

## PHARM 543 FINAL REVIEW SHEET (WEEKS 6 TO 10)

### Notes:

1) 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.

2) Although this summary only covers material from the 2nd half of the quarter, the final exam is comprehensive. Therefore, please review 1st half contents as well.

### I. Fraudulent Billing & CMS

- Fraud defined as **deliberate** deception for unfair or unlawful gain
- 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, BOP inspections, wholesalers, manufacturer reps, consumers, providers, fellow employees.

### II. Board of Pharmacy Rules

#### A) WAC 246-858 through 905

- Pharmacist C.E.
- Pharmacist and Pharmacy Licensing
- Pharmacist Responsibilities
- Procedures for the Impaired Pharmacist
- 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), good compounding practices, 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

## **B) Board of Pharmacy Rules – 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.
- A pharmacist is required 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:
  - Nondisciplinary
  - Educational
  - Cannot impose sanctions
  - With mailing- case is closed
- A Statement of Charges (SOC) is:
  - Formal discipline
  - Wide range of sanctions possible from reprimand to revocation
  - Right to a board hearing
- Uniform Disciplinary Act
  - Covers all sorts of licensees not just pharmacists

## **III. Drug Diversion and Counterfeiting**

- Drugs are diverted from any site where they are stored, stocked, administered, prescribed or dispensed
- 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

## **IV. 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”
- Understand how the Natural Death Act was modified by Initiative 1000
- 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
  - Witnesses cannot be attending MD or an employee of the attending MD or an employee of the health facility in which declarant is a patient

- 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 how directives can be revoked
- **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**
  - Patients with major mental health issues can approve/disapprove of specific mental health treatments even at time of incapacity
  - Important because durable power of attorney (AIF) cannot consent for most acute mental health situations. In WA, AIF cannot consent to therapy involving convulsions, constraints, psychosurgery.

#### **V. Washington State Legend Drug Act Chpt. 69.41 RCW**

- 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.
- 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)
- Defines what a "legible prescription" is.
- Violations of Legend Drug Act include:
  - Obtain, procure, legend drugs by:
    - Fraud, deceit, misrepresentation
    - Forgery, alteration of Rx or written order
    - Concealment of material fact
    - False name or address
- Unlawful to sell, deliver, possess legend drug EXCEPT on order or Rx of MD, DO, etc.

#### **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

69.41.075 RCW 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 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 than brand products

## VI. Labor Laws

- Your legal protection is dependent on your characteristics (who you are as an employee) AND characteristics of your employer.
- 4 types of workplace laws: Labor management relations, Discrimination, Employee protection, Wrongful discharge/Common law protections
- What does it mean to be an "at will" employee?
- Title VII of 1964 Civil Rights Act covers hiring, firing, wages, terms and conditions of employment in addition to protection on the basis of race, color, sex, national origin, religion

- What does harassment mean and include?
- Americans with Disabilities Act—What is covered under this Act?

## **VII. Pharmacy Practice Act 18.64 RCW**

- There is a lot of information in this section – would recommend that you review the entire section
- Know definition of Practice of Pharmacy
- Be familiar with requirements for licensing of pharmacists and pharmacy licensing rules/procedures
- Understand requirements for prescription records and prescription labels
- What is the role of the Department of Health?
- What are the requirements of a nonresident pharmacy?
- Differentiate a Pharmacy Technician vs a Pharmacy Assistant

## **VIII. Institutional Pharmacy Practice**

### Medicare vs. Medicaid

- What are the differences between Medicare and Medicaid?
- Medicare rules are called Conditions of Participation (CoP). All healthcare entities that service Medicare patients must follow these rules (note: currently, no CoP rules for ambulatory pharmacies)
- State agencies inspect for compliance to CoP rules
- Be familiar with CoPs for hospitals—42 CFR 482.25
- JCAHO accreditation = CoP compliant
  - Be familiar with JCAHO recommended abbreviations for prescription writing
- Be familiar with WAC 246-873—BOP Inspection/Rules

### PDMA

- Prescription Marketing Act of 1987 (PDMA)- attempt to curb diversion of legend drugs, then counterfeits—Under PDMA, to whom may a hospital or healthcare entity sell drugs?
- Be familiar with drugs susceptible to counterfeit according to the NABP

### Needles and Syringes

- It is lawful for any person over 18 to possess sterile syringes & needles for the purpose of reducing blood-borne diseases

## **IX. Pharmacist Liability**

- Pharmacists in WA may be liable for harm if the harm is caused as a result of:
  - Negligence, “express warranty” made about a drug, concealment of information or deliberate misrepresentation of a drug
- A Pharmacist in WA is NOT liable for harm if the harm is caused by a product dispensed “as is” from a manufacturer
- Tort
  - Violation of a legal duty imposed on an individual based on a relationship with

another individual (e.g. healthcare provider/patient)

- Elements of tort claim: duty, breach, causation, damages/harm
- Be familiar with pharmacist's duty (WAC 246-863-095)
- What are some ways to stay out of trouble/avoid errors?
- As recommended in class, what should you do if you determine that an error has occurred (error management)?