TRANSITION GUIDE TO

Pharmacy Practice and the Law

TENTH EDITION

Richard R. Abood, BS Pharm

JD; Kimberly A. Burns, RPh, JD

Frederick Frankhauser, JD, MBA, Pharm

Paperback with Navigate Advantage Access
ISBN: 9781284280135 | 400 pages | © 2025

Navigate Advantage Access Only
ISBN: 9781284280203 | © 2025

The *Tenth Edition* of ***Pharmacy Practice and the Law*** goes beyond preparation for the board exam, helping students understand and critically analyze the law that governs both the profession and the products they distribute. The Tenth Edition continues to include the most up-to-date federal, legal, regulatory, and policy developments, as well as new developments to various medical/pharmaceutical programs. Challenging, open-ended discussion questions and edited cases are included in every chapter to facilitate discussion and critical thinking. Critical issues are discussed in non-legal, easy-to-understand language. ***Pharmacy Practice and the Law, Tenth Edition*** is the most comprehensive and engaging resource for teaching the facts of federal pharmacy law, and for encouraging critical thinking and analysis on relevant issues.

New to The Tenth Edition

There have been several legal/regulatory developments that have occurred since the publication of the *Ninth Edition*. This *Tenth Edition* includes those developments most relevant to the pharmacy profession. A brief chapter by chapter description of substantive changes includes:

Chapter-specific changes are outlined in the following:

Chapter 2 Federal Regulation of Medications: Development, Production, and Marketing

Changes in Chapter 2 from the previous edition include new or updated discussions of:

- PDUFA VII
- Food and Drug Omnibus Reform Act (FDORA)
- Structure of the Food and Drug Administration
- FDA regulation of tobacco and non-tobacco nicotine
- Nonprescription Drug Labeling
- Proposal to change (NDC) number from 10 to 12-digit format
- FDA public dashboard for medications with an approved REMS
- Emergency Use Authorization
- Drug Competition Action Plan
- Marketed unapproved drugs
- Expanded access and right-to-try laws
- FDA regulation of software considered as a medical device
- OTC hearing aids
- Medical devices and the Unique Device Identifier (UDI)
- The Modernization of Cosmetics Regulation Act (MCRA) of 2022
- Promoting prescription drugs and devices for off-label uses

Chapter 3 Federal Regulation of Medications: Dispensing

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

- Dispensing written, oral, and electronic prescriptions
- Labeling requirements (comparing federal, state, and company)
- Switch from prescription to OTC: full switch vs partial switch
- Nonprescription drug products with additional conditions for use

Continues on next page.

JONES & BARTLETT LEARNING

Jones & Bartlett Learning | 25 Mall Road | Burlington, MA | 01803
www.jblearning.com | phone: 1-800-832-0034 | fax: 978-443-8000

Source Code: Abood10eTG

Pharmacy Practice and the Law TENTH EDITION

- Emergency Contraception (Plan B and the morning after pills)
- Conscience clause
- Collaborative agreements, statewide protocols, test to treat initiatives and immunizations
- Drug Quality and Security Act of 2013
- Hospital and health system compounding
- Insanitary conditions at compounding facilities
- Compounding using bulk drug substances
- State Memorandum of Understanding (MOU) with FDA
- Safe handling of hazardous drugs including USP 800
- Substitution of biosimilar biologics
- Purple book transition to searchable database
- Drug supply chain security updates including track and trace using electronic data exchange
- National licensure standards for wholesale drug distributors and third-party logistic providers
- Importation of prescription drugs from Canada

Chapter 4 The Closed System of Controlled Substance Distribution

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

- Classification of controlled substances Medical and recreational use of marijuana
- Schedule III - proposed rules to revoke federal exempted butalbital products
- Requirement for all DEA registrants to report suspicious orders
- Distributing versus dispensing (constructive delivery)
- Applications for DEA registration and reregistration
- Modification, transfer, and termination of registration
- Expansion of treatment of addicts outside of OTPs
- Elimination of the DEA "X" number and patient limits under DATA 2000
- Practical considerations with the elimination of the DEA "X" number

Chapter 5 Dispensing Controlled Substances

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

- Those allowed to prescribe controlled substances
- Issuance of prescriptions
- Correcting a written controlled substance prescription
- Purpose of a controlled substance prescription including legitimate medical purpose and usual course of professional practice
- The pharmacists corresponding responsibility and potential legal concerns
- The DEA 2022 Pharmacist's Manual
- Federal/State efforts to balance pain treatment with the opioid epidemic
- Concerns with the 2016 CDC Guidelines leading to the 2022 revisions
- CMS requirement for electronic prescribing of schedule II – V prescriptions
- Partial filling of schedule II prescriptions under CARA
- Pharmacy requirements when making changes to electronic prescriptions
- Transfer of controlled substance prescriptions between pharmacies for initial dispensing on a one-time basis
- Transferring of prescription information for refill purposes
- Return of controlled substances to pharmacy for disposal
- Options for hospitals regarding patients admitted with controlled substances
- Limited exceptions to telemedicine prescribing of controlled substances without a prior in-person exam
- Recent DEA settlements involving pharmacies and record keeping violations
- Inventory records
- Options for prescription files
- Options for disposal and destruction of controlled substances
- How to address breakage and spillage of controlled substances
- Updates to DEA Form 106
- Recent DEA enforcement actions against pharmacies
- Execution of single-sheet DEA Order Form 222
- Distribution of schedule I and schedule II drugs between registrants
- Lost and stolen DEA Order Form 222

Continues on next page.

JONES & BARTLETT LEARNING

Jones & Bartlett Learning | 25 Mall Road | Burlington, MA | 01803
www.jblearning.com | phone: 1-800-832-0034 | fax: 978-443-8000

Source Code: Abood10eTG

TRANSITION GUIDE TO

Pharmacy Practice and the Law TENTH EDITION

Chapter 6 Federal Regulation of Pharmacy Practice

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

- Proposed changes regarding the HIPAA privacy rule
- Proposed changes under HIPAA regarding a pharmacy's "Notice of Privacy Practices"
- Proposed changes regarding improving HIPAA's information sharing for care coordination
- Proposed changes regarding HIPAA's right to access provisions
- Penalties and enforcement under HIPAA
- Health Information Technology infrastructure
- Electronic Health Records
- Medicare Part D beneficiary costs and enrollment updates
- Changes to Medicare Part D under the Inflation Reduction Act of 2022
- Insulin prices limited to $35 per month in all Part D plans
- Medicare to start negotiate prices of certain drugs in the future
- Capping out-of-pocket spending for Part D beneficiaries
- Electronic prescribing requirements for Part D plans
- MTM updates
- Medicare and provider status for pharmacists
- Prescription drug coverage under Medicaid
- Key pricing terms used by states for reimbursement under Medicaid
- Medicaid updates
- Medicare/Medicaid fraud and abuse laws
- The False Claims Act (FCA)
- The Anti-Kickback Statute (AKS)
- Compounding pharmacies not protected under certain new safe harbors
- Stark law updates
- Long-term care unnecessary and psychotropic drugs
- Prescription Benefit Managers (PBMs)
- 340B drugs
- Flexible Spending and Health Savings Account Debit Cards

Chapter 7 State Regulation of Pharmacy Practice

Changes in Chapter 7 include new or updated discussions of the following items:

- Licensing of pharmacies
- Telepharmacy
- Nonresident (Internet) Pharmacies
- Grounds for discipline including unprofessional conduct and moral turpitude
- Collaborative Practice Agreements, prescriptive authority, and state protocols, including Test to Treat initiatives
- Emergency Refill Authorization
- Pandemic Response and the Impact on Standards of Practice, including state and federal COVID-19 efforts expanding the role of the pharmacist

Chapter 8 Pharmacist Malpractice Liability and Risk Management Strategies

Changes in Chapter 8 include new or updated discussions of the following items:

- Pharmacists with expanded scope of practice activities
- Malpractice insurance
- Whether FDA-approved labeling preempts state product liability actions
- Strict liability and pharmacists

KEY FEATURES

Study Scenarios and Questions follow each section to enforce the concepts that they have learned.:

- Take-Away Points highlight the most important information in each section.
- Case Studies conclude each chapter and give students real-world examples.

INSTRUCTOR RESOURCES

Qualified Instructors will receive a full suite of Instructor Resources, including the following::

- More than 250 slides in PowerPoint format
- A Test Bank containing questions for each chapter
- Instructor's Manual
- Case Studies with questions and answers

JONES & BARTLETT LEARNING

Jones & Bartlett Learning | 25 Mall Road | Burlington, MA | 01803
www.jblearning.com | phone: 1-800-832-0034 | fax: 978-443-8000

Source Code: Abood10eTG