Pharmacy Law Quick Reference Guide

1906 Pure Food and Drug Act

- The first federal law regulating drugs
- Prevented manufacture/sale/distribution of inaccurately labeled food and drugs across state lines
- Required that labels contain accurate information about a medication's strength and purity

1938 Food, Drug and Cosmetic Act

- Required drugs to be therapeutic
- Prohibited adulteration and misbranding
- Adulteration - unsanitary packing, or when strength, quantity, or purity differs from the package label
- Misbranding - false labeling or the absence of warning labels

1951 Durham-Humphrey Amendment

- Separated medication into two groups:
- OTC
    - Required to have cautions and warnings
    - Required to name all ingredients and quantities
- Legend (Prescription)
    - Required to have (on the label): Caution: Federal law prohibits dispensing without a prescription.

1962 Kefauver-Harris Amendment

- Standardized labeling requirements
- Required package inserts on legend medication
- Mandated good manufacturing processes

1970 Controlled Substances Act (CSA)

- Regulated use and distribution of medications that could lead to abuse
- Created the DEA
- Set up drug schedules

1970 Poison Prevention Act (PPA)

- Goal: reduce accidental poisonings in children
- Required use of child safety caps on substances that are potentially harmful (99.9% of drugs)
- Those child safety caps should be significantly difficult for a 5 year old to remove
- Exceptions:
    - Nitroglycerin
    - A waiver from the patient
    - Certain (less than harmful) medications

1972 Drug Listing Act

- Compiled a "list" of all marketed medications and assigned those medications NDC numbers.
- Example: 06242-5413-52
    - first 5 digits designate the manufacturer
    - the next 4 digits are the product code
    - the last 2 digits are the package size code

1983 Orphan Drug Act

- Enables manufacturers to create medications for use in rare disease.
- 50% tax incentive
- 7 year exclusive market exclusivity
- Research grants for clinical testing
- A "rare disease" effects less than 200,000 people in the United States

1984 Waxman-Hatch Act

- "The Drug Price Competition and Patent Term Restoration Act"
- Ensured brand name drug manufacturers would be entitled to market exclusivity for a period of time
- Allowed for less expensive generics to enter the marketplace after that period expired

1990 OBRA

- "Omnibus Budget Reconciliation Act"
- Initially required pharmacists to offer counseling to all Medicaid and Medicare patients
- It has since been expanded to require pharmacists to offer counseling to all patients on all fills of a prescription

1990 Anabolic Steroid Control Act

- Anabolic steroids promote muscle growth yet have serious health consequences when they are abused
- This act reclassified Anabolic Steroids as CIII, providing for greater penalties when sold or used illegally

1996 HIPAA

- "Health Insurance Portability and Accountability Act"
- Defined Protected Health Information
- Pharmacies were required to institute policies to protect patients' PHI
- Severe civil and criminal penalties were put into place to protect PHI

1997 FDA Modernization Act

- Sped up approval of new medications
- Modified many of the steps in the approval process (as seen in Chapter 4)
- Changed "caution: Federal Law prohibits dispensing without a prescription" to "Rx Only"

2003 Medicare Prescription Drug Modernization Act

- Established a part of Medicare to assist with the purchasing of Prescription Meds
- "Medicare Part D"
- All Medicare enrollees are eligible

2005 Combat Methamphetamine Epidemic Act

- Required all vendors of pseudoephedrine and ephedrine to sell those products from behind the counter of a pharmacy
- Required record-keeping of all sales
- Limited amount of those products sold
- 3.6 g per day and 9.0 g per 30 day

State Board of Pharmacy Links

Alabama	Hawaii	Massachusetts	New Mexico	South Dakota
Alaska	Idaho	Michigan	New York	Tennessee
Arizona	Illinois	Minnesota	North Carolina	Texas
Arkansas	Indiana	Mississippi	North Dakota	Utah
California	Iowa	Missouri	Ohio	Vermont
Colorado	Kansas	Montana	Oklahoma	Virginia
Connecticut	Kentucky	Nebraska	Oregon	Washington
Delaware	Louisiana	Nevada	Pennsylvania	West Virginia
Florida	Maine	New Hampshire	Rhode Island	Wisconsin
Georgia	Maryland	New Jersey	South Carolina	Wyoming