2006 Pharmacy 543 Final Exam Review

(The final exam is cumulative, so don’t forget what you learned before the mid-term! Below is a summary of everything post-midterm.)

**Fraudulent billing & CMS**
- Fraud defined as **deliberate** deception for unfair or unlawful gain
- Identify various types of fraud e.g
  a. **Purposeful fraud**: Examples are dispensing generic and billing for brand, dispensing nothing and billing for brand, misrepresentations on applications, ghost patients, unnecessary services, kickbacks, upcoding and unbundling
  b. **“Unwitting” fraud**: e.g where prescriptions billed but not picked up, Medicare patients paying for services, price database and algorithm errors etc
- 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 penalties 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
- Ways of discovery are through audits, board of pharmacy inspections, wholesalers, manufacturer reps, consumers, providers, fellow employees.

**Board of Pharmacy rules**
*(Read WAC 246-858 through 905)*

- **Rules addressing internship** e.g
  - Both intern and preceptor have requirements: intern must work 1500 hours, can work out of state if board accepts, must be making academic progress.
  - Preceptor has to be approved by board of pharmacy, must advise board at start of internship and give reports.
- **Other rules are**:
  - 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
• Customized medication packages, parenterals for home patients, hospital pharmacy standards
• Pharmacy-patient record systems (patient profiles), sales prohibited, good compounding, drug wholesalers, prescription advertising, sales requiring prescriptions, imprints on drugs.
• Good manufacturing practices, drug product substitution, pharmacy technicians, nuclear pharmacy, health care entities, home dialysis programs, miscellaneous rules

Board of Pharmacy Rules-II
Disciplinary Actions
• The 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 jurisdiction 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 (NOC) is:
  o Non-disciplinary
  o Educational
  o Cannot impose sanctions
  o With mailing case is closed
• A Statement of Charges (SOC) is:
  o Formal discipline
  o Wide range of sanctions possible from reprimand to revocation
  o Right to a board hearing
• Uniform Disciplinary Act is the place to look for detailed descriptions of detailed rules for this process
  o Covers all sorts of licensees not just pharmacist

Drug Diversion and Counterfeiting
o Understand the difference between diversion and counterfeiting.
  o Drugs are diverted from any site where they are stored, stocked, administered, prescribed or dispensed
  o Drugs are diverted anytime
There are many ways the drugs are diverted—through theft of drugs, prescription forms; record alteration, fraudulent “wastage”…etc.

Counterfeits include fake medications, diluted medications, expired medications and medications with bogus labels

**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”.

- Understand the terms “qualified patient” and “terminal condition”

- **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.

- Know treatments that may be described in health care directive, what happens to directive after it is written and revocation of directive.

- **Powers of Attorney in fact**
  - Powers invoked only when principal is incapacitated.
  - Can be any trusted friend or family member.
  - **Cannot** be principal’s MD, MD’s employees, or connected to healthcare facility where principal resides or receives care (**unless** spouse, adult child, brother/sister).
  - Access medical records
  - Employ and discharge 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 acute mental health situations. In WA, AIF cannot consent to therapy involving convulsions, constraints, psychosurgery.
- Know requirements for mental health advance directives

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 waiting 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.

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.

• **Washington State Legend Drug Act Chpt. 69.41 RCW**
  o determines how Rx may be prescribed, distributed, and dispensed in WA. Obviates the need for federal intervention for violations that occur in-state and provides convenient way for law to cover all professions.
  o Defines list of most practitioners who may prescribe or administer legend drugs *(The who can prescribe section of the Legend Drug act is RCW 69.41.030)*
  o Defines what a “legible prescription” is.
  o Violations of Legend drug Act include
    o 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
    o Unlawful to sell, deliver, possess legend drug EXCEPT on order or Rx of MD, DO, etc.
    o 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**
- Know about record confidentiality i.e. which records are exempt from public disclosure according to RCW 42.56

**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

**70 RCW Penalties**

- Range from misdemeanour to felony e.g
  - Obtain by fraud etc. = felony
  - Sale, delivery, intent to deliver = felony
  - Possession only = misdemeanor
  - Filling false Rx = felony

**69.41.075RCW Rules and lists**: Board of pharmacy makes rules on legend drugs.

**69.41.080 RCW Animal control**: humane societies and animal control agencies allowed to use certain legend drugs to sedate animals prior to euthanasia or chemical capture (See WAC 246-886). NB/ Ketamine no longer in this list as it is now controlled substance.

**69.41.085 RCW medication assistance**: non-practitioner can assist person in AFH or BH or home to self-administer medication except IV or injectables (albeit may assist with pre-filled insulin syringes)

**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.**

- Pharmacist must ensure that drug manufactured by company that meets FDA standards and complies with FDA rules
- Prescriber not liable for side-effects related to substituted products; no greater liability for pharmacists with substituted products that brand products
- Pharmacists must post visible signs on drug substitution
- Coercion of pharmacist to substitute drug is unlawful
- Preferred drug list (PDL) establishes classes of drugs from which pharmacists can perform drug substitutions (Go to [www.rx.wa.gov](http://www.rx.wa.gov) on information on PDL for Washington State)
- RCW 69.41.190 allows pharmacists filling under state program to substitute drugs **unless** endorsing practitioner indicates DAW (dispense as written) or if Rx for refills of antipsychotics, antidepressants, antiretrovirals etc.

**Labor and Employment Law (L&E Law)**

- Basic principle of L&E law is the idea of the “at will employee.” At will employment means that no Employer can terminate an Employee at any time for an unjustified reason (no cause termination). According to Professor Vaughn, the concept of at will employment is eroding (See below: At Will Rule)
- **Protection under L&E Laws** depend on many characteristics: age, gender, ethnicity, religious affiliation, employment hours, type of firm, etc.—be familiar with the different variables.
- **Sources of L&E Laws:** Federal, State, Statutes, Case Law, Common Law
- Do **public sector employees** have more or less protection than private sector employees? (In case you need some help—more.) What additional sources of law apply to public sector employees?
- **4 types of Workplace Laws:** Labor Management Relations (Unions), Discrimination Law, Employee Protections, Wrongful Discharge/Common Law Protections
- Beginning a Job: Applications and interview procedures must conform to all existing state and federal laws. . . What can an employer ask during an interview? Can they ask about medical conditions? (No)
- **National Labor Relations Act:**
  - Right to join or refrain from joining a union
- Neither employer nor union can discriminate based on your affiliation or beliefs
- 2 major issues: organizing campaign, negotiating a collective bargaining agreement
- Enforcement of Act by National Labor Relations Board
- 180 days to file a complaint

- Major difference with public sector unions is that they cannot strike, otherwise, public sector unions governed similar to that stated under NLRA
- Although there are different sources of L&E Law, the regulation and enforcement of employment law is conducted by State Courts
- Labor contracts over 1 yr. duration must be written
- At will rule: An employer can discharge employees for no cause, good cause or even morally wrong cause without fear of liability. Exceptions: Employment manuals, whistle-blowing, public policy exception (e.g. jury duty), discrimination prohibited by other laws
- If credit reports are used by employers to evaluate potential employees, must comply with Fair Credit Reporting Act
- Know the different laws that ban discrimination in the workplace and what they entail: Title VII of the 1964 Civil Rights Act, Age Discrimination in Employment Act of 1967, Pregnancy Discrimination Act, Title I of Americans with Disabilities Act
- What constitutes harassment? What are examples of harassment at the workplace? What did Professor Vaughn recommend as a general first-line response to perceived harassment? What are the employer’s duties regarding harassment?
- Regulations that protect employees:
  - Family and Medical Leave Act (FMLA)-Federal law- What does this Act entail?
  - Wage and Hour Law
  - Health and Safety Regulations: At a federal level, regulated by Occupational Safety Health Admin. (OSHA), w/in Dept. of Labor. At a state level, regulated by WA Dept. of Labor and Industries
    - Worker’s Compensation: Covers accidents or diseases that arise out of or in the course of employment (employee may also be disabled as a result of injury), Provides medical expenses and earnings replacement due to job injury
- What are some things Professor Vaughn suggests you do if you have a problem at work?
- Note: Make sure to have read the Barnett article (on the course website).

Miscellaneous Laws and Rules [That You Should Know About]
  - Closures must be tested on children and seniors
  - What drugs/dosages are required to have child-resistant packaging? What are the exemptions?
- Patients may request blanket waiver to child-resistant packaging and/or may request non-complying package
- Prescribers may request blanket waivers only for specific patients
- Plastic CR Rx containers may NOT be refilled and should be thrown away after use
- Glass CR Rx containers may be refilled with the provision of a NEW CR cap

• What are requirements if pharmacies want to mail controlled substance through US Postal Service?

• **Prescription Marketing Act of 1987 (PDMA)** passed in response to drug diversion concerns
  - States must license wholesaler distributors
  - Prescription drugs may NOT be re-imported EXCEPT by manufacturer or in emergency
  - Bans sale, trade, or purchase of Rx samples
  - Mandate storage, handling, records-samples
  - Bans trafficking or counterfeiting Rx coupons
  - Prohibit resale drugs by hospitals and other health care entities
  - Loopholes- wholesalers and manufacturers can sell to nursing home pharmacies at low contract prices. Pharmacy has to sign a form stating that drugs are intended only for nursing home patients.
  - What makes a drug susceptible to counterfeit?
  - Know “To whom may a hospital or health care entity sell drugs?” (under PDMA) What is the definition of a health care entity? What are and are not examples?

• **Robinson-Patman Act**
  - Allowed lower Rx prices for hospitals
  - As hospitals developed outpatient services by filling outpatient Rxs, some pharmacists thought hospital pharmacies were unfairly competing with community pharmacies, so they sued.
  - As a result of the lawsuit, the Supreme Court defined what “own use” means regarding Rx sales—What does it mean/Who is included in the definition?

**Institutional Pharmacy Practice**

• What are the differences between Medicare and Medicaid?
  - Be familiar with Medicare rules/conditions/procedures

• What does JCAHO accreditation of a hospital mean in terms of Medicare COP?
  - What are some JCAHO policies on Rxs? Prescription writing abbreviations-What is this all about? What’s the worry about? What happens if, during a JCAHO audit, prescription writing abbreviations are discovered? Is this a big deal?

• During a hospital pharmacy inspection, what does the BOP generally look at?

• Be familiar with additional Medicare Conditions for skilled nursing facilities and WA nursing home rules as they pertain to provision and dispensing of drugs.

**Pharmacist Liability**
• In WA, liability of pharmacist is limited to dispensing a prescription product in the form produced by the manufacturer- no alterations
• Pharmacists can be liable if: negligent, if pharmacist makes an “express warranty” about drug, if pharmacist either conceals info or intentionally misrepresents facts about drug
• **Tort law**- Body of law encompassing negligence.
• Tort- Violation of a duty imposed by law on an individual based upon a relationship to another individual.
• Elements of a tort claim: duty, breach, causation, damages (harm)
• What is a **pharmacist’s duty/professional responsibilities** (Traditionally, technical, in WA)? Be familiar with these!
• What is the significance of **McKee vs. American Home Products**, Washington 1989?
• **Omnibus Reconciliation Act of 1990 (OBRA 90)** established minimum standards of care for pharmacists
  -Although individual states were given latitude, overall, the effect of OBRA 90 was to expand pharmacists’ duties to include:
    -monitoring of patient’s drug therapy
    -intervention when medication problems are detected
    -provide patients with drug info prior to dispensing prescription
• What are some suggested best practices for pharmacists’ to “stay out of trouble?”
• What should you do if an error does occur?