

Third Edition



LAW & ETHICS

FOR PHARMACY TECHNICIANS



JAHANGIR MOINI

LAW & ETHICS

for Pharmacy Technicians

THIRD EDITION

Jahangir Moini, MD, MPH, CPhT

Professor and Former Director

Allied Health Sciences

Pharmacy Technician Program
Everest University
Melbourne, Florida

Professor of Science and Health
Eastern Florida State College



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Jahangir Moini

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DEDICATION

This book is dedicated to the memory of my mother,

To my wife Hengameh,

To my daughters Mahkameh and Morvarid,

And to my precious and beautiful granddaughters,

Laila Jade and Anabelle Jasmin Mabry

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Introduction

This book is designed as a thorough overview of law and ethics in the pharmacy. It reviews federal and state laws and regulations that affect pharmacy technicians, pharmacy students, pharmacists, and other pharmacy employees. Special attention is paid to the Controlled Substances Act and the resultant activities of the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA). The text emphasizes the importance of ensuring that each patient receives the highest quality care possible. It is the responsibility of all pharmacy staff members to assist the pharmacist in respecting the rights of every patient and in providing services that strictly adhere to federal and state laws, as well as to the ethical standards of the industry.

Organization of Content

This book consists of two parts: General Introduction and Appendices. Part I is divided into three sections, and further divided into ten chapters that focus on the foundation of law and ethics, federal laws, and state laws affecting pharmacy practice. Part II contains seven appendices (SEE NOTE ABOVE FOR BETH ABOUT MY ADDING A NEW APPENDIX FOR THE ANSWER KEY), a glossary, and an index. The appendices cover diverse topics, including medication errors, pharmacy technician duties and tasks, state qualifications for pharmacy technicians, state boards of pharmacy, professional organizations, and the U.S. Pharmacopoeial Foundation/National Formulary.

This third edition of *Law & Ethics for Pharmacy Technicians* contains a new chapter (Chapter 5), which is entitled “Medicare and Medicaid.” This edition has been fully updated to cover new federal pharmacy legislation. Chapter 2 has new information about the Office of the Inspector General, contributory negligence, comparative negligence, professional liability, tort reform, and malpractice prevention. Chapter 3 has new information about ethical standards and behavior, as well as ethical issues and personal choice. Chapter 4 has new information about the U.S. Pharmacopeia and National Formulary, as well as the Patient Protection and Affordable Care Act.

Chapter 6 has been updated with information about practitioner self-prescribing, invalid orders, partial filling and refilling of controlled substance prescriptions, compounding or repackaging with controlled substances, exportation of controlled substances, the Methamphetamine Anti-Proliferation Act, and marijuana prescribing and dispensing. Chapter 7 has new information about altered medical records, and how HIPAA relates to pharmacies. Chapter 8 features updated objectives and National Fire Protection Association information. Chapter 10 features updated objectives and information on examination requirements.

Features

Each chapter contains an outline of the key topics, a list of key terms (which are **bolded** in the chapter text), and objectives that the student must be able to meet upon completion of the reading. Following this is a scenario relevant to each chapter, entitled “Setting the Scene,” which includes critical thinking questions to encourage deeper understanding of real-life situations. The answers to these questions are provided near the end of each chapter.

Overviews serve to introduce the student to the key concepts of each chapter. “Focus On” features highlight interesting key points of knowledge. Accurate tables focus on legal and ethical information that must be fully understood in order for the student to master each chapter’s content. Certain chapters contain figures that show legal forms and other paperwork. Chapter summaries serve to reinforce the chapter content, and focus on key ideas from the text.

At the end of each chapter, review questions are given that help students to test the knowledge they have gained from their reading. The questions are given in a variety of formats to encourage more complete comprehension, and include case study questions. Internet sites are listed after this, to provide avenues for further reference and learning beyond the text. Book references for sources used in each chapter follow.

Teaching Package to Accompany the Second Edition

A teaching package has been created for this text to aid instructors as they cover material.

Instructor Companion Website

ISBN-13: 978-1-337-79663-7

This book is accompanied by an instructor companion website with additional free resources for instructors who adopt this text for their class. Resources include the following:

- PowerPoint presentations for each chapter.
- An instructor’s manual that features lecture outlines, teaching strategies, lists of legal cases, and sources for these cases.
- A question bank of additional questions for the creation of tests and quizzes.

ABOUT THE AUTHOR



Dr. Moini was assistant professor at Tehran University School of Medicine for nine years, where he taught medical and allied health students. The author was a professor and former director (for 15 years) of allied health programs at Everest University (EU). Dr. Moini established the associate degree program for pharmacy technicians in 2000 at EU's Melbourne, Florida campus. For five years, he was also the director of the pharmacy technician program. He also established several other new allied health programs for EU, where he was for 24 years. Based on his 39 years of experience as a physician and instructor, he believes that pharmacy technicians should be skillful in various types of compounding, and be confident in the performance of their duties and responsibilities in order to prevent medication errors. Pharmacists and pharmacy technicians must obey state and federal laws, and remain up-to-date on new legislation. Therefore, he stresses the importance of law and ethics in the pharmacy to all of his students.

Dr. Moini is actively involved in teaching and helping students to prepare for service in various health professions, as pharmacy technicians, medical assistants, and nurses. He worked with the Brevard County Health Department as an epidemiologist and health educator consultant for 18 years, offering continuing education courses and keeping nurses up-to-date on the latest developments related to pharmacology, medication errors, immunizations, and other important topics. He has been an internationally published author of 25 allied health books since 1999. He is now a professor at Eastern Florida State College, teaching various subjects for allied health.



THE FOUNDATION OF LAW AND ETHICS

- CHAPTER 1** Introduction to Law
- CHAPTER 2** Principles of Liability
- CHAPTER 3** Ethics in Pharmacy Practice

SECTION



Introduction to Law

OBJECTIVES

Upon completion of this chapter, the reader should be able to:

1. Identify the punishments assessed for felonies and misdemeanors.
2. Differentiate between private law and public law.
3. Explain the role of law and ethics in pharmacy practice.
4. Differentiate between criminal law and civil law.
5. Explain tort law.
6. Describe the U.S. court system.
7. Define the terms *felony*, *malpractice*, and *negligence*.
8. Describe which criminal charges related to healthcare practices.



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KEY TERMS

Administrative law—The body of law governing the administrative agencies (e.g., Occupational Safety and Health Administration or Department of Public Health) that have been created by Congress or by state legislatures.

Appeals—Legal proceedings in which cases are brought to higher courts to review decisions of lower courts.

Contract law—A system of law that pertains to agreements between two or more parties.

Criminal law—The body of law that defines offenses against the public.

Felony—An offense punishable by death or by imprisonment in a state or federal prison for more than one year.

Jurisdiction—The power and authority given to a court to hear a case and to make a judgment.

Law—A rule of conduct or procedure established by custom, agreement, or authority.

Malpractice—Professional misconduct or demonstration of an unreasonable lack of skill, with the result of injury, loss, or damage to a patient.

Misdemeanors—Crimes punishable by fine or by imprisonment in a facility other than a prison for less than one year.

Negligence—A type of unintentional tort alleged when one may have performed or failed to perform an act that a reasonable person would or

would not have done, respectively, in similar circumstances.

Private law—The type of law that governs conflicts between private parties.

Public law—The type of law that governs conflicts between private parties and the government.

Tort—A private wrong or injury, other than a breach of contract, for which the court will provide a remedy.

SETTING THE SCENE

A patient brought a prescription to a pharmacy for a sulfa drug that was prescribed by her physician. The patient is allergic to sulfa drugs, a fact that was noted in the handwritten medical record located in the physician's office. However, the medical records assistant did not transcribe the allergy note into the computerized patient record. The pharmacy technician dispensed the drug because there was no information about the patient's sulfa drug allergy included in the computerized patient record. The technician did not ask the patient if she had any drug allergies. The pharmacist signed off on the prescription and approved the dispensing of the drug. After taking one dose of the sulfa drug, the patient had a severe allergic reaction that ultimately led to her death. The patient's family filed a civil suit against both the pharmacist and the physician for negligence.

CRITICAL THINKING

- What should the pharmacy technician have done to best benefit the patient in this situation?
- Was it appropriate for the patient's family to sue the pharmacist?
- If criminal charges were filed, what possible outcomes might affect the pharmacist, the physician, and the pharmacy technician?

Overview

As the field of pharmacy becomes more complex, understanding of pharmacy law becomes more important. The effect of state and federal government regulations and lawsuits in the field of pharmacy is greater than ever before. Pharmacy has a distinct vocabulary and a set of professional standards and regulations. Once you become familiar with the vocabulary, rules, and regulations, it enables you to understand the ideas, concepts, and structure of the job. Pharmacists and pharmacy technicians need to have a clear understanding

of the laws and regulations related to their field of practice. If these laws and regulations are not understood or not followed, its consequences to the consumer of pharmaceutical products could be life-threatening.

Role of Law

Law is generally defined as a system of principles and processes that is devised by an organized society to deal with problems and disputes without the use of force. Standards for human behavior are established by law. Conflicts emerge when standards are not met. The law is used by individuals and the government to resolve conflicts and enforce established standards.

Law includes statutes, rules, and regulations that govern people and their behaviors, relationships, and interactions with society and with state and federal governments. Law provides order for the resolution of conflicts between individuals, corporations, states, and other entities. The goal of law is to protect the health, safety, and welfare of individual citizens. Law provides guidelines for resolution of disputes in a fair and safe manner.

Although based on solid and long-held beliefs, customs, and principles, the law is always growing and evolving to meet the changes, challenges, and constantly occurring shifts in society. This can be evidenced by the history of drug laws in the United States. In the 1800s and early 1900s, there was no regulation or control over medicinal products. Any substance or product could be claimed to have health benefits or medicinal effects. As a result, contamination of products occurred, leading to injury to consumers, and potentially addictive products were distributed.

In response to these circumstances, laws such as the Pure Food and Drug Act (enacted to ensure accurate labeling and the purity of marketed foods and drugs) were passed. Some of these laws, for example, the Food, Drug, and Cosmetic Act of 1938, resulted in the establishment of agencies such as the U.S. Food and Drug Administration (FDA), which regulates food and drugs along with the labeling of their contents. As time went on, deficiencies in the existing legislation were identified and additional legislation was enacted to continue to improve pharmacological products in the United States. For instance, laws were enacted to make certain substances illegal for public use or to limit how they could be used. Fine-tuning of laws continues today as the need arises.



Focus On...

DIVISIONS OF LAW

In the United States, the legal system divides laws into three categories: criminal law, civil law, and **administrative law**. Administrative law focuses on the regulations set forth and enforced by governmental administrative agencies.

Public Law

Public law governs conflicts between private parties and the government. Sometimes, the difference between private and public law is difficult to ascertain, since certain behaviors can violate both types of law. To help understand the differences more fully, see Table 1-1.

Public law defines appropriate behaviors between individuals, organizations, and the government. The primary sources of public law are written constitutions, regulations, statutes, and decisions of administrative and judicial bodies.

CRIMINAL LAW

Criminal law is concerned with acts against society that are violations of criminal statutes or codes. It is one form of public law. Criminal laws are enforced by representatives of the state against persons or corporations. State or federal governments may impose monetary fines, imprisonment, or even death in certain circumstances for violations of criminal law. **Misdemeanors** are lesser crimes, usually punishable by fines and/or imprisonment for less than one year (e.g., traffic violations, thefts under a certain dollar amount, or attempted burglary). **Felonies** are punishable by much larger fines and imprisonment for more than one year, and in some jurisdictions, certain felonies are punishable by death. Examples of felonies are rape, murder, robbery, domestic violence, and child abuse. A *robbery* is defined as the forcible stealing of property during which a victim is physically injured, is threatened, or is put in fear of bodily injury. Many states hold that certain felony convictions are grounds for revoking licenses to practice in the healthcare field. Practice without a license, falsifying information when obtaining a license, failing to provide life support to those who are terminally ill, and patient abuse are all examples of crimes that may result in criminal prosecutions. The state or

Table 1-1 Private and Public Law

Public Law	Private Law
Administrative Law	Agency
Civil, Criminal, and Appellate Procedure	Commercial Paper
Constitutional Law	Contract Law
Criminal Law	Corporation Law
• Substantive	Intellectual Property Law
• Procedural	Partnerships
Evidence	Personal Property
Taxation	Real Property
	Sales
	Torts
	Trusts and Wills

federal government may press criminal charges against those who violate written criminal codes or statutes.

Criminal law is divided into two areas: *substantive* and *procedural* law. They are differentiated as follows:

- Substantive law defines specific offenses, general principles of liability, and specific punishments. Specific offenses include felonies and misdemeanors.
- Procedural law focuses on the steps through which a criminal case passes, from initial investigation of a crime to trial, sentencing, and the eventual release of the criminal offender.

Table 1-2 explains the differences between criminal and civil law cases.

Private Law

Private law governs conflicts between private parties. Private law is legally referred to as *civil law* since it focuses on private rights and remedies. *Civil law* is a term that may be understood more definitively however, since it is more distinctly compared to criminal law. The primary source of private law comes from court decisions, which can later be modified by regulations or statutes.

CIVIL LAW

In civil law, a plaintiff (injured party) may bring suit against an alleged defendant (wrongdoer). Most civil law cases concern either contract law or tort law. Civil wrongs are often called *torts*. A **tort** is a physical or nonphysical injury to a person by another person. The person causing the injury is legally responsible for his or her actions. The injury may be intentional or unintentional.

Most civil law cases against healthcare workers are for **malpractice** (professional misconduct or **negligence**). *Malpractice* is defined as improper discharge of professional duties or failure to



Focus On...

CRIMINAL LAW

Criminal law involves crimes against the state.

Another segment of public law consists of constitutional provisions, regulations, and statutes. It requires governmental entities and private parties to follow specific courses of action. Government regulations in this area are designed to secure compliance with the goals of law, rather than to punish offenders. Areas of criminal law include administrative, antitrust, constitutional, environmental, labor, and securities law.



What Would You Do?

Brian has had three traffic violations in the past three months. He has also been charged with domestic violence against his girlfriend. You are the pharmacist for whom Brian works, and you are aware of some of these events. One day, you hear him harassing another worker until an argument breaks out. Brian becomes very agitated. Knowing his background, what would you do in this situation?

Table 1-2 Criminal and Civil Law Case Differences

Criminal Law	Civil Law
Parties: Plaintiff is state, county, or federal government (always).	Parties: Plaintiff and defendant may be the government, corporations, or individual persons.
Punishment: Fine and imprisonment.	Punishment: The party who loses cannot be imprisoned even if unable to pay damages assessed by the court.
Source: State or federal statutes.	Source: State or federal statutes and court decisions.
Jury decision: Must be unanimous.	Jury decision: Varies from state to state; certain state courts require a majority vote by a jury in order to issue a decision, while others require a unanimous jury decision. Federal courts require a unanimous jury decision.
Burden of proof: Beyond a reasonable doubt.	Burden of proof: Preponderance of the evidence (defined as <i>more likely than not</i>).
Appeals: Only the defendant may appeal a guilty verdict.	Appeals: Either party may appeal the decision
Decision: The defendant is either guilty or not guilty—there is no <i>partial fault</i> .	Decision: The plaintiff and defendant may both be found partially right and partially at fault.

meet the *standard of care* of a professional person. *Negligence* is defined as a failure to exercise reasonable care and the omission or commission of an act that a reasonably prudent person would or would not do under given circumstances. *Gross negligence* is the reckless and wanton disregard for the standard of care and interest of others and is a criminal offense. Negligence and malpractice are discussed in detail in Chapter 2.

Penalties in civil law are almost completely monetary in nature and represent an attempt to make the injured or wronged person *whole* again. Individuals or entities may bring civil cases against other individuals or entities for harm involving contracts, labor, privacy, or tort issues. The most common torts in healthcare settings are assault, battery, defamation (libel or slander), false imprisonment, intentional infliction of emotional distress, invasion of privacy, negligence, and malpractice.

TORT LAW

Tort is a French word meaning *wrong*. Torts include assault (in general, the threat of violence), battery (contact in a manner that may cause bodily harm), fraud, libel, negligence, medical malpractice, slander, defamation, theft, trespassing, invasion of privacy, and wrongful death. *Assault* is further defined as an intentional act that causes another person to experience the apprehension of being touched in an offensive manner, or of physical harm. When assault results in physical contact, it is called *battery*. *Defamation* is defined as a false statement of fact that causes damage to a person's reputation. *Libel* is written defamation, while *slander* is spoken defamation. *Theft* is the taking of property without consent of the owner.

Tort law often results in civil lawsuits, with the injured party suing the injurer (*tortfeasor*). It is also concerned with duties and rights between parties that exist independent of contracts. Legal issues related to the control and storage of electronic health information fall under a form of civil law called *intellectual property law*.

Intentional torts are those that are committed willfully against a person or property. The offender must intend to commit the act. The injured party may seek a civil case against the person who committed the tort against him or her. Intentional torts include assault, battery, false imprisonment, fraud, libel, slander, trespassing, and invasion of privacy. Some intentional torts may also be prosecuted as crimes in separate court cases. Tort liability may be based on intent, negligence, or *strict liability*, which is the responsibility of a product manufacturer or seller for any defect that unduly threatens personal safety. For intentional torts, legal action requires a legal duty between a plaintiff and defendant, a breach of that duty, and injury that occurs as a result of the breach. Defenses that are available against accusations of intentional torts include consent, privilege, self-defense, the defense of others, and error.

Unintentional torts are those that are committed accidentally. For example, when a pharmacy technician fails to verify accurate information and a patient receives a medication that is less effective than intended, an unintentional tort has occurred. Negligence, malpractice, and product liability are examples of unintentional torts. In negligence, injury to a patient occurs because a healthcare provider has failed to exercise the degree of care required to perform an otherwise permissible action. Civil complaints are designed to *make the victim whole* by restoring whatever was his or her original position before the injury or loss.

CONTRACT LAW

Contract law pertains to agreements between two or more parties. In a contract, each of the concerned parties agrees to do (or not do) certain things. Contracts are legally binding exchanges of promises. The term *contract law* is based on the Latin phrase *pacta sunt servanda*, which means *pacts must be kept*. In contract law, an agreement (contract) sets forth promises to act (or not act) in specific ways, documents the agreement of both parties to act (or not act), and describes what each party receives from the other for performing the contractual obligations. Contracts may be oral or written and must follow applicable state and federal



You Be the Judge

Mark has been working in a retail pharmacy for 17 years. He is a senior technician and a reliable person at work. About a year ago, his wife died, causing him to become very depressed. Last week, he made a mistake while he was compounding two medications. The pharmacist found out about his failure to exercise reasonable care while working. He told Mark that this was a case of negligence and that legal action could be brought based on his error. Mark responded rudely and even pushed the pharmacist. In your judgment, what would be the possible consequences for Mark, taking his entire situation into account? What could he be accused of for being physically violent with the pharmacist?

regulations and statutes. If the terms of the contract are not fulfilled, a breach of contract occurs. The *aggrieved* party may sue to seek compensation or to force performance of the terms of the contract.

The U.S. Court System

There are several levels of courts in each state. Local courts usually deal with civil and criminal cases whose penalties do not exceed certain dollar amounts that are established by the legislature. The next level is a state court with general jurisdiction. This includes any major trial court that has broad powers. Often, cases of negligence, malpractice, elder abuse, and other civil wrongs are tried at this level. Major crimes are also prosecuted in these courts.

A court must have **jurisdiction** over any case that it tries, whether *in personam* (over the person) or *in rem* (over the thing or property). Major trial courts' jurisdiction is based on county lines or similar divisions and is exercisable over the people within those divisions.

When a trial is completed or a case is final in a court of general jurisdiction or one of the specific courts, the case may be appealed to a higher court (usually called an *appeals court*). **Appeals** may only raise issues of law that were found by the jury or judge in the previous case for review; the appeals court is asked to consider these issues as a basis for overturning the previous ruling. The decision of an appeals court is binding on all lower courts in the state if no further appeals are taken.

The top court of a state is usually called its *supreme court*, with the only recourse after that being the *United States Supreme Court*. However, the U.S. Supreme Court chooses to hear only a few cases per term, as determined by vote of at least four justices. The cases chosen are usually the most important and consequential cases that have been presented to it. Once the Supreme Court makes its decision and tries a case, the decision is binding on all state and federal courts.



Focus On...

THE SUPREME COURT

Supreme Court justices are appointed by the president of the United States and approved by the Senate. An appointment to the Supreme Court is a lifetime appointment.

Some cases may be tried in a federal district court. These courts hear cases that raise issues of federal law or those involving parties from different states with an amount in controversy that exceeds \$75,000.

The Differences Between Federal Law and State Law

Neither federal nor state courts are completely independent of each other. Many federal and state laws interact. Federal courts handle crimes under statutes that have been enacted by Congress. Table 1-3 outlines the types of cases related to pharmacy that are handled in federal and state courts.

Table 1-3 Courts Handling Specific Pharmacy-Related Cases

Federal	State	Both
Interstate and international trade/commerce cases	Cases involving state laws or regulations	Crimes that can be punished under federal or state law
Bankruptcy cases	Most private contract disputes	Class action cases
Disputes between individual states	Most trade or professional regulation cases	Environmental regulation cases
	Most professional malpractice cases	
	Most business law cases	
	Most personal injury cases	
	Most worker injury cases	

Source: Adapted from www.uscourts.gov.

Individual states have the authority to enact legislation in any area in which Congress has enacted legislation as long as no conflicts between state and federal laws are created as a result. If a conflict exists, federal law outweighs state law and must be enforced. A conflict may exist if a state law is less strict than the federal law and following the state law would be in violation of the federal law. If, however, the state law is stricter than the federal law, no conflict with the federal law exists and the state law may be followed without causing a violation of the federal law.

Summary

The practice of dispensing drugs is subject to many laws and regulations. Both state and federal laws affect the profession and practice of pharmacy. Often, a felony conviction results in revocation of the defendant’s license to practice. Pharmacy technicians must be familiar with terminology, concepts, and the structure of their jobs; this includes knowledge of the legal issues surrounding pharmacy. A pharmacy technician should understand criminal and civil law, as well as the court system of the United States. Laws that are broken in this profession are punishable by monetary fines and imprisonment.

SETTING THE SCENE

The following discussion and responses relate to the opening “Setting the Scene” scenario:

- The pharmacy technician should have double-checked with the patient to find if she had any allergies to sulfa drugs.

- It was appropriate for the patient's family to sue the pharmacist, since he has supreme responsibility for the welfare of every patient to whom he dispenses.
- If the patient's family wins this case, the pharmacist, pharmacy technician, and the physician may be at risk for additional administrative or criminal actions resulting in fines, imprisonment, and/or the loss of their licenses to practice.

REVIEW QUESTIONS

Multiple Choice

1. Which of the following is a type of punishment for a felony?
 - A. imprisonment for more than one year
 - B. large fines
 - C. death
 - D. all of the above
2. Which of the following types of court cases do local courts usually deal with?
 - A. civil law
 - B. criminal law
 - C. both A and B
 - D. capital punishment
3. Which of the following chooses to hear very few cases?
 - A. local court
 - B. state court
 - C. court of general jurisdiction
 - D. U.S. Supreme Court
4. After a trial is completed or a case is final in a court, the case may be
 - A. stopped.
 - B. waived.
 - C. appealed.
 - D. continued.
5. Which of the following is a crime that may result in criminal prosecution?
 - A. practicing without a license
 - B. falsifying information when obtaining a license
 - C. failure to provide reasonable care
 - D. all of the above

6. Which of the following levels of courts try cases of negligence, malpractice, and elder abuse?
 - A. appeals court
 - B. general jurisdiction court
 - C. state supreme court
 - D. U.S. Supreme Court
7. Supreme Court justices are appointed by the
 - A. President of the United States.
 - B. Congress.
 - C. Senate.
 - D. Attorney General.
8. A system of principles that is devised by organized society to deal with problems and disputes without the use of force is known as
 - A. morality.
 - B. law.
 - C. ethics.
 - D. jurisdiction.
9. Conflicts between private parties and the government are collectively known as
 - A. contract law.
 - B. private law.
 - C. tort law.
 - D. public law.
10. Criminal law is actually a form of which of the following types of law?
 - A. public
 - B. private
 - C. tort
 - D. contract
11. Which of the following types of crimes is punishable by imprisonment for less than one year?
 - A. felony
 - B. mitigation
 - C. misdemeanor
 - D. arbitration
12. Private law is often referred to as which of the following types of law?
 - A. tort
 - B. civil
 - C. administrative
 - D. contract

13. Which of the following correctly describes a contract?
- A. It is a voluntary agreement.
 - B. It involves a specific promise that is made.
 - C. It involves two or more parties.
 - D. All of the above are correct concerning contracts.
14. All of the following are intentional torts, except
- A. battery.
 - B. assault.
 - C. negligence.
 - D. slander.
15. The term *tort* actually means
- A. libel.
 - B. wrong.
 - C. fraud.
 - D. crime.

Matching

- A. Felony
 - B. Public Law
 - C. Criminal Law
 - D. Negligence
 - E. Misdemeanor
- _____ 1. governs conflicts between private parties and the government
- _____ 2. a failure to exercise reasonable care
- _____ 3. a lesser crime usually punishable by fines and imprisonment of less than one year
- _____ 4. punishable by much larger fines and imprisonment for more than one year
- _____ 5. concerned with violations against society

Fill in the Blank

1. Legal proceedings in which cases are brought to higher courts to review decisions of lower courts are called _____.
2. The power and authority given to a court to hear a case and to make a judgment is referred to as _____.
3. Professional misconduct involving an unreasonable lack of skill with the result of injury or damage to the patient is called _____.

4. A private wrong or injury, other than a breach of contract, for which the court will provide a remedy is known as a _____.
5. _____ law is the type of law that governs conflicts between private parties and the government.
6. _____ is a type of unintentional tort alleged when one may have performed (or failed to perform) an act that a reasonable person would (or would not) perform in similar circumstances.
7. _____ law is the type of law that governs conflicts between private parties.
8. _____ law is the body of law that defines criminal offenses against the public.
9. The top court in a state is usually called its _____.
10. Assault and battery or false imprisonment is an example of a/an _____.

CASE STUDY

The mother of a seven-month-old prematurely born infant was given a prescription for phenobarbital, which she took to her local pharmacist. A pharmacy technician, who did not have appropriate training and education to be a pharmacy technician, dispensed a strong oral expectorant medication instead of phenobarbital. Because the pharmacist was so busy, he decided not to check the medication or consult with the mother. She gave the medication to her child for about one month to prevent seizures. Because of the incorrect medication, the infant had a serious brain injury that caused a permanent disability.

1. Who is mostly responsible for this medication error?
2. What would be the consequences of severe seizures in this premature infant?
3. If a lawsuit claiming malpractice results, who may lose their jobs?



Principles of Liability

OBJECTIVES

Upon completion of this chapter, the reader should be able to:

1. Explain the theories of liability.
2. List the four elements necessary to prove negligence and explain them.
3. Explain unintentional negligence.
4. Define malpractice as it relates to pharmacy technicians.
5. Explain why liability insurance is important for pharmacy technicians.
6. Differentiate between vicarious liability and corporate negligence.
7. Compare breach of confidentiality and invasion of privacy.
8. Explain the statute of limitations.



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KEY TERMS

Affirmative defense—A defendant's defense against accused negligence, allowing the presentation of evidence that the plaintiff's condition resulted from factors other than the defendant's negligence.

Assumption of risk—A legal defense preventing a plaintiff from recovering damages if he or she voluntarily accepts a risk associated with the activity.

Comparative negligence—A defense that allows a plaintiff to recover damages based on the amount, usually a percentage, that the defendant is determined to be at fault.

Compensatory damages—Payments for actual loss of income, patient injury, and emotional pain and suffering.

Contributory negligence—Conduct by a plaintiff that is below the standard to which he or she is legally required to conform for his or her own protection.

Corporate negligence—The type of negligence that is focused on the responsibility of the healthcare organization as a whole, and not its individual employees, to provide proper patient services.

Damages—The sum of money that may be recovered in court as financial reparation for any injury or wrong suffered because of a breach of contract, tort, negligence, or medical malpractice. Damages are divided into three types: nominal, actual, and punitive.

Dereliction—A provider's failure to act as any ordinary, prudent peer would act in a similar circumstance.

Direct cause—A continuous chain of events, unbroken by any intervention, that results in an injury, and without which, the injury would not have happened.

Duty of care—An obligation to conform to a particular standard of conduct toward another.

Good Samaritan laws—Those that protect caregivers from civil liability as a result of their attempts to render emergency care.

Liable—Obligated, according to the law; legally obligated.

Malfeasance—The execution of an unlawful or improper act.

Medical malpractice—Medical professional misconduct, which differs from negligence because the tortfeasor is a licensed medical professional.

Misfeasance—The improper performance of an act.

Nonfeasance—The failure to act as a reasonably prudent person would in similar circumstances when there is a duty to act.

Product liability—A tort that makes a manufacturer liable for compensation to anyone using its product if damages or injuries occur from defects in that product.

Proximate cause—An action or event that produces injury in a natural, continuous sequence that is unbroken by any intervening cause.

Res ipsa loquitur—"The thing speaks for itself"; a doctrine applying to negligence, stating that the breach of duty is so obvious that it does not require further proof.

Statute of limitations—That period of time established by state law during which a lawsuit or criminal proceeding may be filed.

SETTING THE SCENE

Kelly, a pharmacy technician, dispensed medication to an HIV-positive patient who is her neighbor. When she went home after work, she told her boyfriend that their neighbor was HIV positive. A few days later, while mowing the lawn, the boyfriend asked the neighbor how he was feeling. The neighbor asked, "What do you mean?" The boyfriend explained that he just wanted to know his health status, since the neighbor had AIDS. The neighbor was furious that Kelly had told her boyfriend about his health status.

CRITICAL THINKING

- What is the legal term for Kelly's action?
- Kelly's action is classified as what type of tort?
- Kelly's action violates which federal acts?

Overview

It is important to understand the principles of liability as they relate to the field of pharmacy. Injuries to patients that may give rise to liability include physical harm, as well as damage to the rights, reputation, or property of individuals or groups. Lawsuits may occur as the result of many liability issues, including improper disclosure of health information. Once the nature of the relationships from which liability can arise is understood, related legal theories and defenses can be studied.

Theories of Liability

In the field of pharmacy and other areas of healthcare, theories of liability are divided into three types: breach of contract, intentional torts, and nonintentional torts. As discussed in Chapter 1, *intentional torts* are committed with the intent to do something that is wrong. *Nonintentional torts* are committed without this intention. Table 2-1 lists some theories of liability as they relate to both types of torts. Most **medical malpractice** lawsuits in the United States are related to nonintentional torts.

Negligence

Negligence is defined as delivery of care that is below the expected standard. The unintentional tort of negligence is the most common type of liability in medicine. It usually means any deviation from the accepted medical standard of care that causes patient injury. Though similar to

Table 2-1 Some Theories of Liability Related to Torts

Intentional Torts	Nonintentional Torts
Assault and battery	Breach of confidentiality
Defamation	Corporate negligence
False arrest	Failure to warn
False imprisonment	Negligence
Intentional infliction of emotional distress	Res ipsa loquitur (the thing speaks for itself)
Invasion of privacy	Vicarious liability
Medical abandonment	

medical malpractice, it is actually a separate legal theory. The *standard of care* is the level of care that a reasonably prudent healthcare professional would have rendered in the same or similar circumstances.

All medical professional liability claims are classified as one of the following:

- **Malfeasance**—The performance of a totally wrongful and unlawful act, such as the prescribing of medications by a person who is not licensed to do so.
- **Misfeasance**—The performance of a lawful act in an illegal or improper manner resulting in damage. For example, an infection caused by not using sterile technique while preparing an intravenous infusion.
- **Nonfeasance**—The failure to act when one should, such as failing to scan a bar code on a package.

THE FOUR DS OF NEGLIGENCE

There are four elements that must be established to prove a healthcare professional guilty of negligence. These elements are required in order to obtain a judgment against a defendant, such as a physician. The plaintiff, such as a patient, must show that all four elements were present. The *four Ds of negligence* are the following:

- **Duty of care**—The healthcare professional owed a duty of care to the accuser. (Caregivers are obligated to conform to particular standards of conduct toward their clients.) A duty is the responsibility established by the physician–patient relationship. The physician is obligated to perform, or not to perform, specific medical procedures to the patient. The patient must prove that this physician–patient relationship existed. Proof of the relationship includes when a patient makes an appointment with, and is seen by, a physician. Additional office visits and treatments further establish this relationship. The physician also has a duty to warn the patient of problems that could result from medications or treatments. In psychiatric cases, if a patient tells the psychiatrist that he or she wants to harm another person, the psychiatrist has a duty to warn the other individual. The duty of *due care* utilizes the *reasonable person standard*, in which all parties have duties to act as reasonable, prudent people of average intelligence would act, under the same or similar circumstances. Medical professionals must act within a standard of care performed by similar professionals in the same or similar community or area. Physicians follow the reasonable actions of other physicians. Nurses follow the reasonable actions of other nurses, and so on.
- **Dereliction**—The healthcare professional breached the duty of care to the patient. Dereliction is also called *neglect of duty*. It may be a physician's failure to act as an ordinary, prudent peer (physician) would act in similar circumstances. The patient must prove that the physician did not perform according to the acceptable standard of care, or that the treatment did not comply with the acceptable standard of care. A surgeon must inform the patient about all risks related to a needed surgical procedure in order to avoid dereliction of duty. If the

outcome of the surgery is different than the patient was informed about, there may be a case to claim dereliction of duty.

- **Direct cause**—The breach of care was a direct cause of the patient's injury. A direct cause is the continuous chain of events, not broken by any intervention that results in injury, and without which, the injury would not have happened. Direct or **proximate cause** means an injury was closely related to the defendant's negligence. It may not be the event that actually caused the injury. There may have been no intervening forces between the defendant's actions and the injury to the plaintiff. This constitutes a *cause-and-effect relationship*. The patient must prove that the defendant's dereliction of duty was the direct cause of the injury. A good example is when a venipuncture results in loss of feeling in the patient's arm. The patient would have to prove there was no intervening cause, such as a sports injury or accident affecting the arm, occurring after the venipuncture but before the loss of feeling developed.
- **Damages**—There is a legally recognizable injury to the patient. The actual damages are any injuries caused by the defendant. Compensation may be sought by the patient for many different types of damages. These include the following:
 - Loss of enjoyment of the patient's life
 - Medical, including hospital, and expenses
 - Pain and suffering
 - Past and future losses of earnings
 - Permanent mental or physical disability
 - Personal injuries

There is no case for negligence if the patient is not injured. If there is patient injury, damages are of various types:

- **Compensatory damages**—Such damages may be rewarded by a court to pay for injuries to the patient. These damages are payments for loss of income, patient injury, and emotional pain and suffering. They are considered past, current, and future damages, including those for lost wages and profits. The court determines the amount of the monetary award based on amount of physical disability, and past, current, and future loss of earnings. *Exemplary damages* are a type of compensatory damages referring to monetary awards that compensate the patient for losses not directly caused by the negligence, such as additional expenses for physical therapy. Non-economic factors include disability, disfigurement, and *loss of consortium*, which means that the patient's ability to have normal sexual intercourse has been impaired. Other monetary awards may be categorized as *special compensatory*, *nominal*, and *punitive damages*.
- **Punitive damages**—Exemplary damages, involving monetary awards by a court to an individual who has been harmed in a significantly willful or malicious way. The award may not be related to the actual costs of injury or harm suffered by the patient. These damages are designed to punish the offender and warn others not to behave maliciously. There may be very large cash awards. Such awards have grown greatly over time and often reach

millions of dollars. Physicians practicing without a license may be punished by large punitive damages to warn them, as well as others, that this offense is serious and potentially very harmful.

- **Nominal damages**—Smaller payments to patients who show their legal rights were violated, even though they may not have any physical harm. Rewards can be as low as \$1. Most states currently require actual damages as compensatory payments instead of simply nominal damages or payments.

In certain states, there is a limit called a *cap* on how much money may be awarded in medical malpractice cases. However, some states have no caps, and plaintiffs may receive millions of dollars. The plaintiff's attorney may receive up to 33.3 percent of payments, plus expenses, in certain states. Such large monetary awards have resulted in medical malpractice insurance premiums for physicians to increase so greatly that they are no longer affordable.

Many physicians have stopped practicing as a result.

For each of these elements, the burden of proof is on the plaintiff. This means the patient's attorney must present evidence of the four Ds of negligence. The term *preponderance of evidence* means that one party in a court case must have a greater weight of evidence than the other. The court will decide in favor of the side with the preponderance of evidence. If both sides present nearly balanced evidence, the court usually decides in favor of the defendant.



Focus On...

WRONGFUL-DEATH STATUTES

If a physician causes a patient's death due to negligence, his or her heirs and dependents may sue the physician for wrongful death. In some states, wrongful-death statutes allow heirs and dependents to collect money from the defendant to compensate for loss of future earnings to the deceased person's estate. The heirs or dependents need not be completely dependent on the deceased person for support, and need only prove that the death caused a financial loss. The defendant's actions must be proven to have been the proximate or immediate cause of death. Many states have caps on the amounts of money that can be awarded in these cases. There are not federal malpractice laws. Government entities are immune from wrongful-death suits, though certain states' employees can be sued for wrongful death.

Office of The Inspector General

The Office of the Inspector General (OIG) was created to protect programs of the Department of Health and Human Services, such as Medicare and Medicaid, against activities that constitute *fraud*. Healthcare payers must use correct diagnosis and procedure codes when deciding to pay

or deny claims. If a code is incorrect, it must be determined whether this was due to an error or due to deliberate fraudulent activities. The OIG is regularly consulted to determine fraud causes. Coding errors must be corrected, and prosecutions can occur when corrections are not made. When the OIG discovers problems in healthcare programs, it reports them to the U.S. Secretary of State as well as Congress. The Office of Counsel to the Inspector General issues fraud alerts, imposes penalties for those found guilty of fraud, provides legal services to the OIG, and represents the OIG in civil cases that are tried under the *False Claims Act*.

The OIG is concerned with lowering costs for federal healthcare programs, increasing quality of patient care and access to care, providing better freedom of choice for healthcare, maintaining balanced competition in the market, and reducing abuse of professional judgment by healthcare providers. Most federal cases concern wrongful receipt of funds, false claims for reimbursement, and improper kickbacks and discounts due to patient referrals. Serious fines and criminal penalties are applied. False claims result in billions of dollars lost every year, with penalties for offenders ranging from \$5,500 to \$11,000 for each false claim submitted. The provider may be found liable for up to three times the amount that can be lawfully claimed. Nurse and office staff members must be made aware of penalties for providing false information.



You Be the Judge

Pamela is a pharmacy technician who recently prepared eyedrops for a patient with glaucoma. The patient used the eyedrops as per the enclosed instructions but experienced no positive effects, and, after one week, was still experiencing minor but continuing visual impairment. The patient went back to her physician and complained about the eyedrops she had used. He checked the eyedrops and found out that they were long past their expiration date. In your judgment, what would the possible consequences be for Pamela since she did not check the expiration date before the medication was dispensed by the pharmacist? In addition, what would happen to the pharmacist because of this error?

Malpractice

When a patient is treated in a manner that is improper or negligent, the pharmacist or pharmacy technician may be sued for malpractice. Negligent behavior that results in injury, damage, loss, or death is referred to as *malpractice*. It is important to understand that malpractice also governs unethical practices. Malpractice lawsuits have increased dramatically. Malpractice insurance covers a wide variety of healthcare practitioners, including doctors, nurses, pharmacists, and even pharmacy technicians. In medical malpractice, the core of every negligence claim is the allegation of a breach of duty of care. This means that the medical professional has failed to maintain a certain standard of care.

Professional liability insurance protects against suits being brought against pharmacists or pharmacy technicians for malpractice. Though amounts of coverage vary, plans are available (e.g., for pharmacists and technicians) that pay \$1 million per claim for up to three claims per year. These policies are able to cover property loss or damage, personal injury, death, and even legal costs.

Having schooling, certification, licensure, registration, and insurance coverage that are adequate according to the requirements of state law will help protect against legal action. Pharmacists and pharmacy technicians may take specific steps that help to protect against errors and other acts that could lead to legal action against them. These steps are as follows:

- Always communicate effectively, accurately, and correctly. Always be straightforward, honest, and descriptive in communications; ask patients to reflect to you their understanding of what you have told them.
- Conversations and documents must be thorough and complete, covering all necessary information that will promote a good patient outcome; every piece of information that affects the patient's health and well-being must be included in communications and patient records.
- Being concise is also important. You are not required to include anything not focused on the patient's health and outcome in conversation or documents; wordiness and restating of information are not necessary, and the patient record should not include information unnecessary to patient care.
- Verbal and written communication must be consistently handled; behaviors and patterns of communication must remain relatively the same for all patients so that the focus on good patient care may be uniform and be maintained for all patients.
- All spoken or written information must be cautiously worded, avoiding terms that may be confused or may misrepresent the intentions of the pharmacy staff. Suggestions for future patient care may be made but should not be phrased as demands or warnings; considerations that may be required, as well as suggestions regarding care, should be indicated in a positive manner.

During a medical malpractice trial, the prosecuting attorney will attempt to show that the defendant deviated from the appropriate standard of care. General standards contained in state laws and regulations will be introduced into evidence. General standards of care can also be found in written materials from sources such as professional associations, accrediting organizations, and textbooks. Healthcare facility policies and procedures, including medical staff bylaws and manuals, may also be used. Often, an institution's policies and procedures may actually establish a higher standard of care than is found in other sources. Expert testimony during a trial may also be used to establish a breach of the standard of care.

After establishing that the standard of care was breached, the prosecuting attorney must establish that the breach actually caused the injury to the patient. This causal connection is sometimes referred to as *causation* and is difficult to prove. *Foreseeability* is examined here. If the medical professional anticipated that the intervening force would occur, then the injury is considered foreseeable. Therefore, the medical professional would be held liable.

Once medical malpractice is proven, the patient is entitled to damages, which may consist of nominal, actual, or punitive damages. *Nominal damages* are small amounts of money awarded to vindicate a right when minimal injury is proven. They are awarded as recognition of a technical invasion of a person's rights. Nominal damages are not awarded if other types of damages are proved. *Actual damages* (compensatory damages) are awarded to *make the plain-*

tiff whole. They are designed to restore the patient's position prior to the injury and compensate for actual loss. They include (but are not limited to) the value of past and future medical expenses. They also include but are not limited to past and future loss of income. *Punitive damages* (exemplary damages) are awarded above and beyond actual damages. There must be proof of malicious, outrageous, or intentional conduct. They are designed to punish wrongdoers, or to make an example of them.

Another type of negligence theory is **res ipsa loquitur**, which means *the thing speaks for itself*. One example is when a sponge is left inside a patient during surgery. Obviously, the sponge was left there by another person, and no other proof is needed for negligence. Res ipsa loquitur is also referred to as *res ipsa* or *RIL*. In these cases, expert witnesses are seldom needed. The defendant's only argument can be one that proves patient injury was not caused by negligence. To succeed in this type of case, the plaintiff must prove three points:

- The injury would not ordinarily occur without someone's negligence.
- The healthcare professional had exclusive control and management over the instrument or cause of the injury.
- The injury could not have occurred as a result of any action by the patient.

However, if the patient had any medical condition or did anything that could have contributed to the cause of any injury, res ipsa loquitur will not apply. In a civil malpractice lawsuit related to this type of negligence, there must have been a physician–patient relationship in which the physician had a specific duty, at a particular standard of care, which was breached. The patient must have been injured due to this breach, and the breach was the proximate cause of injury.

CIVIL MALPRACTICE LAWSUITS

A civil malpractice lawsuit requires the patient to prove the following, in this order:

- There was a healthcare provider–patient relationship.



Focus On...

PUNITIVE DAMAGES

Punitive damages are not usually requested in medical malpractice cases because most cases are based on negligence as opposed to intentional harm.



Focus On...

PUNITIVE DAMAGE CASES

In some states, the plaintiff is also required to prove that the healthcare professional had superior knowledge of the cause of the injury.

- This relationship established duty owed by the healthcare provider to the patient.
- The duty had been upheld at a professional standard of care.
- The healthcare provider breached the duty to the patient.
- The patient had a resulting injury.
- The healthcare provider's breach was the *proximate cause* of the patient's injury.



Focus On...

MALPRACTICE INSURANCE

Malpractice insurance is required for all professionals who practice in any field of medicine.

The *relationship* between healthcare provider and patient is established by contract law. Injury to a patient does not require the healthcare provider to have made an error.

MALPRACTICE INSURANCE

The cost of medical insurance has increased astronomically in comparison with many other types of insurance. This is, in part, because litigation is expensive, and the amount of damages awarded to successful plaintiffs is also rising. In certain areas of medicine, individuals who work under the supervision of others may be required to carry their own malpractice insurance, even though their supervising entity has its own. In the pharmacy, pharmacy technicians are generally insured under the malpractice insurance of their employer.

DEFENSE OF MALPRACTICE SUITS

When a plaintiff presents a malpractice lawsuit, the defendant can put forth a defense. This is known as an **affirmative defense**, and allows the defendant, which is most often a physician or hospital, to present evidence showing that the patient's condition was caused by other factors and not the defendant's negligence. The defendant's attorney will suggest defenses based on law and truth, to support the defendant's case against the accused negligence. The most common defense to negligence is *denial*. Additional defenses include *assumption of risk*, *comparative or contributory negligence*, *borrowed servant*, **good Samaritan laws**, and *statutes of limitations*.

DENIAL DEFENSE

Except for cases of *res ipsa loquitur*, the burden of proof is always on the plaintiff (e.g., a patient), who is required to prove that a defendant, such as a physician, is guilty of wrongful or negligent actions. This is why the *denial defense* is most common in malpractice lawsuits. The physician may deny that a specific procedure was performed. Sometimes, patients are upset about adverse effects of various treatments, resulting in a negligence lawsuit. Though the unexpected effects may be undesirable, they do not generally occur because of any negligence. Signed *informed consent* documents are used by physicians to help prove that potential adverse effects were explained to patients. A jury is used to decide if a plaintiff has proven whether a defendant

probably caused the injury in question. Defendants often call in expert witnesses to prove that the acceptable standard of care was met.

ASSUMPTION OF RISK

A legal defense called **assumption of risk** prevents plaintiffs from recovering damages if they voluntarily accepted risks associated with certain activities. Therefore, the defendant is not guilty of a negligent act because the plaintiff knew of and accepted the risks beforehand. One example is when a patient has been advised to stop smoking by a physician, yet continues to do so, even though the patient is aware of potential health risks. A medical provider who agrees to treat a person with tuberculosis (TB) and assumes the risk of contracting TB will have no case if he or she then contracts the disease. A patient who signs a consent form for open-heart surgery assumes the risks that could be caused by surgical complications.

For assumption of risk to be a valid defense, the plaintiff must know and understand all involved risks and voluntarily choose to accept those risks. Therefore, all patients must be asked to sign an authorization form for all procedures, indicating understanding of involved risks, acceptance of those risks, and giving consent for treatment.

Vicarious Liability

The term *respondent superior* refers to *vicarious liability*, which makes a healthcare organization, such as a pharmacy, responsible for any negligent act by one of its employees. Since the individual is responsible for negligence, so too are his or her supervisors. However, the individual employee must be found legally negligent in order for the superiors or company also to be found legally negligent. The court will examine who hired the employee, who pays the employee, who has the power to fire the employee, and who controls the details of the employee's work.

Corporate Negligence

Corporate negligence differs from vicarious liability because it focuses on the responsibility of the healthcare organization as a whole, and not its individual employees, to provide proper patient services. This responsibility cannot be delegated to employees. The organization must adhere to its own bylaws and any applicable state statutes concerning its credentials.

Contributory Negligence

The term **contributory negligence** refers to conduct of a plaintiff that contributes to the cause of an injury. If the patient is determined to have partially or fully been at fault for the injury, he or she may not be allowed to recover any monetary damages. These decisions differ between the states. For example, contributory negligence may have occurred when a patient was instructed to *take one tablet per day* but took three tablets per day instead and experienced a life-threatening outcome. In many jurisdictions, there is no form recovery possible when contributory negligence has occurred.

Comparative Negligence

Comparative negligence means that where the patient is shown to have contributed to the negligence that caused harm to himself or herself, and the pharmacist was also negligent, the amount of recovery of damages may be reduced because of the patient's actions. In other words, though damages may be awarded to the patient because of something the pharmacist did wrong, the patient's own actions reduce the amount that can be recovered. Adequate documentation of all health information may be the only way to support defense of either contributory or comparative negligence cases. The plaintiff may recover damages based on the amount of the defendant's fault. This is often determined to be a percentage of fault, such as 60 percent the fault of the defendant and 40 percent the fault of the plaintiff. A good example of comparative negligence is when a physician is proven to have been negligent, but the patient was proven to have failed to continue with follow-up care, and was further injured, showing that the patient was also responsible for his or her own injury.

Professional Liability

Professionals of all types are legally responsible, or **liable**, for their actions. In the healthcare field, professional liability includes many factors, such as the actual facility, its grounds, protection against theft and disasters, use of company vehicles, safety for all individuals, and protection against any hazardous materials.

CIVIL LIABILITY

Due to the increase in negligence and respondeat superior lawsuits, many medical professionals have become reluctant to withdraw or withhold treatment when this is requested by patients or their family members. When the duty to continue treatment is present, an informed patient should sign a clearly stated refusal for this treatment. If treatment were continued after the patient refused it, the medical professionals involved can be liable for *battery*.

PHYSICAL CONDITIONS OF THE PREMISES

All medical facilities must exercise the proper standard of care concerning the physical conditions of the premises. If regulatory standards are violated and any accident or injury occurs, the facility and its management may be held liable. However, if, for example, a patient was aware of a situation that could cause injury and chose to ignore it, the facility may not be liable for any injury that occurred. A good example is choosing to walk on a wet floor after being told of its condition, and then falling. In this case, the facility would not be held liable.

ILLEGAL SALE OF DRUGS

The majority of healthcare facilities have controlled substances stored on the premises. Healthcare employees are carefully screened for histories of drug abuse or possession. Theft of narcotic

drugs must be protected against, since they can easily be sold or used personally by the guilty party. Lack of proper security systems and barriers can make it easier for theft of controlled substances. Offenders can lose their licenses to practice and face fines or imprisonment. One example of this type of theft is when documentation is altered to state that a patient received a medication, when in fact it was stolen by a healthcare staff member.

PROMISE TO CURE

The *promise to cure* a patient, using a specific procedure or treatment, falls under the jurisdiction of *contract law*, and not under *civil law*. Many states have passed laws that require all promises to cure to be made in writing.

Tort Reform

Tort reform is also referred to as *malpractice reform*. This controversial issue differs between the states, with the majority of states passing reforms that limit an injured individual's ability to sue healthcare professionals. Some states have a cap on the amounts that can be awarded as damages. Many practitioners, companies, and insurers want tort reform to help protect them from high-cost lawsuits. Due to limits on amounts that can be recouped, situations occur in which a jury awards an amount that is so small that it does not even cover the costs of the attorneys involved. Punitive damages are rarely awarded, though when they are, they can reach millions of dollars.

Tort compensation is easier to apply to property damage, since values can be assessed. When a person's body or mind is damaged by a medical practitioner, it is much harder to determine a dollar amount in relation to the injury. It is also difficult to determine a dollar amount to cover a person's pain and suffering. Due to high costs, malpractice cases have put physicians out of business, with many practices being closed, even though negligence was not proven. It may take years before a case even makes it into a courtroom, or before it can be settled.

Malpractice Prevention

Medical professionals have a duty not to inflict harm upon their patients. They must always take their jobs seriously, be careful in what they say to patients, and ensure adequate safety measures, good communication, and appropriate documentation. General suggestions that help to prevent malpractice lawsuits include the following:

- Acting within the scope of practice at all times
- Never attempting to provide care beyond the scope of training or experience
- Keeping patient waiting times to a minimum and explaining any delays
- Never promising patients that they will be cured or that they will recover
- Educating staff members about lawful and unlawful conduct

- Providing staff training on professional conduct and standard of care
- Offering ongoing training and education for all staff members
- Treating patients with courtesy and respect—this is very important in reducing the likelihood of lawsuits
- Always identifying the correct patient before treatment begins, using identification bracelets and addressing patients by name
- Avoiding criticizing staff members and superiors publicly, where this could be overheard by patients
- Avoiding diagnosing and prescribing medications over the telephone as much as possible

SAFETY

It is important to ensure the safety of all patients, staff members, visitors, and anyone else who enters the facility. Safety measures include the following:

- Ensure that patients use canes, walkers, and other assistive devices while in the facility—do not let them leave these devices behind
- Conduct periodic equipment inspections
- Verify that all electrical cords are properly grounded
- Maintain all equipment so that it is ready to use and also safe
- Place all biohazardous waste and sharps, including needles, into correctly labeled containers
- Keep all floors clean and clear of any debris
- Use warning signs when needed, to alert individuals to wet floors, slippery or unsafe conditions, construction areas, and fresh paint
- Understand and follow Occupational Safety and Health Administration (OSHA) guidelines
- Always open doors carefully to avoid injury to anyone on the other side
- Install lock systems for all doors, windows, and drawers
- Establish a disaster plan, and conduct periodic fire drills, and other types of drills as needed for the staff members
- Lock up all controlled substances (narcotics)

COMMUNICATION

Communication, whether between staff members and patients, other staff members, superiors, or other individuals, must always be handled professionally. This includes communication that is spoken, written, given over the telephone, e-mailed, or faxed. Steps that can be used to improve the quality of communication include the following:

- Use clear wording for all statements, explaining details fully
- Discuss all patient fees before beginning treatment