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TABLE OF CONTENTS

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Title 5 Government Organizations and Employees
Title 10 Aliens and Nationality
Title 15 Commerce and Trade
Title 18 Crimes and Criminal Procedure
Title 21 Food and Drugs
Title 26 Internal Revenue Code
Title 29 Labor
Title 31 Money and Finance
Title 34 Crime Control and Law Enforcement
Title 35 Patents
Title 38 Veterans’ Benefits
Title 42 The Public Health and Welfare

VOLUME 2
Code of Federal Regulations Titles
Title 5 Administrative Personnel
Title 10 Energy
Title 16 Commercial Practices
Title 20 Employees’ Benefits
Title 21 Food and Drugs
Title 24 Housing and Urban Development
Title 26 Internal Revenue
Title 29 Labor
Title 32 National Defense
Title 38 Pensions, Bonuses, and Veterans’ Relief
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**TABLE OF CONTENTS**

**BINDER I**

**Ch. 1 DISPUTE RESOLUTION**
- Arbitration
- Mediation

**Ch. 2 FRAUD AND ABUSE**
- Fraud Compliance
- Government Investigations and Enforcement
- Internal Investigations
- Physician Compensation
- Stark Law

**Ch. 3 GOVERNANCE**
- Board Operations
- Conflicts of Interest
- Corporate Responsibility Doctrine
- Executive Compensation
- Sarbanes-Oxley

**Ch. 4 GOVERNMENT REIMBURSEMENT**
- Medicaid
- Medicare

**Ch. 5 HEALTH CARE DELIVERY MODELS**
- Accountable Care Organizations
- Clinically Integrated Networks
- Medical Group Practices

**Ch. 6 HEALTH CARE FINANCE**
- Big Data Issues
- Breach Notification
- Business Associates
- Electronic Health Records

**General Data Protection Regulations**
- HIPAA Privacy
- HITECH Act
- Medical Record Management and Operations
- Mobile Apps and New Technologies
- Telemedicine and Telehealth
- Vendor Agreements

**BINDER II**

**Ch. 8 INDUSTRY TRANSACTIONS**
- Acquisitions
- Affiliations and Joint Ventures
- Contracting
- Due Diligence
- Health Insurance Managed Care Contracts
- Licensure
- Real Estate and Leases
- Service Agreements

**Ch. 9 LABOR AND EMPLOYMENT**
- Drug Testing
- Employment Policies
- Health Care Workforce and Staffing
- Immigration
- Physician Employment
- Sexual Harassment

**BINDER III**

**Ch. 10 LIABILITY AND LITIGATION**
- Crisis Communications
- Legal Services
- Risk Management

**Ch. 11 LIFE SCIENCES**
- Clinical Trials
- Food and Drug Law
- Medical Research
- Secondary Use of Data

**Ch. 12 LONG TERM CARE**
- Emergency Preparedness
- Facility Operations
- Patient Issues
- Staffing

**Ch. 13 MEDICAL STAFF**
- Medical Staff Bylaws
- Peer Review and Disciplinary Proceedings

**Ch. 14 PATIENT CARE ISSUES**
- Advanced Directives
- Discrimination
- EMTALA
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**TABLE OF CONTENTS**

- Acknowledgments
- About the Author
- **PART I**
  - Ch. 2 How Historic Civil Rights Acts and the Affordable Care Act Section 1557 Apply to Health Care Entities
- **PART II**
  - Ch. 9 Evolution of Federal and State Mental Health Parity Laws
  - Ch. 10 U.S. State Vaccine Laws
- **PART III**
  - Ch. 11 Federal Discrimination Law and Commercial Health Insurance, Coverage, and Benefits
  - Ch. 12 Discrimination Laws for Federal Health Programs and Benefits
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  - Ch. 13 Federal Health Care Conscience Statutes
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- Index

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- Ch. 2 Patient Care
- Ch. 3 Medicare
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- Ch. 5 Fundamentals of Health Law Fraud and Abuse
- Ch. 6 Tax-Exempt Issues
- Ch. 7 Antitrust Law
- Ch. 8 The Source of Payment: The State and Federal Regulation of Private Health Care Plans
- Ch. 9 Regulation of Hospitals
- Ch. 10 Representing Physicians
- Ch. 11 Post-Acute Providers and Suppliers
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TABLE OF CONTENTS

PART ONE: BASICS
Ch. 1 Glossary of Key Terms
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Ch. 3 OIG Model Compliance Guidance by Provider Type
Ch. 4 Background Checks and Excluded Persons
Ch. 5 Government Program Participation and CMS Billing Revocation Authority
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Ch. 8 What to Do When the Government Knocks
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Ch. 10 The Relationship between Enforcement and Compliance
Ch. 11 False Claims
Ch. 12 Repayments and Self-Disclosures
Ch. 13 Internal and External Audit Basics

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Ch. 14 Medical Necessity, Claims, and Payment Processes
Ch. 15 Stark and Anti-Kickback Prohibitions
Ch. 16 EMTALA Compliance
Ch. 17 Health Care Civil Rights and Nondiscrimination Under Section 1557 of the Affordable Care Act
Ch. 18 Health Information Privacy and Security Laws
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1.3 Anti-Kickback Statute
1.4 Other

**Part 2 by State**

**Part 3 by Entity Type**
3.1 Health System
3.2 Hospital
3.3 Outpatient
3.4 Individual Practitioner
3.5 Behavioral Health
3.6 Home Health and Hospice
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The Stark Law: Comprehensive Analysis + Practical Guide
SEVENTH EDITION
Charles B. Oppenheim, Benjamin A. Durie, Amy M. Joseph, Authors

This updated, revised, and expanded edition of The Stark Law: Comprehensive Analysis + Practical Guide is an in-depth critical analysis of Stark Law authority, interpretation, and enforcement. Sharing a wealth of insight, the authors provide an analytic overview, address the legal effect of the regulations and the regulatory process, and analyze the implications of various federal cases and enforcement activity. Throughout the book, the authors include practical resources for advising clients on complying with the current state of the law and regulations, as well as a look at what future direction the law might take. They identify key definitions and interpretive changes, illuminate problem areas, and suggest guidance for navigating each of them.

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TABLE OF CONTENTS
Ch. 1 Introduction and Background
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Ch. 4 Temporary Noncompliance and Curing Imperfect Performance
Ch. 5 Ongoing Challenges and Recurring Questions
Ch. 6 Analysis of Group Practices
Ch. 7 Value-Based Arrangements and Care Coordination
Ch. 8 Permissible Joint Ventures
Ch. 9 Addressing Potential Violations and Current Enforcement Activity
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TABLE OF CONTENTS

Ch. 1 The Fraud Enforcers: Who Are They and What Do They Do?
1.1 Overview
1.2 Department of Justice
1.3 Department of Health and Human Services
1.4 Other Federal Agencies
1.5 Multi-Agency Federal Initiatives
1.6 Congress
1.7 States
1.8 Private Payers
1.9 Private Citizens

Ch. 2 Federal Anti-Kickback Laws
2.1 Overview
2.2 Evolution of The Anti-Kickback Statute
2.3 Safe Harbor Regulations
2.4 Fraud Alerts and Special Advisory Bulletins
2.5 Additional Guidance and Advisory Opinions
2.6 Case Law
2.7 Other Anti-Kickback Authority
2.8 Major Issues in Anti-Kickback Interpretation and Enforcement

Ch. 3 Federal Physician Self-Referral Prohibitions
3.1 Overview
3.2 Legislative and Regulatory History
3.3 The Statutory Prohibition and Definitions of Key Terms
3.4 Stark Law Exceptions
3.5 Definition of Group Practice
3.6 Penalties and Enforcement
3.7 Advisory Opinions
3.8 Self-Referral Disclosure Protocol
3.9 Other Federal Self-Referral Restrictions
3.10 Major Issues in Stark Law Interpretation

Ch. 4 Administrative Sanctions Available to Federal Enforcers
4.1 Overview
4.2 Exclusion from Medicare, Medicaid, And Other State Health Care Programs
4.3 Imposition of Civil Monetary Penalties
4.4 Suspension of Payments
4.5 Hearing and Appeal Rights of Individuals and Entities Subject to Exclusion and CMPS

Ch. 5 The False Claims Act and Other Means of Federal Enforcement of Health Care Fraud and Abuse Laws
5.1 Overview
5.2 The Federal Civil False Claims Act
5.3 Other Civil Laws Pertaining to False Claims and Fraudulent Billing Activities
5.4 Criminal Laws Pertaining to False Claims and Fraudulent Billing Activities
5.5 Enforcement Theories Applicable to Multiple Segments of The Health Care Industry
5.6 Enforcement Activities Specific to Particular Segments of The Health Care Industry
5.7 False Claims Actions and Issues Under the Bankruptcy Code

Ch. 6 State and Private Initiatives to Combat Fraud
6.1 Overview
6.2 State Self-Referral Laws
6.3 State Anti-Kickback Proscriptions
6.4 State Fee-Splitting Proscriptions
6.5 State Commercial Bribery and Racketeering Statutes
6.6 State Statutes Regarding Deceptive Trade Practices and Consumer Protection
6.7 State Sunshine Acts Applicable to Pharmaceutical and Medical Device Manufacturers
6.8 State Initiatives to Prevent and Detect Fraud
6.9 Trade Associations
6.10 Private-Payer Initiatives to Address Health Care Fraud

Ch. 7 Compliance and Self-Reporting
7.1 Overview
7.2 Why Have a Compliance Program?
7.3 Federal Sentencing Guidelines
7.4 The Sarbanes-Oxley Act of 2002
7.5 Compliance-Related Resources
7.6 Elements of An Effective Compliance Program
7.7 Demonstrating Effectiveness: Conducting an Effectiveness Review
7.8 CIAs and Other Types of Compliance Agreements
7.9 Self-Reporting and Voluntary Disclosure
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> Updates to the Health Care Fraud Self-Disclosure Protocol
> And more

TABLE OF CONTENTS

PART 1 FALSE CLAIMS ACT HISTORY
Ch. 1:00 Congressional Goals in Passing and Amending the Statute
Ch. 1:01 The 1863 Act and Its Immediate Aftermath
Ch. 1:02 The 1943 Act
Ch. 1:03 Case Law Developments Before the 1986 Amendments
Ch. 1:04 The 1986 Act
Ch. 1:05 The 2009 False Claims Act Amendments
Ch. 1:06 The 2010 Amendments to the False Claims Act

PART 2 APPLICATION OF THE FALSE CLAIMS ACT SUBSTANTIVE PROVISIONS
Ch. 2:00 Substantive Provisions of the False Claims Act: An Introduction
Ch. 2:01 The Meaning of “Person” Under the False Claims Act
Ch. 2:02 The Meaning of “Cause” to Present a False or Fraudulent Claim
Ch. 2:03 False or Fraudulent under the FCA
Ch. 2:04 An FCA “Claim,” “Record,” or “Statement” and Presentment under Subsections 3729(a)(1)(A) and (a)(1)(B)
Ch. 2:05 Knowledge under the False Claims Act
Ch. 2:06 Materiality
Ch. 2:07 Conspiracy
Ch. 2:08 Reverse False Claims

PART 3 CIVIL ACTIONS FOR FALSE CLAIMS
Ch. 3:00 Qui Tam Provisions: An Introduction
Ch. 3:01 Responsibilities of Attorney General—§ 3730(a)
Ch. 3:02 Actions by Private Parties—§ 3730(b)
Ch. 3:03 Rights of the Parties in Qui Tam Actions—§ 3730(c)
Ch. 3:04 Award to Qui Tam Plaintiff—§ 3730(d)
Ch. 3:05 Section 3730(e) Bars to Qui Tam Actions—§ 3730(e)
Ch. 3:06 Expenses and Fees for Which the Government is Responsible
Ch. 3:07 Whistleblower Retaliation Provision—§ 3730(h)
Ch. 3:08 Discovery in Relator-Only Lawsuits
Ch. 3:09 Application of Fed. R. Civ. P. 9(b) to the False Claims Act

PART 4 DAMAGES AND CIVIL PENALTIES
Ch. 4:00 The Computation of Damages and Civil Penalties under the FCA: An Introduction
Ch. 4:01 Pre-1986 Cases Regarding the Scope of Damages under the FCA
Ch. 4:02 The 1986 Legislative Amendments
Ch. 4:03 FCA Damages: Principles and Proof
Ch. 4:04 Practice Areas Raising Damage Issues
Ch. 4:05 Civil Penalties
Ch. 4:06 Constitutional Limitations on Civil Penalties

PART 5 FALSE CLAIMS ACT PROCEDURE AND JURISDICTION
Ch. 5:00 Introduction
Ch. 5:01 False Claims Procedure
Ch. 5:02 FCAJurisdiction

PART 6 CIVIL INVESTIGATIVE DEMANDS
Ch. 6:00 CIDs: An Introduction
Ch. 6:01 CIDs as Administrative Subpoena
Ch. 6:02 Compliance with the Terms of Section 3733
Ch. 6:03 Relevance and Undue Burden
Ch. 6:04 Bad Faith and Abuse of Process
Ch. 6:05 Responding to the CID

PART 7 THE VOLUNTARY DISCLOSURE PROGRAM
Ch. 7:00 Submitting a Voluntary Disclosure: An Introduction
Ch. 7:01 The Operation of the Inspector General’s Voluntary Disclosure Program
Ch. 7:02 The Benefits and Risks Associated with Voluntary Disclosures
Ch. 7:03 Settling the Matter
Fraud and Abuse Investigations Handbook for the Health Care Industry
SECOND EDITION WITH DOWNLOADABLE CONTENT
Paul W. Shaw, Robert A. Griffith, Authors

This Second Edition of Fraud and Abuse Investigations Handbook for the Health Care Industry provides not only the legal context surrounding health care fraud investigations, but also the insight critical to managing the process—and potentially the outcomes that follow. It is accessible for health care administrators, executives, medical directors, office managers, and physicians who need to arm themselves with a broad understanding of fraud and abuse enforcements.

The authors examine each stage of a fraud and abuse investigation, beginning with an overview of federal and state enforcement agencies, and concluding with a discussion of the potential collateral consequences of an investigation. They have supplemented their analysis extensively with sample documents, including indictments, requests for records, subpoenas, internal response memoranda, and responses to auditors, prosecutors, and more.

Highlights include:
- Critically important changes in the handling of mandated and voluntary disclosures of overpayments
- Department of Justice voluntary disclosure guidelines for False Claims Act cases
- A chapter on responding to Medicare and Medicaid audits and initiating appeals, with insight into the post-payment audit process, practical advice on how to respond to a request for records or audit findings, and a description of each step of the appeal process, including settlement procedures
- A chapter on administrative sanctions, discussing the potential risk of sanctions under the Civil Monetary Penalties Law, exclusion from Medicare and/or Medicaid, mandatory vs. permissive exclusion, due process, Medicare and Medicaid program payment suspensions, enrollment denials, and revocations
- A chapter on audits by private payers, examining audit-generating conduct and how to respond to a private payer audits and findings
- A chapter on the collateral consequences that may follow a health care fraud and abuse investigation, including impact on private health insurance participation, state medical board licenses, and more

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Table of Acronyms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ch. 1 Introduction</td>
</tr>
<tr>
<td>Ch. 2 Overview of Enforcement Agencies</td>
</tr>
<tr>
<td>Ch. 3 The Statutory Framework for Fraud and Abuse Investigations</td>
</tr>
<tr>
<td>Ch. 4 Requests for Information, Investigatory Demands, and Subpoenas</td>
</tr>
<tr>
<td>Ch. 5 Responding to Requests for Information</td>
</tr>
<tr>
<td>Ch. 6 Handling On-Site Demands for Records and Access</td>
</tr>
<tr>
<td>Ch. 7 Retaining Attorneys and Professionals During an Investigation</td>
</tr>
<tr>
<td>Ch. 8 Post-Payment Audits Using Statistical Sampling</td>
</tr>
<tr>
<td>Ch. 9 Responding to Medicare/Medicaid Audits and Initiating Appeals</td>
</tr>
<tr>
<td>Ch. 10 Audits by Private Payers</td>
</tr>
<tr>
<td>Ch. 11 Internal Audits and Investigations</td>
</tr>
<tr>
<td>Ch. 12 Mandated and Voluntary Disclosures of Overpayments</td>
</tr>
<tr>
<td>Ch. 13 Administrative Sanctions</td>
</tr>
<tr>
<td>Ch. 14 Prejudgment Remedies and Criminal Forfeiture</td>
</tr>
<tr>
<td>Ch. 15 Criminal and Civil Settlements</td>
</tr>
<tr>
<td>Ch. 16 Collateral Consequences of a Fraud and Abuse Investigation</td>
</tr>
</tbody>
</table>

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Health Information

NEW EDITION

Telehealth Law Handbook
SECOND EDITION WITH DOWNLOADABLE CONTENT

Jennifer R. Breuer, Editor
Kyle Y. Faget, Andrea L. Frey, Jennifer A. Hansen, Elinor A. Hiller, Melania Jankowski,
Amy M. Joseph, Amy F. Lerman, Joseph P. McMenamin, Kerry K. Sakimoto, Jeremy D. Sherer,
Melissa Sobel Snyder, Sean T. Sullivan, Christine Burke Worthen. Authors

The COVID-19 pandemic ushered in not only an extraordinary need for health care providers to build telehealth capabilities, but also extraordinary regulatory flexibility, as federal and state authorities enacted emergency exceptions and permanent changes to longstanding requirements that had previously posed challenges to the adoption of telehealth. In this changed environment, the American Health Law Association is pleased to bring you the expanded and updated second edition of Telehealth Law Handbook.

The editor and authors of this new edition have expanded the contents to reflect considerations key to understanding today’s telehealth legal and operational environment. Maintaining their concise and practical approach to the subject, the authors explain and assess the current state of the law, highlighting risks and opportunities for readers to consider today and into the future. Also included: two 50-state surveys and downloadable sample practice tools.

AHLA recommends this book to advisors of health care entities, technology developers, policy makers, payers, investors, and anyone working to offer telehealth to patients, wherever they may be.

TABLE OF CONTENTS

Ch. 1  Telehealth Models
Ch. 2  Telehealth Regulatory Requirements
Ch. 3  Licensing Issues for Physicians
Ch. 4  Considerations for Non-Physician Telehealth Providers
Ch. 5  Payment and Reimbursement
Ch. 6  Fraud and Abuse
Ch. 7  Privacy and Security Issues in Telehealth
Ch. 8  Liability Issues
Ch. 9  Mobile Health Technology
Appendix A  50-State Survey: Telehealth Medicaid Coverage Laws
Appendix B  50-State Survey: Telehealth Commercial Insurance Coverage Laws
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NEW PUBLICATION

Health Information Privacy & Breach: A 50 State Survey
FIRST EDITION
Carol L. Eoannou, Managing Editor
Foreword by Jonathan M. Joseph

With the vast expansion of telehealth, it has become routine for providers, patients, and health care data to virtually cross state lines. AHLA has done a deep dive into the laws of privacy and data breach in all 50 states and the District of Columbia to develop this new title. Each state’s survey consists of a detailed and well-organized analysis of the jurisdiction’s regulatory framework.

This resource is designed to assist health care industry stakeholders and advisors meet their obligations under state law regarding the digital information created, maintained, and exchanged for the benefit of patients and consumers. Whether responding to a possible data breach or drafting policies related to health record privacy and security, this invaluable publication will facilitate compliance with the highly variable laws regulating this digital data.

**TABLE OF CONTENTS**

**SAMPLE STATE SURVEY CONTENTS**

**BREACH NOTIFICATION LAWS**

For General Data Breach Notification
Type of Information Triggering Notification
Information Definition
Breach Event Requiring Notice
Breach Event Definition
Exemptions
Notice Requirements
Form
Timing
Substitute Notice
Who Must Be Notified of Breach?
Additional Notices
Content of Notice
Delayed Notice of a Data Breach
Potential Penalties Enumerated in the Statute

For Medical Data Breach Notification
Type of Information Triggering Notification
Information Definition
Breach Event Requiring Notice
Breach Event Definition
Notice Requirements
Form
Timing
Substitute Notice
Who Must Be Notified of Breach?
Additional Notices
Content of Notice
Delayed Notice of a Data Breach
Potential Penalties Enumerated in the Statute

**HEALTH CARE PRIVACY LAWS**

Definitions
Patient Access to Records in Various Settings
Health Care Providers
Patient Right to Receive Copies of Patient Medical Records?
Patient Request Process
Possible Exemptions to Patient Access to Records
Exemptions
Restrictions on Use and Disclosure of Health Information
Health Care Entities and Practitioners
Insurers
Government Entities
Other

Exemptions
Privileges
Conditions
Condition-Specific Disclosure Requirements
Alcohol and Substance Abuse
Communicable Diseases
Controlled Substances
Genetic Testing
Infectious Diseases (including HIV/AIDS)
Mental Health and Substance Abuse
Trauma

**GENERAL PRIVACY LAWS**

Consumer Data Protection Act
Exemptions
Exemption for Health Information
Exemption for Entities Under HIPAA

**HELPFUL LINKS**
Market Access, Pricing, and Reimbursement of Drugs and Devices: Legal Principles and Practice
FIRST EDITION
Rujul H. Desai, Stefanie A. Doebler, Kristie C. Gurley, Anna D. Kraus, Editors and authors
Shruti C. Barker, Beth Braiterman, Elizabeth Brim, Tara Carrier, Andrew B. Do, Matthew F. Dunn, Daniel Grant, Alexander B. Hastings, Claire Jacob, Mingham Ji, Sanchi Khare, Caitlin E. Kouy, Michael S. Labson, Kassandra Maldonado, Krysten Rosen Moller, Raymond Ngu, Jennifer Pittsch, Molly Ramsden, Kendra Roberson, Tiffany P. Rodriguez, Sarah M. Schuler, Chelsea Segal, Olivia Vega, Allison Whelan, Authors

Market Access, Pricing, and Reimbursement of Drugs & Devices is a brand new publication that provides a uniquely extensive examination of the legal and business considerations relating to drug and device manufacturing and distribution, including market access, pricing, reimbursement, and promotion. Each chapter serves both early career and experienced practitioners, providing a strong foundation for understanding medical product market access, as well as advanced topics for readers who have been practicing in the pharmaceutical and device industry for many years.

Written through a lens of advising life sciences companies engaging in market access activities, this treatise will prove useful to stakeholders across the medical product supply chain, including manufacturers, distributors, payers, health care providers, government regulators, and numerous additional entities that facilitate access to and distribution of medical products.

TABLE OF CONTENTS
Introduction
PART I Mechanics of Pricing and Reimbursement
Ch. 1 U.S. Market Access Framework
Ch. 2 Drugs and Biologics Pricing and Reimbursement
Ch. 3 Medical Devices and Diagnostics Pricing and Reimbursement
Ch. 4 Government Price Reporting
Ch. 5 Commercial Channel
Ch. 6 Government Purchaser Channel
PART II Compliance and Promotion
Ch. 7 Fraud, Waste, and Abuse Issues
Ch. 8 Communications with Payers
Ch. 9 Support for Patients
PART III Emerging Trends
Ch. 10 Measuring and Contracting for Value
Ch. 11 State Market Access and Drug Pricing Laws
Table of Acronyms

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Pharmaceutical and Medical Device Compliance Manual
SECOND EDITION
Co-published with Seton Hall Law School’s Center for Health & Pharmaceutical Law & Policy
Ela Bochenek, Carl H. Coleman, Amy Matey, Editors
Marc Adler, Joseph S. Calarco, Bret A. Campbell, Colleen A. Conry, Scott Cunningham, Scott D. Danzis, Sujata Dayal, Marc I. Eida, Jacob T. Elberg, Brett R. Friedman, Gary F. Giampetruzzi, Christopher R. Hall, Patrick M. Hromisin, Mark Krueger, Bruce A. Levy, Veronica Lopez, Joseph W. Metro, Gregg Shapiro, Brian P. Sharkey, Anna Spencer, Robert E. Wanerman, Constance A. Wilkinson, Christopher D. Zalesky, Authors

This edition synthesizes what can be an overwhelming quantity of authority into understandable analysis and practical action. The authors share their valuable perspectives on creating, managing, and monitoring an effective compliance program in today’s complex enforcement and business environment.

Study of this Manual will enable compliance professionals and lawyers to understand the government’s expectations of an effective compliance program and ethical business practices, as well as how the government discovers potential enforcement actions, its approach to pursuing such actions, and what behaviors can constitute mitigating factors for a company in the event of a legal violation.

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TABLE OF CONTENTS

Ch. 1 Enforcement Authorities
Ch. 2 Thou Shalt Not Buy Business: The Implications of The Anti-Kickback Statute on The Drug and Device Industry
Ch. 3 False Claims Act
Ch. 4 Advertising, Labeling, and Promotion
Ch. 5 Drug and Device Development and Approval
Ch. 6 Federal Health Care Programs: Coverage and Reimbursement of Prescription Drugs and Medical Devices
Ch. 7 International Anti-Bribery and Anti-Corruption Laws
Ch. 8 Major Privacy Laws and Their Impact on Life Science Companies
Ch. 9 Federal and State Transparency Laws
Ch. 10 Elements of an Effective Compliance Program
Ch. 11 Prescription Drug Price Regulation
Ch. 12 Pharmaceutical Industry Interactions with Patient Organizations: Defining Regulatory Parameters
Ch. 13 Compliance 2.0: Compliance Analytics in the Era of Big Data
Ch. 14 The Art and Science of Health Care Compliance in the Pharmaceutical and Medical Device Industries: Principles, Choices, Questions, Tools
Vaccine, Vaccination, and Immunization Law
SECOND EDITION
Brian Dean Abramson, Author with Dorit Reiss, Peter O. Safir, and John R. Thomas

This complete, fully referenced work is a one-stop source for understanding vaccine and vaccination law from every angle. Coverage includes:

- State regulation of physicians, pharmacists, and others who prescribe and administer vaccines
- Public mandates
- Limitations on employers’ ability to require vaccination
- Privacy considerations surrounding individuals’ vaccination status
- Compensation and potential liability relating to vaccine injuries
- Government regulation of vaccine testing and approval for sale, manufacture, advertising, and distribution
- Regimes for rationing vaccines in the event of a shortage
- Protocols for responding to an epidemic, pandemic, or bioterror attack using an infectious disease
- Patent protection, trademarks, and trade secrets

Also included: state-by-state coverage of vaccination requirements for both health care workers and patients.

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<thead>
<tr>
<th>Member</th>
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</tbody>
</table>

Appendix A CDC Table of Vaccine Names
Appendix B CDC Table of Vaccine Acronyms & Abbreviations
Appendix C CDC Vaccine Price List
Appendix D FDA Guidance for Industry on Review of Vaccine Labeling Requirements
Appendix E Afluria® Vaccine Package Insert, by Seqirus®
Appendix F Vaccine Information Statement (VIS) for Varicella (Chickenpox) Vaccine
Appendix G IAC Model Standing Orders for Administering Influenza Vaccine to Adults
Appendix H 42 U.S.C. Part F—Licensing of Biological Products and Clinical Laboratories (§§262–262a)
Appendix I 42 U.S.C. Subchapter XIX, Part 1—National Vaccine Program (§§300aa–1 to 300aa–6)
Appendix K 26 U.S.C. §9510—Vaccine Injury Compensation Trust Fund
Appendix L 42 U.S.C. Subchapter XIX—Grants to States for Medical Assistance Programs, §1396s—Program for Distribution of Pediatric Vaccines
Appendix N Jacobson v. Massachusetts, 197 U.S. 11 (1905)
Appendix O Zucht v. King, 260 U.S. 174 (1922)
Appendix P VAERS Table of Reportable Events Following Vaccination
Appendix Q Industry Guidance for Filing VAERS Reports: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS–1)
Appendix R Vaccine Injury Table
Appendix S Vaccine Rules of the United States Court of Federal Claims
Appendix T Guidelines for Practice Under the National Vaccine Injury Compensation Program
Appendix U List of Countries, Territories and Areas: Vaccination Requirements and Recommendations for International Travelers, Including Yellow Fever and Malaria

TABLE OF CONTENTS

Ch. 1 Introduction to Vaccine Law
Ch. 2 Regulation of Vaccines
Ch. 3 Vaccine Patents
Ch. 4 Vaccine Patent Litigation
Ch. 5 Other Intellectual Property Protection for Vaccines
Ch. 6 Vaccination Funding, Payment, and Access Issues
Ch. 7 Vaccine Mandates and Requirements
Ch. 8 Vaccination Exemptions
Ch. 9 Employer Mandates and Other Private Vaccination Efforts
Ch. 10 U.S. State Vaccine Laws
Ch. 11 Vaccine Adverse Event Reporting and Other Reporting Requirements
Ch. 12 Vaccine Injury Claims
Ch. 13 Specific Vaccines and Components
Ch. 14 International and Comparative Vaccine Laws
Ch. 15 Anti-Vaccine Activism and the Law
Representing Physicians Handbook
FOURTH EDITION
A Task Force of the AHLA Physician Organizations Practice Group
Michael F. Schaff, Task Force Chair
Lisa Gora, Coordinating Editor
with numerous Contributing Authors

From regulatory compliance and business formation and operation, to tax consequences and reimbursement issues, this informative Handbook has become a go-to source for those who represent physicians in the increasingly complex physician practice world. Each chapter is written by a practitioner in his or her area of expertise, addressing critical issues such as the structure of physician groups, regulatory issues, employment arrangements, reimbursement, hospital relations, professional liability, joint ventures, and more.

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TABLE OF CONTENTS
Ch. 1 Physician Practice Organization
Ch. 2 Overview of Regulatory Issues Affecting Physicians
Ch. 3 Telemedicine
Ch. 4 Employment Agreements and Other Working Relationships
Ch. 5 Life Cycle of Association: The Buy-In and the Buy-Out
Ch. 6 Tax Principles Concerning Buy-Outs and Related Post-Withdrawal Compensation Issues
Ch. 7 Tax Consequences Resulting From Choice of Entity
Ch. 8 Practice Breakups and Physician Departures
Ch. 9 Reimbursement of Physician Services
Ch. 10 Physician/Hospital Relationships
Ch. 11 Professional Liability: A Primer on Malpractice Insurance and Risk Management
Ch. 12 Physician Joint Ventures
Ch. 13 The Sale and Purchase of a Medical Practice
Ch. 14 Hospital-Based Physician Representation
Ch. 15 Use of Non-Competition Covenants in Physician Employment Relationships
Ch. 16 Labor and Employment
Ch. 17 Industry Relationships
Ch. 18 Compliance, Compliance Plans, and Process for the Physician Practice
Ch. 19 Non-Physician Practitioners
Ch. 20 Physician Ancillary Services
Ch. 21 Physician Recruitment Agreements
Ch. 22 Physician Agreements
Ch. 23 Background on Concierge Care
Ch. 24 Physician In-Office Drug Dispensing and Compounding Arrangements
Table of Cases
Table of Statutes
Index

If you represent physicians, don’t miss these related titles:
The Stark Law, p. 8
Health Care Transactions Manual, p. 20
Corporate Practice of Medicine, p. 21
The Complete Medical Staff, Peer Review, and Hearing Guidebook
FIRST EDITION WITH DOWNLOADABLE CONTENT

Christopher A. Adelman, S. Allan Adelman, Mayo B. Alao, Charles Chulack, Joshua Hodges, Maggie Martin, Lauren M. Massucci, Hala Mouzaffar, and Dan Mulholland, Authors

Readers will find a concise and comprehensive discussion of issues commonly faced by attorneys and others working in and around the interdependent relationship of a health care entity and its medical staff. The authors examine this complex relationship from both practical and legal perspectives. From application to separation, this work provides analysis, cautions, recommendations, and examples of provisions for bylaws and associated documents—sample tools that can be tailored to suit the needs of a variety of health care entities.

The Complete Medical Staff, Peer Review, and Hearing Guidebook addresses trends toward informal resolution, increased integration, growing reliance on allied health professionals, and much more.

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TABLE OF CONTENTS

PART 1: MEDICAL STAFF
Ch. 1 Introduction: Historical Perspective on the Medical Staff/Hospital Relationship
Ch. 2 Basic Statutory, Regulatory, and Accreditation Matters
Ch. 3 Health Care Quality Improvement Act of 1986
Ch. 4 Underlying Legal and Business Issues Impacting the Hospital/Medical Staff Relationship
Ch. 5 Organizational and Drafting Tips for Medical Staff Bylaws and Related Documents
Ch. 6 Key Provisions of Health Care Entity Bylaws
Ch. 7 Overview of Medical Staff Bylaws
Ch. 8 Credentialing Procedures
Ch. 9 Privileging: Procedures for Determination of Clinical Privileges
Ch. 10 Bylaws as a Foundation for Peer Review

PART 2: PEER REVIEW
Ch. 11 Introduction to Peer Review
Ch. 12 Categorizing Concerns that Can Be Addressed by Peer Review
Ch. 13 Process for Initiating an Investigation
Ch. 14 Use of Informal Resolution in Peer Review
Ch. 15 Precautionary Suspension of Physician Privileges
Ch. 16 Automatic Relinquishment of Clinical Privileges
Ch. 17 Injunctions Challenging Peer Review Actions
Ch. 18 Special Considerations for the Peer Review of Employed Physicians
Ch. 19 Using a Patient Safety Organization to Protect Peer Review Information
Ch. 20 Allied Health Professionals
Ch. 21 HIPAA Privacy Rule Considerations

PART 3: PEER REVIEW HEARING
Ch. 22 Introduction and Overview of Applicable Law
Ch. 23 Bylaws Providing a Foundation for a Successful Hearing
Ch. 24 When is a Hearing Required?
Ch. 25 Notice to Practitioner
Ch. 26 Role of Legal Counsel
Ch. 27 Use of Hearing Officer
Ch. 28 Selection of Hearing Committee Members, Arbitrator, or Hearing Officer
Ch. 29 Pre-Hearing Procedures, Including Discovery
Ch. 30 Burden of Proof and Evidentiary Standards
Ch. 31 Making a Hearing Record
Ch. 32 Conduct of Hearing
Ch. 33 Hearing Committee Decision and Report
Ch. 34 Proceedings after Hearing Committee Report
Health Care Finance and Transactions

Health Care Transactions Manual: Understanding the Consequences of the Health Care Deal
FIRST EDITION WITH DOWNLOADABLE CONTENT
Kim Harvey Looney, Glenn P. Prives, Deborah Farringer, Editors

Health care transactions pose unique and complex legal questions arising from intense federal and state regulation and enforcement. This Manual is the ideal guide for gaining an understanding of the legal landscape, and for managing the risks involved in structuring health care deals.

What makes sense in the business world does not always make sense in the health care world, and this publication is your key for knowing the difference and avoiding potential pitfalls. The Manual will help you understand nuances such as:

- When seemingly straightforward business terms can veer toward health care fraud and abuse
- How health care organization and/or management structure can impact the deal
- The need to comply with both non-disclosure terms and federal and state privacy laws when conducting due diligence
- How increased collaboration between health care entities may give rise to antitrust issues
- How tax-exempt status may be impacted in the course of a deal between exempt and non-exempt entities
- The need to consider state and federal environmental implications as they relate to radioactive materials used in patient care

With contributions from more than a dozen attorney practitioners, the Manual provides invaluable practical guidance covering everything from the transactional basics to deep-dive discussions for negotiating complicated deals. The book also contains more than 20 downloadable exhibits, ranging from a Sample Preliminary Due Diligence Request to a Sample Closing Checklist.

TABLE OF CONTENTS

Ch. 1 Organizing the Health Care Transaction
Ch. 2 Health Care Transaction Fundamentals: Licensing, Ownership, Reimbursement, Fraud, and Other Liabilities
Ch. 3 Laws Relating to Corporate Operations: Intellectual Property, Environmental Laws, Franchises, Securities, and Employment Law
Ch. 4 Antitrust Issues in Health Care Transactions
Ch. 5 Tax Issues in Health Care Transactions
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The corporate practice of medicine (CPOM) doctrine seeks to keep non-physician corporation owners from interfering with a physician’s professional judgment. CPOM application is far from simple, and adoption and enforcement vary by state. States adopt various models—with exceptions—and others eliminate the prohibition completely, while some states have CPOM prohibitions that are not enforced.

In the latest edition of this popular guide, the authors have expanded coverage to include an even broader range of health care professionals. You will find the latest information on practice restrictions by state as they relate to: behavioral health providers, chiropractors, optometrists, and more. CPOM researchers typically need to review a tangled web of statutes, regulations, case law, and attorney general or agency opinions to gain useful insight. The authors have provided a time-saving roadmap to help you:

- Learn which model of the doctrine a specific state follows
- Discover sources to consult for more detail
- Explore related issues like fee splitting and the unlicensed practice of medicine

This survey is invaluable to attorneys who represent health care entities, organizations, businesses, physicians, and investors looking for opportunities in this complex regulatory sector. Use it to efficiently gain a thorough exploration of the doctrine in each state and the District of Columbia.
Antitrust

Antitrust and Health Care: A Comprehensive Guide
SECOND EDITION
Christine L. White, Saralisa C. Brau, David Marx Jr., Authors and Editors
Joshua H. Soven, Shoshana Speiser, and Kati Williams, Contributing Authors

The Second Edition of this publication squarely meets the practitioner’s need for a clear, concise overview of general antitrust principles, along with analyses of their application to the health care sector.

The authors draw on their significant government enforcement and private sector counseling and litigation experience to provide practical insights for:

- Developing antitrust compliance and “sensitivity training” programs
- Identifying conduct and language that could create antitrust “red flags”
- The creation, distribution, and use of emails, electronic documents, and other materials
- Antitrust safety zones, defenses, and immunities

TABLE OF CONTENTS

| Ch. 1  | Introduction |
| Ch. 2  | Antitrust Overview |
| Ch. 3  | Mergers, Acquisitions, and Issues of Legality |
| Ch. 4  | Premerger Notification and Transaction Planning |
| Ch. 5  | Joint Ventures |
| Ch. 6  | Provider Networks and Managed Care Contracting |
| Ch. 7  | Trade Associations, State Regulatory Bodies, and Group Purchasing Organizations |
| Ch. 8  | Medical Staff Privileges, Exclusive Physician Contracts, and Peer Review |
| Ch. 9  | Monopolization |
| Ch. 10 | The Robinson Patman Act |
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AHLA’s Health Care Fraud Settlement Index (NEW), p. 7
Health Care Transactions Manual: Understanding the Consequences of the Health Care Deal, p. 20
Health Care Contracts: A Clause–By–Clause Guide to Drafting and Negotiation, p. 5
This classic work provides unparalleled practical coverage of the themes and trends in managed care contracting. It is filled with concise and detailed advice for addressing the issues that arise for both payers and providers in managed care network relationships.

The Eighth Edition traces the managed care contracting process, from preparing to negotiate the contract, to formation and implementation, to termination issues. With contributions from more than 20 authors, the book includes nearly 300 sample clauses, many from the authors' own files. The clauses provide variations in language to illustrate potential advantage to the respective parties, as well as factors to consider when negotiating in today's dynamic legal and business context.

The authors address emerging issues in managed care contracting, including:

- Managed care penetration into Medicare and Medicaid
- Value-based payments and the associated financial and operational considerations
- Large health systems launching as independent payers or through integrated delivery models
- The rise of direct-to-employer contracting
- A growing need to address uses and ownership of data
- Increasing focus on considerations when a provider does not have a contract with a payer

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TABLE OF CONTENTS

Ch. 1 Introduction: Basics of Contracting and Negotiating
Ch. 2 Accountability and Collaboration in Payer-Provider Relationships
Ch. 3 Antitrust Issues in Payer-Provider Contracting
Ch. 4 Key Contract Definitions
Ch. 5 Policy and Procedure Amendments
Ch. 6 Payer Programs and Policies: Utilization Management and Quality Assurance
Ch. 7 Payment Methodologies
Ch. 8 Term and Termination Provisions
Ch. 9 Insurance Requirements and Indemnification
Ch. 10 Other Material Contract Provisions
Ch. 11 Provisions Related to Data Sharing
Ch. 12 Dispute Resolution
Ch. 13 Protecting Against Insolvency
Ch. 14 Medicare Managed Care Contracting
Ch. 15 Medicaid Managed Care
Ch. 16 Direct-to-Employer Contracting
Ch. 17 Considerations in the Absence of a Contract Between Provider and Payer
Appendix A Glossary of Health Plan Contracting Terms
Appendix B Table of Sample Clauses
Appendix C Physician Group Practice Provider Agreement Template With Commentary
Health Care Delivery Models

Representing Hospitals and Health Systems Handbook
FIRST EDITION
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with numerous additional Authors and Editors

Operating the health care entity—whether an established business, or one that has been newly created—receives thorough treatment in this *Handbook*. Coverage includes:
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> Payment methodologies
> Operational issues, including patient relations, privacy, grievance rights, and consent to treatment

From attorneys to providers to lenders, anyone who needs to understand the intricacies and complexities of hospitals and health systems will consider this book an indispensable resource.

**TABLE OF CONTENTS**

**PART 1 BACKGROUND AND HISTORY**
Ch. 1 Background and History

**PART 2 ESTABLISHING AND MAINTAINING HOSPITALS**
Ch. 2 Licensure, Certification and Related Requirements
Ch. 3 Medicare Enrollment and Certifications

**PART 3 SOURCES OF REVENUE-PAYMENT FOR HOSPITAL SERVICES**
Ch. 4 Sources of Revenue
Ch. 5 Medicare Payment Adjustments
Ch. 6 Rural Hospitals and Other Providers
Ch. 7 Other Medicare Payment Issues
Ch. 8 Medicare Provider-Based Status
Ch. 9 Medicare Audits and Appeals Process
Ch. 10 Medicare and Medicaid Alternative Payment Models
Ch. 11 Medicaid
Ch. 12 Private Payers
Ch. 13 The Uninsured and Underinsured

**PART 4 FRAUD AND ABUSE PRINCIPLES FOR HOSPITALS**
Ch. 14 Federal Fraud and Abuse Laws
Ch. 15 State Fraud and Abuse Laws
Ch. 16 Fraud and Abuse Issues Unique to Hospitals
Ch. 17 Compliance with Fraud and Abuse Laws

**PART 5 RELATIONSHIPS WITH PHYSICIANS**
Ch. 18 Common Arrangements with Physicians
Ch. 19 Hospital-Physician Alignment Strategies
Ch. 20 Medical Staff Issues

**PART 6 HOSPITAL OPERATIONAL ISSUES**
Ch. 21 Patient Relations
Ch. 22 EMTALA
Ch. 23 Risk Management
Ch. 24 Privacy and Medical Records
Ch. 25 Telehealth—The Newest Age of Health Care Delivery
Ch. 26 Hospital Contracting Issues
Ch. 27 340B Issues
Ch. 28 Clinical Research

**PART 7 TRANSACTIONS**
Ch. 29 Transactions

**PART 8 INTEGRATED HEALTH SYSTEMS**
Ch. 30 Other Providers

**PART 9 MISCELLANEOUS**
Ch. 31 Academic Medical Centers
Ch. 32 Public Hospitals
Ch. 33 Children’s Hospitals
Ch. 34 Antitrust Issues for Hospitals and Health Systems
Ch. 35 Tax Issues
Ch. 36 Governance
Ch. 37 Labor and Employment
Ch. 38 Real Estate Issues

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- State self-referral laws and their impact on ASCs

**TABLE OF CONTENTS**

Ch. 1  Introduction and Background  
Ch. 2  Anti-Kickback and Self-Referral Issues  
Ch. 3  Tax-Exempt Status and Tax-Related Issues  
Ch. 4  State Self-Referral Issues  
Ch. 5  Reimbursement  
Ch. 6  Medicare Certification, Licensing, and CON (Certificate-of-Need) Issues for ASCs  
Ch. 7  Antitrust Considerations Affecting ASCs  
Ch. 8  Compliance

Exhibit 1  ASC Safe-Harbor Regulations of the Anti-Kickback Statute  
Exhibit 2  Sample Compliance Plan  
Exhibit 3  Sample Operating Agreement  
Exhibit 4  Sample Policy for Antitrust Compliance

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