University of Maryland Eastern Shore School of Pharmacy

PHARMACY LAW - FEDERAL

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Different types of U.S. laws

- Statutory law
- Administrative law
- Common law
- Criminal law
- Civil law

Laws

Statutory law

- Written law passed by a legislative body
- May be either:
  - Federal
  - State
  - Local municipalities

Statutory Laws (cont)

A Bill is a proposed law under consideration by a legislature.

A U.S. Bill does not become law until it is passed by both houses of the legislature and signed by the President.

Once a bill has been enacted into law, it is called a Statute.

Statutory Laws (cont)

U.S. Congress - biennial sessions

2012 – 2013 session is the 113th congressional session

During the 113th session, 500+ Bills have been introduced that would have some affect on at least some areas of pharmacy practice to a degree.

Of the 650+ introduced Bills (March 2014), only 3 have passed and been signed into law to this point.

2013 – 2014 Passed and Signed Bills

H.R. 475 To amend the Internal Revenue Code of 1986 to (S.B. 391) include vaccines against seasonal influenza within the definition of taxable vaccines

H.R. 2094 School Access to Emergency Epinephrine Act (S.B. 1503)

H.R. 3204 Drug Quality and Security Act (S.B. 957/959)- (compounding/track and trace---discussed later)

LAWS (CONT)

Administrative law

The body of law that governs the activities of administrative agencies of government (e.g. tribunals, boards or commissions).

Civil law

Civil law (or civilian law) is a legal system inspired by Roman law, the primary feature of which is that laws are written and codified.

Common law (Case law)

Common law is law developed by judges through decisions of courts and similar tribunals rather than through legislative statutes.

It serves as a guide for future decisions.

LAWS (CONT)

Criminal law

Criminal law, or penal law, is the bodies of rules with the potential for severe impositions as punishment for failure to comply.

Criminal punishment, depending on the offense and jurisdiction, may include execution, loss of liberty, government supervision (parole or probation), or fines.

**It is important to note that even if found not guilty criminally, a defendant may still be sued civilly or face administrative sanctions.

Laws vs Regulations

Pharmacy Laws (Federal or State)

Statutes passed by a legislative body (federal or state).

Maryland Pharmacy Regulations

Regulations are standards adopted in Maryland by the Maryland Board of Pharmacy, as rules to implement, interpret, or make specific the laws passed by the Maryland Legislature dealing with pharmacy.

Maryland Pharmacy Regulations:

Are developed by the Board, in conjunction with State pharmacy stakeholders,

Must be approved by the Office of Administrative Law, and

Filed with the Secretary of State.

Basis of Pharmacy Law

Pharmacy Law is a dual system –consisting of:

1. Bodies of information on:

   Drugs

   Drug distribution

   Drug therapy

2. Systems within which the above information may be used to resolve conflicts and protect the public

Purpose of Pharmacy Law

Protect patients from harm that may occur if medications are used inappropriately.

This includes both:

1. Potential dangers of using drugs correctly for therapeutic reasons (i.e. side effects)

2. Inappropriate use for:
   - Legitimate conditions
   - Abuse

Purpose of Pharmacy Law (cont)

Pharmacy Law is used by legislatures, administrative agencies and courts of law to:

1. Define the responsibilities for pharmacists and others who are involved, at differing levels, in the manufacture, distribution, prescribing and dispensing of medications and devices.

2. Provide for accountability for actions taken.

3. Provide an opportunity for responsible persons to account for their actions and perhaps avoid liability that may arise from adverse outcomes.

Answer

To make it simple, remember:

**Pharmacists must always comply with the most restrictive law!!

Federal Agencies

FDA

DEA

FTC

EPA

FDA

FDA

Food and Drug Administration

Supervises the development, testing, safety, and effectiveness of prescription and OTC medications

Approve medications before they can be sold in the US

Regulates advertising of prescription medications

Regulates manufacturer labeling

Deals primarily with MANUFACTURING

FDA and Prescription Product Advertising

The US Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) sets standards for the issue of "fair balance" and substantiated claims.

OPDP regularly sends out what are known as "Untitled Letters," which serve as admonishments to companies to cease using certain marketing materials, but fall short of the severity of formal “Warning Letters” and usually do not indicate that enforcement actions will be forthcoming.

By and large those activities have all related to four classes of violations:

- Overstating the benefits of a product
- Understating or not stating the risks associated with the product
- Making misleading or unsubstantiated claims
- Not presenting the risks of a product in fair balance with its benefits

FDA (CONT)

The FDA regulates 6 main categories of diagnostic, preventative or therapeutic products:

- Drugs
- Vaccines
- Biologics
- Medical Devices
- Blood and Plasma Products
- Veterinary Products

Enforcement Powers of FDA

The FDA is the enforcement agency for the Federal Food, Drug and Cosmetic Act

and

Certain related statutes such as provisions of the Public Health Service Act relating to approval of biologic products.

Enforcement Powers of FDA (cont)

The concept of "intended use" is central to FDA enforcement efforts with respect to most of the products it Regulates, (i.e.):

An apricot pit is only considered a drug if it is intended for the treatment of cancer (laetrile)

**A drug is considered misbranded and illegally marketed if it is intended for a certain approved use and is labeled for another, unapproved use.

Approved Drug Uses

It has been accepted practice that practitioners may prescribe approved drugs for uses that are not indicated on the FDA-approved labeling as long as:

There is a general consensus that the off-label use is scientifically viable as indicated in published studies, and

The use is not experimental, and

The drug has not been shown to cause patient harm.

Approved Drug Uses (cont)

To enforce the FDA-approved use provision, the FDA and the DOJ have levied stringent fines against many manufacturers for actively promoting a drug, or drugs, for off-label (FDA unapproved use(s):

Tap Pharm	Lupron (2001)	$875 million
Merck	Rebates	$1.6 billion
Serono	Serostim (2005)	$704 million
Cephalon	Actiq/Provigil/Gabitril(2008)	$425 million
Eli Lilly	Zyprexa (2009)	$1.4 billion
Pfizer	Bextra/Celebrex/Geodon/ Lyrica/Zyvox (2009)	$2.3 billion
Abbott	Rebates	$1.6 billion
GlaxoSmithKline	Paxil/Welbutrin (misbranding) Avandia (false claims) (2012)	$3 billion
Abbott	Depakote (2012)	$1.5 billion
Janssen	Resperdal (2013)	$1.6 billion

Approved Drug Uses (cont)

Since issuing increasingly stringent fines has not stopped the practice of advertising drug products for FDA unapproved use(s), the FDA and the DOJ have turned to another method to try to discourage manufacturers from continuing unlawful advertising activities:

1. Bringing criminal charges against company supervisors and executives

2. Banning the offending manufacturer from doing ANY business with, or for, the various federal prescription benefit plans (i.e. Medicare, Medicaid, Tricare)

Park Doctrine

The U.S. government is increasingly using the "Park Doctrine" as a tool to prosecute pharmacy owners and corporate officers for federal Food, Drug, and Cosmetic Act (FDCA) violations.

In *United States v. Park* (1975), the U.S. Supreme Court determined the federal government could criminally prosecute individuals in a position of authority for an organization's violations of the FDCA, as long as these individuals had enough power in the organization to prevent the violations.

Under this doctrine, the government can criminally prosecute responsible individuals for a misdemeanor even if they were not aware of the circumstances surrounding the violations, or did not intend for the circumstances that led the violations to occur.

The Park Doctrine is also called the Responsible Corporate Officer Doctrine.

Approved Drug Uses (cont)

Any time a pharmacist (or pharmacy management) may know that a prescribed drug is being used for a FDA unapproved use, the pharmacist must be diligent and take care not to become a willing participant in working with an overzealous drug manufacturer to promote a drug(s) for a known unapproved use without FDA approval.

Under the federal Anti-Kickback Statute, it is illegal for a drug company to pay doctors to induce them to write prescriptions for the company's drugs that are reimbursed by federal health care programs.

FDA AND ADVERTISING

In March 2012, the FDA issued a new draft guidance that will implement a requirement for pre-dissemination review of direct-to-consumer television advertisements.

Advertisers must summit any television advertisement to the FDA for review no later than 45 days before the dissemination of the television advertisement.

This will initially apply to products which:

- Require REMS
- Are for Schedule II medications
- Are for medications with a recently updated boxed warning, contraindications or warnings
- Are otherwise identified by the FDA as subject to the pre-dissemination provision

Enforcement Powers of FDA (cont)

The FDA may:

Issue warning letters to request voluntary compliance with FDA requests.

Initiate injunction proceedings to prevent further distribution of a drug.

Seize drug(s)/devices.

Criminally prosecute responsible individuals for non-compliance

Recent (2013) U.S. Supreme Court Decision

The U.S. Supreme Court has ruled that generic manufacturers are NOT necessarily held to the same labeling standards as brand manufacturers.

In Pliva, Inc. vs Mensing, the Supreme Court ruled that although a brand manufacturer (Wyeth) must include all warnings and possible side effects, the generic manufacturers are not necessarily required to include all of the same information.

Under current FDA regulations, generic manufacturer cannot update labeling, even if they become aware of a potential risk not mentioned in the labeling. Brand-name manufacturer must update warnings and precautions on product labeling before obtaining FDA approval. In other words, the generic manufacturer is required only to match its labeling to brand-name labeling

RPhs should be aware of the possibility that there may be differences in labeled warnings to make sure patient counseling is complete and accurate

FDA – Generic Program

FDA to Begin Major Generic Drug Testing Effort (Feb. 2014):

Generic drugs that make up almost 80 percent of U.S. prescriptions are being tested in the first widespread safety and quality evaluation run by the Food and Drug Administration.

The $20 million effort, coming as concerns grow over the quality of products from abroad, started in September without any public notice. At least a dozen academic centers are involved in a testing program that will run through 2017, agency officials confirmed. The research this year will focus on heart drugs, ADHD treatments, immunosuppressants, anti-seizure medicines, and antidepressants.

Testing of generic drugs previously has been done only on an occasional basis in the U.S. The program, testing medicines made domestically and overseas, reflects a new emphasis by the FDA on the quality of generic drugs.

Limitations On FDA Enforcement

Limited to “foods”, “drugs”, “cosmetics”

- Most supplements not covered (discussed later)

May not issue recalls !!

- Must request manufacturers to “voluntarily” issue a recall

Drug Recall Process - FDCA

As stated previously, the FDA does not actually have recall power.

Recalls are technically "voluntary" for the manufacturer.

However, the FDA can enforce the statutes "strongly" against any company who does not "voluntarily" withdraw its product(s) when requested.

1. The FDA may force the manufacturer to shut down an entire assembly line (may affect the supply of more than one drug)
   – "drug shortages??"
   6 months to 1½ years to retool and restart manufacturing
2. The FDA may close the entire manufacturing facility until the facility passes FDA inspection(s)

DRUG RECALL PROCESS

Drug Recall Process

Manufacturer Recalls vs Removals

Some companies issue exhibit recall-like notices, but for very different reasons, such as ending a product or replacing it with a new version that improves upon the existing design. These are not recalls, and do not need to be publicly announced.

On 21 February 2013, FDA released a new draft guidance document aimed in part at establishing the requirements for distinguishing between defect-based or failure-based recalls and products recalled for “improvements”.

For example, if a product is being corrected to address a quality violation, the correction would generally be considered a recall." Meanwhile, if the product has no violations, it could be considered a product enhancement.

Drug Recall Process (cont)

But what is a violation, anyway? The newly issued guidance explains that FDA considers any product that:

Fails to meet specifications,

Fails to perform as intended,

Is below the quality the product represents itself as having, or

Is adulterated or misbranded

constitutes a violation, and would be considered a recall if removed from the market.

Drug Recall Process – FDCA (cont)

Recall Classes:

Class I Recall

Reasonable probability that the product WILL cause serious adverse health consequences or death

Class II Recall

Applies when the product MAY cause temporary or medically reversible health consequences, but the probability of serious adverse health consequences is remote

Class III Recall

Applies when a product is not likely to cause adverse health consequences

Pharmacy Recalls

FDA guidelines require manufacturers to issue written notices sent by first-class mail with the envelope and letterhead conspicuously marked, preferably in red, URGENT: DRUG RECALL.

A pharmacist is responsible for knowing which drug products have been recalled. Dispensing or distributing a recalled product may violate the FDCA because the product is considered either adulterated or misbranded.

The pharmacist would also likely be subject to civil liability in the event of patient injury.

Drug Recalls

Best Practice:

Pharmacy should maintain a binder or log book that is kept chronologically and documents the action(s) taken by the pharmacy in handling specific recalls

Record should document:

- Date of recall and date of return
- Method of return (i.e. wholesaler/manufacturer)
- Quantity returned (zero if none)
- Lot number(s) returned
- Expiration date(s) returned

FDA -- MANUFACTURING

FDA Regulation of Drug Manufacturing

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA).

cGMPs provide for written policies that assure proper design, monitoring, and control of manufacturing processes and facilities.

Manufacturer failure to comply with cGMPs means a product(s) will be considered "adulterated" and its distribution or sale is then considered illegal.

cGMPs (cont)

Up to 40% of the drugs Americans use are imported

Around 80% of the active ingredients in drugs are made in foreign facilities.

100% of surgical masks and gloves are imported from China.

The FDA only inspected 4 percent of the more than 6,700 foreign manufacturing sites in 2009, according to data from the U.S. Government Accountability Office.

All manufacturing facilities in the United States, however, are subject to FDA inspection every two years.

DEA

DEA

Drug Enforcement Administration

Established in 1973 to serve as the primary agency for enforcing all federal drug laws

Designated agent to enforce all provisions of the CSA

DEA (CONT)

With respect to pharmaceutical CDS, the DEA's role is two-fold:

1. Prevent diversion and abuse
2. Ensure an adequate** (quota system) and uninterrupted supply of CDS to meet the country's medical, scientific and research needs

DEA (CONT)

Requires that all CDS transactions take place within the "closed system" of distribution established by Congress.

All legitimate handlers of CDS must be registered with DEA and maintain strict accounting for all CDS transactions

- DEA Form 225
  - Manufacturers, distributors, exporters, importers, labs, research
- DEA Form 224
  - Dispensers, teaching institutions
- DEA Form 363
  - Narcotic treatment programs

Assigns prescribers' DEA numbers authorizing them to prescribe controlled substances

Monitors CDS trends and usage data

DEA INSPECTIONS

DEA INSPECTIONS

A principal mechanism for ensuring compliance and determining noncompliance by DEA registrants is through a DEA audit.

Such audits are on the rise for various reasons:

First, pharmaceutical drug abuse has eclipsed that of the abuse of "hard" illicit drugs. This is a phenomenon which has not gone unnoticed by law enforcement and has triggered greater scrutiny of medical providers who are assumed to be part of the problem.

In addition, the federal government is looking for funds for a variety of reasons, and audits resulting in fines are an income source.

All DEA registrants are caught in this crossfire.

Authority of DEA to Perform Inspections

Grant of authority; scope of inspections

1. For the purpose of inspecting, copying, and verifying records, reports, or other documents, the Attorney General is authorized to enter controlled premises and to conduct administrative inspections.

2. Such entries and inspections shall be carried out through employees designated by the Attorney General.

3. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises:
   (a) appropriate credentials and
   (b) a written notice of his inspection authority (an administrative inspection warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

Authority of DEA to Perform Inspections (cont)

"Controlled premises" means –

1. Places where original or other records or documents are kept and
2. Places, including factories, warehouses, and other establishments, and conveyances, where persons may hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals

Warrants

A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if a judge or United States magistrate judge issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service.

Authority of DEA to Perform Inspections (cont)

The DEA inspector shall have the right –

(A) to inspect and copy records, reports, and other documents;

(B) to inspect the premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found therein.

(C) to inventory any stock of any controlled substance or listed chemical therein and obtain samples of any such substance or chemical.

Authority of DEA to Perform Inspections (cont)

Situations not requiring warrants:

A warrant under this section shall NOT be required for the inspection of books and records pursuant to an administrative subpoena, nor for entries and administrative inspections (including seizures of property) –

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking

Authority of DEA to Perform Inspections (cont)

Proper Bounds of an Audit

Generally, the audit is a review of records at the registered location designed to determine whether the registrant is in compliance with its responsibilities under law and regulation.

The authority to audit does not extend to a review of financial data, sales or pricing data, or personal records which happen to be located at the registered premises. Nor does it include a review of patient charts.

Generally speaking, the DEA is there for two reasons:

(1) to ensure that the registrant is keeping those records required to be kept, and

(2) to do an accounting to ensure there is no diversion.

However, if there are problems with the registrant's records, or any significant accounting issues (overages or underages) involving CDS, the registrant should be prepared for what may be a wild ride, with varying consequences.

Authority of DEA to Perform Inspections (cont)

Also, the registrant should be aware that the right to audit does not include the right to interview witnesses, including the registrant and employees of the registrant.

Even if the audit is pursuant to administrative warrant, there is no requirement that individuals answer questions or submit to interviews.

The registrant should be aware that the choice to speak belongs to the individual, and that anything an employee or the registrant says during the audit may be introduced in an administrative, civil, or criminal proceeding against the individual.

Statements made by a registrant in order to be helpful and courteous may well be thrust back at them as admissions of noncompliance and possibly guilt.

All registrants are well advised to be mindful of this potential and to consider declining to speak other than as necessary without having consulted with counsel or having counsel present during the interview.

Such counsel requests are a way of ensuring that the registrant is appropriately and fairly protected given the possibility of jeopardy.

FTC

FTC

The Federal Trade Commission (FTC) is an independent agency of the United States government, established in 1914 by the Federal Trade Commission Act.

Its principal mission is consumer protection and the elimination and prevention of what regulators perceive to be harmfully anti-competitive business practices, such as a coercive monopoly

FTC

The FTC carries out its mission by investigating issues raised by reports from consumers and businesses, congressional inquiries, or reports in the media.

These issues include false OTC advertising and other forms of fraud.

FTC investigations may pertain to a single product, a single company or an entire industry.

If the results of the investigation reveal unlawful conduct, the FTC may seek voluntary compliance by the manufacturer or business through:

- issuing a consent order
- filing an administrative complaint, or
- initiating federal litigation.

FTC (CONT)

The Federal Trade Commission (FTC) regulates advertising of dietary supplements in newspapers, magazines, and in radio and television commercials.

The FTC does require that all information about supplements be truthful and not misleading.

FTC (CONT)

The FTC charged the manufacturer of "Airborne" with falsely advertising that it could cure or prevent the common cold.

The FTC won court cases resulting in substantial monetary fines:

Manufacturer = $30,000,000
Walgreens = $6,000,000
CVS = $3,000,000
Rite Aid = $500,000

Now, as a side note, the manufacturer of Airborne has changed the drug's formulation and is promoting the new formulation as an aid to the body's immune system.

FTC (CONT)

Consumers and health professionals may file complaints regarding false or misleading claims regarding dietary supplements to the FTC at:

https://www.ftccomplaintassistant.gov/

Or by calling:

1-877-382-4357

EPA

EPA (CONT)

Disposal creates real problems - even empty containers may be (are) classified as hazardous.

DEA, DOT, and even the Joint Commission report violations to EPA (as well as state regulators)

Next proposal for healthcare-specific hazardous waste rules should be released in 2013. EPA sets the baseline for hazardous materials regulations. Many states are even more stringent.

Stay tuned – the new rules are expected to have a far greater impact on pharmacies than the current rules.

FEDERAL LAWS

CODE OF FEDERAL REGULATIONS (CFR)

Code of Federal Regulations

The CFR forms the basis for all federal regulation of pharmacy practice in the U.S.

The CFR has evolved over many years and is still evolving (usually follows a series of identified incidents)

Each state has its own individual State Code, but the Federal Code forms the beginning point for all laws pertaining to pharmacy.

PURE FOOD AND DRUG ACT - 1906

PURE FOOD AND DRUG ACT

Pharmacy, as a profession, can be traced back at least 4000 years.

The federal regulation of drugs “officially” began in 1906 with the passage of the Pure Food and Drug Act.

Prohibited the manufacture, sale, or transportation of adulterated food products and poisonous patent medicines.

The 1906 Act paved the way for the eventual creation of the Food and Drug Administration (FDA) and is generally considered to be that agency's founding date, though the agency existed before the law was passed and was not named the FDA until later.

FOOD, DRUG AND COSMETIC ACT (FDCA) - 1938

FOOD, DRUG AND COSMETIC ACT (FDCA)

Food, Drug and Cosmetic Act (FDCA)

Passed after 107 patients died after taking a legally marketed tonic (contained diethylene glycol)

Provided for oversight on the safety of food, drugs, and cosmetics.

Required that new drugs be shown to be SAFE for use under the conditions described on the label and approved by the FDA prior to marketing.

Food, Drug and Cosmetic Act (cont)

Actually only specifies 3 basic illegal acts:

- Adulteration
- Misbranding
- Introducing an unapproved drug into interstate commerce

The complexity arises in that many diverse activities can be included under the "umbrella" of those 3 basic illegal acts.

This Act was challenged by a pharmacist in 1948 who contended that the federal law did not apply to his operations because his acts only affected intrastate transactions.

The U.S. Supreme Court declared that the jurisdiction of the Federal Act also extends to transactions between the pharmacist and the patient.

This ruling meant that the FDCA does apply to drugs held for sale in a pharmacy.

DURHAM-HUMPHREY AMENDMENT - 1951

DURHAM-HUMPHREY AMENDMENT

The Durham-Humphrey Amendment

Divided drugs into two basic categories:

- Legend drugs (Rx)
- Over-the-counter drugs (OTCs)

The Durham-Humphrey Amendment (cont)

Legend Drug:

1. Legend drugs can only be legally obtained by prescription.

2. Legend drugs are those drugs that are not considered safe for use without direct medical supervision (for example, prescribed by a physician).

   It is against the law to give legend drugs to persons who do not have a valid prescription.

3. Legend drugs must have the following statement printed on the manufacturer's stock bottle labels:

   "Caution: Federal law prohibits dispensing without a prescription"

The Durham-Humphrey Amendment (cont)

Over-the-Counter Drugs

Over-the-counter (OTC) drugs can be legally obtained without a prescription.

Generally, OTC drugs are considered safe for use without direct medical supervision.

The Durham-Humphrey Amendment also authorized:

- Oral prescriptions
- Refills for prescription drugs

FOOD ADDITIVES AMENDMENT - 1958

Food Additives Amendment - 1958

This amendment to the FDCA:

Required components added to food products to receive premarket approval for safety

Contains the "Delaney Clause" which prohibited the approval of any food additive that might cause cancer

In 1960, Congress amended the FDCA to also require manufacturers prove the safety of color additives in foods, drugs and cosmetics.

KEFAUVER-HARRIS AMENDMENT - 1962

KEFAUVER-HARRIS AMENDMENT

The Kefauver-Harris Amendment

Passed following the Thalidomide tragedy in Europe

A drug item must be proven SAFE and EFFECTIVE before it can be sold.

Drug manufacturers must register on an annual basis with the FDA.

In addition, manufacturers must be inspected once every two years.

The generic name of the item must be written on the item's label and the generic name must be used in any advertising for the item.

The Kefauver-Harris Amendment (cont)

The Kefauver-Harris Amendment marked the establishment of the Good Manufacturing Practices (GMP) requirements.

The Kefauver-Harris Amendment also has provisions that govern the reporting of adverse drug reactions and the testing of investigational drugs.

An investigational drug is a new drug that has not yet been approved by the FDA for general use by the public as a safe and effective drug.

- An investigational drug may NOT be used without the prior written approval of the Surgeon General.

MEDICAL DEVICE AMENDMENTS - 1976

MEDICAL DEVICE AMENDMENTS

Medical Device Amendments

Passed following a U.S. Senate finding that faulty medical devices had caused 10,000+ injuries and 731 deaths.

The MDA granted the FDA oversight and approval of medical devices, something that had been left out of the FDCA of 1938.

**States were prohibited from establishing or continuing any scheme of regulation which was different from, or in addition to, any requirement applicable under federal law

MEDICAL DEVICE AMENDMENTS (CONT)

The Medical Device Amendments required:

- Classification of devices according to function
  - Class 1 – not subject to premarket approval
  - Class 2 – Subject to performance standards
  - Class 3 – Life-supporting of life-sustaining – require premarket approval by FDA
- Conformance with GMP regulations
- Adherence to record keeping and reporting requirements

Stay tuned – medical devices now a HOT topic!

FEDERAL DEFINITIONS

Adulterated Drug

A drug or device shall be deemed to be adulterated—

(1) If it consists of any filthy, putrid, or decomposed substance; or

(2) If it:

(A) Has been prepared, packed, or held under unsanitary conditions; or

(B) Is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice;

(3) If its container is composed of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) If it bears or contains, for purposes of coloring only, a color additive which is unsafe

Misbranded Drug

A drug or device shall be deemed to be misbranded for:

(a) False or misleading label.

(b) Contents of label incorrect or incomplete

(c) Prominence of information on label incorrect

(d) Incorrect or incomplete designation of drugs or devices by established names

(e) Incorrect or incomplete directions for use and warnings on label

(f) False representations as recognized drug

(g) Containing deteriorated drugs

(h) Misleading container; imitation; offer for sale under another name

(i) Unapproved color additives, packing or labeling

(j) Prescription drug advertisements misleading

FEDERAL PRESCRIPTION EXEMPTION

Federal Prescription Exemption

Some medications were considered so potentially hazardous to health that the law (FDCA) recognized that they are not capable of being labeled for sale and effective use without medical supervision.

For those medications, an exemption was created – the requirement for a prescription before the pharmacist may dispense them to a patient.

Those medications must bear the "federal legend" on each manufacturer's stock bottle.

Caution: Federal Law Prohibits Dispensing Without A Prescription

Caution: Federal Law Restricts This Device To Sale By Or On The Order Of A Licensed Healthcare Practitioner

Recently, the FDA has allowed manufacturers to use:

Rx Only

Every CDS stock bottle must have the drug schedule prominently imprinted on the label in a large font (i.e. CIII, CIV, etc)

Every CDS stock bottle must have a seal that will disclose any tampering or opening of the container.

THE SOCIAL SECURITY ACT - 1965

The Social Security Act of 1965

The Social Security Act of 1965 was signed into law as an amendment to existing Social Security legislation.

This legislation included the establishment of the Medicare program.

Medicare Parts:

Medicare Part A is hospital insurance that helps cover inpatient care in hospitals, skilled nursing facility, hospice, and home health care.

Medicare Part B helps cover medically-necessary services like doctors' services, outpatient care, home health services, and other medical services (includes some medications).

Medicare Part D offers prescription drug coverage to everyone with Medicare.

Medicare Records

Medicare Prescription Record

Medicare requires providers to retain prescription-related records for 10 years after the most recent refill (directly pertains to Medicare Part D prescriptions).

The National Community Pharmacists Association (NCPA) recommends that for a given prescription the pharmacy should retain records such as prescription hard copies, end of the day prescription reports, and signature receipts for the entire 10 year period.

Medicare does allow these records to be kept in an electronic image format, so if you scan your prescriptions into your computer system it may be less burdensome to comply with the requirements.

New Medicare Part D Requirement

In June 2010, CMS announced that all pharmacies will be required to provide a written standardized notice to Part D beneficiaries when their prescriptions will NOT be covered and the reason for denial.

The notice must include a way for the beneficiary to request an exception to rejections due to the Part D plan's formulary.

New Medicare Part D Requirement(cont)

The Office of the Inspector General (part of HHS) has asked CMS to require the prescriber to include the patient's diagnosis on each new prescription. So far, CMS has not acted on this request.

This would allow the pharmacist to submit a code (during adjudication) that would indicate that the drug was being used for an accepted medical indication. Drugs falling outside the accepted indications would not be covered.

OIG could potentially use the following as official sources:

- U.S. Pharmacopeia
- American Hospital Formulary Service Drug Information
- Drugdex Information System

Medigap

Medigap insurance was designed by private insurance companies to cover the “gaps” found within the government provided medicare program.

In 1990, Congress passed a law that required all states to comply with Medigap provisions.

Medicare Fraud

The Joint Department of Justice-HHS Medicare Fraud Strike Force is a multi-agency team of federal, state and local investigators designed to combat Medicare fraud through the use of Medicare data analysis techniques and an increased focus on community policing.

In September 2011, a nationwide takedown by Medicare Fraud Strike Force operations in 8 cities resulted in charges against 91 defendants, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately $295 million in false billing.

Medical Assistance Program (Medicaid) - 1965

Medicaid is a joint federal and state program. Each state establishes its own eligibility standards, benefits package, payment rates and program administration under broad federal guidelines. As a result, there are essentially 56 different Medicaid programs - one for each state, territory and the District of Columbia.

Federal Medicaid law requires every state to provide basic healthcare coverage for certain groups.

Medicaid coverage is automatically given to individuals receiving certain other public assistance, such as Supplemental Security Income (SSI), Temporary Cash Assistance (TCA), or Foster Care.

Low-income families, children, pregnant women, women with breast or cervical cancer, and aged, blind, or disabled adults may also qualify for Medicaid.

Eligibility for Medicaid is re-determined every 12 months,

COMPREHENSIVE DRUG ABUSE AND CONTROL ACT - 1970

The Controlled Substances Act (CSA)

The CSA is actually Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

The CSA replaced the Harrison Narcotics Act - 1914

It provides the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of CDS is regulated.

The legislation passed in 1970 created five Schedules (classifications) for drugs and specified varying qualifications for a substance to be included in a specific Schedule.

CSA (CONT)

Established a "closed system" to track and account for all CDS from import or manufacture through wholesale distribution to the ultimate user.

Facilitated the creation of the Office of Diversion Control

Enacted to provide limited access and increased accountability of controlled substances

Everyone involved with CDS must register -- from manufacturers (including importers) down through dispensers

All registrants are assigned an unique number known as the registrant's DEA number.

DEA Numbers

A valid DEA number consists of:

2 letters, 6 numbers, & 1 check digit

The first letter is a code identifying the type of registrant (see following screens)

The second letter is the first letter of the registrant's last name

Of the seven digits that follow, the seventh digit is a "checksum"that may be calculated as:

Add together the first, third and fifth digits (Sum 1)

Add together the second, fourth and sixth digits and multiply that answer by 2 (Sum 2)

Add Sum 1 and Sum 2 and call this *CHECK*

The rightmost digit of *CHECK* (the digit in the ones place) is used as the check digit in the DEA number

DEA Numbers (cont)

Registrant type (first letter of DEA Number):

A - Deprecated (may be used by some older entities)

B - Hospital/Clinic (nearing exhaustion at this time)

C - Practitioner

D - Teaching Institution

E - Manufacturer

F - (will now be used as the initial letter)

G - Researcher

H - Analytical Lab

J - Importer

(cont)

DEA Numbers (cont)

L - Reverse Distributor

M – Mid-Level Practitioner

N - Military Practitioner

P – U - Narcotic Treatment Program

X - Suboxone/Subutex Prescribing Program

Hospital

Use internal code numbers – must be kept on file in hospital

Example BN1234567-012 where 012 = prescriber's facility number

DEA Numbers (cont)

Pharmacies, as dispensers, register for a 3 year period

*Notable exception – "If employed by a registered pharmacy or institution, a pharmacist does not have to register individually with the DEA"

Since pharmacists in some states may now prescribe (at least in collaborative practices), the DEA has issued DEA numbers to pharmacists in the following states (2010):

- California
- Florida
- Massachusetts
- Montana
- New Mexico
- New York
- North Carolina
- North Dakota
- Washington

CSA (CONT)

The Statute passed by Congress created the initial listings of which drugs were included in each CDS classification.

Currently, 2 federal agencies determine which substances are eligible to be added or removed from the various schedules:

- The Food and Drug Administration (FDA)
  - Determines if a drug is safe or effective
  - May make initial recommendations
  - **********
- The Drug Enforcement Administration (DEA)
  - Determines a drug's potential for abuse and how it should be regulated (which schedule – if any)

Permanent placement within a Schedule still requires an act of Congress

How many classes of federally scheduled medications currently exist?

CSA (CONT)

Combat Methamphetamine Epidemic Act of 2005 added another pseudo-schedule:

Scheduled Listed Chemical Product (SLCP):

A SLCP is defined as a product that contains ephedrine, pseudoephedrine or phenylpropanolamine that may be marketed and distributed in the U.S. as a nonprescription drug.

Only solid, oral dosage forms (tabs, caps) are restricted – Not elixirs or syrups

This means that there are actually 6 classes of federally scheduled medications.

Synthetic Drug Abuse Prevention Act of 2012

This legislation, contained within the Food and Drug Administration Safety and Innovation Act of 2012, banned compounds found in synthetic stimulants, synthetic marijuana and synthetic hallucinogens.

These designer drugs are now listed as Schedule I

Under Maryland Law, once the federal government lists a substance as Schedule I, it is automatically considered a Schedule I substance in Maryland.

New substances have been created which are not currently individually listed, (i.e):

- 2C-l (Smiles)
- Gravel

CONTROLLED DRUG SCHEDULES

CSA (CONT)

Schedule I

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.“

No prescriptions may be written for Schedule I substances.

Schedule I substances are subject to very strict production quotas and scrutiny by the DEA.

CSA (CONT)

Schedule II

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Such substances are subject to production quotas by the DEA.

May lead to drug shortages near end of year.

CSA (CONT)

Schedule III

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence

CSA (CONT)

Schedule IV

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

CSA (CONT)

Schedule V

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

ADDICTION

Harrison Narcotics Tax - 1914

The Harrison Narcotics Tax Act regulated and taxed the production, importation, and distribution of opiates.

Provided for the registration of and imposed a special tax on all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations.

Physicians could prescribe narcotics to patients in the course of normal treatment, but not for the treatment of addiction.

ADDICTION

Definition of any addiction-

The state of being enslaved to a habit or practice or to something that is psychologically or physically habit-forming, as narcotics, to such an extent that its cessation causes severe trauma

Addict means:

Any individual who habitually uses any narcotic drugs so as to endanger the public morals, health, safety or welfare, OR

Is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to their addiction

Physical Dependence

Physical dependence means:

> A state resulting from chronic use of a drug that has produced tolerance and where negative physical symptoms of withdrawal result from abrupt discontinuation or dosage reduction.

Physical dependence can develop from low-dose therapeutic use of certain medications as well as misuse of recreational drugs such as alcohol.

Higher doses are often required to produce the same medical effect of the medication.

The higher the dose used typically the worse the physical dependence and thus the worse the withdrawal symptoms.

Drug Dependent

A person is considered to be drug dependent if he exhibits at least 3 of the following:

1. A strong desire or sense of compulsion to take the drug;
2. Difficulties in controlling drug-taking behavior in terms of its onset, termination, or levels of use;
3. A physiological withdrawal state when drug use is stopped or reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of a closely related substance with the intention of relieving or avoiding withdrawal symptoms;
4. Evidence of tolerance, such that increased doses of the drug are required in order to achieve effects originally produced by lower doses;
5. Progressive neglect of alternative pleasures or interests because of drug use, increased amount of time necessary to obtain or take the drug or to recover from its effects;
6. Persisting with drug use despite clear evidence of overtly harmful consequences, such as harm to the liver, depressive mood states or impairment of cognitive functioning.

Drug Abuse

Drug Abuse

The intentional self-administration of an illegal or legal medication for a non-medical purpose (such as altering one's state of consciousness).

Drug Diversion

The transfer of a prescription or OTC medications from a lawful to an unlawful channel of distribution or use.

Drug Abuse (cont)

Why are people increasingly abusing prescription and/or OTC drugs?

- Easier to obtain
- Not illegal
- Less shame
- Legitimate manufacturers
- Perception of being safe

Drug Abuse (cont)

Law Enforcement Screening Criteria:

- Prescriber
  - Prescribing pattern different from that of other prescribers in area
  - Writes for antagonistic drugs
- Patient
  - Frequent pharmacy visits
  - Presents multiple Rxs for same drug from different prescribers
  - Prescriptions show evidence of possible forgery
- Pharmacy
  - A number of patients appear within a short time period for the same controlled drug(s) from the same prescriber's office
  - A large number of new patients show up with controlled prescriptions from the same prescriber's office

Drug Abuse (cont)

Pharmacists should be on alert for "red flags" such as:

- Patients altering prescriptions
- Many "younger" patients with same prescriptions
- Stolen prescription pads
- Scanned or copied prescriptions
- Authentic-looking prescriptions with fake prescriber information (i.e. phone number)
- Prescribers located far away from pharmacy vicinity
- Unusual large quantities or directions
- No abbreviations on written prescription
- Erasures
- Unusual legibility
- Cash prescriptions vs insurance
- CDS prescriptions presented late at night or on weekends
- Patient(s) seem nervous or in a hurry
- Percent of controlled prescriptions vs non-controlled

Internet Pharmacies

As of June 2012, NABP monitoring of approx. 200,000 health-related websites revealed:

- 43,058 are active Internet pharmacies
- 225 are legitimate (0.5%)
- 1,210 are potentially legitimate (2.8%)
- 41,623 are not legitimate (96.7%)

Internet Pharmacies (cont)

The U.S. Food and Drug Administration, in partnership with international regulatory and law enforcement agencies, took action one week in Sept. 2012 against more than 4,100 Internet pharmacies that illegally sell potentially dangerous, unapproved drugs to consumers.

Actions taken include civil and criminal charges, seizure of illegal products, and removal of offending websites.

2012 year's effect – Operation Pangea V – resulted in the shutdown of more than 18,000 illegal pharmacy websites and the seizure of about $10.5 million worth of pharmaceuticals worldwide.

Drug Abuse (cont)

What should the pharmacist do if abuse or diversion are suspected?

- Call prescriber
- Refuse to dispense prescription
- Call authorities

- Report suspicious internet pharmacies
  - 1-877-RxAbuse (1-800-792-2873)
- Report (search) incidents of theft
  - RxPatrol (www.rxpatrol.org)
- Prescription drug monitoring programs (NASPER)

Drug Abuse (cont)

NASPER – National All Schedules Prescription Electronic Reporting

- National electronic system monitoring Schedule II, III and IV CDS
- Pharmacists in participating states are required to report CDS prescription information to HHS
- Certified providers, including pharmacists, have access to patient information

Maryland Prescription Drug Monitoring Program -2013

POISON PREVENTION PACKAGING ACT OF 1970

Poison Prevention Packaging Act of 1970 (cont)

The packaging required by the PPPA must be designed or constructed to be significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly.

Prescription drugs may be dispensed in non-child-resistant packaging upon the specific request of the prescribing doctor or the patient.

Poison Prevention Packaging Act of 1970 (cont)

The PPPA was enforced by the FDA until 1973, when the enforcement responsibility was transferred to the Consumer Product Safety Commission (CPSC).

The FDA may still act on violations of the PPPA if:

- Reported by the CPSC
- Reported by consumers
- Identified during a FDA or other agency inspection

ANTI-TAMPERING REGULATIONS - 1982

ANTI-TAMPERING REGULATIONS

Anti-Tampering Regulations:

Passed following the deaths of 7 people in Washington State from taking Tylenol that had been laced with cyanide

Person bought Tylenol capsules, used a needle to inject the cyanide and then returned the product to the store for a refund– almost impossible to detect any tampering was done

Pharmaceutical manufacturer GlaxoSmithKline is warning consumers (March 2014) that some bottles of its over-the-counter weight loss drug Alli have been "tampered with" in at least seven US states.

GSK said the tampered products had packaging that appeared to look authentic, but that the façade quickly eroded once the packaging was opened.
Some bottles contained a "range of tablets and capsules of various shapes and colors," while other had no manufacturer labeling or other measures meant to protect against product tampering.

ANTI-TAMPERING REGULATIONS (CONT)

Other more recent cases:

1. Nurse removed meperidine from vial replacing it with normal saline.

2. Physician assistant replaced hydrocodone tablets with ibuprofen (with identifying markings scratched off).

3. Pharmacist removed fentanyl patches from sealed boxes and resealed and returned the boxes to the secured narcotics stock.

4. With at least 16 physicians and drug distributors prosecuted for the purchase or sale of non-approved cancer treatments, the Partnership for Safe Medicines (PSM) is advising patients receiving such treatments in medical offices to ask to see their mediation's packaging.

Patients should examine the medications to ensure "accurate labeling, good condition of the package," and that the language printed on the packaging is English.

ANTI-TAMPERING REGULATIONS (CONT)

FDA anti-tampering regulations require that "cosmetic liquid oral hygiene products" and vaginal products, contact lens solutions, and most over-the-counter drugs to be packaged in tamper-resistant packages.

Products' packaging must be "distinctive by design," and the package labeling must indicate to consumers what tamper-resistant measures are being used.

The Federal Anti-Tampering Act makes tampering with consumer products a felony punishable by up to 10 years in jail.

Tamper-resistant packaging is defined as a package that has "an indicator or barrier to entry, which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred."

THE CONTROLLED SUBSTANCE REGISTRANT PROTECTION ACT - 1984

The Controlled Substance Registrant Act of 1984

Pharmacists and pharmacy owners were highly concerned about increasing pharmacy robberies.

Prior to the enactment of this Act (1984), it was not a violation of any federal law to rob a pharmacy.

This Act mandates a federal investigation if:

- The cost of the stolen CDS >$500
- A registrant or other person is killed or suffers "significant" injury
- Interstate or foreign commerce is involved in either the planning or the execution of the crime

FALSE CLAIMS ACT - 1986

False Claims Act

The False Claims Act imposes liability on persons and companies (typically federal contractors) who defraud governmental programs.

The law includes a "qui tam" provision that allows people who are not affiliated with the government to file actions on behalf of the government (informally called "whistleblowing").

Persons filing under the Act stand to receive a portion (usually about 15–25 percent) of any recovered damages.

Claims under the law have typically involved health care, military, or other government spending programs, and dominate the list of largest pharmaceutical settlements. In 2008 there were 378 qui tam cases filed, and in 2013 that number soared to 752 cases.

False Claims Act (cont)

In 2012, the federal government recovered approximately $5 billion from settlements and judgments in cases filed under the FCA.

This amount marks the third consecutive fiscal year in which the government recovered more than $3 billion.

Attorney General Tony West recently stated that the government views the FCA as the primary weapon in its arsenal:

> *"The False Claims Act is, quite simply, the most powerful tool we have to deter or redress fraud."*

AMERICANS WITH DISABILITIES ACT - 1990

Americans with Disabilities Act of 1990

The ADA is a wide-ranging civil rights law that prohibits discrimination based on disability.

It affords similar protections against discrimination to Americans with disabilities as the Civil Rights Act of 1964, which made discrimination based on race, religion, sex, national origin, and other characteristics illegal.

Disability is defined by the ADA as "...a physical or mental impairment that substantially limits a major life activity.“

Certain specific conditions are excluded as disabilities, such as substance abuse.

Americans with Disabilities Act of 1990 (cont)

The ADA provides that a disabled individual is one who can show:

He has a physical or mental condition that substantially limits a major life activity (such as walking, talking, seeing, hearing, learning, or working); or

He has a history of a disability (such as a cancer that is in remission); or

He is believed to have a physical or mental impairment that is not transitory (lasting or expected to last six months or less) and minor (even if she does not have such an impairment).

Americans with Disabilities Act of 1990 (cont)

In 2013, the American Medical Association (AMA) set forth its new policy recognizing obesity as a medical disease.

Although the AMA's determination has no legally binding effect, its position reignites the question of whether obesity is a disability under the Americans with Disabilities Act (ADA) and could bolster ADA disability claims by employees and applicants for employment.

While the AMA's new position could generate additional research, treatment, or care for obese patients, the position also bolsters employees' ability to hold their employers accountable for discriminatory treatment based on their weight.

Americans with Disabilities Act of 1990 (cont)

ADA Requirements:
The Americans with Disabilities Act (ADA) requires places of public accommodation, including hospitals, doctors' offices, ambulatory surgery centers and other healthcare providers, to offer people with disabilities equal access to goods, services, and facilities.

Healthcare providers are required to provide qualified sign language interpreters and other auxiliary aids to individuals who are deaf, hard of hearing, or who have speech disabilities, free of charge, in situations in which the medical services involve important, lengthy or complex oral communications with patients or companions.

The specific type of auxiliary aid required depends on multiple factors including the nature and length of the communication; the patient's or companion's communication skills and knowledge; and the individual's stated need for an auxiliary aid.

Examples of auxiliary aids include, but are not limited to, qualified interpreters on site or though video remote interpreting (VRI) services, written materials, exchanging written notes, video text displays, or the use text telephones (TTYs).

Americans with Disabilities Act of 1990 (cont)

Recent DOJ settlements provide insight into what auxiliary aids or services are considered necessary to comply with the ADA. Healthcare providers should review existing policies and practices governing effective communication with individuals who are deaf or hard of hearing to ensure that:

- Their policies cover not only the time period when the individual will be receiving medical services, but that they also include protocols for communicating with patients and companions during intake and discharge;
- Their policies specifically place the expense of the auxiliary aid on the healthcare provider; and
- Their policies provide a mechanism for responding to requests to other types of disabilities, including those involving vision or mobility impairments.

Healthcare providers should also ensure that all staff are regularly trained on communicating with deaf or hard of hearing patients and companions so they will be ready to respond effectively and appropriately to a request for an auxiliary aid, including the use of a qualified interpreter.

Americans with Disabilities Act of 1990 (cont)

Limited English proficiency policies must be revisited --

The requirements to provide appropriate auxiliary aids complement healthcare providers' obligations to provide interpreter services for patients with Limited English Proficiency (LEP) as required by the Civil Rights Act of 1964 as well as the Joint Commission's standards for accreditation.

Healthcare providers who do not currently have such comprehensive communications policies should consider developing them to ensure equal access to their services.

OMNIBUS BUDGET RECONCILIATION ACT OF 1990 (OBRA)

OBRA ’90

Omnibus Budget Reconciliation Act of 1990

Requires RPhs to keep patient records (profiles) for Medicaid patients to reduce incidence of drug interactions, duplication and side effects

Requires RPhs to make the offer to counsel all Medicaid patients regarding the proper use of their medications

VETERANS HEALTH CARE ACT - 1992

VETERANS HEALTH CARE ACT

Veterans Health Care Act of 1992

Referred to as the 340B Drug Pricing Program

Requires drug manufacturers to provide outpatient drugs to certain covered entities at a reduced price

The original purpose of the 340B program was to enable covered entities to stretch scarce federal resources to reach more patients.

VETERANS HEALTH CARE ACT (CONT)

These covered entities were listed as:

- Health Resources and Service Administration (HRSA) grantees
- Federally Qualified Health Centers (FQHCs)
- Family planning clinics
- HIV/Ryan White clinics
- State-operated AIDS drug assistance programs
- Black lung clinics
- Hemophilia treatment centers
- Urban Indian organizations
- Native Hawaiian health centers
- Sexually transmitted disease and tuberculosis clinics
- Disproportionate share hospitals

340B Program (cont)

The 340B price defined in the statute is a ceiling price, meaning it is the highest price a covered entity would have to pay for a given outpatient drug.

Entities may negotiate below ceiling prices with manufacturers.

As a result, 340B prices have been found to be roughly 50% of the Average Wholesale Price (AWP).

340B Program (cont)

For commercially-insured patients, the entity can bill the insurance company at the standard rate payable by the patient's insurance plan.

The 340B Program law and guidelines do not dictate how the entity is to bill third parties or address how reimbursement amounts are to be used.

This has resulted in some 340B clinics providing medications to patients at far cheaper prices than a non-340B pharmacy can even purchase the medications.
(unfair practice ??)

340B Program (cont)

Covered entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the covered entity.

The definition of a patient states: "An individual is a 'patient' of a covered entity only if:

(1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care: and

(2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains for the covered entity; and

(3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided to the entity.

340B Program (cont)

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Any individual registered in a State operated or funded AIDS program will be considered a "patient" of the covered entity for purposes of this definition.

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA) - 1994

DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA)

1994 – Dietary Supplement Health and Education Act (DSHEA)

The passage of DSHEA defined "dietary supplements" as a separate regulatory category.

It also expanded the types of products that could be marketed as "supplements".

DSHEA made the manufacturers responsible for ensuring that their dietary supplements are safe before marketing (do NOT have to prove effectiveness).

The most logical definition of "dietary supplement" would be something that supplies one or more essential nutrients missing from the diet.

DSHEA went far beyond this to include vitamins, minerals, herbs, amino acids, and other dietary substances designed to supplement the diet.

Dietary Supplements (cont)

What is a dietary supplement?

Under the FD&C Act, dietary supplements—technically regulated as food products, not as pharmaceuticals—must be "ingested" via an oral route.

While this may seem intuitive to some, 20 companies have received Warning Letters from FDA since 2001 referencing their failure to market a dietary supplement product ingested orally.

"We note that only products that are intended for ingestion may be lawfully marketed as dietary supplements," FDA said. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal products, are not to be treated as dietary supplements.

Dietary Supplement Health and Education Act (DSHEA) - (cont)

Although many such products (particularly herbs) are marketed for their alleged preventive or therapeutic effects, the 1994 law has made it difficult or impossible for the FDA to regulate them as drugs.

Since its passage, even hormones, such as DHEA and melatonin, are being advertised as supplements.

Federal regulations governing dietary supplements don't go far beyond requiring manufacturers to follow CGMP (Current Good Manufacturing Practices).

- Processed consistently
- Meet quality standards
- Must report "serious" adverse events
- FDA may conduct routine and for-cause inspections

Dietary Supplements (cont)

FDA DOES have the authority to enforce truth-in-advertising restrictions for dietary supplements.

Dietary supplement manufacturers may:

State that a product will benefit a nutrient deficiency

State the role of the supplement in affecting the function of the body

State the mechanism by which a supplement acts to maintain a function of the body

Manufacturers may NOT:

Make claims about the supplement's ability to diagnose, mitigate, prevent, treat or cure disease.

Dietary Supplements (cont)

Six Tips for Avoiding Fraudulent Products

FDA said six claims in particular should raise warning bells for consumers as they are, more likely than not, an indication that the product is a potentially dangerous rip-off:

- Any product claiming to be an all-in-one cure for multiple diseases or conditions
- Any product relying solely on personal testimonials for claims of efficacy or safety
- Any product claiming to treat a condition quickly
- Any product claiming to be "all natural"—so are poisonous mushrooms says FDA
- Any product claiming to be a "miracle cure"
- Any product claiming to be based on conspiracy theories—the cure "the pharmaceutical industry and the government are working together to hide information about" is just trying to cover for its own insecurities, FDA wrote.

"If a real cure for a serious disease were discovered, it would be widely reported through the media and prescribed by health professionals—not buried in print ads, TV infomercials or on Internet sites," FDA concluded.

Dietary Supplements (cont)

Some manufacturers seek approval outside the FDA to gain legitimacy for their dietary supplement products.

One company that provides verification is the U.S. Pharmacopeia (USP), a Maryland-based non-governmental Agency.

USP sets certain standards for prescription and OTC medications manufactured or sold in the U.S.

- Quality
- Purity
- Strength
- Consistency of product

You may see supplements stating "USP Approved"

- Does not mean FDA approved – may still be subject to FDA actions

Dietary Supplements (cont)

In December 2010, the FDA mounted a new effort to discourage the sale and use of over 300 products sold as “dietary supplements” that have been determined to actually contain drug compounds.

Among the most common offenders:

- Weight loss products containing sibutramine
- Muscle building products containing aromatase inhibitors or anabolic steroids
- Male enhancement products containing sildenafil or related compounds
- Other compounds that have been identified in products claiming to be dietary supplements include:
  - Warfarin
  - Beta blockers
  - Anticonvulsants
  - Statins
  - Benzodiazepines

Dietary Supplements (cont)

FDA is increasing their enforcement ante:

Warning letters – issued for infractions (may be minor)

Import alert for detention – Companies on alert status will not be able to get their products through customs and into the U.S.

Administrative detention – gives FDA the power to detain any food or supplement that “is believed to be adulterated or misbranded”. This allows FDA to freeze shipments for up to 30 days.

Injunction proceedings – may allow a federal court to declare an entire shipment or company to be in violation of cGMP, thus requiring destruction of all involved products.

Criminal prosecution – may result in million dollar fines plus imprisonment.

Consumers Site for Research on Dietary Supplements for Safety Concerns

A new search tool from LegitScript provides information on dietary supplements and other similar health care products indicating whether a product is known to be unsafe or marketed with unsupportable claims.

The LegitScript Healthcare Product Search contains data on thousands of supplements and health care products collected from regulatory authorities around the world.

The search tool can be used to research whether a product is known to contain toxins or active pharmaceutical ingredients, is marketed with unsupportable claims, or has some other problem suggesting a health risk.

LegitScript indicates that “While many supplements have no known problems, thousands of others have been tested or reviewed by some reliable authority – not only the US FDA, but also its counterparts in countries ranging from Canada and EU countries to Singapore or Australia – and found to either contain dangerous ingredients or inappropriately imply safety or medical effectiveness.”

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (HIPAA) - 1996

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT

1996 - Health Insurance Portability and Accountability Act (HIPAA)

Establishes regulations for the use and disclosure of Protected Health Information (PHI).

PHI is any information held by a covered entity which concerns health status, provision of health care, or payment for health care that can be linked to an individual.

This is interpreted broadly and includes any part of an individual's medical record or payment history.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (CONT)

There are two ways in which a company can become subject to HIPAA:

(1) it functions as a health plan, health care provider or health care clearinghouse which could potentially make it a HIPAA "covered entity", or

(2) acts on behalf of a covered entity in assisting in the performance of a function involving the use or disclosure of medical information, which could potentially make it a HIPAA "business associate".

Most health tech companies that become subject to HIPAA's privacy and security requirements do so because they engage in activities that make them "business associates".

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (CONT)

Two important factors may help in deciding whether a company is a "business associate":

1. To be a business associate, a company must be acting "on behalf of" a covered entity.

   While there is limited guidance on what "on behalf of" means, it can be interpreted as excluding from the "business associate" definition companies that do not sell or provide services specifically intended or designed for use by covered entities.

   Companies that act as mere conduits for medical information such as the phone companies and the Postal Service are not considered business associates.

2. The medical information must have originated from a covered entity.

   Companies that not only collect medical information from consumers, but also exchange health related information with covered entities can be considered business associates.

   The HIPAA privacy and security requirements impose significant demands on companies, especially early stage companies that may lack the resources to develop robust HIPAA compliance programs.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (CONT)

The Administrative Simplification Standards adopted by Health and Human Services (HHS) under HIPAA apply to any entity that is a:

- Health care provider that conducts transactions in electronic form
- Health care clearinghouse
- Health plan

An entity that is one or more of these types of entities is referred to as a "covered entity".

In short, an organization that routinely handles health information in any capacity is in all probability a covered entity.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (CONT)

Covered entities MUST:

Ensure the confidentiality and integrity of all PHI the entity creates, receives, maintain or transmits.

Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

Protect against any reasonably anticipated uses or disclosures of such information that are not permitted. Prohibiting most health plans from using or disclosing genetic information.

Ensure compliance by their entire workforce.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABLITY ACT (CONT)

A covered entity may disclose PHI:

To facilitate treatment, payment, or health care operations, or

If the covered entity has obtained authorization from the individual

However, when a covered entity discloses any PHI, it must make a reasonable effort to disclose only the minimum necessary information required to achieve its purpose.

HIPAA (CONT)

Challenge to HIPAA requirements:

Drive-thru pharmacies (with speakers):

Everyone in vicinity hears whatever is said

May need to request that patient come into the pharmacy to maintain confidentiality

Certainly NOT why most patients using of drive-thru pharmacies want to do.

Some companies are now using telephone handsets so that only the person on the other end hears the conversation.

HIPAA (CONT)

Emerging Issue:

Social Networking:

LinkedIn	Twitter
Facebook	MySpace
YouTube	

People post daily activities, including work situations

5 nurses posted pictures of a wounded patient on Facebook (did not identify by name) – fired & hospital fined (2011)

Physician in RI fined & fired for posting information online regarding a trauma patient (did not identify patient by name)

Caution:

Communications over wireless networks may be easily intercepted by anyone near the pharmacy unless the network is encrypted.

HIPAA (CONT)

HIPAA covered entities must now use only the National Provider Identifier (NPI) to identify healthcare providers in standard transactions – includes adjudication of claims.

Prior to HIPAA, pharmacies and insurers used the prescriber's DEA number as an identifier.

This resulted in pharmacies reporting of prescribers' prescribing patterns and sometimes incorrect reporting (incorrect DEA # used).

HIPAA (CONT)

Some examples of penalties for violations of HIPAA:

$50,000 + 1 year jail term for false claims

$100,000 + 5 year jail term for false pretenses

$250,000 + 10 year jail term for intent to sell, transfer or use identifiable health information for commercial use, personal gain or malicious harm.

HIPAA (CONT)

As more and more individuals, entities and attorneys seek medical information, issues will only become more prevalent.

Most healthcare practices look to HIPAA as the governing law that determines the proper use and disclosure of patient data, but state laws and professional obligations also must also be considered.

Under HIPAA, a covered entity generally may not use or disclose an individual's protected health information without a written authorization or providing the individual the opportunity to agree or object.

There are, however, a number of thorny exceptions, such as requests made in the course of judicial or administrative proceedings, or disclosures to law enforcement.

Confidentiality in Pharmacy Area

Pharmacy personnel should never discuss:

- Patients
- Patients' medications
- Patients' disease states or conditions
- Patients' purchases (including OTCs)

Emergency Events

In the event of a large scale emergency event (natural disaster or terrorist event), do HIPAA regulations and restrictions still apply?

1. Yes
2. No

HIPAA Privacy in the Aftermath of Hurricane Sandy (cont)

Healthcare providers are allowed to share PHI as necessary to carry out treatment.

After Hurricane Katrina, the HHS Office for Civil Rights issued a Hurricane Katrina Bulletin: HIPAA Privacy and Disclosures in Emergency Situations on September 2, 2005.

Treatment was broadly defined to include:

(a) sharing information with other providers (including hospitals and clinics);
(b) referring patients for treatment (including linking patients with available providers in areas where the patients have relocated), and
(c) coordinating patient care with others (such as emergency relief workers or others that can help in finding patients appropriate health services).

It also clarified that when a health care provider is sharing information with a disaster relief organization authorized by law, like the American Red Cross, it is unnecessary to obtain a patient's permission to share PHI if so doing so would interfere with the organization's ability to respond to the emergency.

HIPAA Privacy in the Aftermath of Hurricane Sandy

HHS provides guidelines for disclosures before and during emergencies. HHS developed a flowchart decision tool to assist healthcare providers during a public health emergency.

The Flowchart Decision Tool asks three essential questions:

First, who is the source of the information to be disclosed?
Second, to whom is the information being disclosed?
Third, does the covered entity have a signed authorization permitting the disclosure?

A valid authorization includes:

(a) a meaningful description of the information to be disclosed;
(b) the name of the individual or the name of the person authorized to make the requested disclosure;
(c) the name or other identification of the recipient of the information;
(d) a description of each purpose of the disclosure;
(e) an expiration date or an expiration event that relates to the individual; and
(f) a signature of the individual or their personal representative and the date.

HIPAA (CONT)

Indiana recent case:
On July 26, a jury in Indiana awarded $1.44 million to a Walgreens customer based on allegations that the customer's pharmacist accessed, reviewed, and shared the customer's prescription history with others, who then used the information to intimidate and harass the customer.

The customer filed suit against both the pharmacist and Walgreens claiming that both parties had breached their statutory and common law duties of confidentiality and privacy.

The complaint also included claims of negligence, invasion of privacy, and publication of private facts against the pharmacist and claims of negligent training, supervision, and retention against Walgreens for continuing to employ the pharmacist even after discovering the incident.

HIPAA (CONT)

Pharmacists fill more than just prescriptions !!

Pharmacists, as licensed professionals, are subject to codes of ethics and other standards of practice that limit and, in some cases, prohibit personal relationships with patients/clients.

Pharmacists have a unique relationship with patients, including access to confidential and sensitive information.

Pharmacists are placed in a position of trust regarding medical conditions and treatments thereof, and must respect the privacy of their patients.

HIPAA (CONT)

Hiding in plain sight:

- Failure to scrub patient data from digital copiers returned to leasing company results in $1.2 million fine

HIPAA (CONT)

Refill reminder programs in jeopardy???

American Recovery and Reinvestment Act of 2009 (ARRA) permits payments from drug manufacturers to pharmacies for reminder-refill mailings, but only if the payments are found to be “reasonable in amount.”

HHS, in turn, concluded that the term “reasonable in amount” should mean that pharmacies should not be able to profit from refill reminders. Eliminates any payments from drug companies to pharmacies operating refill reminder programs.

One possible solution may be to obtain patient permission or an official “authorization” to receive the refill reminders. In that case, a pharmacy would be able to market reminders to the patient until the patient withdraws the authorization. In this scenario, the “reasonable amount” requirement would not apply.

PATIENT PROFILES

QUESTION?

Under HIPAA guidelines, who is allowed to have access to a pharmacy patient's prescription profile?

1. Patient
2. Spouse
3. Minor (< age 18)
4. Court appointed guardian
5. Legal representative
6. 1 & 2 above
7. All of the above

HIPAA Privacy or Security Rule

Individuals who believe that a covered entity has violated their (or someone else's) health information privacy rights or committed another violation of the HIPAA Privacy or Security Rule may file a complaint with OCR at: http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html.

HIPAA (CONT)

Many states may have more stringent privacy rules than HIPAA, particularly in the areas of behavioral health, human immunodeficiency virus, substance abuse and patients' genetic information.

The federal rule governing the use of Medicaid information and the federal regulations governing substance abuse treatment records are also more stringent than HIPAA.

HIPAA does NOT preempt more stringent state and federal laws, regulation and rules!!!

To BYOD or NOT to BYOD

BYOD

BYOD - (Bring Your Own Device).

This is the term used when a company chooses to forgo issuing company-owned mobile computing devices (think smartphones and tablets), and encourages (allows) employees to use their own personal mobile devices for business purposes.

BYOD (CONT)

For better or for worse, many companies have opted to institute a BYOD policy for a number of reasons. Here are just a few rationales for BYOD:

Employees likely already have a smartphone or tablet or both.

Allowing employees to use their own devices provides flexibility.

Companies can save money by not having to buy and troubleshoot mobile devices.

BYOD facilitates participation in the mHealth and telehealth movements.

Even the market trends illustrate that BYOD is here to stay as market adoption of smartphones is projected to increase to 68% by 2016, up from 12% in 2008.

BYOD (CONT)

However, BYOD in the healthcare context can significantly increase risks related to protecting patient information, among other problems (e.g. malware and risks to patient safety).

Countless anecdotes arise from healthcare companies that involve breaches of health information stored on smartphones that lack passwords, unsecured SMS texting of health information by providers, and even photos being taken of patients which are promptly shared through social media websites.

These activities can result in multiple violations of Federal (HIPAA / HITECH) and state privacy and security laws.

To avoid the liabilities arising from non-compliance with applicable privacy and security laws and regulations, healthcare entities should implement controls around the various devices floating around their organizations.

BYOD (CONT)

Specific steps healthcare entities can take address privacy and security risk of allowing a BYOD environment?

- Adopt a mobile device policy and implement related procedures.
- Periodically train employees on appropriate use of personal mobile devices.
- Require strong passwords.
- Encrypt personal mobile devices.
- Require enabling inactivity time out functions.
- Implement role-based access controls.
- Consider installing GPS location and remote-wipe capabilities.
- Turn off cloud backup capabilities.
- Sanction employees that violate the company policy.
- Conduct a risk analysis . . . **AND MITIGATE THOSE RISKS!**

BYOD (CONT)

In September 2012, Massachusetts Eye and Ear Infirmary agreed to pay $1.5 million to the HHS to settle allegations of violations of the HIPAA Security Rule.

The hospital was investigated by the Office of Civil Rights (OCR) after the hospital submitted a breach report in April of 2010 notifying the OCR of the theft of a personal laptop containing unencrypted electronic protected health information (PHI) of hospital patients and research subjects.

OCR's subsequent investigation discovered that the hospital failed to comply with various requirements of the HIPAA Security Rule when it failed to:

- Implement security measures to protect the confidentiality of the electronic PHI
- Conduct a risk analysis of the confidentiality of PHI maintained on portable devices; hospital created, maintained and transmitted via portable devices;
- Secure PHI contained in portable devices via encryption or to document the rationale for not using encryption;
- Adopt policies that restricted access to electronic PHI to only authorized users of the portable devices; and
- Adopt policies that addressed the proper way to identify, report and respond to security incidents like a laptop theft.

FDA MODERNIZATION ACT - 1997

FDA MODERNIZATION ACT

1997 – FDA Modernization Act

Modified the process for getting approval for clinical studies, testing subjects and having new drugs approved for human use.

Objective was to improve pharmaceutical research and drug delivery, decrease potential health problems associated with exposure to toxins (specifically mercury) and modify regulations on food, drugs and other medical devices to ensure that higher quality products are available on the market.

1997 – FDA Modernization Act (cont)

Reduced the time for the approval (fast-track) of new pharmaceutical drugs.

Required the FDA to specify which drugs should be required to carry pediatric labeling.

Removed restrictions on dissemination of off-label uses of pharmaceutical drugs to medical professionals, insurers and government agencies, but not to consumers.

This provision is opposed by the FDA, who still considers off-label use to be illegal.

COMBAT METHAMPHETAMINE EPIDEMIC Act - 2005

Combat Methamphetamine Epidemic Act 2005

Sellers must follow requirements for retail sales of OTC products containing ephedrine, pseudoephedrine and phenylpropanolamine (precursors to methamphetamine)

Sellers must perform an annual self-certification with DEA that shows compliance with CMEA requirements

PSEUDOEPHEDRINE

Sale of pseudoephedrine or ephedrine:

1. It shall be dispensed, offered for sale, sold, or distributed only from behind a checkout counter or in a locked storage container where the public is not permitted.

2. A licensed pharmacist, sales clerk, or pharmacy technician shall require that any person purchasing, receiving, or otherwise acquiring any such substance shall be age 18 or older, and record the sale in a written logbook, electronically, showing the date of the transaction, name of the person, and the amount of such substance.

The written logbook or electronic record shall be retained for at least 12 months.

A person may purchase no more than 3.6 grams per day

A person may not acquire more than 9 grams of any such substance within any 30-day period.

U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act - 2007

U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007.

In 2007, Congress passed a law entitled the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007.

How could an appropriations law regarding Katrina and Iraq affect pharmacy?

It included a single paragraph that addressed the misuse of existing prescription pads used by prescribers and the ability of those pads to be altered by patients. It stated:

> Due to federal law, the use of tamper-resistant prescription pads/paper is required for all written prescriptions for outpatient drugs, including those for OTC drugs or products, for Medicaid clients.

Tamper-Resistant Prescription Pads

The following prescriptions or situations are **exempt** from this requirement:

Prescriptions transmitted by telephone, by fax or electronically.

Prescriptions paid for by a managed care entity.

When a prescriber administers or provides the drug directly (such as samples) to the patient.

Written prescriptions prepared in an institutional setting where the prescriber writes the order into the medical record and then the order is given by medical staff directly to the pharmacy, such that the patient never has the opportunity to handle the written order.

Prescriptions written for any medical item, service or equipment that is not considered an outpatient drug.

Tamper-Resistant Prescription Pads (cont)

The law specifies 3 different characteristics that must be incorporated into the prescription pads/paper:

1. Characteristic #1: One or more features designed to prevent unauthorized copying of a completed or blank prescription form.

2. Characteristic #2: One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

3. Characteristic #3: One or more features designed to prevent the use of counterfeit forms.

One feature from each characteristic must be present.

Tamper-Resistant Prescription Pads (cont)

Characteristic #1: One or more industry-recognized features designed to prevent unauthorized copying of completed or blank prescription form.

a. The word "Void", "Illegal", or "Copy" appears when the prescription is photocopied.

b. Micro-fine printed security message generated by a computer, electronic medical records system or other electronic means. The message may serve as a signature line or border.

c. Coin-reactive ink or security mark. The pad or paper identifies an area on the pad/paper where the ink changes color or reveals wording or a picture when that area is rubbed by a coin.

d. Security print watermark. Specific wording is printed on the front or back of the prescription paper and can only be seen when viewed at an angle.

e. Paper with a watermark. This is paper that contains a watermark that can be seen when backlit.

Tamper-Resistant Prescription Pads (cont)

Characteristic #2: One or more industry recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

a. An erasure-revealing background. If an erasure or modification is attempted, the background will show marks or the color of the underlying paper where alterations were made.

b. Toner fusing technology for laser-printed prescriptions. The computer-printed information cannot be lifted from the surface of the paper without damaging the paper.

c. Chemical-reactive paper. This is paper that contains features that show discoloration or reveals a hidden message if solvents are used to attempt to wash the ink from its surface.

d. Plain bond paper combined with inkjet-printing so that erasures and modifications cannot be made without damaging the paper.

e. Pre-printed quantity check-off boxes indicated in ranges of no more than 25 per range combined with a written quantity.

f. Pre-printed refill indicator where the number of refills allowed is marked or no refills or "NR" is marked when no refills are authorized.

g. Characters surrounding the authorized dispensing quantity and the number of refills. Special characters such as a series of asterisks must be repeated on both sides of the numbers indicating the quantity and the number of refills authorized, (e.g., Quantity ***50*** Refill ***3***)

Tamper-Resistant Prescription Pads (cont)

Characteristic #3: One or more industry recognized features designed to prevent the use of counterfeit forms.

a. Security features listed visibly in a box, band or border on the prescription.
This must be a complete listing of all of the security features incorporated into the prescription pad/paper in order to minimize tampering.

b. Security threads. Metal, fluorescent or plastic security threads are embedded into the prescription pad/paper.

c. Thermochromic ink. All or some of the pad is pre-printed with ink that changes color when exposed to heat and then changes back to its original color when cooled.

RYAN HAIGHT ACT OF 2008

Valid Prescription as Defined by the Ryan Haight Act

The Ryan Haight Act provided a federal definition for a valid internet prescription:

A "valid prescription" means that:

1. The prescription must comply with the long standing requirement of being issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, and
2. The prescribing practitioner must either:
   (i) Have conducted at least one in-person medical evaluation of the patient, or
   (ii) Meet the definition of a "covering practitioner"

Ryan Haight Act Definitions (cont)

In-person medical evaluation

Means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

Covering practitioner

Means a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

(i) Has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) Is temporarily unavailable to conduct the evaluation of the patient.

On-Line Pharmacy

On-Line Pharmacy

Means a person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled dangerous substance by means of the Internet.

The term "online pharmacy" includes:

(i) Any web site, or operator of a web site, that sells, or offers to sell, any CDS or a prescription therefor to a person in the United States;

(ii) Any person who pays a practitioner to write prescriptions for CDS for customers of such a web site;

(iii) Any person who pays a pharmacy to fill prescriptions for CDS that were issued to customers of such a web site;

(iv) Any pharmacy that knowingly or intentionally fills prescriptions for CDS that were issued to customers of such a web site; and

(v) Any person who sends an e-mail that:

a. offers to sell a CDS or a prescription for a CDS;
b. directs buyers to a web site operating in violation of this act; or
c. otherwise causes or facilitates the delivery, distribution, or dispensing of a CDS in a manner not authorized by the Act.

On-Line Pharmacy (cont)

The definition expressly excludes the following categories:

(i) Manufacturers or distributors who do not dispense controlled substances to an unregistered individual or entity;

(ii) A registered pharmacy whose dispensing of controlled substances via the Internet consists solely of:

(a) Refilling prescriptions for controlled substances in schedules III, IV, or V

(b) Filling new prescriptions for controlled substances in schedules III, IV, or V

VIPPS

Verified Internet Pharmacy Practice Sites (VIPPS)

NABP Program:

To ensure public health, VIPPS accreditation requires an Internet pharmacy to comply with the licensing and survey requirements of each state to which it dispenses pharmaceuticals.

VIPPS-accredited pharmacies meet nationally endorsed standards of pharmacy practice, and they demonstrate compliance with standards of privacy and authentication and security of prescriptions, adhere to quality assurance policy, and provide meaningful consultation between patients and pharmacists.

VIPPS pharmacy sites display the VIPPS Seal on their Web sites.

The Seal is a key benchmark for consumers to measure the quality of a pharmacy's practice, and by clicking on the VIPPS Seal, they are able to access verified information about the pharmacy.

VERIFIED INTERNET PHARMACY PRACTICE SITES (VIPPS) – (CONT)

Websites that have been certified by NABP should display the following seal:

The VIPPS website is: http://vipps.nabp.net/verify

VET-VIPPS

VET-VIPPS

www.**nabp.net**/programs/accreditation/**vet-vipps**

VET-VIPPS

In a meeting coordinated by the Federal Trade Commission (FTC) on October 2, 2012, veterinary and pharmacy experts affirmed the practice of pharmacists dispensing veterinary prescriptions.

NABP staff provided an overview of the Vet-VIPPS® (Veterinary-Verified Internet Pharmacy Practice Sites) accreditation program for online pharmacies that dispense veterinary drugs.

An American Veterinary Medical Association (AVMA) spokesperson stated that the organization stands “behind the AVMA's principles of Veterinary Medical Ethics which encourages veterinarians to honor a client's request for a written prescription."

“Pharmacists have played, should play and will play in the future of veterinary medicine. Their role is seen as especially relevant in the dispensing of long-term therapeutic drugs such as prescription anti-inflammatories for arthritis and medications for heartworm control”.

e-ADVERTISER APPROVAL

e-Advertiser Approval

e-Advertiser Approval

Sites that have received e-Advertiser Approval status do not fill new prescription drug orders via the Internet, and thus, are ineligible for VIPPS.

They do accept refill requests from their existing customers, provide drug information or pharmacy information, or offer other prescription drug-related services.

Sites that have received e-Advertiser Approval status have been found to be safe, reliable, and lawful. These sites are listed on the NABP Web site as Approved e-Advertisers.

AWARxE

NABP program

Mission Statement:
AWARERX.ORG is an information source providing authoritative resources about medication safety, prescription drug abuse, medication disposal, and safely buying medications on the Internet.

http://www.awarerx.org/

Through the AWARxE Web site, the program also encourages consumers to keep the national, toll-free poison control center phone number, 800-222-1222, readily available for use in the event of a suspected overdose or a medication error.

Calls to poison control centers are free and anonymous, and are handled by experts. Calls are accepted 24 hours a day, seven days a week, and help is available in over 150 languages.

MENTAL HEALTH PARITY AND ADDICTION EQUITY ACT - 2008 (MHPAEA)

Mental Health Parity and Addiction Equity Act of 2008

Provisions in 2013 regulations as amended by ACA:

1. Elimination of the exception contained in the interim final regulations for differences in nonquantitative treatment limitations between medical/surgical benefits and mental health or substance use disorder benefits

2. A plan must assign covered intermediate mental health/substance use disorder benefits (such as residential treatment, partial hospitalization, and intensive outpatient treatment) in a consistent manner to the existing six classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications:
   (a) inpatient in network
   (b) inpatient out of network
   (c) outpatient in network
   (d) outpatient out of network
   (e) emergency care
   (f) prescription drugs

HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH) - 2009

Health Information Technology for Economic and Clinical Health Act - 2009

The HITECH Act also widens the scope of privacy and security protections available under HIPAA; it increases the potential legal liability for non-compliance; and it provides for more enforcement.

Greatly strengthens HIPAA and enforcement for violations.

The Act requires that patients be notified of any unsecured breach. If a breach impacts 500 patients or more then HHS must also be notified.

The Act provides individuals with a right to obtain their PHI in an electronic format. The Act also prohibits the sale of PHI without authorization and express consent allowing the selling entity to receive remuneration for any disclosed PHI.

Business associates are now directly "on the compliance hook" since they are required to comply with the safeguards contained in HIPAA.

Civil penalties for willful neglect are increased under the HITECH Act. These penalties can extend up to $250,000, with repeat/uncorrected violations extending up to $1.5 million.

Health Information Technology for Economic and Clinical Health Act – 2009 (cont)

Office of Civil Rights (OCR) – part of HHS

- Perform pharmacy audits to assess the privacy and security of healthcare providers

- Request written documentation of the pharmacy's privacy and security efforts – must be returned to OCR within 10 business days

- Perform actual site visits lasting 3 to 10 business days
  - Interview personnel
  - Observe processes and operations to determine compliance

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA) - 2010

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

2010 Patient Protection and Affordable Care Act (PPACA)

Pharmacy opportunities:

1. Medication therapy management

Establishes a stand-alone grant program that will ensure MTM services

Provides mechanisms for patient-centered self-management programs that will improve patient outcomes in:

Patients taking 4 or more drugs or any high-risk medications

Patients with 2 or more chronic diseases

Patients who are at high risk of developing medication-related problems

2010 Patient Protection and Affordable Care Act (cont)

2. Integrated-care models for patient-centered medical homes

Providers with expertise in pharmacotherapy will be fully engaged in integrated, collaborative, team-based approaches to delivering care.

Must involve local primary care providers to give patients access to pharmacist-delivered MTM services, including medication reconciliation.

Must provide 24 hour transitional care program, including medication reconciliation, on admission to and discharge from hospitals, nursing homes, and other institutional settings.

Maryland website: http://www.marylandhealthconnection.gov/

PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

Implementation dates:

2010 – Patient Bill of Rights – must be posted in hospitals and must be proactively disseminated

- Lifetime dollar caps – removed

2011 – Donut hole adjustments – reduced

- 50% discount on branded drugs

2012 – ACOs (Accountable Care Organizations) may be formed

2013 – Preventive care services received funding

2014 – State Exchanges begin operating (states may elect to use federal program or build their own health exchanges

2015 – Physicians paid on value (not volume)

- Payments tied to patient care & outcomes

MARYLAND PCMH

As of June 2013 – 52 medical practices approved and registered

Must incorporate 6 elements of care to be approvable:

- Expanded office hours
- Care management plan
- Patient self-care support
- Referral tracking and follow-up
- CQI implementation
- Electronic data management of patients

2010 Patient Protection and Affordable Care Act (cont)

The Patient Protection and Affordable Care Act changed the rules regarding OTC expenditures, allowing reimbursement for those items only when purchased with a doctor's prescription.

A simple prescriber's note will no longer suffice for an OTC tax benefit. A written or electronic drug order meeting the legal requirements of a prescription in the state where the medical expense is incurred, issued by an individual legally authorized to issue a prescription, is required for reimbursement.

Also affects Flexible Spending Arrangements (FSAs), Health Savings Accounts (HSAs) and Health Reimbursement Accounts (HRAs).

2010 Patient Protection and Affordable Care Act (cont)

The U.S. Department of HHS announced new guidelines requiring health insurance plans beginning on or after August 1, 2012 to cover several women's preventive services, including birth control and voluntary sterilization with no co-pays.

The Obama administration has released an amendment to the prevention regulations that allows religious institutions offering health insurance to their employees the choice of whether or not to cover contraception services.

Besides contraceptive use, the list includes screenings for conditions such as gestational diabetes and the human papillomavirus (HPV), as well as breastfeeding support and counseling on sexually transmitted diseases.

Required immunizations for routine use in children, adolescents, or adults recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention without co-pays, co-insurance, deductibles, or other cost-sharing requirements.

2010 Patient Protection and Affordable Care Act (cont)

Proposed Rules -- March 2012 (Overpayments):

This section requires a person who has received an overpayment to report and return the overpayment to the government (or intermediary, carrier or contractor, if appropriate) and to state in writing the reason for the overpayment.

The rules define an overpayment as any funds that a person receives or retains under the Medicare or Medicaid program to which the person, after applicable reconciliation, is not entitled. A person is defined as a Medicare supplier or provider.

A person with an identified overpayment must report and return the overpayment by the date, which is 60 days after the date on which the overpayment was identified.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT (FDASIA) - 2012

Food and Drug Administration Safety and Innovation Act (FDASIA) - 2012

Established two new statutes:

1. Generic Drug User Fee Act (GDUFA)

   Sets fee structures for generic drugs

2. Biosimilar User Fee Act (BsUFA)

   Sets fee structures for biosimilars

Granted authority to FDA to regulate medical gases

Food and Drug Administration Safety and Innovation Act (FDASIA) – 2012 (cont)

Registration and listing requirements are expanded under FDASIA.

The law now requires the following:

- Registrants must provide a unique facility identifier and point-of-contact email address for each facility.
- Foreign facilities must register and list with FDA or face a determination that their products are misbranded (and thus not eligible for U.S. import).
- Establishments manufacturing drug excipients must register and provide listings.
- All drug importers must register.

FDASIA also empowers FDA to require electronic submission of drug information for importers as a condition of granting entry of their products into the United States.

Food and Drug Administration Safety and Innovation Act (FDASIA) – 2012 (cont)

Enhanced enforcement powers to detect and react quickly against adulterated or counterfeit drugs

Expands FDA's tools for inspection and related enforcement, allowing FDA to take the following actions:

- Destroy counterfeit or adulterated imported products..
- Bar entry of imported drugs from an establishment deemed to have delayed, limited, or denied an inspection.
- Take into account the results of inspections conducted by parallel foreign regulatory authorities.
- Deem failures of quality controls in manufacturing and assurance of raw material safety to be violations of good manufacturing practices (GMPs) and a basis for an adulteration violation.
- Require notification if a regulated party knows that the use of a drug could lead to serious injury or death, or if a drug is stolen or has been counterfeited.
- Assess higher penalties for:
  - (1) Knowingly and intentionally adulterating a drug, where that drug has a reasonable probability of causing serious adverse health consequences or death
  - (2) Engaging in activities related to knowingly and intentionally forging and/or counterfeiting drugs, including selling and dispensing
  - (3) Trafficking in counterfeited drugs.

Food and Drug Administration Safety and Innovation Act (FDASIA) – 2012 (cont)

Drug Supply Chain

One major reform is the Act's requirement for FDA to implement a new risk-based schedule for drug facility inspections.

FDA is required to implement a new facility identifier system into its establishment registration structure for both domestic and foreign establishments engaged in the manufacture, preparation, propagation, compounding or processing of drugs.

The legislation gives FDA explicit extraterritorial jurisdiction over any violation of the FDCA relating to any article intended for import into the United States.

It also increases the penalties for intentionally adulterating a drug and intentionally selling or dispensing counterfeit drugs, and establishes criminal penalties for counterfeit drug trafficking (maximum penalty to $4 million and up to 20 years in prison).

Food and Drug Administration Safety and Innovation Act (FDASIA) – 2012 (cont)

Improving patient access and incentivizing innovation for serious diseases

Provides for priority review vouchers to sponsors of drugs for rare pediatric diseases.

Broadens the qualification for designation as "fast-track products" by including products intended for a "serious or life-threatening disease or condition.

Pediatric Studies and Exclusivity Are Here to Stay:

- FDASIA permanently reauthorizes the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA).
- It also requires studies in neonates or a rationale why such studies are not necessary.
- Failure to meet pediatric study or reporting requirements will result in the product being misbranded.

DRUG QUALITY AND SECURITY ACT - 2013

Drug Quality and Security Act - 2013

Two main sections:

Drug Quality (compounding) – Title I

Security (track and trace) – Title II

Drug Quality and Security Act - 2013

Main provisions of Drug Quality:

I. Sets up a first "safe harbor" by amending the FDCA to:

Exempt state-licensed pharmacies and federal facilities from the FDCA new drug approval process;

Exempt state-licensed pharmacies and federal facilities from the FDCA cGMP procedures and reporting requirements

Exempt state-licensed pharmacies and federal facilities from certain labeling requirements (manufacturer labeling requirements)

Intended for smaller "traditional" compounding operations, which compound in response to prescriptions (or, in limited quantities, in anticipation of prescriptions) and are engaged in minimal out-of-state distribution.

Drug Quality and Security Act - 2013

Key requirements under first safe harbor:

- Outsourcing Facility must be state-licensed
- Compounding must be performed by a licensed pharmacist or physician
- Must be in response in a prescription or anticipation of a prescription
- Must use approved drug substances (includes inactive ingredients)
- May not compound drugs that have been withdrawn for safety or effectiveness reasons
- May not compound drugs that are essentially copies of commercially available drug products:
  - On a regular basis
  - In inordinate amounts

Drug Quality and Security Act - 2013

2. Sets up a second "safe harbor" by amending the FDCA to:

   Exempt sterile drug compounders (called "outsourcing facilities" in this legislation) from the FDCA new drug approval requirements

   Exempt sterile drug compounders from some drug labeling requirements

   Exempt sterile drug compounders from some drug distribution requirements

   Sterile drug compounders:

   Remain subject to cGMP

   May only compound with drug substances that are on a "clinical need" list to be established and maintained by the FDA

   May distribute out of state without limitations

   May compound large quantities of products on FDA's drug shortage list without prescriptions (or without the requirement of anticipatory prescriptions)

Drug Quality and Security Act - 2013

Key requirements under second safe harbor:

Facility must register annually with the FDA ($15,000?/year)

Must use only FDA designated drug substances (includes inactive ingredients) --- must be for substances based on "clinical need"

May not compound drugs that have been withdrawn for safety or effectiveness reasons

May not compound drugs that are essentially copies of commercially available drug products unless it is on the drug shortage list.

Must get pre-approval of elements to assure safe use for REMS-like drugs (must demonstrate that the facility and the compounding process provides comparable protection to the REMS

May NOT engage in wholesale distribution

Drug Quality and Security Act - 2013

Any compounder that does not fall under one of the two newly created “safe harbors” would fall under the definition of a FDA drug manufacturer.

FDA would then have full jurisdiction and would consider that “compounding facility” to be a manufacturer, and be subject to all FDA regulations.

Drug Quality and Security Act - 2013

FDA has started referring pharmacies to the state boards of pharmacy for possible administrative actions.

(Florida, Missouri, Oklahoma, New Jersey)

FDA now believes that it has the power to:

1. Inspect state-licensed non-outsourcing facilities
2. Determine whether a state board of pharmacy is capable of properly overseeing FDA-identified corrections
3. Take further action(s) should it feel that the board is not doing its job sufficiently

Drug Quality and Security Act - 2013

Title II of the act aims to reduce drug shortages, theft, counterfeiting and diversion with the initiation of a uniform national framework for tracing drugs throughout the pharmaceutical supply chain.

Title II – track and trace system:

Establishes a unit-level interoperable drug tracing system, to be phased in over the course of 10 years, that will require companies to provide information about each drug to the next party in the supply chain (Pedigrees). After January 2015, dispensers may NOT accept ownership of any product unless the prior owner provides a complete pedigree.

Formally recognizes third-party logistics providers as part of the drug supply chain;

Creates minimum and maximum licensure standards for wholesale distributors and third-party logistics providers, but preserves state authority for licensure issuance and fee collection; and

Requires the FDA to keep and make available to the public a database that enables consumers and members of the drug supply chain to identify appropriately licensed wholesalers.

TERMINOLOGY AS DEFINED IN PHARMACY LAWS

TERMINOLOGY

Statutes and Regulations begin with a listing of terms used within the Statute or Regulation along with the definition as used in that specific Statute or Regulation.

It is important to recognize that the same term(s) may have a different definition from Statute-to-Statute or from Regulation-to-Regulation.

Read carefully to determine how the term is defined in the specific Statute or Regulation under consideration

DEFINITIONS

DRUG (per FDCA) means:

(A) articles recognized in the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, or any supplement to either of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

DEFINITIONS (CONT)

LABEL

Means a display of written, printed, or graphic matter upon the immediate container of any article

LABELING

Means all labels and other written, printed, or graphic matters

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article

The FDA has determined that their labeling requirements also apply to any product information sent directly to medical professionals or elsewhere (not just materials sent with drug products).

Expiration Dating

Pharmaceutical labeling includes an expiration date.

The expiration date is determined on the basis of FDA review of stability studies performed by the sponsor.

Those studies must demonstrate that the drug would not degrade to the point that it no longer meets its specifications over a certain period (i.e. ~2-3 years)

Expiration Dating (cont)

In some cases, further testing may be used to show that the drug would still be within its specifications for a longer period of time.

The FDA does have a program called the Shelf-Life Extension Program (SLEP).

A sponsor or government agency may request the FDA test a specific lot number(s) to see if the expiration date may be extended.

SLEP

The Shelf-Life Extension Program was established in 1986 under an inter-agency agreement between the DoD and the FDA.

SLEP participants:

- US Air Force
- US Army
- US Navy
- US Marines
- Strategic National Stockpile –since 2004
- Dept. of Veterans Affairs (VA) – since 2005
- USPS – since 2005
- Bureau of Federal Prisons – since 2009

SLEP (CONT)

SLEP Drug Candidates:

SLEP is designed (cost effective) for the testing of specific batches of large stockpiles of medical materials that have been held in environmentally controlled locations.

Only FDA approved prescription drug products nominated by program participants.

Drugs that are purchased in very large quantities, such as ciprofloxacin, doxycycline, Tamiflu.

Representative samples from one location are sent to the FDA for stability testing.

The first time a specific lot is tested in SLEP, a maximum 2 year shelf life extension is given (assuming that the product passes).

SLEP (CONT)

The same lot may be retested annually or semi-annually to confirm extended expiration dating or to permit further extension.

A specific lot may be tested and the expiration date extended a maximum of 3 times.

Some products (i.e. antibiotics) may only be granted an extension of 1.5 years on retest cycles.

SLEP materials must be relabeled in accordance with FDA regulations (very expensive!!).

Any product that fails SLEP testing must be destroyed.

OFFICIAL COMPENDIA

Official Compendia under FDCA

Official United States Pharmacopoeia (USP/NF),

Official Homoeopathic Pharmacopoeia of the United States (HPUS),

Any supplement to either one of the above

ADULTERATED DRUG

VS

MISBRANDED DRUG

ADULTERATED DRUG

Adulterated Drug Definition (cont)

Adulterated drug (cont)

If it is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium.

If it is a drug and any substance has been:

(1) mixed or packed therewith so as to reduce its quality or strength or

(2) substituted wholly or in part.

MISBRANDED DRUG

Misbranded Drug

Misbranding - if:

Its labeling is false or misleading in any particular:

It is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

Its label does not bear adequate directions for use; including warnings against use in certain pathological conditions; or by children where its use may be dangerous in health; or against unsafe dosage, or methods, or duration of administration or application;

It does not comply with the color additives provisions listed under Section 706 of the Act; or

If there is any representation that created an impression of official approval because of the possession by the firm of an FDA registration number.

Misbranded Drug Definition (cont)

**Cardinal Rule

Medication in a filled prescription vial may never be returned to an original manufacturer's stock bottle.

PRESCRIPTION EXEMPTION

Prescription Exemption (cont)

There are 2 ways for a product to be classified as prescription-only:

1. Demonstrated lack of safety if used without medical supervision

2. The sponsor may request a prescription-only classification in the product's NDA.

PRESCRIPTIVE AUTHORITY

Prescriptive Authority

Professions who may prescribe are defined by Statutes.

Federal law specifies certain professions that may prescribe.

State laws may grant other professions authority.

Prescriptive authority may also be contained within contracts (i.e.):

- Physician – physician assistant
- Physician – nurse practitioner

ADEQUATE DIRECTIONS FOR USE

vs

ADEQUATE INFORMATION FOR USE

Adequate Directions For Use vs Adequate Information For Use

Consider the following Rx:

Anusol HC Supp

#12

Sig: 1 bid

What would you type for that sig?

Volunteer?

NON-COMPLIANCE

Non-Compliance

Some reasons for patients' non-compliance:

59 percent said they stopped taking their medication because they were feeling better and didn't think it was necessary to continue.

25 percent said they stopped because they weren't feeling any better.

37 percent were worried about side effects.

24 percent said their drugs were too expensive.

>50 percent failed to comply due to literacy issues (including label comprehension).

Prescription Labels (cont)

ISMP – "Institute For Safe Medication Practices"

ISMP has done many patient studies to show how pharmacists can communicate more effectively with their patients

They have found that:

Half of patients say that prescription information and labels they receive are written in language that is hard to read or understand.

The ISSUE: Low Health Literacy (the ability to read, understand and act on health information)

What group of patients may be most at risk?

Ethnic minority groups

Older patients

The MAJORITY = white, native-born Americans

Prescription Labels (cont)

“Drugs don’t work in patients who don’t take them.”

– C. Everett Koop, MD, Former Surgeon General

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.”

– World Health Organization

Prescription Labels (cont)

USP is adding a new section: Chapter 17 - Prescription Container Labeling

Label Standards

- Organize prescription label in a patient-centered manner
- Emphasize instructions and other information important to patients
- Simplify language
- Give explicit instructions
- Include purpose for use
- Limit auxiliary information
- Address limited English proficiency
- Improve readability

Prescription Labels (cont)

Are there any Federal laws or regulations pertaining to patients and the provision of healthcare information?

Yes, there are the Culturally and Linguistically Appropriate Service (CLAS) standards.

There are actually 14 standards, but only 4 are mandates (numbers 4 – 7). The mandates are Federal requirements for all healthcare providers that are recipients of Federal funding.

The rest are just recommended guidelines.

Prescription Labels (cont)

Standard 4

Must offer & provide language assistance services at no cost to each patient exhibiting limited English proficiency in a timely manner during all hours of operation.

Standard 5

Must provide verbal and written information to each patient in their preferred language informing them of their right to receive language assistance services.

Prescription Labels (cont)

Standard 6

Must assure the competence of any language assistance provided. Friends and family should not be considered as a language source except on the request of the patient.

Standard 7

Must make available easily understood patient related materials. Must post signs in the languages of the commonly encountered groups represented in the area.

PATIENT PACKAGE INSERTS (PPIs)

Patient Package Inserts (cont)

Many drugs or drug classes are currently required to be dispensed with special patient information. The 1st seven drug-classes that required patient package inserts in 1981 were:

(1) Oral contraceptives.
(2) Estrogens.
(3) Medroxyprogesterone acetate injectable drug products.
(4) Isoproterenol inhalation drug products.
(5) Oral postcoital contraceptives.
(6) Intrauterine devices regulated as contraceptives.
(7) Progestational drug products.

MANY OTHERS have been added since.

Patient Package Inserts (cont)

The Food and Drug Administration (FDA) determines the requirements for patient package inserts:

- Brand name/Generic name/Approved indications
- Clinical pharmacology
- Contraindications/Side effects (warnings)
- Drug abuse and dependence potential
- Dosage and administration (including information regarding possible overdoses)
- Any "Black Box" warnings
- Physical characteristics of the medication including color, shape, markings, etc, and storage information (e.g., "Do not store above 86°")
- A toll-free number and Internet address to encourage more widespread reporting of information regarding suspected adverse events.

Patient Package Inserts (cont)

***Important Note

Pharmacists must include a PPI with each prescription dispensed
(for required products), whether new or refill.

Failure to include a PPI means the prescription may be considered misbranded.

This not only applies to community pharmacies (ambulatory patients), but also to institutional pharmacies.

Inpatients must receive a PPI before the administration of the first dose, and then at least once every 30 days thereafter.

Patient Package Inserts (cont)

In 2006, the FDA began requiring manufacturers to use a new PPI format to make the information more readable and easier to locate.

The new PPIs include:

- A table of contents
- A "Highlights" section at the beginning summarizing the most important information including black-box warnings, indications and uses and dosage and administration
- A "Patient Counseling Information" section to help health professionals advise patients about how to use their medication and the potential side effects the patient may expect

Patient Package Inserts (cont)

The new format only applies to PPIs for drugs submitted for approval after 2006, but the FDA is encouraging manufacturers to use the new format for all of their medications.

Health professionals currently have access to all drug information at "DailyMed":
www.fda.gov/cder/news/FactsatFDA.htm

Or at:

Facts@FDA

Black Box Warning

What is a "black box warning" and why are they required?

The black box warning is set apart as the most prominent information included in a product insert.

Any warning elevated to the status of a black box warning must be bolded (the heading must be in all capitals, not the text of the warning) and "boxed" by a solid black line on all four sides.

Must accompany any labeling or product insert for distributed or dispensed prescription drugs.

Black Box Warning (cont)

A black box warning is indicated in the following three situations, but may be used in other situations to highlight warning information that should be particularly important to the prescriber:

1. There is an adverse reaction so serious in proportion to the potential benefit from the drug that it is essential that it be considered in assessing the risks and benefits of using the drug.
   This includes potentially life threatening or permanently disabling adverse reactions.
2. There is a serious reaction that can be prevented or reduced in frequency or severity by patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patient in a specific manner, or avoiding use in a specific clinical situation.
3. The FDA approved the drug with restrictions on use and distribution to assure safe use."

Patient Package Inserts (cont)

PPIs must also contain information regarding use during pregnancy and lactation.

- Category A – Well-controlled studies have not shown any risk to the fetus
- Category B – Animal studies have not shown any risk to the fetus
- Category C – No well-controlled or animal studies have been conducted
- Category D – Positive evidence of fetal risk exists, but the potential benefits may be acceptable
- Category X – Potential risk to the fetus clearly outweighs any potential benefit

FDA would like to replace the categories by having the manufacturers actually list the potential risks of using the drug during pregnancy and lactation

Black Box Warning (cont)

When introduced the black box warnings were the strongest form of warning on possible side effects that the FDA could issue.

The intent was to educate the prescriber and have the prescriber make a medical decision regarding whether the benefit of using the drug outweighs the possibility of the patient developing a potentially serious side effect(s).

The prescriber should discuss the possible side effect(s) with the patient and involve the patient in the decision.

In reality, the prescriber often does not discuss the issue with the patient, or the patient (sick –just wants to get better) decides to take the medication regardless.

Patient Package Inserts (cont)

In 1980, the FDA enacted regulations requiring PPIs be supplied to patients for all prescription drugs. Due to public concern regarding the cost of those regulations, which would be passed on to the patient, the FDA was forced to revoke those regulations in 1982 – just before the actual implementation date.

The FDA was still not satisfied, so in 1995 the agency issued a final rule requiring supplying patients with:

- MedGuides, or
- Consumer Medication Information (CMI)

A pharmacist that does not supply the required PPI, MedGuide, or CMI is guilty of misbranding.

MedGuides

The MedGuide portion of the final rule listed what the FDA determined to be a few designated drugs that posed a "serious and significant" concern to public health.

FDA estimated that no more than 5 drugs per year would probably require the issuance of a MedGuide. That number is now approximately 200 drugs.

They are to be issued if:

- Certain information is necessary to prevent serious adverse effects
- Patient decision-making (whether to take the drug or continue to take the drug) should be informed by information about a known serious side effect with a product, or
- Patient adherence to directions for the use of a product are essential to its effectiveness

MedGuides (cont)

MedGuides must:

- Be supplied by the manufacturer to distributors or dispensers
- Be provided by the dispensers each time the medication is filled or refilled
- Be approved by the FDA prior to dissemination
- Be written is nontechnical language
- Contain approved uses
- Identify serious adverse reactions
- Indicate and educate on proper use
- Contain cautions

A complete listing of drugs requiring MedGuides can be found at: www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Consumer Medication Information (CMI)

The Consumer Medicine Information (CMI) rule was designed to inform consumers about prescription medications. CMI provides information about the medication and is written by the pharmaceutical manufacturer.

CMI is to provide the patient with important facts to knowbefore, during and after taking a specific medication.

The content of a CMI is defined by legislation and includes headings such as how to take a medication, it's side effects and a description of the product.

OFF-LABEL USE OF MEDICATIONS

Off-Label Use of Medications

The FDA prohibits drug manufacturers from promoting "off-label uses" for their medications.

Off-label use of a drug is defined as any use of a drug for a condition or in a manner not appearing on the drug's FDA approved labeling.

Physicians, however, are not prohibited from prescribing drugs for off-label use.

NEW DRUG APPROVAL PROCESS

New Drug Approval Process

The process of approval of new drugs is one of the most controversial aspects of the FDCA.

One side = FDA is too lenient and permits new drugs to be marketed without adequate studies for safety and efficacy.

Second side = FDA too strict and prevents the use of perfectly safe and effective remedies for patients that are ill or near death.

New Drug Approval Process (cont)

The FDCA states: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application has been granted.

The application for a NDA includes massive amounts of information because often FDA reviewers require additional information to reach a "comfort zone" regarding product safety and efficacy.

To get a newly discovered drug from the first laboratory stage, it requires, on average:

12 years, and

Over $350 million to get a new drug from the laboratory onto the pharmacy shelf.

In part because so many drugs fail, large pharmaceutical companies spend at least $5 billion per new medicine.

FDA uses panels of experts to make a determination on the safety and efficacy of new drugs.

FDA is not bound by the decision of the panel. It may accept or reject the panel's recommendation.

Investigational New Drugs (IND)

(1) Before any clinical testing of a new drug is undertaken, the manufacturer of the drug or the sponsor of the investigation of the drug submit to the Secretary reports of preclinical tests of the drug, including tests on animals, that are adequate to justify the proposed clinical testing;

(2) The manufacturer of a new drug that is proposed to be distributed to investigators for clinical testing or the sponsor of the investigation obtain a signed agreement from each investigator who is involved that:

(i) The patients to whom the drug is administered will be under that investigator's personal supervision or under the supervision of an investigator who is responsible to that investigator; and

(ii) The investigator will not supply the drug to any other investigator, or to any clinic, for administration to a human being; and

(3) The manufacturer of a new drug or the sponsor of the investigation of the drug keep records of, and make reports to the Secretary of, the information obtained from the investigational use of the drug, including analytical reports by investigators, as the Secretary finds will assist in the evaluation of the safety and effectiveness of the drug.

New Drug Approval Process (cont)

Sponsors who want to have a new drug product approved in the U.S. must submit a New Drug Application (NDA).

- Review and approval of a NDA typically requires approximately 6 months

Sponsors who want to have a new generic product approved in the U.S. must submit an Abbreviated New Drug Application (ANDA).

Sponsors who want to have a new biologic product approved in the U.S. must submit a Biologic License Application (BLA).

Investigational New Device (IDE)

Devices must be covered by an investigational device exemption (IDE).

IND and IDE regulations require patient safeguards, including in most cases:

- Institutional Review Board (IRB) supervision of investigations
- Informed consent by subjects
- Reporting to the FDA

FDA CHANGES DEVICE LISTING AND REGISTRATION REQUIREMENTS - 2012

All proprietary names under which a device is marketed must be reported when a device is first listed and during the annual update of registration and listing information.

Drug/device combination products must be identified as a combination product, and the type of combination product (e.g., convenience kit, prefilled drug delivery device, etc.) must be selected from the list displayed in the FDA Unified Registration and Listing System (FURLS).

All contract manufacturers and sterilizers of finished devices must register and list regardless of whether they put the device into commercial distribution or return the device to the manufacturer or specification developer for distribution.

Initial importers must identify the manufacturers of the devices they are importing.

FDA CHANGES DEVICE LISTING AND REGISTRATION REQUIREMENTS – 2012 (CONT)

Foreign establishments exporting devices to the U.S. must identify all known U.S. importers of their devices.

Establishments located in foreign trade zones must now register and list, as well as identify themselves as being located in a foreign trade zone.

All foreign establishments that are required to register must now pay an annual registration user fee .

New Drug Approval Process (cont)

The FDA uses a numeric classification system to indicate the potential new drug's chemical type

And

A letter classification to indicate its therapeutic potential

New Drug Approval Process (cont)

Numeric classification system indicating the chemical type:

1. New molecular entity
2. New salt or ester form
3. New dosage form
4. Combination of compounds
5. Duplicate of existing product
6. Marketed by same company, but for a new indication

New Drug Approval Process (cont)

Letter classification system indicating the therapeutic potential:

P – drug may represent a therapeutic advance for one or more of these reasons:

No other effective drugs are available

More effective or safer than other drugs

Has important advantages as compared to other drugs (convenience, less side effects, etc.)

S - drug has therapeutic properties similar to other drugs already on the market

INDs and IDEs (cont)

In some circumstances, the IND or IDE authority may be an appropriate mechanism for use of an unapproved product during an emergency.

For instance, FDA regulations permit the use of investigational drugs if:

For an immediately life-threatening disease or condition

There is no comparable or satisfactory alternative treatment**

There is sufficient evidence of safety and effectiveness

There is a reasonable basis to conclude that the drug may be effective and would not expose the patient to unreasonable and significant risks

New Drug Approval Process (cont) Clinical Testing

If the FDA gives the green light, the "investigative" drug will then enter three phases of clinical trials:

Phase 1 uses 20-80 healthy volunteers to establish a drug's safety and profile. (about 1 year)

Phase 2 employs 100-300 patient volunteers to assess the drug's effectiveness. (about 2 years)

Phase 3 involves 1000-3000 patients in clinics and hospitals who are monitored carefully to determine effectiveness and identify adverse reactions. (about 3 years)

New Drug Approval Process (cont) Clinical Testing

After approval, each product is assigned an unique identification number:

NDC (National Drug Code)

- 1st 5 digits = manufacturer
- 2nd 4 digits = drug
- 3rd 2 digits = package size

UPC (Universal Product Code)

- 12 digits
- Not found on prescription products

What may not be known is that after a product has been discontinued for >5 years, the NDC Number may be reassigned to another product

Proposed Device Identification Number

U.S. Food and Drug Administration proposed that most medical devices distributed in the United States carry a unique device identifier (UDI).

An UDI includes:

a device identifier, which is a unique numeric or alphanumeric code specific to a device model; and

a production identifier, which includes the current production information for a device.

The FDA is focusing on the highest-risk medical devices first and exempting low-risk devices from some or all of the requirements.

Interestingly, FDA does NOT assign UDIs, but accredits outside agencies:

1. GS1, which administers the Global Trade Item Number (GTIN)
2. HIBCC, (Health Industry Business Communications Council) which administers the Supplier Labeling Standards (SLS).
3. ICCBBA, (International Council for Commonality in Blood Banking Automation) (ICCBBA) which is responsible for blood and transplant products.

New Drug Approval Process (cont) Clinical Testing

After final approval, the drug becomes available for physicians to prescribe.

Even at this stage, the drug manufacturer must continue to report cases of adverse reactions and other clinical data to the FDA.

A new rule in 2010 changed the definition of reportable adverse events to only include:

- Events directly associated with the new drug, and
- Excluded other events that might occur to enrolled patients (i.e. car accidents and unrelated medical issues)

New Drug Approval Process (cont) Clinical Testing

The National Institutes of Health has created a new website, NIH Clinical Research Trials and You

Clinical trials are essential for identifying and understanding ways to prevent, diagnose, and treat disease. Research has shown that among the greatest challenges to recruitment of volunteers is the lack of general knowledge about what trials involve, where they are carried out, and who may participate.

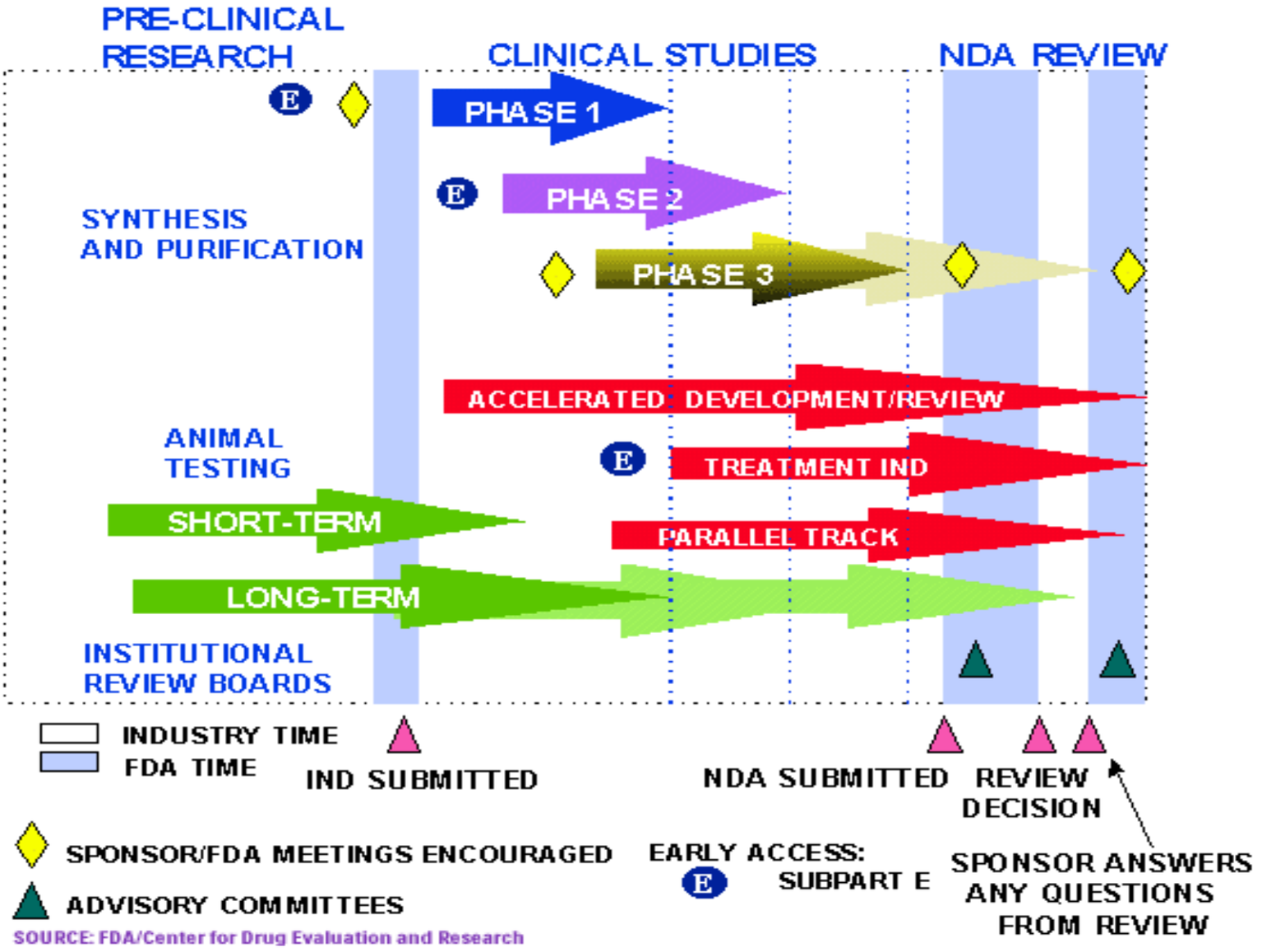
The ability to recruit the necessary number of volunteers is vital to carrying out clinical research that leads to health and medical advances and this new, centralized resource will make it much easier for the public and health professionals to learn about clinical trials and how people can participate in them."

Visitors to the website will find information about:

- The basics of clinical trial participation
- First hand experiences from actual clinical trial volunteers
- Explanations from researchers
- Links on how to search for a trial or enroll in a research matching program

In addition, health care professionals can read about evidence-based strategies for talking with patients about trials, print audience-tested posters to help promote trials in clinics and offices, and find other educational materials.

New Drug Approval Process – Clinical Testing(cont)



Drug Approvals

Once a drug is approved, the manufacturer is awarded a patent so that the manufacturer may recoup expenses incurred during the development process.

How long is a patent valid for an approved drug?

1. 7 years
2. 10 years
3. 17 years
4. 20 years

Drug Approvals (cont)

Court: 'Pay-for-Delay' Practice Anticompetitive, Illegal:

In a potentially precedent-setting decision, a federal California court has declared that payments made by companies to delay generic competition—also known as pay-for-delay settlements—are anti-competitive and illegal.

FTC Supports Decision -- FTC has called the agreements "pernicious" and noted the agreements resulted in more expensive drugs for consumers.

Proposals to end pay-for-delay agreements have also received support from the US Food and Drug Administration.

Drug Approvals (cont)

All medical products must have labeling that is not false or misleading.

All medical products must NOT be adulterated.

Originally, many drugs that were already on the market were grandfathered, so that they could remain on the market.

The FDA has now required manufacturers to submit their previously grandfathered products to the NDA process.

FDA has now ruled that all drugs on the market must be:

- FDA approved
- Safe
- Effective

FDA FAST TRACK APPROVAL PROGRAM

Fast Track Approval

The FDA will grant a drug sponsor expedited approval of a drug intended to treat life-threatening illnesses if the drug:

1. Demonstrates the potential to address currently unmet medical needs for the condition, and
2. Has an effect on a clinical endpoint that is reasonably likely to predict clinical benefit

Approval is conditional on the completion of clinical studies to verify the drug's clinical benefit

If further studies do not substantiate the drug's benefits or the drug's safety, then the FDA may use expedited procedures to remove the drug from distribution.

FDA's EXPANDED ACCESS (COMPASSIONATE USE) PROGRAM

FDA's Expanded Access (Compassionate Use) Program

Let's back up for a quick moment: Under current US Food and Drug Administration (FDA) regulations, if a company wants to conduct a clinical trial on a drug, it first needs to obtain regulatory approval to do so. It does this by submitting an investigational new drug (IND) application to FDA, which is essentially an exemption from federal law (which otherwise bans unapproved drugs from entering into interstate commerce) that allows a drug to be manufactured and investigated.

Under the terms of the IND, sponsors are tightly regulated, and are only able to use the drug on patients enrolled in the clinical trial. This is done to ensure that the drug is used safely, that the correct patients are enrolled in the trial, and that all side effects can be monitored.

Over the last two decades, FDA has moved to allow sponsors to expand access to their products, more commonly known as "early access programs" or "compassionate use exemptions."

FDA's Expanded Access (Compassionate Use) Program

Not all patients are eligible for expanded access programs. Only patients with serious or immediately life-threatening diseases with no comparable or satisfactory therapeutic alternatives are eligible.

Even then, the company must agree that to provide the drug to the patient and obtain FDA approval under one of several types of special INDs.

The most important concept in expanded access programs is that the patient be aware of the risks he or she is undertaking, and that the company minimizes unnecessary risks to the extent possible. For that reason, FDA requires that all proposed uses first be approved by an Institutional Review Board (IRB), and that the patient (or the patient's parent or guardian) sign an informed consent form.

FDA's Expanded Access (Compassionate Use) Program

Expanded access works, in general, in one of two ways: Either a company with an experimental product creates a new clinical trial for a patient through the use of an IND, or it amends an existing clinical trial to add new types of participants through the use of a "protocol amendment.“

Once a company determines which approach it wants to take, it then needs to decide on how many patients it is willing to accommodate. There are four general types of expanded access INDs and protocols:

Single Patient (Emergency Access): Used to grant access to a single patient who does not have time to obtain written permission from FDA

Single Patient (Regular Access): Used to allow a single patient access to a trial

Intermediate Size: Used for intermediate-sized patient populations

Treatment: Used for large patient populations (i.e. widespread use).

PANDEMIC AND ALL-HAZARDS PREPAREDNESS REAUTHORIZATION ACT (PAHPRA)

Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA)

Among the law's many provisions is one that allows FDA to temporarily approve a medical product if it determines that an emergency is likely to occur

Quick Use Based on Emerging Flu Threat:

The first product approved by the agency is the CDC's Human Influenza Virus Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay, approved on 22 April 2013.

The agency's 2013 EUA approval letter notes that CDC will be required to track and report adverse events, maintain records of the device's usage, ensure that only qualified facilities use the device, and post information regarding its safe use on its website. The EUA is in effect until it is specifically revoked by FDA.

Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) – (cont)

Other products are on their way as well:

FDA is already working to approve new flu detection devices and new treatments—and specifically vaccines—to market as fast as possible.

One new approach is “organs-on-chips” technology – uses microchips to mimic possible body reactions to infectious diseases rather than using human or animal subjects for testing.

COMBINATION DRUGS

BIOSIMILARS

BIOSIMILARS

Biologics Price Competition and Innovation Act- 2010

Following passage of this Act, FDA is proposing a new expedited approval process for biosimilars. It would be like an inverted pyramid (essentially beginning with a smaller Phase III patient testing).

Would NOT require generic companies to duplicate testing for safety and efficacy already done by the innovator product manufacturer.

Would require generic companies to show (test) at a minimum:

- Similarity
- Immunogenicity
- Other elements that the FDA decide may need further testing

TABLET SPLITTING

Tablet Splitting

To address the increasing cost of many medications, prescribers and insurance companies are writing, or requiring, prescriptions be written for a larger dosage product than the patient needs with instructions to cut the tablet in half to get the needed dosage (i.e. an 80 mg tablet with directions to take a 40 mg dose).

This has resulted in patients (pharmacists) trying to cut medications (even unscored) in half or even fourths and as a result, perhaps not having the correct dosage of active ingredient if each new dosage unit.

Tablet Splitting (cont)

In September 2011, FDA issued guidance recommendations to sponsors of new drug applications (NDAs) regarding criteria that should be met to facilitate tablet splitting (scored tablets):

Dosage amount after splitting must not be below the minimum therapeutic dose indicated on the label

The split dosage form should be safe to handle and not pose risk of unintended drug exposure (teratogenic, chemo)

Controlled or delayed dosage forms where the control mechanism of drug release can be compromised must not have a scoring feature

The split dosage form should meet established stability requirements for 90 days at 25C when stored in a pharmacy bottle with no seal

GENERIC SUBSTITUTION

Orange Book (cont.)

Orange Book – Rating for generics

AA – Identical action - Bioequivalent

AB – Bioequivalent

AN – Bioequivalent Inhalation product

AT – Bioequivalent (T = topical product)

BC – Extended Release – No data submitted – Not interchangable

Covera-HS & Calan-SR

BD – Products with known problems

AG (not an orange book rating) – means authorized generic

Orange Book

Lists approved drug products with their therapeutic equivalence evaluations

Identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act.

Drugs on the market were previously approved only on the basis of safety

Effectiveness is now covered by the ongoing Drug Efficacy Study Implementation [DESI] review

DESI Reviews

In 1962, Congress passed the Drug Amendments of 1962 Act. That Act required the FDA to determine the effectiveness of drugs that were already on the market (DESI review).

If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled uses, the FDA may withdraw approval of the marketing of the drug.

***No federal funding may be used to pay for a drug on the DESI listing – published every quarter

That means that states may not use federal funds to pay for those drugs – must use 100% state funding. The loss of federally funding is essentially a death knell for drugs carrying the DESI designation (insurance plans also refuse to cover DESI drugs). So the only viable market is the dwindling class of cash patients.

OTC Reviews for Safety and Effectiveness (cont)

OTCs were initially included in the DESI review, but the FDA concluded that they did not have the resources to complete reviews for each OTC product. In 1972, the FDA implemented a process of reviewing OTC medications by therapeutic class.

They use advisory panels for each therapeutic class to review data relating to claims and active ingredients.

The advisory panels issue a "final monograph" for each therapeutic class which must then be approved by the FDA.

The "final monograph" sets allowable claims, labeling and active ingredients.

If an OTC medication is marketed in accordance with the "final monograph", then it is considered to be safe and effective.

The FDA "final monographs" use the acronyms:

GRAS = recognized as safe
GRAE = recognized as effective

Orange Book (cont)

Inclusion of products on the Orange Book listing is independent of any current regulatory action.

Inclusion of products on the list is dependent on the manufacturer submitting their product(s) for inclusion.

The list only contains therapeutic equivalence evaluations for approved multisource prescription drug products.

The listing of therapeutic equivalence evaluations in this publication are not official FDA actions, and does not affect the legal status of products.

FDA GREEN BOOK

FDA Green Book

Approved Animal and Veterinary Drug Products:

The Generic Animal Drug and Patent Restoration Act requires that each sponsor of an approved animal drug must submit to the FDA certain information regarding patents held for the animal drug or its method of use.

The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public.

This list must be updated monthly

The list, known as the "Green Book," was first published in January 1989.

Updates have been added monthly since then. Each January, the list is published in its entirety.

PHARMACY COMPOUNDING

VS

MANUFACTURING

Pharmacy Compounding vs Manufacturing

The FDA and the State Boards of Pharmacy all recognize the need for manufacturing drugs on a large scale. Because manufacturers produce large quantities of drugs that could adversely affect the health of larger numbers of citizens, the FDA requires manufactures to comply with clearly defined regulations.

These regulations require manufactures to prove a new drug is safe and effective before marketing it to the public.

Additionally, the FDA inspects manufacturers to make sure they comply with the strict quality standards of the Current Good Manufacturing Practices (cGMP).

Pharmacy Compounding vs Manufacturing (cont)

A problem may exist when a compounding pharmacy produces large batch quantities of a drug, because this also may affect the health of a large number of citizens and may be considered to be manufacturing by the FDA.

A pharmacy may not sell compounded products to other health care entities.

At what point does the pharmacy become a manufacturer (according to the FDA) and be required to comply with all Federal and State regulations regarding manufacturers?

Pharmacy Compounding vs Manufacturing (cont)

A drug product may be compounded if:

1. The pharmacist uses bulk drug substances that comply with USP standards AND complies with USP Chapter 795 regulations

2. It is compounded by a FDA registered establishment
   --- Pharmacies do not have to register – *depending on quantity

3. The product is not commercially available or is not available in the prescribed strength or dosage form

4. The product has not been shown to present adverse effects on safety or effectiveness

**The compounded products dispensed do not exceed 5% of the total prescription volume for the pharmacy

Pharmacy Compounding vs Manufacturing (cont)

The U.S. Department of Health and Human Services has identified several mitigating factors that make compounding illegal. The following circumstances exceed the boundaries of traditional compounding and may warrant FDA enforcement action:

- Violating the triad of care
  - Medication is compounded without the prescribing physician's specific Authorization

- Compounding mass quantities of drug products before receipt of a prescription and intended for large numbers of patients (considered manufacturing)

- Compounding commercially available drug products

- Receiving, storing, or using drug components that do not meet compendia requirements (i.e. sterility)

- Using an FDA unapproved drug

Pharmacy Compounding vs Manufacturing (cont)

The definition does allow the pharmacist to prepare a product for "anticipatory compounding".

Anticipatory compounding is defined as a pharmacist preparing a batched compounded product based on routine, regularly observed prescribing patterns of a prescriber.

All compounding pharmacies should be accredited (voluntary at this time).

Accreditation does provide evidence that standards based on proven quality are utilized.

Compounding pharmacy accreditation may be provided by:

Pharmacy Compounding Accreditation Board (PCAB)

CDS REQUIREMENTS

New Pharmacy DEA Registration

Every pharmacy that intends to carry and dispense a controlled substance must be registered with the DEA via a DEA Form 224

Must be maintained at the registered location

Must be available for inspection

Must be renewed every 3 years utilizing DEA Form 224a

- Chains may submit one DEA Form 224b instead of being required to submit a form for each individual location

New Pharmacy Application (cont)

Once registered, a pharmacy must notify DEA of:

- Change of business address
- Closure
- Transfer of business

DEA may deny, suspend or revoke a DEA registration if it has been determined that the registrant:

1. Falsified the application
2. Has been convicted of a felony relating to a CDS
3. Has had a state license suspended, revoked or denied
4. Has committed any act which would render possession of a DEA registration inconsistent with the public welfare
5. Has been excluded from participation in the Medicare or Medicaid program

Controlled Substance Record Keeping Requirements

The following records should be maintained at the registrant's location (at address identified on the registration):

- Executed CII order forms-[222s] (as well as unused and voided forms)

- Inventory records (must be kept a minimum of two years from date of record)

- Drug dispensing records (must be kept a minimum of two years from the date of record)

Inventory Requirements for Controlled Substance Registrants

Each person registered to handle Controlled Substances must maintain a CDS Biennial Inventory. The inventory should be:

Maintained at the registered location.

Available for 2 years after the substance is used or is disposed.

Repeated every 2 years (annually recommended)

Updated on the effective date of a new substance being added ***

Inventory Requirements for Controlled Substance Registrants (cont)

The inventory should contain the following information:

For Schedule II Controlled Substances: An exact count of the dosage units must be made.

Schedule II substances must be separated from other substances on the inventory.

The inventory must include the following:

Name, address, and DEA registration number;

Date the inventory was taken and whether it was at the beginning or end of the business day;

Name of controlled substance;

The form of the substance (i.e., tab, cap, ml);

The number of units or volume of each commercial container;

The number of commercial containers of each substance form;

If generic, name of manufacturer;

Signature of preparer and date of inventory on form.

Inventory Requirements for Controlled Substance Registrants (cont)

For Schedule III - V Controlled Substances:

Counts of the dosage units may be estimated unless the container has 1000 or more dosage units

If the container does contain 1000 or more dosage units, then an exact count must be made

Transfer (Sale) of Controlled Substances (cont)

A pharmacy may hire an outside firm to inventory, package and arrange for the transfer of its CDS

The pharmacy is responsible for the actual transfer of the CDS and for the accuracy of the inventory and records

Schedule II CDS must be transferred via a DEA Form 222 (or the electronic equivalent)

In the case of a lost or stolen DEA Form 222, the pharmacist must:

- Complete a second order form
- Prepare a statement which includes the lost form's serial number and date of order to accompany the second order
- Sign a verification statement that the first order was never received and attach that to the second order
- Notify the DEA Diversion Field Office of the serial number of the lost form(s)

Transfer (Sale) of Controlled Substances

Pharmacies may only receive or transfer controlled substances via an invoice (considered a "record of transfer"- required by CSA).

Records of transfer must contain:

Name of CDS, dosage form, strength, number of dosage units per container and the number of containers

Date of transfer, date of receipt, name, address and registration number of the supplier and receiver

Transfer (Sale) of Controlled Substances (cont)

Schedule II – Schedule V CDS:

Invoice serves as record of transfer.

Invoice must accompany the CDS through all phases of the shipping process.

Failure to possess the invoice may result in a charge of illegal possession.

Recognized Methods of Distributing Controlled Substances

Manufacturer to pharmacy

Manufacturer to wholesaler to pharmacy

Manufacturer to warehouse to pharmacy

Pharmacy to patient via Rx

Pharmacy return to supplier

Pharmacy transfer to another pharmacy

Pharmacy sale to physician office

Pharmacy return to reverse distributor for destruction

Transfer (Sale) of Controlled Substances (cont)

Pharmacies may order Schedule II CDS by either of 2 methods:

1. DEA Form 222

2. CSOS

DEA Form 222

DEA Form 222s must be obtained from the registration branch of the DEA

Triplicate form:

Pharmacy (receiver) must send completed copies 1 and 2 to the supplier

Supplier keeps copy 1 (brown)

Supplier forwards copy 2 to the DEA (green)

Must be forwarded to DEA by the end of the month of final shipment (allows for initial partial shipment)

Pharmacy (receiver) keeps 3rd copy (blue)

May only be used to order CII medications

A diagonal line must be drawn through any unused lines

Only valid for the address listed on the DEA 222 Form

If a mistake is made by the pharmacist in filling out the form, the supplier must void the entire form, and require the pharmacy to submit an entire new form

DEA Form 222 (cont)

On receipt of a Schedule II shipment, the receiving pharmacist must:

Sign the invoice; and

Initial each line on the pharmacy copy of the DEA Form 222

Attach the invoice to the pharmacy copy of the DEA Form 222.

File the invoice and DEA Form 222 in a separate file from other non-CDS pharmacy invoices (should be kept chronologically)

DEA Form 222

Any registrant may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Form 222 by granting a power of attorney to each individual.

The power of attorney must be signed by the same person who signed the most recent application for registration or renewal of registration as well as the individual being authorized to obtain and execute the DEA Form 222.

CSOS

Controlled Substance Ordering System

2005 - DEA proposed a final rule allowing for the electronic ordering of CDS

ALLOWS registrants to order CDS electronically and to maintain electronic records

Registrants must:

Apply to DEA and be approved for a digital certificate.

If an approved registrant resigns or is fired, the DEA Certification Authority must be notified within 6 hours

Sign an electronic order for a CDS with their unique digital signature issued to the purchaser by the DEA

Complete ALL blank data fields on the electronic order form

CSOS (CONT)

Digital Certificates

A digital certificate is essentially an authorized digital identity that contains information about its owner.

CSOS digital certificates, issued by the CSOS Certification Authority (CSOS CA) for electronic ordering of controlled substances, contain subscriber data used for controlled substance orders.

The CSOS CA acts as a "trusted party", meaning that others can trust that the information in your digital certificate is valid because the CSOS CA issued it after verifying your information. When placing an electronic controlled substance order, the order is "signed" with the digital certificate.

Suppliers must verify each ordering certificate with DEA before an order may be fulfilled.

CSOS (CONT)

CSOS Signing Certificates contain the following information:

- Subscriber name
- Subscriber E-mail address
- Registrant location name and location address it is registered with DEA
- Registrant DEA Number ("hashed", or encoded)
- Authorized ordering schedules
- Certificate validity period - ending when the associated DEA Registration expires

CSOS (CONT)

Advantages of CSOS:

Purchasers may order CII – CV CDS on same form

Allows for faster turn-around of orders

Allows for the possibility of ordering smaller quantities

May result in a smaller number of ordering errors

CDS PRESCRIPTIONS

Prescription Files

Pharmacies have 2 options for filing prescriptions:

1. Three (3) Separate Files
   i. Schedule II
   ii. Schedule III, IV, and V
   iii. Schedule for all non-controlled drugs

2. Two (2) Separate Files
   i. Schedule II
   ii. All other drugs

   CDS must be indicated with a red C stamp (not less than one inch high) in bottom right corner

   Red C stamp not required for electronic recordkeeping if printout of CDS Rxs capability is available

CDS Rxs – Specific Requirements

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a CDS prescription.

The determination of the validity of the prescription must be made before the prescription is dispensed.

CDS Rxs – Specific Requirements (cont)

The Federal Code of Regulations states:
"A prescription for a CDS to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice".

Thus, the responsibility for proper prescribing rests on the prescriber, BUT a **corresponding responsibility** rests with the pharmacist who fills the prescription.

Any person knowingly filling an improper prescription, as well as the person issuing it, SHALL be subject to the penalties provided for violations on law relating to CDS.

CDS Rxs – Specific Requirements (cont)

What does "corresponding responsibility" really mean?

It means that the pharmacist is also "on the hook" for the veracity of the prescription

Consequences for pharmacists who shirk this responsibility include:

- Criminal prosecution (fines, incarceration, probation)
- Civil proceedings
- Administrative actions by the Board of Pharmacy (fines, probation, suspension, practice restrictions)

CDS Rxs – Specific Requirements (cont)

To be subject to most legal penalties, the pharmacist must "be knowing" in most cases.

Two ways for a pharmacist to knowingly fill a prescription for an illegitimate purpose:

1. The pharmacist know the prescription is illegitimate (e.g., the pharmacist faked the prescription and filled it).

2. The pharmacist recklessly disregards whether the prescription is for a legitimate medical purpose (aka "reckless disregard")

CDS Rxs – Specific Requirements (cont)

Some examples of prescriptions NOT for a "legitimate medical purpose":

Issuing prescriptions for CDS without a bone fide physician-patient relationship

Issuing prescriptions in exchange for sex

Issuing several prescriptions at once for a highly potent combination of CDS

Charging fees commensurate with drug dealing rateher than providing medical services

Issuing prescriptions using fraudulent names

Self-abuse of CDS by practitioners

CDS Rxs – Specific Requirements (cont)

Factors the DEA and courts may review in their decisions:

Whether the pharmacy monitors and documents the physical proximity of patients (in respect to physician's office) who present a prescription for a CDS.

Whether the patient has exhibited a history (or evidence) of "doctor shopping" or "pharmacy shopping" when seeking CDS.

Whether patients at a specific pharmacy include a disproportionate number of cash patients.

Whether the pharmacy dispenses a disproportionate number of CDS prescriptions as compared to total dispensed prescriptions.

Whether a pharmacy complies with DEA regulations pertaining to verifying legitimacy or patients and their prescriptions for CDS.

Whether a pharmacy complies with DEA regulations pertaining to record-keeping and security requirements regarding CDS and CDS prescriptions.

CDS Rxs – Specific Requirements (cont)

Arguments have been made that all a pharmacist can do is call the prescriber and seek verification of a questionable prescription.

In the case “United States vs Hayes”, the court said that verification of a prescription may not, in itself, be enough to establish that a pharmacist has met the “corresponding responsibility” doctrine in situations where the prescriptions are obviously false or not issued for a legitimate medical purpose.

CDS Rxs – Specific Requirements (cont)

The law does not require a pharmacist to dispense a prescription of doubtful, questionable or suspicious origin.

To the contrary, a pharmacist may be prosecuted for a felony & even sued civilly.

Case – East Main Street Pharmacy

East Main Street Pharmacy – 2009 – From Sept. 2005 to Feb. 2006, the pharmacy filled 6619 CDS prescriptions (4979 from Dr. Paul Volkman).

95 of filled prescriptions were for CDS

Most were filed as cash prescriptions

98% of patients did NOT live in the vicinity of the pharmacy

Most patients received prescriptions for opiods, benzodiapines, and carisoprodol

Patients received early and overlapping refills

Pharmacy made no attempt to contact other pharmacies to determine if they were filling a particular prescriber's prescriptions, or a reason why they were not

Case – East Main Street Pharmacy (cont)

DEA performed an inspection and determined that the pharmacy had violated its "corresponding responsibility" under federal regulations to not fill unlawful prescriptions.

Reasons given during the trial:

- Ample evidence showing that the pharmacy repeatedly dispensed cocktailed prescriptions for ocycodone, hydrocodone, alprazolam and carisoprodol
- No individualization of dosing by the prescribing prescriber
- Filling multiple prescriptions for the strongest formulations of hydrocodone and alprazolam
- Filling multiple requests for early dispensing of refills
- Filling & refilling prescriptions of patients and prescribers located hundreds of miles from the pharmacy
- Filled prescriptions for patients arriving in travelling groups

CDS Rxs – Specific Requirements (cont)

All prescription labels for any CDS must contain the following warning statement:

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

The pharmacist must dispense the completed CDS prescription to the patient or the patient's agent.

To provide the CDS to anyone else is considered distribution, not dispensing.

AMA Response

AMA deems “inappropriate inquiries from pharmacies to verify the medical rationale behind prescriptions, diagnoses and treatment plans to be an interference with the practice of medicine and unwarranted.”

CII PRESCRIPTIONS

CII Rxs – Specific Requirements

Must be a written prescription (not oral)!

Must be manually signed by prescriber (pen-to-paper)!

CII Rxs – Specific Requirements (cont)

Exceptions:

Faxed CII Rx – may be faxed by prescriber & filled by pharmacist as long as an original handwritten prescription is presented before actual dispensing

Faxed Rx may serve as an original for patients undergoing home infusion/IV pain therapy

Faxed Rx may serve as an original for patients in long-term-care facilities (comprehensive care)

Faxed Rx may serve as an original for patients in hospice care

CII Rxs – Specific Requirements (cont)

Exceptions (cont):

Emergency situations:

RPh may dispense an oral or faxed CII if immediate administration is necessary for the proper treatment of the patient and the prescriber can NOT provide a written Rx prior to dispensing.

In the case of a legitimate emergency, what steps must the pharmacist take in order to dispense the medication to the patient?

CII Rxs – Specific Requirements (cont)

Pharmacist MUST:

Only dispense a quantity that is sufficient to treat the patient during the emergency period (usually defined as 72 hours)

Immediately reduce the Rx to writing (must contain all necessary information except prescriber signature) and write "Authorization for Emergency Dispensing" across top of Rx

Make a "good faith" effort to ensure prescriber's identity (if not known to RPh)

Obtain the prescriber's written, signed prescription within 7 days

Attach the prescriber's written prescription to the pharmacist's written "emergency: prescription upon receipt

CII Rxs – Specific Requirements (cont)

In November 2007, DEA published a Final Rule in the Federal Register that dealt with the "Issuance of Multiple Prescriptions for Schedule II Controlled Substances"

This allowed prescribers to write 3 prescriptions (one-month supply each) for schedule II CDS at one time to be filled sequentially to maintain their patients' medications (limit the total to a 90 day supply)

Must include the earliest date on which a pharmacy may fill each prescription (**pharmacy may not fill until date indicated on the prescription)

*Unfortunately, this rule also stated that any CII prescription written by the prescriber may not be modified orally (by the prescriber talking with the pharmacist)!!

ELECTRONIC CDS PRESCRIPTIONS

Electronic CDS Prescriptions

The DEA has released its *Interim Final Rule on Electronic Prescriptions for Controlled Substances*, which went into effect on June 1, 2010.

According to the DEA, "The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically.

The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions.

Remember that all state laws regarding the prescribing and dispensing of controlled substances remain in effect; this federal rule does not preempt existing inconsistent or different state-based laws.

Electronic CDS Prescriptions (cont)

Prescribers must prove their identities with 2 of the following 3 factors to receive authentication credentials used to sign electronic CDS prescriptions:

- Password (verified & authorized)
- Token – security card (hardware option authorized and verified)
  - Must be retained by the prescriber and NOT shared by any other person
- Biometric identifier:
  - Fingerprint(s)
  - Iris scan
  - Handprint(s)
  - Facial scans

Electronic CDS Prescriptions (cont)

Federal requirements for CDS e-prescriptions:

Prescribers must transmit e-prescriptions as soon after signature as possible. Note: no requirement for when or who may transmit.

Multiple CDS prescriptions for one patient are not allowed using just one signature.

Issuing multiple CDS prescriptions for different patients using just one signature is also prohibited.

Prescriptions must remain in an electronic state – converting them to fax is NOT allowed

**Prescribers may print e-prescriptions after signature, but they MUST be labeled "copy only – not valid for dispensing". It is possible that an electronic prescription and the same paper prescription may be seen at different pharmacies.

Electronic CDS Prescriptions (cont)

Before beginning to use the technology necessary to comply with the DEA regulations, a pharmacy must have in place hardware and software that meets minimum security measures.

Generally, the technology application must be able to import, display, and store the required contents of a controlled substance prescription accurately and consistently.

The are two alternatives for obtaining this assurance.

1. Hire a third party to perform an audit on the application to determine that each of the standards is met.
2. Have the application certified by a DEA-approved certification organization.

Electronic CDS Prescriptions (cont)

The pharmacy must limit access to the technology that records the receipt, processing, and dispensing information for electronically prescribed controlled substances medication orders.

The access control may be set to use individual names or by roles, such as pharmacist, pharmacy intern, or pharmacy technician.

This control measure must also define who has permission to annotate, alter (where alteration is permitted by DEA regulations), or delete controlled substance prescription information.

CII Rxs – Specific Requirements (cont)

Once a prescription is created electronically, all records of the prescription must be retained electronically.

These records must be kept for a minimum period of two years (Maryland requirement is 5 years).

In addition, pharmacy application service providers must backup files daily.

CII Rxs – Specific Requirements (cont)

The pharmacy's system is required to run an internal audit for potential security incidents daily and generate a report of any identified problems.

If the software generates a report and, upon investigation, the person designated to administer access controls for the pharmacy determines that the issuance or records of controlled substance prescriptions has been compromised or could have been compromised, the pharmacy must be reported DEA within one business day.

In general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access.

CDS PRESCRIPTION TRANSFERS

CDS Rxs – Specific Requirements (cont)

Transfers of refills:

Must be communicated directly between 2 licensed pharmacists

Transferring pharmacist must write "VOID" on the face of the original prescription

Transferring pharmacist must record name, address and DEA registration number of the new pharmacy, name of receiving pharmacist, name of transferring pharmacist, the date of the transfer and the number of refills remaining on the prescription.

**In Maryland, a registered pharmacy technician is now allowed to give the refill as long as a licensed pharmacist receives the information.

Transfer of Refills (cont)

Receiving pharmacist must:

Write the word "transfer" on the face of the new prescription, and

Record the:

- Date of issuance of original prescription
- Original number of refills authorized on original prescription
- Date of initial dispensing, dates on any previous refills
- Number of valid refills remaining
- Original pharmacy's name, address, DEA registration number and transferring prescription number
- Name of transferring pharmacist

PARTIAL FILLS OF PRESCRIPTIONS

Federal Laws on Partially Filling a CDS Prescription

Law is silent on subject unless for a controlled drug.

Only valid for the total number of tablets authorized by the prescriber.

Schedule II:

No refills EVER !!! (even if prescriber insists)

PATIENT RETURNS OF CDS MEDICATIONS

Patient Returns of CDS Medications

May a pharmacist take back a previously dispensed CDS medication from a patient.

The DEA says NO, NEVER!!

Secure and Responsible Drug Disposal Act - 2010

Prior to this act, ultimate users could only dispose of CDS by:

- Flushing
- Discarding
- Surrender to law enforcement
- Seeking assistance from the DEA

Now – new rule says that DEA is asking for comments on allowing the pharmacist (or other legally designated individual) to take back CDS medications – for destruction only!!

- New proposal published in Federal Register in December 2012 would allow pharmacies to maintain collection receptacles for patients' return of medications

Patient Returns of CDS Medications

Next DEA Prescription Drug Take-Back Day to Take Place in April

Consumers across the country will have another opportunity to help prevent abuse and misuse of prescription drugs by disposing of any unneeded or unwanted medications during the next DEA National Prescription Drug Take-Back Day, Saturday, April 26, 2014.

On this day, from 10 AM to 2 PM, consumers may safely dispose of unwanted medications at one of thousands of collection sites coordinated by DEA and provided by law enforcement agencies and community organizations in all 50 states and United States jurisdictions.

CDS DESTRUCTION

Destruction of Unwanted CDS

Methods for a pharmacy to dispose of expired/damaged CDS:

1. Through a reverse distributor registered with DEA
   - Pharmacy responsible for actual transfer
   - Pharmacy responsible for inventory and records
   - If Schedule II CDS, the reverse distributor must issue the DEA Form 222
2. Submit a request to DEA to allow the pharmacy to destroy
   - Must submit DEA Form-41(Registrants Inventory of Drugs Surrendered) with all items itemized and identities of at least 2 individuals responsible for the destruction
   - Must submit at least 2 weeks prior to actual destruction date
   - Must wait for DEA to approve & notify the pharmacy in writing
   - Must be destroyed by 1 person and have at least 1 witness (both must be identified previously on DEA Form-41)
   - Must have confirmation from local environmental authorities that the proposed method of destruction is not associated with any hazards
   - After the destruction of the CDS, the signed copies of the completed DEA Form-41 must be mailed to the DEA

Destruction of Unwanted CDS (cont)

3. Hospitals may dispose of CDS – must follow written procedures

4. Comprehensive care facilities may dispose of CDS – must follow written procedures

   The new proposed regulations would only allow a pharmacy servicing a comprehensive care facility to maintain a collection receptacle in the facility for:

   Unused/discontinued meds

   Meds remaining after patients' deaths

Breakage/Spillage of CDS

The breakage or spillage of CDS does not constitute a “loss”.

Any recoverable CDS must be disposed of according to the preceding methods (DEA requirements).

The disposal must be reported on DEA Form 41.

Any loss in transit (including breakage) must be reported by the receiving pharmacy upon discovery by using DEA Form 106. Once the pharmacy has signed for the receipt of the shipment, it becomes the pharmacy’s responsibility for reporting any discovered shortages.

CSA VIOLATIONS

Violations Under CSA

It is unlawful for any person to knowingly or intentionally:

(1) manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit controlled substance.

(3) obtain by means of order forms issued under this statute controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

Employment Restrictions

If a person has been convicted of a CSA violation:

A pharmacy registrant may NOT employ an individual in a position allowing access to CDS that has been convicted of a felony relating to CDS or has had an application denied, revoked or surrendered for "cause".

"For cause" means any federal or state administrative, civil or criminal action relating to the individual's handling of CDS.

"Position" may mean anywhere in a pharmacy that carries any CDS

A pharmacist must be automatically reported to the Healthcare Integrity and Protection Integrity Data Bank --HIPDB (discussed later).

Employment Restrictions (cont)

Once reported to HIPDB, only the registrant may apply to the DEA administrator for a waiver or for removal from the databank listing.

Waiver requests will be thoroughly investigated by the appropriate DEA field office.

A waiver request will not even be considered unless there is a valid reason to believe that diversion is unlikely to occur.

HHS reported that, as of April 2013, approximately 51,000 individuals were excluded from any participation in federal health care programs.

IMPORTATION

Importation of Medications

The FDCA prohibits the interstate shipment (which includes importation) of unapproved new drugs.

Unapproved new drugs are any drugs, including foreign-made versions of US approved drugs, that have not been manufactured in accordance with and pursuant to a FDA approval.

Importation of Medications (cont)

A recent 2010 FDA guidance makes clear the limited circumstances for which importation of unapproved drugs for personal use may occur:

If the drug is for treatment of a serious condition for which effective treatment may not be available domestically

The drug is not considered to present an unreasonable risk

The drug is for patients continuing a treatment began in a foreign Country

The drug is for personal use only, AND

The amount of the drug does not generally exceed approximately a 3 month supply -
If the medication is for a CDS, then no more than a combined 50 dosage units is allowed (not 50 units of each CDS)

Importation of Medications (cont)

Recent advertisements in U.S. newspapers and magazines claim that Congress has made the personal importation of drugs a legal practice.

Other advertisements and certain Internet sites state that personal importation of up to a 90-day supply of prescription medications is legal.

Neither of these claims is true

Importation of Medications (cont)

FDA statements:

1. From a public health standpoint, importing prescription drugs for personal use is a potentially dangerous practice.

2. The FDA and the public have no assurance that unapproved products are effective or safe, or have been produced under U.S. good manufacturing practices.

3. Therefore, unapproved drugs may be contaminated, subpotent, superpotent, or counterfeit.

4. In addition, some websites based outside the U.S. offer to dispense prescription drugs without a prescription by a licensed practitioner or a physical examination, bypassing the traditional doctor-patient relationship.

5. As a result, patients may receive inappropriate medications due to misdiagnoses, or

6. They may take a product that could be harmful, or fatal, if taken in combination with other medicines they might be taking.

Re-importation of Drugs (cont)

The Canadian government has also clarified its position: "Canada cannot be responsible for the safety of products exported to U.S. customers".

While Canada regulates its domestic supply, it does not regulate exported drugs.

A recent NABP study on Canadian internet sites found that 95% of the sites that included Canada, or Canadian, in their sites' names were not even located in Canada. Most were from South Africa, India and China.

Re-importation of Drugs (cont)

Disturbing Facts on Drugs:

- 40% of U.S. drug products are manufactured in other countries
- 80% of active ingredients are imported from other countries

In developed countries, less than 1% of drugs are counterfeit

In other countries, 40% – 50% are counterfeit

New organized crime target – counterfeit drugs

- Almost no jail time
- Relatively small fines
- Huge markup >5000%

REMS

REMS

REMS = Risk Evaluation and Mitigation Strategies

FDA program

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

Manufacturers must report all serious adverse events associated with their FDA identified medication(s) through the FDA's MedWatch program as well as through the FDA's approval processes.

Serious adverse event means:

> If, after receiving any dose of medication, the patient experiences a life-threatening event or dies.

MEDWATCH (CONT)

The reporting of adverse events through the MedWatch program is:

- Mandatory for manufacturers
- Voluntary for all others

The program has been so successful that FDA is currently receiving approximately ½ million reports of health problems associated with FDA approved medications yearly:

- 40% reported that hospitalization was necessary
- 15% reported a death

MedWatch (cont)

As of July 2009, pharmacies must provide all patients with the following statement:

> Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

This written notification may occur:

- On a sticker attached to the prescription package
- On a preprinted vial cap
- On a separate sheet of paper
- In patient medication information distributed by the pharmacy
- In a MedGuide

MedWatch

Reporting of adverse events for medications:

- FDA's MedWatch
  - Healthcare professionals
  - Consumers
  - 1-800-332-1088 or www.fda.gov/Safety/MedWatch
- FDA's Adverse Event Reporting System (AERS)
  - Database of adverse events dating back to 1969

MedWatch (cont)

In general, CDER considers postmarket safety issues to be significant if they have the potential to lead to any of the following actions:

- Withdrawal of an approved drug from the market.
- Withdrawal of an approved indication.
- Limitations of a use in a specific population or subpopulation.
- Additions or modifications to the Contraindications or Warnings and Precautions sections of the labeling, to the Medication Guide or other required Patient Package Insert
- Establishment of or changes to the proprietary name/container label/labeling/packaging to reduce the likelihood of medication errors.
- Establishment or modification of a risk evaluation and mitigation strategy (REMS).
- A requirement that a sponsor conduct a safety-related postmarket clinical trial or observational epidemiological study.

REMS (CONT)

Components of REMS:

RiskMAPS

ETASUs (Elements To Assure Safe Use)

RISKMAPS

Ongoing evaluations of drug safety risks

May allow some medications to remain on the market despite having shown serious adverse events.

Examples:

- Clozapine
- Thalidomide
- Isotretinoin

ETASUs

Elements To Assure Safe Use

- Prescriber certification
- Dispensing only to specially certified hospitals or offices
- Pharmacy certification
- Patient enrollment
- Healthcare provider training
- Requiring of patient medication guides and/or patient package inserts

ETASUs (cont)

Examples of medications requiring some form of ETASU as December 2010:

- Tracleer
- Aranesp
- Epogen/Procrit
- Exalgo
- Ocycontin CR
- Byetta
- Simponi
- Remicade
- Victoza

REMs (cont)

Manufacturers must provide the FDA with a plan to carry out the REMs, including ETASUs, for their product.

Manufacturers must maintain a secure database to ensure that:

Audits ensure compliance with all requirements

REMs reporting timetables are met at:

- 18 months after initial approval
- 3 years
- 7 years
- FDA may require more frequent monitoring, depending of the seriousness of potential risks

REMS (CONT)

Each time one of the drugs subject to the REMS is dispensed, pharmacists would be required to provide the patient with a medication guide explaining the safe use, storage and disposal of the medication.

	Guide must be given at patient's or agent's request	Guide must be given each time the drug is dispensed	Guide must be given only at time of first dispensing
Inpatient	Yes	No	No
Outpatient	Yes	Yes	Yes

REMS (CONT)

There may be further restrictions, such as only allowing certain enrolled pharmacies to dispense substances requiring REMS. Those pharmacies are required to undergo specialized training (usually annually).

The REMS program is rapidly being expanded to new medications.

More older medications with substantial documented problems are being added to the REMS program.

REMS (CONT)

FDA introduces new safety measures for extended-release and long-acting opioid medications – 2012

The U.S. Food and Drug Administration approved a (REMS) for extended-release (ER) and long-acting (LA) opioids.The opioid REMS is part of a federal initiative to address the prescription drug abuse, misuse, and overdose epidemic.

Manufacturers will be required to train prescribers by making educational programs available to prescribers based on an FDA Blueprint.

Requires companies to make available FDA-approved patient medication guides on the safe use of these drugs.

The companies will also be required to perform periodic assessments of the implementation of the opiod REMS and the success of the program in meeting its goals.

REMS (CONT)

Pharmacy implications –

Only certain pharmacies may be licensed to carry/dispense certain REMS medications.

More and more drugs will require pharmacists to dispense mandatory medication guides

The REMS program will provide an opportunity for prescribers and pharmacists to learn more about potential dangers associated with REMS medications.

The impact of REMS will probably become a major source of additional liability for pharmacists in the event of a serious adverse event occurring.

FDA SENTINEL INITIATIVE

FDA Sentinel Initiative

A national electronic system will transform FDA's ability to track the safety of drugs, biologics, medical devices--and ultimately all FDA-regulated products once they reach the market. Launched in May 2008 by FDA, the Sentinel Initiative aims to develop and implement a proactive system that will complement existing systems that the Agency has in place to track reports of adverse events linked to the use of its regulated products.

Monitoring the safety of its regulated products is a major part of FDA's mission to protect public health. The Sentinel System should enable FDA to actively query diverse automated healthcare data holders—like electronic health record systems, administrative and insurance claims databases, and registries—to evaluate possible medical product safety issues quickly and securely.

Data will continue to be managed by its owners, and questions will be sent to participating data holders. Within pre-established privacy and security safeguards, these data holders will evaluate the information and send summary results to FDA.

Data is expected to more quickly identify drug abuse trends.

SECURE AND RESPONSIBLE DRUG DISPOSAL ACT of 2010

Secure and Responsible Drug Disposal Act of 2010

The law amends the Controlled Substances Act to give the Attorney General authority to promulgate regulations to allow patients to deliver unused prescription controlled substances "to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion."

The law also allows for the authorization of controlled substance disposal by pharmacies servicing long-term health care facilities on behalf of patients.

Secure and Responsible Drug Disposal Act of 2010 (cont)

3 main points for ultimate user disposal:

1. Take-back events
2. Mail-back programs
3. Collection receptacles

Secure and Responsible Drug Disposal Act of 2010 (cont)

1. Take-back Events

   Primarily law enforcement

   Some pharmacy involvement

2. Mail-back programs

   Authorizes certain registrants to hold take-back events or programs and mail-back donated medications to "collectors"

   - Law enforcement agencies
   - Manufacturers
   - Distributors (reverse distributors)
   - Retail pharmacies

   Must provide an approved procedure for the tracking and auditing of returnable liners and packages containing CDS.

Secure and Responsible Drug Disposal Act of 2010 (cont)

3. Collection receptacles

Law enforcement agencies

Retail pharmacies

Retail pharmacies servicing a comprehensive care facility may maintain collection receptacles at the long-term care facilities.

The long-term care facilities are permitted to dispose of controlled substances on behalf of an ultimate user that resides or has resided at that facility (only through a collection receptacle maintained by a retail pharmacy)

**Once medications are deposited in a collection receptacle, they may not be opened, inventoried, or otherwise inspected.

Secure and Responsible Drug Disposal Act of 2010 (cont)

Authorized collectors must utilize an on-site method of destruction.

The method of destruction must render the CDS into an irretrievable state.

- Flushing – not allowed
- Mixing with coffee grounds or kitty litter not allowed

- Allowed methods:
  - Chemical digestion
  - Incineration

RESTRICTIVE DISTRIBUTON SYSTEMS

RESTRICTIVE DISTRIBUTON SYSTEMS

iPledge

CSAT

Methadone

Suboxone

REMS

ACCUTANE

Requirements for Accutane

High potential for birth defects

SMART - (System to Manage Accutane Related Teratogenicity)

"iPLEDGE"

Wholesalers must register

Prescribers must register

Pharmacies must register

Requirements for Accutane (cont)

Patients must meet certain requirements before being qualified to receive medication.

Requirements of the iPledge program includes:

- Using two methods of contraception or practicing 100% abstinence during treatment,
- Having negative pregnancy tests each month (for women of childbearing potential),
- Seeing your doctor monthly, and
- Submitting to regular blood tests as needed

Patients who qualify receive an iPledge card with an identification number. They must have this number each time they pick up their medication.

Requirements for Accutane (cont)

The pharmacist filling an Accutane prescription must verify through the iPledge system website (or over the phone) that all criteria has been met.

The pharmacist must obtain authorization before filling the medication.

The iPledge program also requires the patient's prescription be picked up within 7 days.

Opioid (Narcotic) Addiction Treatment Programs

Opioid (Narcotic) Addiction Treatment Programs

The Drug Addiction Treatment Act of 2000 (DATA 2000)

Permits physicians who meet certain qualifications to treat opioid addiction with Schedule II, III, IV, and V narcotic medications that have been specifically approved by the Food and Drug Administration for that indication.

Requires the approval and certification by the Center for Substance Abuse Treatment (CSAT), as well as the applicable state methadone authority.

Opioid (Narcotic) Addiction Treatment Programs (cont)

If a practitioner wishes to prescribe or dispense Suboxone or Subutex, the practitioner must request a waiver from CSAT.

Approved and certified practitioners are then referred to as DATA-waived practitioners.

DATA-waived practitioners may only treat 30 (individually) to 100 (group practice) patients at one time.

- After 1 year, an individual practitioner may request a waiver allowing him to treat up to 100 patients

DATA waived practitioners are issued an unique physician's prescribing number beginning with "X" which must be included on each prescription. (DEA number must also be present).

METHADONE

Methadone

An authorized provider may not dispense methadone for maintenance, directly or by prescription, unless:

(1) the authorized provider is associated with a controlled drug therapy program authorized by the Alcohol and Drug Abuse Administration of the Department; or

(2) an emergency or medical situation exists under regulations that the Department adopts.

SUBOXONE

Requirements for Suboxone

Physicians must hold a current State medical license, a valid DEA registration number, and must meet one or more of the following conditions:

- The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- The physician holds an addiction certification from the American Society of Addiction Medicine.
- The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.
- The physician has completed not less than eight hours of training with respect to the treatment and management of opioid-addicted patients

Each physician is limiting to prescribing Suboxone to no more than 30 – 100 (group practice) patients - 30 patients per physician

Must notify the government of their intent to use SUBOXONE for treatment of opioid-dependent patients and be assigned a special physician's prescribing number beginning with "X“.

Requirements for Suboxone (cont)

Physicians must write their "X" DEA number on all SUBOXONE and SUBUTEX prescriptions to treat opioid dependence.

As a pharmacy student, you are most likely already well acquainted with HIPAA, as well as HIPAA compliance.

You may not be as familiar with 42 CFR Part 2. This regulation states that any patient-identifying information pertaining to treatment for substance abuse must be handled with a **greater** degree of confidentiality than patients' general medical information.

Requirements for Suboxone (cont)

Before a physician can disclose any information to a third party about a patient's treatment for substance abuse, that physician must first obtain the patient's signed consent.

Consequently, if a physician were to call in a patient's SUBOXONE prescription without first receiving the patient's signed consent to do so, that physician would be in violation.

When a physician directly transmits a SUBOXONE prescription to your pharmacy, any re-disclosure of that patient-identifying information by the pharmacy is prohibited without the patient's signed consent.

NEGLIGENCE

Errors (cont)

Medical errors are now the #1 cause of death and injury in the U.S. - (2011)

- 784,000 deaths due to medical errors
  - Heart – only 700,000
  - Cancer – only 560,000
  - Accidents – only 125,000
- 2.2 million ADRs per year
  - 450,000 occur in hospitals
  - 530,000 affect Medicare outpatients
  - 800,000 occur in comprehensive care facilities

51.5 million medical errors occur during the filling of 3 billion prescription annually

- 4 errors per 250 Rxs per pharmacy per day (2 clinically significant per week)
- Estimated – in hospitals, there is one error per patient per day

Errors (cont)

If admitted to a hospital worldwide, your chances of dying due to a medical error would be approximately 1 in 10 (1 in 300 in U.S.)

The U.S. has a much worse record for hospital deaths than Europe (approximately 3 times worse)

Intensive Care Units – most expensive and best staffed hospital component:

> Fortunately, the majority of reported error events resulted in temporary or reversible patient harm, but there was, on average, 1 potentially fatal event per day.

Errors (cont)

High Alert Drugs

ISMP list at:

www.ismp.org/Tools/highalertmedications.pdf

Sample Potential Problem Categories:

- Chemotherapy
- Electrolytes
- Narcotics
- Anticoagulants
- Insulin
- Sound-Alike/Look-Alike

Errors (cont)

Categories of mistakes:

Prescribing errors	70%
Administration errors	10%
Documentation errors	10%
Communication errors (occurring by the person calling in (or receiving) an oral Rx)	12.4%
Drug Dispensing errors	7%
Medication Monitoring errors	3%

Negligence

Negligent act

A deviation from the accepted, recognized standard of care that a health care provider ordinarily exercises in the same of similar cicumstances.

Typically the law defines negligence as follows:

Duty: The defendant owed a duty to the plaintiff (or a duty to the general public, including the plaintiff);

Breach of Duty: The defendant violated that duty;

Proximate Cause: As a result of the defendant's violation of that duty, the plaintiff suffered injury; and

Injury: The plaintiff suffered an injury which was a reasonably foreseeable consequence of the defendant's action or inaction.

Negligence (cont)

Common defenses against negligence:

Release - The plaintiff signed a release agreement

Contributory Negligence - This rule holds that where a plaintiff contributes in any way to the cause of his or her own injury, the plaintiff's cause of action is barred.

NEGLIGENCE (CONT)

Maryland is currently one (1) of five (5) U.S. jurisdictions that still apply "contributory negligence" as a defense. Under Maryland case law, a plaintiff's contributory negligence totally precludes any recovery for damages.

A current Maryland Court of Appeals case, *Coleman vs Soccer Association of Columbia ,et al.*, may abolish this & substitute a system of "comparative fault" - same as most U.S. jurisdictions.

"Comparative fault" would essentially hold each party responsible for damages in proportion to the individual party's fault.

Types of Negligence Damages

Court negligence damages awards:

1. Compensatory Damages
2. Punitive Damages
3. Nominal Damages
4. Court Costs and Attorney's Fees

Negligence Damages (cont)

Compensatory Damages

There are two basic types of compensatory damages: actual and general.

Actual damages reimburse an individual for funds paid out-of-pocket for medical treatments, lost wages, substitute transportation, property replacement or repair, and rehabilitation.

General damages include estimates of loss not involving actual monetary expenditure. Mental anguish, disfigurement, future medical expenses, future lost wages, long-term pain and suffering, loss of consortium, and loss of opportunity are some examples.

Punitive Damages

Punitive damages are meant to punish a defendant for acts of gross negligence or intentional misconduct that cause personal injury to the plaintiff.

They are not calculated by the extent of the actual injury, but rather are meant to prevent the defendant, or others in similar situations, from allowing the same sort of incident to happen in the future.

Negligence Damages (cont)

Nominal Damage

In a case where the evidence of actual damages is slight, the courts may still choose to award the plaintiff a small sum of money to acknowledge that he or she was legally wronged by the defendant.

These nominal damages may only be sought in intentional tort cases where a physical injury to the plaintiff is not required for a defendant to be found guilty.

Court Costs and Attorney's Fees

If a personal injury case is settled in favor of the plaintiff, he or she may also have recourse to recover some of the expenses of taking the case to court.

These court costs could include filing and process server fees, obtaining deposition and court transcripts, payment to translators and attorney and expert witness fees.

Duty to Warn

Traditionally

Learned Intermediary Doctrine - The prescribing physician is in the best position to warn patients of dosages, side effects, etc.

Pharmacists - No Duty to Warn

Duty to Warn

Modern Trend

- Pharmacist may have expanded "duty to warn"

- Specific knowledge about a potential danger
  - Patient interactions
  - Computer information & claims
    - Allergies
    - Interactions
    - Patient histories
- Clear error on face of prescription
  - Overdosages
- Voluntarily assuming a duty to advise patients about their medications (also - companies may advertise that their computer system will prevent mishaps/errors)
  - Wrong information
  - Incomplete information
  - Failure to ward about known side effects

Liability Insurance

Should you have an individual pharmacist liability insurance policy?
???????????

Keep in mind that almost every liability policy includes language similar to:

"…policy does not pay for damages arising out of a willful violation of a regulation or statute relating to pharmacy services, or any violation of a criminal or penal statute or criminal act"

"…policy does not pay for damages or injuries arising out of the insured rendering or failure to render professional health care services"

QUESTIONS??