Pharmacy Law Overview

From Civil Liability to Criminal Prosecution
Law That Matters To Pharmacists

Robert P. Esgro, R.Ph., Esq.

Pharmacy Lawyer and Consultant

610-308-6666
Bob@PharmacyLawyer.com
Pharmacy Law Overview – From Civil Liability to Criminal Prosecution

EDUCATIONAL OBJECTIVES
At the conclusion of this program, participants will be able to:
- Review selected laws that apply to pharmacy practice.
- Gain understanding of the basic elements of a negligence claim in pharmacy malpractice.
- Understand when pharmacists actions can lead to criminal prosecution
- Identify the differences between a civil suit, criminal prosecution and pharmacy board action.
Civil Suit

Pharmacy Malpractice Negligence

Negligence – Lack of diligence or care – Failure to use reasonable care

1. **Ordinary Negligence** – Level of care or skill which is acceptable and appropriate by a reasonable prudent pharmacist under similar circumstances.

2. **Gross Negligence** – Reckless disregard or acting so recklessly that there is a lack of concern
Civil Suit

_Gross Negligence_

Examples of gross negligence would be if the pharmacist was intoxicated while on duty, a reoccurring and known problem within a hospital/chain which is not corrected, or working without a license.
Civil Suit

Plaintiff must prove each of these 4 elements to succeed

1. **Duty** to Perform in a certain way
2. **Breach of Duty** – Did do what you should have done
3. **Cause of Harm or Causation**
4. **Damages** have occurred
“Duty to Warn”

Common term in pharmacy law but what does it mean.

It means that a pharmacist has duty to warn of obvious dangers and possibly speak with the physician regarding the risks associated with a medication.
Elements of a Civil Lawsuit

**Duty** to Perform in a certain way.

Everyone makes mistakes. But how would a reasonable pharmacist have performed in a similar situation.

“Standard of Care” – Malpractice cases in some states require an expert to determine if there was a breach in the standard of care. The reasonable pharmacist. Not the most conservative or best pharmacist.
Civil Suit

Elements of a Civil Lawsuit

**Breach of Duty** – Did you do what you should have done

Did you fall below the standard of care of a reasonable pharmacist

should you have called the doctor to check an order
did you misfill
did you “blow through” a DUR contraindication, drug interaction, or high dose alert.
Civil Suit

Elements of a Civil Lawsuit

Your actions were the Cause of Harm, known as **Causation**

Even though someone was injured by a product or service, were you the cause of it?

**Hospital** – did you administer the drug, were there floor procedures violated which caused the harm?

**Nursing Home** – The wrong order was sent in, filled correctly when a resident is injured. Were you the cause?

Are you expected to know lab results before dispensing which could have prevented the injury?
Elements of a Civil Lawsuit

**Damages** must have occurred

Pharmacy Malpractice will likely see damage claims from the injured party and the spouse/significant other.

Making a mistake or breaching the duty is not enough if a patient was not injured.
Common Defenses to a Civil Suit

**Learned Intermediary Rule**

A legal term used to describe the physician's relationship with the patient. Excluding pharmaceutical companies and pharmacists

Some state courts have held that the physician is in the best position to warn patients. Therefore removing claims against other groups
Assumed Risk

Patient was well informed of the risk and understood the consequences.
Difficult to successfully use in defense.
This is where good communication with the patient and documenting helps.
Agencies with Jurisdiction over Pharmacies

State

Board of Pharmacy
Narcotic Division of State Police
Local Police
County District Attorney
Agencies with Jurisdiction over Pharmacies

*Federal*

Drug Enforcement Agency
Department of Justice
Office of Inspector General
Internal Revenue Service
State Enforcement Laws

- **Pharmacy Practice Act**
  State’s law that regulates the practice of pharmacy

- **State Controlled Substances Act**
  State version of the Federal Controlled Substances Act with more restrictions
State and Local Penalties

State and Local Police – Criminal Charges

Potential for:
- Imprisonment
- House Arrest
- Monetary Fine
- Restitution

Report sent to Board of Pharmacy and federal agencies
State and Local Penalties

Board of Pharmacy

License Revocation
License Suspension
Monetary Fine
Recovery Program
Monitoring
Limits to Practice
Federal Laws

- Controlled Substances Act
- Combat Methamphetamine Epidemic Act of 2005
- HIPAA - Heath Insurance Portability and Accountability Act of 1996
Federal Laws

**Controlled Substances Act**

*Two federal agencies involved*

1. **Dept. Health & Human Services – FDA**
   Charged with the scientific component of this act

2. **Dept. of Justice – DEA**
   Enforcement arm
Federal Laws

*Controlled Substances Act*

Be conscious:

- “fake” prescriptions
  - photo copied script then filled in details
- prescriptions prescribed for “high doses”
  - not for legitimate purpose
- Inventory reconciliation of CII and CIIIs if needed
  - especially in hospital pharmacies
Federal Laws

**Controlled Substances Act**

Protect yourself by:

- Getting to know your customers
  - even in busy pharmacies – even brief patient counseling will help

- Use your judgment in filling CSA medications
  - Don’t fill them automatically even though there is no DUR warning or dosing problem
Federal Laws

*Combat Methamphetamine Epidemic Act of 2005*

- Log book
- Valid photo id
- Vigilance is required

This is a priority area for the DEA
Be on guard for undercover enforcement.
Patients may be unwilling or difficult when as to follow the procedure.
HIPAA

HIPAA includes civil (monetary) and criminal (jail) punishments. Normally it would be easier to bring a civil case based on a violation of privacy.

Cancer clinic employee obtained patient ssn., date of birth, name and address. The information was used to obtain a fraudulent credit card.

Department of Justice handles criminal cases
Department of Health & Human Services handles civil claims
Office of Inspector General – OIG

Department of Health and Human Services is required to exclude as a result of a conviction or plea from federal programs.

For a period of ---
Other Federal Concerns

Office of Inspector General – OIG

5 years
Office of Inspector General – OIG

You can not fill prescriptions for the:
  Medicaid Program
  Medicare Program
  Tricare
You can not be employed by a hospital, nursing home or other provider or supplier that participates in Federal health care.
Other Federal Concerns

Internal Revenue Service

Income Tax Fraud

Profiting from a crime is considered income for income tax purposes.
How Can You Protect Yourself

**Civil or Criminal Protection**

1. Follow company/hospital procedures.
2. Get to know your customers.
3. Work with other pharmacists in a constructive manner.
4. Professional Liability Insurance.
5. Consider what the Reasonable Pharmacist would do.
6. When you take action, document.
7. Don’t be overzealous.
How Can You Protect Yourself

Civil or Criminal Protection

8. Follow up to DUR warnings.
9. When you take action, document.
10. Be alert on all prescriptions, but especially new ones.
11. Exceed CE requirements.
12. Review your personal habits and reconsider if needed.
That Concludes Our Presentation

Time for questions:

Robert P. Esgro, R.Ph., Esq.

610-308-6666
Bob@PharmacyLawyer.com