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Lecture 2
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a. Federal Law vs. State Law

Federal Regulation of Pharmacy Practice guided by rules implemented by the Food and Drug Administration (FDA) and the Drug Enforcement Agency

For purposes of examination remember Food Drug and Cosmetic Act (FDCA) in 1938 establishes the safety, efficacy, and quality of drugs and medical devices; food, cosmetics, and dietary supplements; and products that give off radiation

Drug Enforcement Agency established in 1973 as part of Controlled Substance Act of 1970.

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State Law of Pharmacy Practice regulated by State Board of Pharmacy

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Question: Which law do you follow?
The stricter of the two sets of laws (Federal Law vs. State Law)

b. Professional Standards of Pharmacy Practice

American Society of Health System Pharmacists (ASHP) – Pharmacists practicing in Institutional settings (hospitals, long term care facilities)

United States Pharmacopeial Convention (USP) – Sets standards for the manufacturing and distribution of drugs in United States.
The Joint Commission – Accredits institutional settings (hospitals, nursing homes, etc.)

c. Pharmaceutical Compounding Standards

Standards are set by the following Regulations
USP 795 – Non sterile compounding
USP 797 – Sterile compounding
USP 800 – Standards for handling hazardous drugs

The importance of proper sterile compounding - https://youtu.be/PdAXB2Z76E4
New England Compounding Center – 48 deaths due to contaminated products with fungal meningitis

d. Review Drug Regulation Timeline

Key Regulations that are found on examinations include:

Food and Drug Act of 1906 – prohibits interstate commerce in adulterated or misbranded food, drinks and drugs
1938 Food, Drug, and Cosmetic Act – all new drugs must be proven safe

1951 Durham-Humphrey Amendment – Two classes of drugs (legend drugs versus OTC)

1962 Kefauver Harris Amendment – all new drugs must be both safe and effective

1970 Poison Prevention Packaging Act – requirement of childproof packaging on controlled and most prescription drugs, non-childproof containers may be used when patient or prescriber requests one.

1970 Controlled Substance Act – DEA established; five classes of controlled substances established based on potential chance of patient becoming addicted to medication *Schedule 1* = high potential for abuse and no accepted medical use *Schedule 2*= high potential for abuse with physical or psychological dependence *Schedule 3*= potential for abuse less than schedule 1 and II *Schedule IV*= drugs with low potential for abuse *Schedule V*= drugs with low potential for abuse in relation to Schedule IV

1996 Health Insurance Portability and Accountability Act – health information needs to be maintained with responsibility. Effective security to maintain privacy of health information.

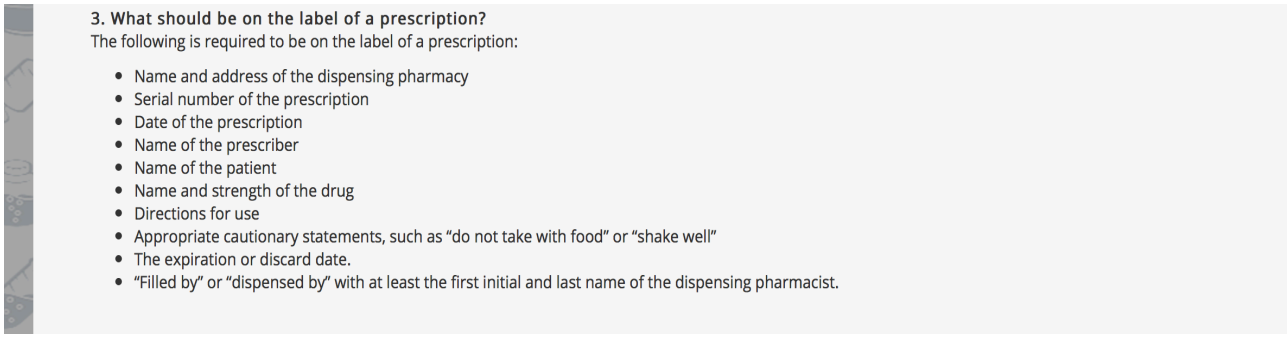
2005 Combat Methamphetamine Epidemic Act – Establishes strict controls on OTC sales of Pseudoephedrine, Ephedrine, and Phenylpropanolamine (3.6 g per day, 9 g per month, 7.5 g if mail order)

CMEA EDUCATION - https://www.youtube.com/watch?v=Pvqv1kf5A3A

e. New Drug Approval

Phase 1 – 20 -100 (small group) of healthy participants
Phase 2-100 or more participants with the Disease State or Symptoms
Phase 3- Several hundred to several thousand (large group) participants to monitor effectiveness
Phase 4 – Post Marketing Surveillance, drug on market and FDA continues to monitor if drug should stay on the market

f. Prescription Label
Alabama Board of Pharmacy Law: http://www.albop.com/FAQ.aspx#Labeling



3. What should be on the label of a prescription?
The following is required to be on the label of a prescription:

- Name and address of the dispensing pharmacy
- Serial number of the prescription
- Date of the prescription
- Name of the prescriber
- Name of the patient
- Name and strength of the drug
- Directions for use
- Appropriate cautionary statements, such as "do not take with food" or "shake well"
- The expiration or discard date.
- "Filled by" or "dispensed by" with at least the first initial and last name of the dispensing pharmacist.

g. Drug Recalls

Class 1 – drug will cause serious adverse effects or death
Class 2 – temporary but reversible adverse effects
Class 3- product not likely to cause adverse effects

h. Controlled Substance

Alabama Board of Pharmacy
http://www.albop.com/FAQ.aspx#Prescriptions_ControlledSubstances

i. Homework

The Pharmacy Technician Sixth Edition read Chapter 7 and Chapter 16
Review lecture notes
Review "Choose the Best Answer" questions from Chapter 7 and Chapter 16