

 CENGAGE

Third Edition



# LAW & ETHICS

## FOR PHARMACY TECHNICIANS



JAHANGIR MOINI

# LAW & ETHICS

## for Pharmacy Technicians

THIRD EDITION

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***Law and Ethics for Pharmacy  
Technicians, 3rd Edition***  
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Library of Congress Control Number: 2018954781

ISBN: 978-1-3377-9662-0

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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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## ACKNOWLEDGMENTS

The author would like to acknowledge the following individuals for their time and effort in aiding him with their contributions to this book.

**LAUREN WHALEN**, *Associate Product Manager*

**JULIET STEINER**, *Learning Design Director*

**DEBORAH BORDEAUX**, *Learning Designer*

**KEN MCGRATH**, *Senior Content Manager*

Additional thanks go to Greg Vadimsky, assistant to the author.

The author also would like to thank the following reviewers:

**PAULA LAMBERT**, M.Ed., CPhT, *Pharmacy Technology Instructor*

North Idaho College  
Coeur d'Alene, ID

**MARTIN MATHIS**, CPhT, *Lead Instructor Pharmacy Technician Program*

Remington College-Cleveland West  
North Olmstead, OH

**LAURISA MCKISSACK**, RPhT, CPhT, *Pharmacy Technician Instructor*

Virginia College Pensacola Campus  
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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. Pharmacopoeia 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
<ul style="list-style-type: none"> <li>• Substantive</li> <li>• Procedural</li> </ul>	Intellectual Property Law
Evidence	Partnerships
Taxation	Personal Property
	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?