The “Acts”

HIPAA

Health Insurance Portability & Accountability Act of 1996

HIPAA - Purpose

- To allow individuals' health information to flow through various systems to promote improved and unified health care for patients.
- Reduces costs in providing health care.

HIPAA in the Pharmacy

- In Pharmacies HIPAA requirements include:
  - Restriction on transmission of Rx data.
  - Provision of private counseling area.
  - Training employees about confidentiality.

HIPAA - PHI

- Personal Health Information (PHI) is information that can be tied to a single person.
  - Prescription #
  - Diagnosis
  - Drug name
  - Type of drug

HIPAA - PI

- Personal Information (PI) is information that can be tied to a single person, but is not necessarily health care related.
  - Name
  - Address
  - Credit card #
  - Date of birth

Why Does HIPAA Impact Us?

- We share patient information with others in the health care system.
  - Physicians offices – transmission of Rx information.
  - Insurance companies – billing of Rx.
  - Pharmacy own database of patient information.

To Whom Does HIPAA Apply in the Pharmacy?

- Everyone.
- Everyone involved in providing health care services and is privy to health and medical information is required to maintain the privacy of the individual patient.

How do we Protect HIPAA Information in the Pharmacy?

- We use validated computer systems that are coded and password protected
- We shred paper that contains patient specific information
- We destroy vials with personal identification

How do we Protect HIPAA Information in the Pharmacy?

- Verbal transactions with insurance companies require coded identifiers to the resolve the patient claim
- Patient signatures are required for release of their medical information

Situations that create risk of HIPAA violations?

- Consultation with the patient
- Loose lips
- Conversations within earshot of others

HIPAA violations

- Why We Care
  - Common sense - personal information needs to be respected
  - Civil Penalties of up to $100/failure and up to $25,000/year can be imposed
  - Criminal Penalties range from $50,000 and 1 year in prison up to $250,000 and 10 years in prison.

HIPAA

For pharmacy technicians, HIPAA means:

- Must not reveal any information on any patient outside the pharmacy.
- Follow procedures and use equipment in your pharmacy that are in place to protect PHI.
- Safeguard all PHI that you use or access, and only access PHI needed to do your job.

Combat Methamphetamine Epidemic Act

- List common ingredients used to make methamphetamine.
- Identify dangers of methamphetamine use.
- Recognize the legal requirements of the CMEA.
- Understand and be able to follow the policies and procedures involved in the sale of related products.

Combat Methamphetamine Epidemic Act

The purpose of the CMEA was to make essential raw ingredients for the clandestine production of methamphetamine unavailable.

CMEA

Ingredients

- OTC products containing
  - Ephedrine – used to treat asthma
    - Examples: Primatene tablets, Bronkaid
  - Pseudoephedrine (PSE) – in many cold and allergy medication
    - Examples: Sudafed, Advil Cough & Cold, Claritin-D

Methamphetamine

Ephedrine and PSE are used to make Methamphetamine which is:

- Highly addictive
- Relatively cheap
- Dangerous to use
- Dangerous to make, but…
- Easy to make

Methamphetamine Abuse

How is methamphetamine used?

- Inhaled
  - Respiratory (Smoked)
  - Nasal (Snorted)
- Injected
- Swallowed

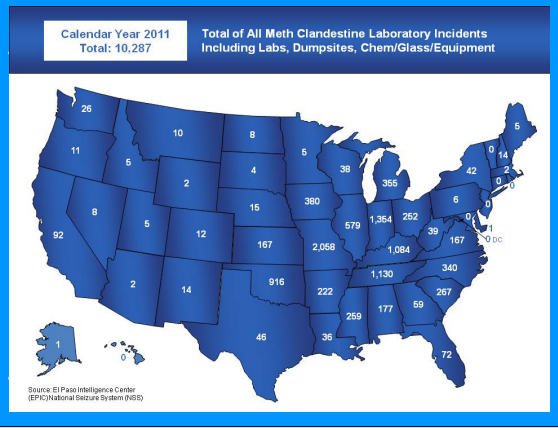
Who Abuses Meth?

Was:

- White, male, blue-collar worker, rural areas

Now:

- Very diverse groups that change over time and geographic area.
- There no longer is a “typical” user.
- In 2005 DEA made 5,870 meth arrests and seized 2,491 kg of drug.



Problems with Methamphetamine Use

- Addictive with short term use
- Users increase dose & frequency of use
- Can cause:
  - Convulsions, irregular heart rhythms, high BP, depression, tremors, fatigue, anxiety, insomnia and paranoia
- Overdose coma/death
- Deep depression can occur upon D/C

Signs of Methamphetamine Use

- ↓ appetite
- Excited speech
- HBP
- Nausea & Vomiting
- Insomnia
- Dilated pupils
- SOB
- Diarrhea
- Increased physical activity

CMEA - Requirements

- Affects product placement.
- Establishes sales limits on products.
- Requires a LOGBOOK to record sales.
- Establishes identification requirements for purchase.

CMEA – Product Placement

- Requires that ALL cold and allergy medication containing these ingredients must be kept in a location where customers do not have direct access.
- Frequently there are tags in the cold and allergy isles that the patient can bring to the pharmacy to request the product.
- Products must be packaged in blister packs

CMEA – Limits on Sale

- Daily sales limit of PSE – 3,600 mg per day
  - Not per sale, but per day
- Monthly sales limit – 9,000 mg per 30 days
  - But not on the same day
- This for the BASE drug.

CMEA – Limits on Daily Sale

Ingredient	Number of tablets = 3,600 mg
25 mg. Ephedrine HCl	175 tablets
25 mg. Ephedrine Sulfate	186 tablets
30 mg Pseudoephedrine HCl	146 tablets
60 mg Pseudoephedrine HCl	73 tablets
120 mg Pseudoephedrine HCl	36 tablets
30 mg Pseudoephedrine Sulfate	155 tablets
60 mg Pseudoephedrine Sulfate	77 tablets
120 mg Pseudoephedrine Sulfate	38 tablets
240 mg Pseudoephedrine Sulfate	19 tablets

CMEA – 30 Day Limits on Sale

Ingredient	Number of tablets = 9,000 mg
25 mg. Ephedrine HCl	439 tablets
25 mg. Ephedrine Sulfate	466 tablets
30 mg Pseudoephedrine HCl	366 tablets
60 mg Pseudoephedrine HCl	183 tablets
120 mg Pseudoephedrine HCl	91 tablets
30 mg Pseudoephedrine Sulfate	389 tablets
60 mg Pseudoephedrine Sulfate	194 tablets
120 mg Pseudoephedrine Sulfate	97 tablets
240 mg Pseudoephedrine Sulfate	48 tablets

Pseudoephedrine Sulfate Calculation

Pseudoephedrine Sulfate 30 mg

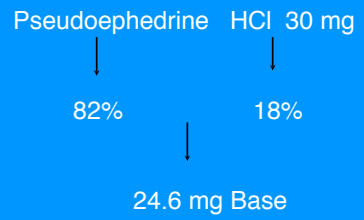
↓ ↓

77% 23%

↓

23.2 mg Base

Pseudoephedrine HCl Calculation



CMEA – Logbook

- Seller must maintain a written or electronic list of sales of these compounds
  - Product name
  - Quantity sold
  - Name and address of purchaser
  - Date and time of the sale
- Purchaser must present a government issued photo ID at the time of purchase
  - ID must be for the person making the purchase
  - Drivers license, passport, State ID, US Military ID

CMEA – Logbook

Exceptions:

- Purchases of < 60 mg of PSE do not require an ID or registration in a logbook.
- This applies to PSE only.

CMEA – Summary

- Sale of PSE restricted to 3.6 g/day or 9.0 g/30 days.
- If my mail order or mobile unit, the limit is 7.5 g/ 30 days.
- There is no age restriction.
- Product cannot be directly accessed by customer.
- ID must be provided before the sale.
- A logbook of sales must be maintained with specified information recorded.

CMEA – Logbook

- Logbook must be maintained for 2 years after the sale.
- Logbook information may be shared with law enforcement.
- Logbook may be used in the event of a product recall.

Fraud, Waste & Abuse

Fraud, Waste & Abuse

- It is estimated that 3 – 10% of health care spending is lost due to fraud. That is between $67B and $230B annually lost due to FWA.
- This figure will grow as our health care spending grows.
- It effects everyone.
- Healthcare fraud is believed to be the second largest white-collar crime in the US.

FWA - Fraud

- Acting in a dishonest manner with the intent to obtain a benefit for service to which you know you are not entitled.
- Example: Pharmacist billing insurance AND the patient for the same prescription.

FWA - Waste

- Behavior or conduct that results in the use of more resources than needed.
- Example: Prescribing a medication for 30 days with a refill when it is unlikely to be needed for that period of time.

FWA - Abuse

- Inappropriately taking advantage of the Medicare Part D program for personal benefit.
- Example: Billing for services that are not necessary or are not standard of care.

The False Claims Act

- Prohibits persons from knowingly submitting false claims or records in order to obtain payment from the government.
- Potential penalties for violation:
  - Fines of up to $11,000 per false claim
  - Treble damages.
  - Exclusion from participation in federal health programs.

The Anti-Kickback Statute

- This prohibits anyone from offering inducements to purchase or use health products or services if they are reimbursable by the federal government.
- Potential penalties for violation:
  - Exclusion from participation in federal healthcare programs.
  - Criminal penalty of fines of up to $25,000; and/or imprisonment of up to 5 years.
  - Civil penalty of up to $50,000 per act plus treble damages.

FWA - Risks

Everyone involved in the administration of Medicare benefits is capable of engaging in fraudulent, wasteful, or abusive activities.

FWA – Pharmacy Risks

- Inappropriate billing practices
  - Billing multiple payers.
  - Billing for brand when dispensing generics.
  - Billing for prescriptions that are never picked up.
  - Billing more than dispensed.
- Kickbacks, including remuneration schemes that induce or reward the pharmacy to steer patients to certain drugs or plans.

FWA – Pharmacy Risks

- Diverting drugs
- Prescription drug shorting
- Prescription forging or altering
- Dispensing expired or adulterated drugs
- Splitting prescriptions to enhance dispensing fees
- Failure to follow refill instructions

FWA - Manufacturers

- Illegal off-label promotion
- Illegal usage of free samples
- Inadequate or inappropriate documentation of pricing and reimbursement information
- Inappropriate marketing, product promotion, discounts, grants, support services, or other remuneration
- Inappropriate relationships with formulary committee members or payments to pharmacy benefit managers

FWA - Beneficiary

- Misrepresentation of coverage status, health status, or identity
- Identity theft
- Prescription forging, altering, theft of DEA number or prescribing pad
- Prescription diversion and inappropriate use
- Stockpiling of prescription drugs
- Concealing other coverage
- Obtaining medically unnecessary services
- Submitting false claims

Poison Prevention Packaging Act 1970

PPPA - 1970

- It was well established that medications and household products accounted for a significant number of poisonings and deaths in young children each year.
- At one point about 500 deaths annually in children under 5 due to drugs and household products.

PPPA - 1970

- Earlier attempts failed to remedy the problem.
  - Hazardous product labels
  - Awareness campaigns
  - Reduction of the # children's ASA tablets to 36 in a single bottle.

PPPA - 1970

- At this time one manufacturer was using a safety closure bottle and made data available for review.
- Two pilot studies using “safety” caps as a barrier were performed.
  - US study reduced unintentional ingestions from 210 to 27.
  - Canadian study demonstrated similar results.

PPPA - 1970

- Barriers were tested on children and adults
  - Given 5 minutes – 80% of 200 children 42 to 51 months old should NOT be able to open the bottle
  - Given 5 minutes – 90% of 100 adults 18 – 45 years old should BE able to open the bottle.
- CPSC – Consumer Product Safety Commission was made responsible for this in 1973.

PPPA - 1970

- In 1986 the CPSC realized that children were increasing being poisoned by their grandparent's drugs.
- Because older patients had difficulty with the closures, they left bottles loosely closed or open.
- Testing procedures were amended to have adults aged 50 – 70 as the test subjects for closures.

PPPA - 1970

- What does all of this mean for the Pharmacy Technician?
  - One of the intake questions you will ask is, "Do you want safety or Non-Safety Closures"?
  - On every prescription filled, you will need to note what type of closure should be used.

PPPA - 1970

Substances covered by the regulations

- Aspirin
- Prescription medications
- OTC drugs
- Iron containing drugs
- Tylenol (acetaminophen)
- Benadryl
- Advil/Motrin
- Furniture polish
- Solvents – turpentine, methanol, paint thinners
- Acids
- Permanent wave neutralizers

PPPA - 1970

Exceptions

- SL Nitroglycerin
- Certain birth control pills
- Some hormone replacement
- Some sodium fluoride products
- Selected sizes of OTC products which bear warning labels
  - “This package for households without young children”
  - “Package Not Child-Resistant”
- Patients may elect to have ‘Non-Safety” closures

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