Legal Issues and Prescribing

Preventing Malpractice and Other Awful Experiences

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Disclosures

- I have nothing to disclose

Objectives

- Identify the source of laws regulating prescribing practice
- Name 3 most commons prescribing practices that result in legal liability
- Describe safe prescription practices regarding controlled substances
- Describe the consequences of negligent prescribing

The Basics

- 5 Rights
  - Right Patient
  - Right Drug
  - Right Dose
  - Right Route
  - Right Time

“Rights” Required of Prescribers

- Readable prescription
- Rightly informed patient

Laws You Should Know

- Federal Laws
  - DEA
- KNOW YOUR STATE LAWS
  - Who may prescribe
  - What may be prescribed
  - Controlled/noncontrolled
  - Every state regulates prescribing how to write a prescription
  - handle samples
  - Controlled substances
  - Keep abreast of changes
Legal Liability for Prescription Errors

- Negligence/Medical Malpractice
  - Large sums awarded
- Regulatory Consequences
  - Discipline
  - Loss of license
- Responsibility to third parties
  - Case Example

Prescribing Controlled Substances

- Maintain an active DEA license
- Follow Federal and State law
- Follow prescription pad requirements (Florida)

Federal Controlled Substance Prescription Requirements

- Date of Issue
- Patient’s name and address
- Practitioner’s name, address, and DEA number
- Drug name
- Drug strength
- Quantity prescribed
- Directions for use
- Number of refills
- Manual signature of prescriber

Prescription Florida Example

- Prescription pad requirements
  - Counterfeit-proof paper
  - Unique tracking ID
  - Space for DEA number
  - If electronic must use a unique tracking number
  - Must be printed (not cursive) if handwritten
  - Dated with the date the prescription is written
  - Numbers must be written out
  - thirty

Controlled Substance Proper Prescribing

- NEVER, NEVER, NEVER presign a prescription for controlled substances
- Never post date a prescription
- Know faxing and “calling in” rules
- Know controlled substance schedule number and follow correct rules

The Patient Exam and Decision-Making

- Must examine the patient in the regular course of treatment
- Must determine that the controlled substance is the best treatment and within the standard of care
- Watch for interactions and contraindications
- Assure no other source for controlled substance meds
- Document findings and rationale
- Prescribe for no longer than necessary
Legal Liability for Overdose

- Negligence
- Criminal liability

Pharmaceutical Samples

- Regulated by federal and state law
- Most laws regulate manufacturers
- Healthcare Professionals have duties and responsibilities regarding samples
  - Distribution to patients
  - Labeling and packaging responsibilities
  - Storage requirements
  - Logs for intake and distribution

Samples: What You May Not Know

- Receipt of samples must be at the request of the health care professional (HCP)
  - Signed receipt returned to the representative
- Out of date samples must be returned to the manufacturer

After Hours Prescribing

- Know the patient
- Know the medications patient is taking
- Ask or know allergy information
- When covering for another provider have an agreement regarding patient prescribing
  - Categories of drugs prescribed
  - Whether controlled substances will be allowed

"Calling In" Prescriptions

- Limit calls to only when necessary
- Have a policy and procedure in place
- Only you or only a knowledgeable staff member should call in a prescription
- Ask for read back to assure that there is an understanding of the correct medication

Refills and Repeat Prescriptions

- Have a policy and procedure in place
  - Implement it
  - Stick to it
- Identify staff with appropriate skills and education to communicate with patients
- Have only prescribing practitioners authorize the refills
- Have defined limits for refills
Refills and Repeat Prescriptions

- Assure staff gets all necessary information
  - Changes in medical conditions
  - New medications from other providers
  - Newly identified allergies
  - Recent laboratory studies
- Assure proper in office in person follow-up
- Identify medications requiring special attention
  - Coumadin
  - Controlled substances

Prescribing for Self, Friends and Family

- Don’t do it!
- Never for controlled substances
- Exceptions
  - Emergency situations
  - When no other alternative is available and delay in providing the medication will cause an adverse clinical reaction
  - Create a medical record

Off Label Prescribing

- Medication is being used in a manner not specified in the FDAs approved packaging label.
- Not illegal to prescribe for off label use
- Estimates 20-60% of all prescriptions written are for off label therapies
- Often represents the “standard of care”

Most Common Off-Label Prescribing

- Pediatric drugs
  - Lack of FDA studies to prescribe for children
  - Studies likely never to be done
- When prescribing off-label for pediatrics consider
  - Whether the drug has been FDA approved
  - Whether the off-label use has been subjected to scientific testing and has been approved in at least 2 peer reviewed articles
  - Whether the off-label use is not experimental

Causes of Action for Off Label Prescribing

- Lack of informed consent
  - No duty to inform patient of off label use
  - Negligence/medical malpractice
    - “A physician is free to use a medical device for an off-label purpose, if, in the physician’s medical judgment, he or she believes that use of the device will benefit the patient.” Alvarez v. Smith

Guidelines for Decision-Making

- Made with the patient’s knowledge
- Motivated by desire to benefit the patient
- Based upon expert medical opinion
- Supported by peer reviewed literature
- Supported by local colleagues
Safe Practice

- Inform the patient of off label use
- Document the conversation
- Obtain informed consent
  - Written preferred
  - Oral must be documented in patient record

Summary

- Prescribing is a serious responsibility
- Know the laws and rules associated with prescribing and follow them
- Institute policies and procedures that reduce opportunities for error
- Always educate your patient
- Avoid “casual” prescribing