
PHARMACY PRACTICE AND THE LAW

Sixth Edition

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JONES AND BARTLETT PUBLISHERS

Sudbury, Massachusetts

BOSTON TORONTO LONDON SINGAPORE

World Headquarters

Jones and Bartlett Publishers
40 Tall Pine Drive
Sudbury, MA 01776
978-443-5000
info@jbpub.com
www.jbpub.com

Jones and Bartlett Publishers
Canada
6339 Ormindale Way
Mississauga, Ontario L5V 1J2
Canada

Jones and Bartlett Publishers
International
Barb House, Barb Mews
London W6 7PA
United Kingdom

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Production Credits

Publisher: David Cella
Acquisitions Editor: Katey Birtcher
Associate Editor: Maro Gartside
Production Director: Amy Rose
Senior Production Editor: Renée Sekerak
Marketing Manager: Grace Richards
Manufacturing and Inventory Control Supervisor: Amy Bacus
Composition: Glyph International
Cover Design: Nancy Deutsch and Kristin E. Parker
Cover Image: © Ali Mazraie Shadi/Shutterstock, Inc.
Printing and Binding: Malloy, Incorporated
Cover Printing: Malloy, Incorporated

Library of Congress Cataloging-in-Publication Data

Abood, Richard R.

Pharmacy practice and the law / Richard R. Abood. — 6th ed.
p. cm.

Includes bibliographical references and index.

ISBN 978-0-7637-8129-3 (alk. paper)

1. Pharmacists--Legal status, laws, etc.—United States. 2. Pharmacy—Law and legislation—United States. 3. Drugs—Law and legislation—United States. I. Title.

[DNLM: 1. Legislation, Pharmacy—United States. 2. Ethics, Pharmacy—United States. 3. Legislation, Drug—United States. 4.

Liability, Legal—United States. QV 33 AA1 A154p 2011]

KF2915.P4A93 2011

344.7304'16—dc22

2010002762

6048

Printed in the United States of America

14 13 12 11 10 10 9 8 7 6 5 4 3 2 1

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PREFACE

In this *Sixth Edition of Pharmacy Practice and the Law*, I have continued the effort David Brushwood and I began several years ago with the *First Edition*: to provide a resource that is useful both for teaching the facts of pharmacy law and for stimulating critical thinking about issues in the field. The *Sixth Edition* retains the format of the *Fifth Edition* while incorporating several of the relevant changes that have recently occurred in pharmacy law. Please refer to the section “New to the *Sixth Edition*” for a more detailed description of the changes between the *Fifth Edition* and this *Sixth Edition*.

Some of the changes and updates are the result of suggestions from faculty who are using this book as an assigned text in their pharmacy law courses. I greatly appreciate the valuable feedback from those who use this book and hope that feedback continues. Although I acknowledge with gratitude the input from many trusted colleagues, I accept full responsibility for any omissions or deficiencies anyone may find with this *Sixth Edition*.

This book should appeal 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 the 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 may even wish to supplement the book with current articles or additional cases on the various legal topics.

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The edited cases at the end of each chapter are the same as those in the *Fifth Edition*. Cases are included because they lead to challenging discussions, stimulate critical thinking, help students learn legal rules better and in greater depth, and enhance 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 may not always exist; rather, there may be several answers to some of the questions. The notes following each case serve to answer some 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 *Fifth Edition* excepting, of course, the updates made to reflect current law and current issues. As in the *Fifth Edition*, this edition includes study scenarios and study questions after various chapter sections. The instructor can use these to lead class discussions.

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, whereas 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 conditions of participation 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 only overview state law issues. This edition contains a discussion of some important recent regulatory trends occurring among the states, and more discussion of the similarities and differences between state pharmacy practice acts.

Finally, Chapter 8 provides an overview of malpractice liability for order processing and pharmaceutical care activities, with specific tips on liability avoidance through risk management programs. Chapter 8 is important, not just in order to understand legal risk, but also to understand both historic and current judicial and thus 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 book remains the same, faculty who have used this book in the past should not have to make major adjustments in the way they use this new edition. It is my hope that the text challenges students to think about professional issues and problems, develop alternative solutions to them, and justify their choice of the most appropriate solution.

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 book in their classrooms and have provided me valuable suggestions.

NEW TO THE *Sixth Edition*

Several legal/regulatory developments directly affecting pharmacy practice or drug products have occurred since the publication of the *Fifth Edition* in 2007. This *Sixth Edition* has attempted 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. Most notably, the discussion of the *North Carolina Board of Pharmacy v. Rules Review Com'n* case within the section “Law Made by Administrative Agencies” is updated to reflect the North Carolina Supreme Court’s reversal of the state court of appeal’s decision. This decision is important as it reflects one approach by state pharmacy boards to reduce dispensing errors.

Chapter 2

The Food and Drug Administration Amendments Act (FDAAA) of 2007 introduced several important changes in the Food, Drug, and Cosmetic Act, many related to drug safety. The chapter includes a brief description of the FDAAA in the “Historical Overview” section and discusses many of the changes the FDAAA made to the FDCA at various places in the chapter including:

- Changes to the law related to drug product recalls
- Requirement of manufacturers to maintain public registries of clinical trials
- Changes to the law related to Phase IV studies
- Expansion of FDA’s authority to require risk evaluation and mitigation strategy (REMS)
- FDA’s strengthened authority over postmarket labeling
- FDA’s mandate to establish a postmarket drug safety information website

x **New to the *Sixth Edition***

- Requirements of pharmacies to provide patients with notification to report adverse drug events
- Changes to FDA’s authority related to direct to consumer (DTC) advertising and recent concerns about DTC advertising by the FDA

The chapter notes and discusses many other developments besides the FDAAA that have occurred since the *Fifth Edition* including:

- The Family Smoking Prevention and Tobacco Act
- The recent FDA warning letter and controversy over Cheerios cereal being considered a drug
- The Dietary Supplement and Nonprescription Drug Consumer Protection Act and its requirements for both dietary supplement and nonprescription drug manufacturers
- FDA’s proposed regulation to amend the current pregnancy labeling requirements
- Update of the discussion of the National Drug Code Number
- Discussion of ANDA patent requirements under the Drug Price Competition and Patent Term Restoration Act (PTRA) and resultant patent strategies and controversies created by drug manufacturers
- FDA’s Investigational New Drug final regulation and new website
- Appellate decision in the *Abigail* case regarding the constitutional right to investigation of new drugs
- Update of political controversies regarding generic biologicals
- PhRMA’s 2009 guide, “Code on Interactions with Healthcare Professionals”
- FDA’s compliance guide on off-label use dissemination to health care professionals, replacing the requirements of FDAMA

Chapter 3

Chapter 3 also includes many changes from the *Fifth Edition*, including discussions of:

- The FDA’s possible policy change regarding behind-the-counter (BTC) drugs
- The federal lawsuit against the FDA over Plan B
- State lawsuits related to conscientious objection and whether pharmacists can refuse to dispense prescriptions to which they are morally opposed
- Follow-up 2008 study revealing the deficiencies of consumer medication information (CMI)
- Recent pharmacy concerns about Medication Guides
- FDA’s action toward pharmacies that compound Bio-identical Hormone Replacement Therapy (BHRT)
- Federal court decision defining pharmacy compounding
- Appellate federal court decision regarding the issue of whether a pharmacy-compounded drug is a “new drug”
- Iowa case concerning the legality of a pharmacy compounding an OTC drug without a prescription
- Additional information related to the pedigree requirement
- FTC actions against pharmacy chains for deceptive and false marketing of dietary supplements

Chapter 4

Changes in Chapter 4 from the *Fifth Edition* include discussions of:

- The shift in policy by the federal government toward state medical marijuana laws
- DEA's actions against wholesalers distributing large quantities of controlled substances to pharmacies
- Restricted distribution of methadone 40 mg tablets
- The Methamphetamine Production Prevention Act of 2008
- U.S. Postal Laws regarding the mailing of controlled substances

Chapter 5

Changes in Chapter 5 in the *Sixth Edition* include:

- Elaboration of the importance in distinguishing a medication order from a prescription
- Discussion of the new starting letter for DEA registrations of practitioners
- Discussion of shift in DEA policy regarding changes a pharmacist can make to a written schedule II prescription
- Elaboration of the meaning of a valid prescription under the CSA
- Discussion of how pharmacists can better ascertain the legitimacy of opioid prescriptions for pain treatment in situations involving multiple prescriptions for large quantities
- Discussion of DEA's final rule allowing the issuance of multiple C-II prescriptions for the same drug to the same patient on the same day
- Summary of proposed DEA regulations permitting the electronic transmission of schedule III, IV, and V controlled substance prescriptions
- Discussion of Internet pharmacy and summary of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008
- Discussion of the DEA's current policy regarding the return of controlled substances from LTCFs and patients to pharmacies for disposal, and the Agency's possible shift in that policy
- Summary of DEA proposed regulation to convert the DEA Form 222 from triplicate to a single-sheet tamper-resistant form

Chapter 6

Within the past few years there have been a multitude of 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.

The 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) and attendant regulations have effected several important changes in HIPAA and health information technology. This chapter discusses many of those changes including:

- The requirements for accounting for disclosures of PHI
- The definition of "minimum necessary"
- What is considered a breach of PHI and the steps a pharmacy must take if it determines a breach has occurred
- Payments in exchange for recommending alternative medications

xii New to the *Sixth Edition*

- The change in privacy and security responsibilities for business associates
- Changes in penalties for violations
- How the law strengthens and emphasizes the adoption of a national health information technology infrastructure
- OCR's position on the disposal of PHI

There have been several changes in Medicare Part D since the *Fifth Edition*, primarily the result of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. The *Sixth Edition* includes discussions of:

- 2009 figures for estimated monthly premiums, deductibles, and the doughnut hole
- Changes in the excluded drug list
- CMS authority to include additional categories and classes of drugs where all drugs must be covered by a plan
- Encouragement of e-prescribing by extending bonuses to prescribers
- Requirement of plans to pay pharmacy claims promptly
- Changes in plan requirements regarding medication therapy management
- Plan and provider marketing limitations
- Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation; competitive bidding and bonding

Additional changes in this chapter include discussions of:

- Regulatory, legislative, and litigation developments concerning average manufacturer's price (AMP) and the federal upper limit (FUL) list
- Litigation and settlement agreements over average wholesale price (AWP) and the likely effect on pharmacy reimbursement
- Litigation action by state pharmacy organizations over state Medicaid reimbursement cuts
- Tamper-resistant prescription pad requirements for written Medicaid prescriptions
- Additional information about the Medicare/Medicaid Fraud and Abuse Statute including the addition of a new safe harbor for gifts related to e-prescribing
- Physician Antiself-Referral Law (Stark Law)
- Legal controversies involving prescription benefit managers (PBMs)
- 340B Drugs
- The Patient Safety and Quality Improvement Act of 2005 (PSQIA)
- The Federal Trade Commission "Red Flag Rules"
- IRS requirement for pharmacies accepting flexible spending and health savings account debit cards

Chapter 7

Chapter 7 includes some additional state law topics not discussed in the *Fifth Edition*, as well as some expanded discussions of issues included in the *Fifth Edition*. Many of these topics were added

or expanded upon because of their current importance and attention in many states. Changes in Chapter 7 include general discussions of:

- The responsibilities of the pharmacist-in-charge
- Internet pharmacy (in addition to the discussion in Chapter 5) including NABP's rating system
- The importance of the definition of pharmacy under state laws
- Ancillary personnel, including functions, qualifications, licensure requirements, degree of supervision, and ratio requirements; and why the qualifications of technicians is under such heavy scrutiny today
- Automation and whether pharmacist checking is required
- The trend to legally mandate pharmacist breaks and pharmacy requirements in the absence of a pharmacist
- General continuing education requirements among the states
- Prospective DUR and the trend to require counseling and/or consumer medication information and labels in the patient's language
- The trend toward standardized medication container labels
- Repository or take-back programs
- Technician checking technician in the hospital pharmacy setting
- Pharmacy continuous quality improvement (CQI) programs and NABP's movement toward implementing a national accreditation program

Chapter 8

Chapter 8 remains largely unchanged. The basic social policy arguments for and against holding pharmacists legally accountable for expanded professional functions have not changed, even with new negligence lawsuits. A discussion is included of the U.S. Supreme Court's decision in 2009 as to whether FDA approval of a drug product's labeling preempts the manufacturer from state product liability. The chapter includes an expanded discussion of pharmacist liability for strict liability and the issue of whether dispensing a prescription is a commercial retail activity or incidental to a professional service.

