect or get a copy of their PHI.
- Restriction request: Pts may ask covered entity to restrict how PHI is disclosed or used-note that covered entity is under no requirement to agree to request for restrictions (under federal law-HIPAA).
- Complaints-Individuals may complain about compliance with privacy policies and procedures of a covered entity..

WA: RCW 70.02. Uniform Health Care Information Act.

- Except as authorized by Act, health care information cannot be disclosed to any other person without pt's written authorization.

<u>Violations of HIPAA and Washington State law in Normal Pharmacy Practice:</u>

- **Avoid careless elevator talk and careless cafeteria talk**-it has the potential to really hurt and harm pts and their families-as well as get you in a lot of trouble!
- Careless disposal or mishandling of patient records includes paper records/receipts, patient-specific medication information generated when processing a prescription.
- Violations of HIPAA-failure to adequately ascertain relationship of pt to person picking up medication or inquiring about medication for pt.
- Forwarding of email with pt information to non-secure site.
- Failure to protect faxed information
- Viewing PHI on computer of patient you are not going to be interacting with.

XV. Ethics-Advance Directives

- **Washington State's Natural Death act** gives competent adults certain powers to direct their future medical care should they become incapacitated, through the use of Advance directives. Under the Natural Death act:
  - any adult person can execute a document directing the withholding or withdrawal of "life sustaining treatment". Pain management/intervention is not included in this statutory definition of "life sustaining treatment". **Why do you think this was done?**
- Checklist for a **valid health care directive:**
  - Must be in writing
  - Must be signed by declarant in the presence of two witnesses:
  - Witnesses cannot be related to declarant by blood or marriage and cannot inherit under the will.
  - Witnesses cannot be attending MD or an E'ee of the attending MD or a health facility in which declarant is pt.
  - Witnesses cannot have a claim against declarant's estate.

Powers of Attorney in fact

- Access medical records
- Employ and d/c health care personnel
- To give, withhold, or withdraw informed consent for medical treatment.
- To exercise and protect rights of principal
- To authorize pain relief
- To grant releases

Mental Health advance directives

- Pts with major mental health issues can approve/disapprove of specific mental health treatments even at time of incapacity
- important because durable power of att'y (AIF) cannot consent for most actute mental health situations. In WA, AIF cannot consent to therapy involving convulsions, constraints, psychosurgery.

XVI. Board of Pharmacy Rules

- The rules important to the practice of pharmacy in Washington are concentrated WAC 246-858 through 905
- These rules address internship
- Preceptor requirements
- Pharmacy C.E.
- Pharmacist Licensing
- Pharmacist Responsibilities
- Procedures for the Impaired Pharmacist
- Pharmacy Licensing
- Prescription records
- Return or Exchange of Drugs
- Pharmacy standards
- Pharmacy Inspections
- Prescription Labeling
- Patient information
- Child Resistant Containers
- Closing a Pharmacy

XVII. Disciplinary Actions

- Then intent of the investigative and disciplinary process is to provide quality protection of the public while providing procedural due process to pharmacist under investigation…
- The BOP has jurisdicition to investigate complaints and take action against licensed pharmacists given to it by statute.
- Know the difference between information and a complaint.
- A pharmacist has a requirement to cooperate with a BOP investigation
- The person who complains to BOP has a right to confidentiality
- The legal processing must be complete in 125 days
- A Notice of Correction is
    - Nondisciplinary
    - Educational
    - Cannot impose sanctions
    - With mailing case is closed
- A Statement of Charges is
    - Formal discipline
    - Wide range of sanctions possible from reprimand to revocation
    - Right to a board hearing
- Uniform Disciplinary Act is the place to look for detailed descriptions of detailed rules for this process
    - Covers all sorts of licensees not just pharmacist

XVIII. Legislative Process in Washington

- Every other year WA has a "short" session.
- Know how a bill becomes a law
- Governor has both veto and partial veto (of full sections only) of a bill
- Effective dates of bills vary-there may be an emergency clause which makes the bill effective when signed; there may be a specific day; normal date is 90 days after session
- The effect of lobbying is profound-know your senator and representatives, visit them, work on campaigns and know the issues and donate $$$
- Pharmacy is a "pervasively regulated profession"
  - Regulated by BOP
  - DEA
  - FDA
  - Consumer Products Safety Commission
  - Medicare/Medicaid
  - OSHA etc. etc

XIX. Pain Management Issues

- What are the 4 A's of pain management? (analgesia; ADLs; adverse effects; aberrant drug taking)
- Opioid abuse seems to increase with opioid prescription use
- Know fed. And state drug laws (you already do!)
- The intractable pain statute RCW 69.50.308(g) adopted in 1993 provides pain management guidelines for "intractable pain".
- WA DOH Pain management guidelines: opioid may be prescribed, dispensed, or administered when there is an **indicated medical need** w/o fear of injudicious discipline."
- Why all these guidelines? There is a hidden deep controversy about whether or not to treat noncancer pain with strong opioids as is done with cancer pain. Given that opioids carry the burden of inducing opioid analgesic tolerance (in everybody) and in creating psychological dependence and addiction (in some)-how to prevent addiction and diversion is a continuing issue for HCPs and pharmacists.
- WA QA Commission adopted pain guidelines into rule in 1999
- Patient pain "contracts" (agreements-not legally binding) can help prevent abuse-patients agree to use a single prescriber and pharmacy and to follow directions for use and not to use extra med'ns. And to submit to tests such as UA's to determine use/abuse.
- Multiple barriers to adequate pain relief
    - Fear of regulators (MDs esp. afraid of the DEA)
    - Patients also worried about opioids and fear of addiction
    - Addiction is psychological (I also think it is neurological-and causes change in the brain in the reward circuits) with loss of control of use of the legally prescribed drug; take drugs to get high and not for pain relief; continued use in spite of bad things happening to self, family an job!!!
    - Differentiate addiction from physical dependence and tolerance (this one is "duh" for you guys, but lots of MDs don't get it)
    - Know the 5 Questions in deciding to Rx opioids

XX. Drug Diversion and Counterfeiting

- Knowing the 4 A's and the behaviors assoc. with drug addiction and misuse really helps in recognizing drug diversion!
- **Everyone diverts drugs-HCPs, pts, abusers.**
- Drugs are diverted from any site where they are stored, stocked, administered, prescribed or dispensed
- Drugs are diverted anytime
- There are may ways the drugs are diverted-thru theft of drugs, prescription forms; record alteration, fraudulent "wastage"…etc.
- Most HCPs involved in drug diversion are doing it for impairment reasons-they are feeding their own addiction….
- Awareness and prevention are really important
- Many pharmacist responsibilities-KNOW THEM!

XXI. End of Life

- Oregon Death With Dignity Act (ODWDA) has extensive procedural protections to protect "abuse" by vulnerable, poor, elderly, incompetent pts. For example only:
  - The pts need to be Oregon resident
  - Must be capable
  - Must have a terminal disease
  - Must be free of significant mental illness
  - Pt must make a written request to attending MD which is witnessed by 2 witnesses
  - There is 15 day waitng period
  - MD has obligations to examine pt and confirm diagnosis, verify capacity, verify voluntariness of request and screen for underlying mental illness
  - If all procedural safeguards are met, pt may receive a prescription for med'ns to be taken by pt alone, w/o aid of MD.

Court cases over ODWDA:

- Attorney General, John Ashcroft issued the "Ashcroft Directive" which said that physician assisted suicide under ODWDA violated the federal Controlled Substances Act (note the lurking federalism issue here-who gets to control the practice of medicine and pharmacy? The feds or the states?) and that MDs would not be prescribing controlled substances for a "legitimate medical purpose" (and therefore face potential criminal charges under DEA and CSA).
- Oregon State with pts rights org'n and HCPs filed suit immediately in US District Court seeking a permanent injunction against enforcement of the "Ashcroft Directive".
- Moved around in the cts and the 9th Circuit upheld the permanent injunction.
- The reasoning of the 9th Circuit-AG was outside of his power/authority when he attempted to control an area of law traditionally reserved for the states (medical practice and prescriptions and dispensing of controlled substances)
- The AG's directive also violated the "plain language" of the CSA (this was a statutory interpretation task the ct did) which expressly limits the federal authority under the CSA to the area of illegal drug abuse and prevention. The prescription of MD to pt with terminal disease for the purpose of assisted suicide was not determined to be in the area of illegal drug abuse and diversion.

- The case has been heard at the US Supreme Court and rumors are that the decision will come down the day of your exam, Monday, December 12.

End of life ethical issues.

- Pts become more vulnerable as they approach death
- Pharmacists can anticipate and appreciate the needs of pts at end of life and not place unnecessary barriers to their access to care.
- Many providers find these pts onerous and burdensome.
- The ethical concept of double effect distinguishes intended outcomes-such as good pain relief-from unintended outcomes-such as resp. depression and death from rapid escalation of opioid infusions and inadequate opioid analgesic tolerance to respiratory depressive effects of the opioid. This concept has been used by MDs, Pharmacists and legal-ethical commentators to justify the potential for hastened death from aggressive pain management. (The US Supreme Court has also given this concept legal authority in *Glucksberg*).

XXII. Labor and Employment Law

- There is a long history of tensions and fights between Employees and their rights and wants for a protected, secure, reasonable workplace, and Employers, who want no restrictions to work conditions work hours, unions etc.
- The base principle that Employers want and that has been based on economic principles of the "free market" in the US, is the idea of **the "At will" employee.**
- At will employment means that an Employer can terminate an Employee at any time for any reason. (**NO CAUSE termination)**
- The harshness of this rule can be tempered multiple ways:
  - The Employee can negotiate between the Employer in the **Employment contract** to put in terms for potential termination (these terms, such as "for cause" and specifying the procedural protections for Employee, put limits on Employer's ability to terminate Employee "at will") (and less likely today-there can be a collective contract such as a union negotiates)
  - State common law has also limited at will termination-and public policy exemptions are one such example
  - Federal laws such as the Civil Rights Act of 1964 put further constraints on at –will termination (there are many other statutes that also touch on "at will" employment-please know the FMLA[2] for your future use..)
  - Public policy state common law limits at will terminations when the termination would violate an important public policy
    - An example of a Public policy exception to at will employment is that an Employee cannot be terminated (at will) for exercising a **statutorily protected right**.

Please note how these Employer rights to "at will" employment from Employees is further constrained by "conscience clause" laws and protection of religious freedom! See power point slides from Martha Whealan's lecture:

- the point being that both the federal case law from the US Supreme Court (*TWA v. Hardison*) and
- Title VII of the 1964 Civil Rights Act (prohibits discrimination on the basis of race, color, **religion**, sex or national origin) require an Employer to make
- "reasonable accommodations" to the Employee to permit the Employee to practice and observe his/her religion.

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[2] FMLA is the Family Medical Leave Act which provides-in part- important new protections for both parents who wish to take time off with a baby and have job protection at the same time! It also provides important job protections for workers who need to take time off from work for illness of either themselves or to care for a family member. This will not be on the exam.

- *Hardison* judicially defined what “reasonable accommodation” meant. The Employer is not required to incur more than a *de minimus* cost in meeting duty of reasonable accommodation of religious beliefs.
- How this applies to pharmacy practice-proposed Cal. Leg’n probably says it best (CA SB 644). “refusal on moral grounds if …notification of Employer in writing…(reasonable accommodation of pharmacist religious/moral beliefs?). Therefore you could not terminate Employee on “at will” grounds (but really because you don’t want to accommodate employee’s religious beliefs) if you, as an employer, have not made “reasonable accommodations” to accommodate Employee’s religious beliefs.

XXIII. Institutional Pharmacy Practice

- What are the differences between Medicare and Medicaid?
- What do you need to know about the Medicare Modernization Act?
- Is the JCAHO Accreditation federal or private?
- What does JCAHO accreditation mean for a hospital to meet Medicare COP?
- JCAHO has a new initiative to prevent Prescription writing abbreviations-what's this all about? What are they worried about? What does it mean if you are subject to a JCAHO site visit and such a prohibited abbreviation is discovered? Is this a big deal or a little deal? Do YOU want to find out? (Hospitals are very afraid of JCAHO visits)
- BOP also inspects hospitals-Why? What are they looking for?
- Additional WA Nursing home rules involve provision and dispensing of drugs-what are they?

XXIV. Misc. Fed. Laws and Rules

- Child Resistant Packaging

  What is the Hx behind this?
  What are the age ranges for testing of closures?
  Which drugs are required to have Child resistant Closure? What are their dosages?
  What are the exemptions?
  What do waivers look like? Can Prescribers request a blanket waiver?

- Change of topic: can the postal service may narcotics? What are the requirements if a pharmacy wants to do this?
- Prescription Marketing Act of 1987 passed in response to drug diversion concerns
  1. states must now license wholesalers
  2. can't reimport prescription drugs except in emerg. Or by manufacturer
  3. but loopholes-wholesalers and manufacturers can still sell to nursing home pharmacies at low contract prices.

4. need the FDA pedigree rules-What are these? Know RFID technology for pedigree and how it might help…

I have not covered Pseudoephedrine issues as they have been well covered in lecture, notes and with 2 excellent student presentations! But I would know them as they relate to pharmacy practice in WA.

XXV. Preceptor-Intern Relations

- From the excellent class presentation this appears to be a point of friction
- Know the requirements!
- Both intern and preceptor have requirements
- Preceptor has to be qualifed for intern to receive proper credit
- Preceptor evaluates intern at the end of the intern rotation
- The intern site evaluation is very open-ended and could be improved?

GOOD LUCK!!!