



PHARMACY PRACTICE AND THE LAW

SEVENTH EDITION

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*I dedicate this edition to my wife, Jeri, and
children, Aaron and Meredith, who
have shared in the journey of this book over
the last 20+ years.*

*I wish to acknowledge David Brushwood, who
coauthored with me the first three editions of
this book and whose valuable contributions
remain in this edition.*





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PREFACE

In this seventh edition of *Pharmacy Practice and the Law*, I have continued the effort David Brushwood and I began several years ago with the very first edition: to provide a resource that is useful for teaching the facts of pharmacy law, providing a degree of depth to support those facts, and stimulating critical thinking about issues in the field. The *Seventh Edition* retains the format of the *Sixth Edition* while incorporating several of the relevant changes that have recently occurred in pharmacy law. Please refer to “New to the *Seventh Edition*” for a more detailed description of the changes between the previous edition and this updated *Seventh Edition*.

Some of the changes and updates are the result of suggestions from faculty who use this book as an assigned text in their pharmacy law courses. I greatly appreciate the valuable feedback from those using this book, and I hope that I continue to receive this feedback. My thanks to Professor Rajul Patel, PharmD, PhD, for reviewing and editing the Medicare Part D section in Chapter 6. Although I acknowledge with gratitude the input from many trusted colleagues, I accept full responsibility for any omissions or deficiencies anyone might find in this *Seventh Edition*.

This text generally appeals to faculty who believe that a pharmacy law course should be much more than preparation for the board examination. The book reflects my position that a pharmacy law course should not be just about memorizing laws and regulations and learning the “rules of the game.” Rather, the course should prepare students to understand and critically analyze the law that governs both the profession and the products they distribute. Understanding requires that students know some history behind the laws, why they exist, how they affect pharmacy practice, and subsequently how to apply the law and how to analyze whether there is a better approach. Understanding pharmacy law is critical to understanding the profession. Pharmacy law reflects the history, social policy, and standards of practice that have created and shaped the profession into its current form. My hope is that this book helps students to understand pharmacy law and, in the process, to develop an awareness and appreciation of the profession they otherwise might not have.

This book contains a great deal of information. Faculty should use their judgment as to how much they expect students to learn. Some might even wish to supplement this text with current articles or additional cases on the various legal topics. The text contains several cites to the *Federal Register*, *Code of Federal Regulations*, statutes, public laws, and websites for those wishing to delve deeper into the many topics presented.

The edited cases at the end of each chapter are the same as those in the *Sixth Edition*. Cases are included because they lead to challenging discussions, stimulate critical thinking, help students learn legal rules better and in greater depth, and kindle student interest. Each case starts with an overview designed to provide a brief explanation of

the case and to generally cue the students as to what issues to think about as they read the case. As much as possible, the court's own language has been retained. By doing so, students learn that law is seldom "black and white" but rather requires a considerable measure of reasoning and analysis to reach a decision. Faculty should recognize that the questions raised in the overview are designed to stimulate discussion. A specific correct answer might not always exist; rather, there could be several answers to some of the questions. The notes following each case serve to address the questions arising from the case and to clarify certain points about the case.

The structure of all eight chapters remains essentially the same as that of the previous edition except, of course, for the updates. As in the *Sixth Edition*, this edition includes study scenarios and study questions after various chapter sections. The instructor can use these to lead class discussions. Additional study scenarios and study questions can be found in the Instructor Manual.

Chapter 1 provides an overview of law and the legal system. Chapters 2 and 3 cover the federal regulation of medications, with Chapter 2 describing the basic regulatory framework of food and drug law and Chapter 3 applying that framework to pharmacy practice.

Chapters 4 and 5 discuss relevant provisions of the federal Controlled Substances Act (CSA). Chapter 4 provides an overview of the framework of the CSA while Chapter 5 applies that framework more specifically to pharmacy practice.

The main focus of Chapter 6 is the significant influence of the federal government on the state-regulated practice of pharmacy and on business and financial issues related to the profession. From the standards established in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) to the Medicare and Medicaid laws and the federal antitrust laws, federal requirements for drugs have a profound effect on the professionals who dispense and monitor drugs. This chapter also discusses some very important recent developments involving privacy, electronic records, and pharmacy reimbursement.

Chapter 7 describes some of the basic principles of state regulation of pharmacy practice, including licensure and standards setting. Chapter 7 is intended to provide only a general overview of state law issues and contains a discussion of some important recent regulatory trends occurring among the states and discussions of the similarities and differences among state pharmacy practice acts.

Finally, Chapter 8 provides an overview of malpractice and product liability for order processing and pharmaceutical care activities, with specific tips on liability avoidance through risk management programs. Chapter 8 is important, not just to understand legal risk but also to understand the conflicting judicial opinions of the societal expectations of pharmacists, why those expectations exist, and whether they are changing. Courts mirror societal values and sometimes provide us with both flattering and unflattering perspectives of our profession.

Because the overall structure of the text remains the same, faculty who have used this text in the past should not have to make major adjustments in the way they use this new edition.

I am indebted to David Brushwood, for his friendship and for being my coauthor for the first three editions of this book, and also to those who have used this text in their classrooms and provided valuable suggestions.



NEW TO THE SEVENTH EDITION

Several legal/regulatory developments directly affecting pharmacy practice or drug products have occurred since the publication of the *Sixth Edition* in 2010. This *Seventh Edition* attempts to include many of these recent developments relevant to the profession. A brief chapter-by-chapter description of those changes follows.

CHAPTER 1

Chapter 1 remains largely unchanged. Important legal terms have been accented with quotation marks so as to be more readily identifiable. A recent federal court decision where inmates sued the Food and Drug Administration (FDA) for allowing unapproved thiorientinal to be shipped into the country was added to the notes of *Heckler v. Chaney*.

CHAPTER 2

To the historical section was added a brief description of the Patient Protection and Affordable Care Act (PPACA, or ACA) and the FDA Safety and Innovation Act of 2012. Important provisions from each of these laws as they relate to pharmacy were added throughout Chapter 2 and in other chapters of the book.

Other changes in the chapter include new or updated discussions of the following topics:

- Whether the FDA can regulate electronic cigarettes as drug/device combination products
- Probiotics as nutraceuticals
- The FDA's enforcement emphasis on the Park Doctrine
- The FDA's reconsideration of the linear bar code requirement for labeling
- Risk evaluation and mitigation strategy (REMS) generally and REMS for extended-release and long-acting opioid drugs
- Litigation related to the legality of "pay for delay"
- Brand-name manufacturer use of a REMS requirement restricting drug distribution
- 505(b)(2) drugs
- FDA enforcement actions directed at unapproved drugs and revised compliance guidance
- FDA website where approved drug products can be identified
- Biosimilars under the Biologics Price Competition and Innovation Act
- FDA's Bad Ad Program

CHAPTER 3

Chapter 3 changes from the previous edition include new or updated discussions of these topics:

- State-standardized prescription labels
- A proposed class of drugs called “nonprescription under conditions of safe use”
- Emergency contraception product issues
- Conscientious objection and whether pharmacists can refuse to dispense prescriptions to which they are morally opposed
- FDA compliance guide related to MedGuides and REMS
- Proposed single-page consumer medication guides
- A drug information website for pharmacists
- Federal court decision analyzing whether compounding medications for animals constitutes manufacturing rather than compounding
- FDA’s position on whether current bioequivalence standards are adequate for narrow therapeutic drugs
- The pedigree requirement under the Prescription Drug Marketing Act
- “Track and trace” requirements required by the FDA Amendments Act (FDAAA)

CHAPTER 4

Changes in Chapter 4 include new or updated discussions of the following items:

- “Herbal incense” and “bath salts” as schedule I substances
- Federal government policy related to state medical marijuana laws
- Carisoprodol as a schedule IV substance
- Reverse distributors included under the law as distributors
- The Drug Enforcement Administration’s (DEA’s) Distributor Initiative Program
- The DEA’s interpretation of “constructive delivery”
- The Combat Methamphetamine Epidemic Act of 2005 and the Methamphetamine Production Prevention Act of 2008

CHAPTER 5

Changes in Chapter 5 include new or updated discussions of the following topics:

- Recent DEA actions as to whether a pharmacist can make changes to a written schedule II prescription
- Electronic refill records
- REMS for long-acting and extended-release opioid products
- REMS for transmucosal immediate release fentanyl products
- Electronic transmission prescription requirements
- Return of controlled substances to pharmacy by nonregistrants
- The Secure and Responsible Drug Disposal Act of 2010
- Central fill pharmacies
- Internet pharmacy prescriptions
- State electronic prescription monitoring programs
- Recent long-term care facility (LTCF) pharmacy issues including
 - LTCF nurses as agents of the prescriber
 - Dispensing from LTCF emergency kits

- Central recordkeeping requirements
- The filing of controlled substance prescriptions
- Disposal of controlled substances by a pharmacy
- Records of theft or loss
- Form 222 requirements
- Controlled substance ordering system (CSOS)

CHAPTER 6

Within the past few years there have been several significant changes or proposed changes in law related to electronic records, Medicare Part D, federal reimbursement determinations for prescriptions, and average wholesale prices. Perhaps there has never been a more uncertain financial climate for pharmacies.

Changes in Chapter 6 from the previous edition include new or updated discussions of these topics:

- Medicare Part D
 - Enrollment period
 - Beneficiary cost
 - Covered drugs
 - Electronic prescribing
 - Printed notice requirement
 - Fraud and abuse
 - Durable medical equipment accreditation exemption
- Average manufacturer price (AMP) regulation
- Centers for Medicare & Medicaid Services (CMS) proposed new benchmark to determine estimated acquisition cost
- U.S. Supreme Court decision on state Medicaid reimbursement cuts
- Fourteen-day dispensing cycle for long-term care facilities
- LTCF consultant pharmacist issues
- Flexible spending accounts

CHAPTER 7

Few changes were made to Chapter 7 in the *Seventh Edition*. The discussion of citizenship as a requirement for licensure was updated with a 2011 federal court decision. The continuing education section now includes a discussion of the National Association of Boards of Pharmacy's (NABP) collaborative effort with the Accreditation Council for Pharmacy Education (ACPE) called CPE Monitor where pharmacists and technicians can now be registered electronically. The discussion of state-standardized prescription labels was moved to Chapter 3.

CHAPTER 8

Chapter 8 remains largely unchanged; however, some important additions are included. The discussion under duty of care of whether a healthcare provider owes a duty to a third party was expanded by including summaries of two contrasting cases, one from Utah and one from Nevada. A subsection was added to the section on expanded view of pharmacist duty that discusses a compromise judicial position between no duty of care and a general duty of care. Correspondingly, the notes after the *Happel* case (see Case 8-1) were amended. The product liability section includes

a recent state court opinion as to whether the learned intermediary doctrine is a defense when a manufacturer engages in direct-to-consumer advertising. The discussion of *Wyeth v. Levine* is expanded and supplemented with the U.S. Supreme Court's decision on the issue of whether the holding in *Levine* extends to generic drug manufacturers.