



## Pharmacy Practice and the Law, Eighth Edition Includes Navigate 2 Advantage Access

By **Richard R. Abood, BS Pharm, JD**-Professor Emeritus Pharmacy Practice, Thomas J. Long School of Pharmacy and Health Sciences, University of the Pacific, Stockton, California

**Kimberly A. Burns, RPh, JD**-Professor of Pharmaceutical Sciences, Lake Erie College of Osteopathic Medicine (LECOM) School of Pharmacy, Erie, Pennsylvania

### Changes to the Eighth Edition

There have been several legal/regulatory developments that have occurred since the publication of the *Seventh Edition* in 2012. This *Eighth Edition* includes those developments most relevant to the pharmacy profession. An additional change from the *Seventh Edition* is the inclusion of “Take Away Points” after each major section in each chapter. A brief chapter-by-chapter description of substantive changes includes:

#### Chapter 1

Chapter 1 remains largely unchanged. The section “Distinguishing Criminal, Civil and Administrative Law” was moved and placed under the “Sources of U.S. Law” section and a Rhode Island case, *Blais v. Rhode Island Department of Health* is mentioned.

#### Chapter 2

In the Historical Overview section, new statistics for the Orphan Drug Act of 1983 are added and a brief description of the Drug Quality and Security Act of 2013. This law is extensively discussed later in Chapter 3.

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

- The Food and Drug Administration organizational structure
- Regulation of e-cigarettes
- Medical foods
- Nutraceuticals and functional foods
- Health claims for foods and dietary supplements
- The Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Dietary supplement product investigation by the New York Attorney General's office
- Clarification of FDA authority over drug product recalls
- Adulteration examples in pharmacies
- Misbranding example in pharmacies regarding drug name on the label
- Unit dose labeling requirements for prescription drugs
- Proposed electronic distribution of package inserts
- Pregnancy warning requirements in labeling
- National Drug Code Number
- Prescription Drug User Fee Act's effect on NDA review time
- FDA's Drug Rating and Classification System
- FDA's adverse event reporting system (FAERS) database
- FDA's REMS program
- Postmarket drug safety information for patients and providers
- Exclusion payments by drug manufacturers (pay-for-delay agreements)
- Generic drug labeling controversies created by the courts
- Section 505(b)(2) NDAs

- Individual patient access to investigational drugs for serious diseases, including state “right to try” laws
- Expedited approval of drugs intended to treat serious or life-threatening illnesses
- Biologics and biosimilars
- Medical devices for general wellness, including computer software and mobile applications
- Unique device identifier requirement for devices
- Medical device expedited approval process
- Physician Payment Sunshine Act
- FDA regulation regarding the promotion of prescription drugs and devices through the social media
- FDA regulatory authority over “off-label” use
- Replacement of *WLF v. Friedman* with *U.S. v. Caronia* in the case studies section

### **Chapter 3**

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

- Expiration or beyond-use dating including USP and FDA guidelines
- Emergency contraception and Plan B
- Medication Guides
- Medication Guides and REMS
- The pharmacy compounding provisions under Section 503A
- The Drug Quality and Security Act of 2013, including FDA compliance and draft compliance guides
- USP compounding requirements

- Pedigrees, counterfeit drugs and drug supply chain security
- The Drug Supply Chain Security Act of 2013
- Importation of prescription drugs for personal use
- FDA inspection authority of pharmacies

## **Chapter 4**

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

- State versus federal authority
- Medical and recreational use of Marijuana
- Hydrocodone combination products rescheduled to a schedule II substance
- Tramadol as a schedule IV substance
- DEA reference available to identify controlled substances authority for mid-level practitioners by discipline and state
- Distributing versus dispensing (constructive delivery)
- Treatment of addicts outside of OTPs (DATA)
- The Combat Methamphetamine Epidemic Act of 2005 and the Methamphetamine Production Prevention Act of 2008
- Deletion of the *Seeley v. State of Washington* case in the “Case Studies” section.

## **Chapter 5**

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

- DEA registration number of prescribers to include “G” as a beginning letter
- DEA electronic resource available to help verify active DEA registrations
- Recently released educational video (“Red Flags”) for pharmacists to assist in properly exercising their corresponding responsibility

- Dispensing of schedule II controlled substances
- State multiple-copy and security prescription form programs
- Partial filling of schedule III, IV, or V prescriptions
- Return of controlled substances to pharmacy for disposal, including the newly created DEA definitions of “collection” and “collector”
- Long-Term Care (LTC) Pharmacy
- Inventory requirements
- Distribution from a pharmacy to another practitioner
- Disposal or destruction of controlled substances

## **Chapter 6**

Changes in Chapter 6 include new or updated discussions of the following items:

- OBRA '90 flow chart
- Recent updates and modifications to HIPAA
- Expansion of HIPAA to directly apply to business associates
- Updates to the HIPAA notice of privacy provision
- Modifications to HIPAA regarding patients request to access and obtain copies of PHI
- Update on the status of the accounting for disclosure rules
- Modifications to breaches of PHI
- New changes to HIPAA regarding marketing, sale of PHI, and patient authorizations
- Expanded penalties and enforcements under HIPAA
- Medicare Part D beneficiary costs
- Medicare Part D covered drugs and plan formularies
- Medicare Part D pharmacy access and “any willing provider”

- Medicare Part D fraud and abuse
- Medicare and provider status for pharmacists
- Medicaid reimbursement for multiple-source drugs
- Medicaid estimated acquisition cost and average wholesale price
- Litigation over state Medicaid cuts
- Medicare/Medicaid fraud and abuse laws
  - The false claims act
  - The anti-kickback statute
- Long term care facility short-cycle dispensing
- Robinson-Patman Act and the Brand-Name Prescription Drugs litigation
- 340B drugs

## **Chapter 7**

Few changes were made to Chapter 7 in the *Eighth Edition*. The discussion of licensing of pharmacists was updated. The section discussing the definition of the practice of pharmacy now reflects the term drug therapy management. The section on ancillary pharmacy personnel was updated to reflect recent NABP changes and state trends regarding pharmacy technicians. The section on continuous quality improvement was also updated to discuss the recent advances in accreditation of outpatient pharmacies.

## **Chapter 8**

Chapter 8 is essentially unchanged.