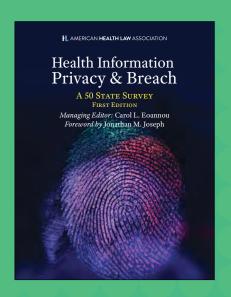
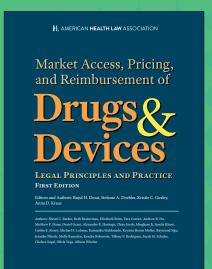
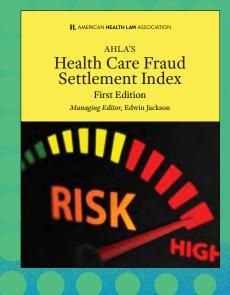
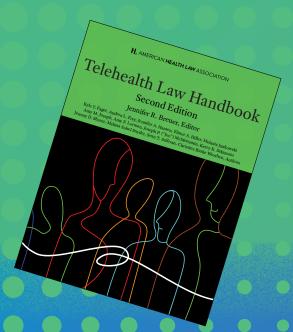
# PUBLICATIONS 2023-2024 Catalog













# Trusted education. CLE on demand.

Recorded from AHLA's esteemed in-person events, CLE-ePrograms deliver insights from industry experts on your schedule. Earn credit on demand with a variety of programs, including:

- Fundamentals of Health Law
- Physicians and Hospitals Law Institute
- Institute on Medicare and Medicaid Payment Issues
- ▶ Health Care Transactions
- And more!



educate.americanhealthlaw.org







# Dear Health Law Professional:

As the nation's largest, nonpartisan, educational nonprofit devoted to legal issues in the health care field, we maintain excellence in health law by educating and connecting the health law community. Whether it is just-in-time education or publishing trusted resources, we help you solve current challenges in today's ever-changing health care environment.

With over 12,000 members and more than 25,000 engaged health law professionals, AHLA has deep roots with expert practitioners, representing clients and organizations across the entire health care spectrum, who have dedicated their time and expertise to AHLA-produced publications and other resources. We thank all authors and contributors of the publications listed in this catalog who have provided critical resources that will benefit anyone who advises physicians, hospitals, health systems, specialty providers, payers, life sciences companies, and many other health care stakeholders.

As you work to become more effective leaders in health law, this catalog offers dozens of titles addressing both fundamental and emerging issues facing the health law community today, providing you with a foundation of knowledge in all areas of health law. Current AHLA members will receive a discount on all AHLA publications at the LexisNexis® Store, at AHLA in-person programs, educational webinars, and more. Interested parties can join AHLA at www.americanhealthlaw.org/join.

We invite you to browse our portfolio, published in alliance with LexisNexis® and look forward to serving your educational needs now and into the future.

mw/ae

David S. Cade Executive Vice President/Chief Executive Officer American Health Law Association

# **TABLE OF CONTENTS**

Essential Resources	2
Fraud and Abuse	7
Health Information	13
Life Sciences	15
Physicians	18
Health Care Finance and Transactions	20
Antitrust	22
Health Insurance	23
Health Care Delivery Models	24
Index	25



**ORDER TODAY** 

ONLINE at lexisnexis.com/AHLA

CALL **866.471.0909** 

# **Essential Resources**

# **UPDATED ANNUALLY**

# **AHLA's Federal Health Care Laws & Regulations**

2021 - 2022 EDITION WITH 2022 SUPPLEMENT AND EBOOK

William W. Horton, Editor

Dee Anna D. Hays, John A. Meyers, Daniel F. Murphy, Serra J. Schlanger, Paul W. Shaw, Faraz R. Siddiqui, Donald B. Stuart, Kelly A. Thompson, Judith A Waltz, Editorial Advisory Board

AHLA's Federal Health Care Laws & Regulations incorporates the most significant and timely U.S. statutes and regulations, selected by health law practitioners who know what longstanding essentials and new authorities you will turn to again and again. The 2021 - 2022 edition contains:

- > Federal Statutes current through 117th Congress 2nd Session, P.L. 117-159
- > Federal Regulations current through July 27, 2022
- > Regulations on surprise medical and air ambulance bills
- > COVID-19 Emergency Temporary Standard for health care workplaces
- > Updated exemptions for telehealth services
- > Latest changes to the Social Security Act
- > Enactment of the Competitive Health Insurance Reform Act of 2020
- > Amendments to the Internal Revenue Code of 1986 to ensure continuity of care
- > Requirement for Maintenance Price Comparison Tool for group health plans
- > Regulatory changes to the Public Health Service Act
- > Public awareness campaign on the importance of vaccinations
- > Improving transparency by removing gag clauses on price and quality information
- > Updated health care provider requirements
- > Modifications to coverage under CHIP for pregnant and postpartum women
- > Important legislation and regulations relating to Federal, Food, Drug, and Cosmetic Act, the Infrastructure Investment and Jobs Act, Social Security Act, Affordable Care Act and much more

11,364 pages, 5 volumes, softbound with eBook, Pub. #26742, © 2021

### Member

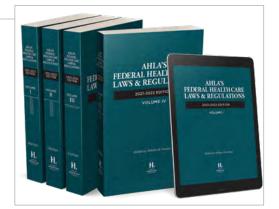
**\$399** | ISBN 9781663304919 **\$394** | eISBN 9781663304957

# **BEST VALUE!**

Print purchase also includes the eBook.

Non-member

**\$479** | ISBN 9781663304926 **\$474** | eISBN 9781663304964



#### **TABLE OF CONTENTS**

#### VOLUME 1

# **United States Code Titles**

- Title 2 The Congress
- 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
- Title 41 Public Contracts and Property Management

# VOLUME 3

# Code of Federal Regulations, continued

Title 42 Public Health

### VOLUME 4

# Code of Federal Regulations, continued

Title 42 Public Health, continued

Title 45 Public Welfare Index

2022 SUPPLEMENT

New edition coming this Fall

# **UPDATED ANNUALLY**

# AHLA's Guide to Health Care Legal Forms, Agreements, and Policies THIRD EDITION WITH 2023 SUPPLEMENT, INCLUDING DOWNLOADABLE CONTENT

This cornerstone of your health law library is designed to help you work more efficiently and accurately by bringing together hundreds of documents, checklists, and policies in one place. The Guide represents the cumulative work of scores of health care attorneys and providers who share their real-time, practical experience with colleagues. With the wealth of sample tools contained in the Guide, users have a go-to source for readily extracting and adapting material needed in their day-to-day work.

With three volumes of material, the Guide offers an unprecedented collection spanning: health care transactions, corporate compliance, facility operations, fraud and abuse, governance, health information, contracting, labor and employment, physician practices, reimbursement, and more.

The 2023 update includes more than 50 must-have resources, ranging from leases to valuebased arrangements to legal department metrics—as well as two state surveys on balance billing laws and assisted living infection control regulations.

Purchase includes digital access to the entire contents of the Guide. Download and adapt these tools to your clients' needs today.

4,866 pages, 3 volumes, loose-leaf with annual supplement and downloadable forms content, Pub. #27635, © 2020 **MORE THAN 50** 

Member

\$565 | ISBN 9781663304919

Non-member

\$665 | ISBN 9781663304926



# **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

# Ch. 7 HEALTH INFORMATION

Big Data Issues **Breach Notification Business Associates** Electronic Health Records General Data Protection Regulations

HIPAA Privacy

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** 

Informed Consent

Patient Safety & Security

# Ch. 15 TAX AND NONPROFIT

Charity Care

Tax Exempt Status

Print subscribers can download the contents of all three volumes at no additional cost.

# NEW PUBLICATION

# **Federal Health Care Discrimination Law**

# SECOND EDITION

David Didier Johnson, Author

Federal Health Care Discrimination Law is intended to help health care providers and plans understand the laws that address discrimination in health care services and coverage.

Interpretations of even longstanding laws are continually shifting, requiring health care providers, insurers, and the professionals who advise them to take frequent stock of what it is required to comply with federal anti-discrimination authorities. Affordable Care Act Section 1557 and related laws, for example, require new inquiries into health care operations; the terms, conditions, and administration of coverage; plan and provider communications with enrollees and patients; and hospital administration and rules of conduct.

Available in print and eBook formats 700 pages, 1 volume, softbound, Pub #26867, © 2023

#### Member

**\$184** | ISBN 9781663362162 **\$179** | eISBN 9781663362186

#### Non-member

**\$224** | ISBN 9781663362179 **\$219** | eISBN 9781663362193



# **TABLE OF CONTENTS**

Acknowledgments

About the Author

Ch. 1 Introduction

# PART I

- Ch. 2 How Historic Civil Rights Acts and the Affordable Care Act Section 1557 Apply to Health Care Entities
- Ch. 3 Race, Color, and National Origin Discrimination
- Ch. 4 Sex Discrimination
- Ch. 5 Disability Discrimination
- Ch. 6 Age Discrimination
- Ch. 7 Communication Disabilities and Non-English Speakers
- Ch. 8 Affordable Care Act Section 1557 and the Federal Financial Assistance Civil Rights Acts: Entities Covered, Administrative Obligations, and Enforcement

#### 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

# PART IV

Ch. 13 Federal Health Care Conscience Statutes Table of Cases

Index

# **Fundamentals of Health Law**

# SEVENTH EDITION WITH EBOOK

Anita Beth Adams, Barry D. Alexander, Bernadette M. Broccolo, Anthony H. Choe, Anthea R. Daniels, Rebecca E. Dittrich, Sandra M. DiVarco, Anjali N.C. Downs, Geoff A. Drucker, Catherine A. Hurley, Raymond J. Lindholm, Carol Colborn Loepere, Thomas Wm. Mayo, John J. Miles, Yetunde Oni, Kristen Rosati, Ross E. Sallade, Michael F. Schaff, Susan O. Scheutzow, Daniel J. Schwartz, Nancy A. Sheliga, Kerrin B. Slattery, Craig H. Smith, Melissa A. Soliz, Authors

This Seventh Edition of *Fundamentals of Health Law* is a thorough resource for individuals who need to understand not only fundamental health law requirements, but also the complex web of legal relationships among patients, providers, suppliers, payers, technology vendors, researchers, and others.

# **TABLE OF CONTENTS**

- Ch. 1 Terminology
- Ch. 2 Patient Care
- Ch. 3 Medicare
- Ch. 4 Medicaid Fundamentals
- 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
- Ch. 12 Health Care Transactions and Contracting
- Ch. 13 Bioethics
- Ch. 14 Data Sharing for Clinical Integration and other "Big Data" Initiatives
- Ch. 15 Dispute Resolution

Index

Available in print and eBook formats 679 pages, softbound with eBook, Pub. #26940, © 2018

### Member

**\$149** | ISBN 9781522153313

\$143 | eISBN 9781522153337

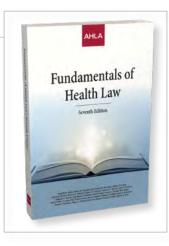
# Non-member

\$199 | ISBN 9781522153320

\$190 | eISBN 9781522153344

### **BEST VALUE!**

Print purchase also includes the eBook.



# Health Care Contracts: A Clause-By-Clause Guide to Drafting and Negotiation

# FIRST EDITION WITH DOWNLOADABLE CONTENT

Dorthula Powell-Woodson, Bethany A. Corbin, Editors in Chief

Matthew M. Brohm, Stacey L. Callaghan, Matthew Cin, Cynthia M. Conner, Ritu Kaur Cooper, Geoff Drucker, Douglas S. Eingurt, Alex Foster, Sarah Hogan, Lindsay P. Holmes, David Kopans, Robin L. Larmer, Michael L. Lawhead, Rachel Ludwig, Stanford L. Moore, Megan C. Phillips, Cynthia Y. Reisz, Angelique M. Salib, Susan O. Scheutzow, Gregory A. Tanner, Cori Casey Turner, Jennifer Whitton, Authors

Health Care Contracts: A Clause-By-Clause Guide to Drafting and Negotiation provides contract drafters with the foundational knowledge necessary to draft sound health care contracts. Sample contract language and analysis is provided throughout this title so that a new (or new to health care) attorney doesn't have to start from scratch.

From the Health Insurance Portability and Accountability Act to the federal Anti-Kickback Statute and the False Claims Act, the health care industry is unique in the volume and scope of its regulations. Transactions and business arrangements that are permissible in other industries may run afoul of fraud and abuse laws in the health care context. For this reason, it is not enough to simply know how to draft a contract. The health care attorney must know much more, including whether the proposed venture is even permissible under federal and state health care laws. If not, the attorney must devise creative contracting solutions to achieve the client's ultimate objective, including restructuring the deal if necessary.

This First Edition tackles the major regulations and risk areas for health care organizations that must be adequately considered and addressed in any contract. Infused with insights and knowledge from health care experts across the United States, this product serves a crucial guide for learning as you work and includes a complimentary digital component with customizable content.

Available in print and eBook formats

246 pages, 1 volume, softbound, including downloadable clauses, Pub. #28223, © 2021

# Member

**\$169** | ISBN 9781663323699 **\$164** | eISBN 9781663323705

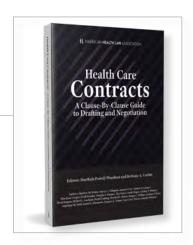
### Non-member

**\$205** | ISBN 9781663323835 **\$200** | eISBN 9781663323842

# **TABLE OF CONTENTS**

- Ch. 1 Introduction to Health Care Contracting, Issue Spotting, and Regulatory Considerations
- Ch. 2 The Health Care Lawyer's Role
- Ch. 3 Representations and Warranties
- Ch. 4 Indemnification Provisions
- Ch. 5 Limitation of Liability and Provisions
- Ch. 6 Force Majeure Provisions
- Ch. 7 Information Technology Provisions
- Ch. 8 Fraud and Abuse Provisions
- Ch. 9 Health Care Contracts and Privacy
- Ch. 10 Termination Provisions
- Ch. 11 Dispute Resolution Provisions

Appendix Table of Sample Clauses





# **Health Care Compliance Legal Issues Manual**

#### FIFTH EDITION

Ann T. Hollenbeck, Karen Lovitch, Lester J. Perling, Cynthia F. Wisner, Editors

Brooke Bennett Aziere, Amy Bailey, Douglas A. Blair, Elizabeth Callahan–Morris, Kyle E. Calvin, Elizabeth Carder–Thompson, Ritu Kaur Cooper, Thomas S. Crane, Gerald "Jud" E. DeLoss, Kyle Y. Faget, Emily Black Grey, Gerald M. Griffith, Nancy Bonifant Halstead, Jake Harper, Kenneth E. Hooper, Gabriel L. Imperato, Kevin Kifer, Ronald H. Levine, Melissa L. Markey, Joseph Metro, Macauley Rybar, Alexandra B. Shalom, Albert W. Shay, Harry R. Silver, E. John Steren, Drew Stevens, Sarah E. Swank, Teresa A. Williams, Amanda M. Wilwert, Howard J. Young, Authors

This edition of the *Health Care Compliance Legal Issues Manual* continues to be the authoritative source for every health care stakeholder, providing strategies for addressing the full scope of legal issues critical to health care compliance. Users will want to consult this instructional text for answers to these questions and more:

- > What constitutes a compliance program?
- > How do I conduct an internal investigation?
- > Do I know the audit basics?
- > What must I consider prior to deciding on repayments and disclosures?

With contributions from more than 20 esteemed authors and editors writing in their respective areas of expertise, the authors provide practical guidance for complying with requirements, as well as coverage of emerging and unsettled areas of compliance risk.

# **TABLE OF CONTENTS**

# PART ONE: BASICS

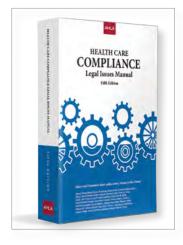
- Ch. 1 Glossary of Key Terms
- Ch. 2 What Is a Compliance Program?
- Ch. 3 OIG Model Compliance Guidance by Provider Type
- Ch. 4 Background Checks and Excluded Persons
- Ch. 5 Government Program Participation and CMS Billing Revocation Authority
- Ch. 6 Corporate Transparency and Disclosure
- Ch. 7 Regulatory Advice and Liability Issues

# PART TWO: INVESTIGATIONS AND ENFORCEMENT

- Ch. 8 What to Do When the Government Knocks
- Ch. 9 Managing an Internal Investigation
- 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

# PART THREE: KEY AREAS OF COMPLIANCE CONCERN

- Ch.14 Medical Necessity, Claims, and Payment
- 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
- Ch.19 Behavioral Health
- Ch. 20 Research Compliance
- Ch. 21 Antitrust Laws
- Ch. 22 Drugs, Devices, and Life Sciences Entities
- Ch. 23 Exempt Organizations and Other Tax Compliance Issues



Available in print and eBook formats 792 pages, softbound, Pub. #27060, © 2019

#### Member

**\$197** | ISBN 9781522173410 **\$192** | eISBN 9781522173434

#### Non-member

**\$239** | ISBN 9781522173427 **\$234** | eISBN 9781522173441



For more information on these titles, EMAIL: Publishing@AmericanHealthLaw.org.

# Ask Us About

# **Upcoming New Titles**

- > Taxation of Hospitals and Health Care Organizations, Third Edition
- > Representing Hospitals, Second Edition
- > Enterprise Risk Management for Health Care Entities, Fourth Edition

Visit lexisnexis.com/ahla for the complete portfolio of titles!

# Fraud and Abuse

# NEW PUBLICATION

**UPDATED ANNUALLY** 

# **AHLA's Health Care Fraud Settlement Index**

FIRST EDITION WITH DOWNLOADABLE CONTENT

Edwin Jackson, Managing Editor

This brand new practice tool indexes more than 300 recent health care fraud settlements, making it possible for you to efficiently evaluate the enforcement landscape.

Review settlements indexed by allegation, state, or entity type to spot enforcement trends and assess your clients' risk. Facilitate your further research using detailed charts, which include:

- > Entity type (12 types, including health systems, hospitals, individuals, laboratories, and more)
- > Recovery amount
- > Allegation type (False Claim, Anti-Kickback, Stark, and others)
- > Summary of allegations
- > Party names
- > Participating agencies
- > Court, including docket numbers
- > URLs for press releases, settlement agreements, corporate integrity agreements, and more

This print desk reference includes a digital download linking directly to cited materials. Fraud counsel, compliance personnel, litigators, and anyone interested in health care fraud enforcement will want to keep this index close at hand.

376 pages, softbound with digital download, Pub. #26947, © 2023

Member

\$149 | ISBN 9781663354068

Non-member

\$179 | ISBN 9781663354075

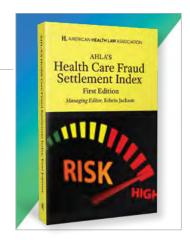
### **TABLE OF CONTENTS**

# PART 1 BY TYPE OF ALLEGATION

- 1.1 False Claims Act
- 1.2 The Stark Law
- 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
- 3.7 Physical Therapy, Rehabilitation, and Skilled Nursing
- 3.8 Laboratory
- 3.9 Pharmacy
- 3.10 Pharmaceutical Manufacturer
- 3.11 Medical Device Supplier
- 3.12 Other



# 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.

Recent developments on fundamental issues are addressed in this Seventh Edition, including commercial reasonableness, considering the volume or value of referrals or other business generated, and fair market value. The authors expand their analysis on recent areas of focus, including two new chapters on curing temporary noncompliance and exceptions for value-based arrangements.

Continuing areas of concern are also considered in detail, with the benefit of updated analysis. The authors address physician recruitment concerns and detail the evolution in CMS's view of the acceptability of percentage-based compensation, the continuing debate over specialty hospitals, and the viability of gainsharing and clinical comanagement arrangements. Other coverage in this concise and comprehensive work includes models for Stark-compliant physician joint ventures, group practices and their applicable exceptions, developments in self-disclosure, and more.

Available in print and eBook formats 244 pages, softbound. Pub. #27010, © 2021

Member

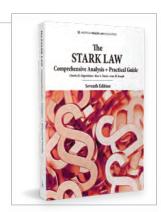
**\$185** | ISBN 9781663328830

\$180 | eISBN 9781663328854

Non-member

\$220 | ISBN 9781663328847

\$215 | eISBN 9781663328861



#### TABLE OF CONTENTS

- Ch. 1 Introduction and Background
- Ch. 2 Overview of Analytic Framework and Key Themes
- Ch. 3 Key Definitions and Interpretations
- 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
- Ch. 10 Proposed Solutions to "Intractable" Stark Problems
- Ch. 11 Practical Tips for Preventing Violations
- Ch. 12 The Future of the Stark Law Appendix A Prohibitions on Self-Referral

Appendix A Prohibitions on Self-Referral by State

# NEW PUBLICATION

# **Health Care Fraud Law: A 50 State Survey**

### FIRST EDITION

From the AHLA Fraud and Abuse Practice Group

No health care professional should be without this indispensable new reference. From fee-splitting restrictions to discount and rebate restrictions to anti-kickback statutes—state fraud and abuse laws can have a significant impact on health care operations. Among their many variations, state laws may apply regardless of whether a government payer is involved.

In this first edition of *Health Care Fraud Law: A 50 State Survey*, volunteers from the AHLA Fraud and Abuse Practice Group have for the first time published a desk reference containing their longstanding member resource, making it available to the health law community at large.

This book jump-starts readers' research on how state law is applied with insight into:

- > Statutory language
- > Regulatory provisions
- > Formal and informal guidance from enforcement agencies
- > Judicial interpretations

The *Survey* is an invaluable starting point for attorneys who represent health care providers, organizations, businesses, and investors looking for opportunities in this complex regulatory sector. Use it to advise clients across disciplines and jurisdictions.

Available in print and eBook formats 698 pages, softbound, Pub. #26989, ©2022

### Member

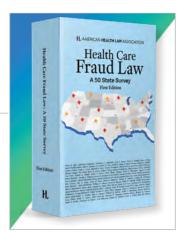
**\$219** | ISBN 9781663344847 **\$214** | eISBN 9781663344861

### Non-member

**\$279** | ISBN 9781663344854 **\$274** | eISBN 9781663344878

# SAMPLE STATE SURVEY TABLE OF CONTENTS

- > Anti-Kickback
- > Fee Splitting
- > Prohibitions on Self-Referral
- > False Claims/Fraud and Abuse
- > Unfair Business Practices
- > General Whistleblower Protections
- > Helpful Links



# Now offering three 50 state survey publications

Corporate Practice of Medicine: A 50 State Survey (Best seller!)

If you represent any type of health care entity or organization, you can't afford to practice without this state-by-state survey of the law. See p. 21.

Health Care Fraud Law: A 50 State Survey (New publication!)

From fee-splitting restrictions to discount and rebate restrictions to antikickback statutes—state fraud and abuse laws can have a significant impact on health care operations. *See above.* 



**Health Information Privacy & Breach: A 50 State Survey** (New publication!) Consult this resource to ensure all state law obligations are met with regard to patient and consumer digital information. **See p. 14**.



#### **UPDATED ANNUALLY**

# **Legal Issues in Health Care Fraud and Abuse**

# FIFTH EDITION WITH ANNUAL CUMULATIVE SUPPLEMENT

Laura F. Laemmle–Weidenfeld, Author

The Fifth Edition offers broad coverage of the full range of U.S. fraud and abuse prohibitions, with practical application for your work in health care today. Addressing the latest trends in investigation, enforcement, and interpretations of the law, *Legal Issues in Health Care Fraud and Abuse* explains the sweeping changes seen in the health care industry, with over 600 pages of expert analysis and fully referenced real-world examples.

With in-depth coverage of the Anti-Kickback Law, Stark Law, False Claims Act, and more, this book is a necessity for anyone who needs to understand the intricacies of how fraud and abuse laws are structured and enforced in the health care context, providing a foundation for your work in health law, covering:

- > How health care is regulated in the U.S.
- > How fraud and abuse laws are enforced by federal and state entities
- > Practical advice on assessing and addressing risk
- > Guidance on navigating relationships with the agencies and individuals enforcing the law's prohibitions

The risks relating to fraud and abuse have evolved significantly, for reasons ranging from the proliferation of health care data, to the expansion of the use of technology in health care, to changes in the regulatory scheme resulting from the shift toward value-based payment. Cumulative annual supplements keep you current by incorporating new rulemaking, advisory opinions, waivers, settlements, enforcement trends, and more.



Available in print and eBook formats 844 pages, softbound with annual supplement, Pub. #26985, © 2020

#### Membe

**\$199** | ISBN 9780769881577 **\$194** | eISBN 9780769881591

### Non-member

**\$265** | ISBN 9780769881584 **\$260** | eISBN 9780769881607

### **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
- 6.8 State Sunshine Acts Applicable to Pharmaceutical and Medical Device Manufacturers
- 6.9 State Initiatives to Prevent and Detect Fraud
- 6.10 Trade Associations
- 6.11 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

# False Claims Act & the Health Care Industry: Counseling & Litigation

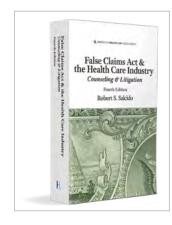
### **FOURTH EDITION**

Robert S. Salcido, Author

In this Fourth Edition of *False Claims Act & the Health Care Industry*, author Robert S. Salcido shares his deep insight on application of this federal statute to entities in the health care industry. Chapters include robust analysis of, and exhaustive citation to, interpretation by legislators, federal district courts, circuit courts of appeal, the United States Supreme Court, and relevant federal agencies.

This edition addresses areas of evolving False Claims Act (FCA) application, including:

- > The necessity that relators alleging a corporate-wide scheme furnish corporate-wide proof
- > Application of the FCA's statute of limitations tolling provision to relators
- > Whether claims are false when alleged facts are consistent with both misconduct and an obvious alternative explanation in accordance with the law
- > Whether a false implied representation must be linked to specific codes and factual representations on the claim form
- > Whether a case should be dismissed if a plaintiff relies on sub-regulatory guidance to establish falsity
- > How courts have applied a "holistic" test to determine whether a false representation is material to the government's determination to pay
- > Whether relators can pursue additional claims against the defendant once the government intervenes
- > What the government must show to dismiss qui tam actions over a relator's objection
- > What link must exist where an alleged FCA violation is based on an alleged violation of the Anti-Kickback Statute
- > Updates to the Health Care Fraud Self-Disclosure Protocol
- > And more



Available in print and eBook formats 1,080 pages, softbound, Pub. #27642, © 2022

#### Member

**\$192** | ISBN 9781663338426 **\$187** | eISBN 9781663338433

#### Non-member

**\$254** | ISBN 9781663338501 **\$249** | eISBN 9781663338518

# **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 FCA Jurisdiction

# 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 of Acronyms

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

Index

Available in print and eBook formats

776 pages, softbound with select downloadable forms content, Pub. #28263, © 2021

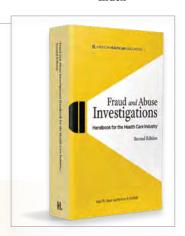
Member

**\$195** | ISBN 9781663315007 \$190 | eISBN 9781663315021 Non-member

\$245 | ISBN 9781663315014

\$240 | eISBN 9781663315038

Purchasers can download 30 of the more than 85 exhibits included in this book and adapt them for individual practice and client needs.



# 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.

Available in print and eBook formats 430 pages, softbound with downloadable content, Pub. #29963, © 2023

B A	_	-	h	_	
М	E		IJ	ㄷ	

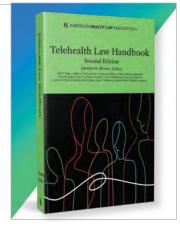
Non-member **\$215** | ISBN 9781663356963

\$275 | ISBN 9781663356970

**\$210** | eISBN 9781663356987 \$270 | eISBN 9781663356994

# **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
- Fraud and Abuse Ch. 6
- 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
- Appendix C Sample Policy: Telehealth Policy and Procedures (downloadable)
- Appendix D Sample Agreement: Employer-**Provider Telemedicine Services** Agreement (downloadable)



# 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



Available in print and eBook formats 524 pages, softbound, Pub. #28231, © 2023

# Member

\$209 | ISBN 9781663347923

\$204 | eISBN 9781663347947

#### Non-member

\$269 | ISBN 9781663347930

\$264 | eISBN 9781663347954

# LIFE SCIENCES

# NEW PUBLICATION

# 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. Koury, Michael S. Labson, Kassandra Maldonado, Krysten Rosen Moller, Raymond Ngu, Jennifer Plitsch, 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.

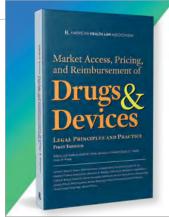
Available in print and eBook formats 382 pages, softbound, Pub. #28266, © 2023

# Member

**\$205** | ISBN 9781663347886 **\$200** | eISBN 9781663347909

### Non-member

**\$265** | ISBN 9781663347893 **\$260** | eISBN 9781663347916



#### **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

# 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.

Available in print and eBook formats 350 pages, softbound, Pub. #28198, © 2019

#### Member

**\$175** | ISBN 9781522178019 **\$170** | eISBN 9781522178033

### Non-member

**\$219** | ISBN 9781522178026 **\$214** | eISBN 9781522178040



# **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.

Available in print and eBook formats 1,082 pages, softbound, Pub. #28107, © 2021

Member

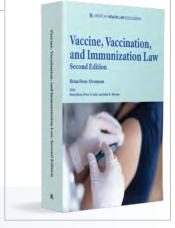
Non-member

**\$185** | ISBN 9781663332172

\$229 | ISBN 9781663332189

\$180 | eISBN 9781663332196 \$2

\$224 | eISBN 9781663332202



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 J 42 U.S.C. Subchapter XIX—Vaccines, Part 2—National Vaccine Injury Compensation

Program (§§300aa-10 to 300aa-34)

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 M 42 U.S.C. §247d-6d—Targeted Liability Protections for Pandemic and Epidemic

Products and Security Countermeasures

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 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

# **PHYSICIANS**

# **Representing Physicians Handbook**

# **FOURTH EDITION**

A Task Force of the AHLA Physician Organizations Practice Group Michael F. Schaff, Task Force Chair Lisa Gora. Coordinatina 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.

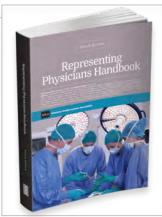
Available in print and eBook formats 786 pages, softbound, Pub. #26965, © 2016

#### Member

**\$186** | ISBN 9781522100201 **\$181** | eISBN 9781522100225

Non-member

**\$259** | ISBN 9781522100218 **\$254** | eISBN 9781522100232



# **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.

Also included in this title are valuable Appendices, which provide important information in a succinct, time-saving downloadable format:

- > Keystones of A Peer Review Investigation
- > Sample Fair Hearing and Appellate Review Plan
- > Sample Investigation Report
- > Letter to Practitioner Regarding Adverse Recommendation and Right to Hearing
- > Letter to Practitioner Regarding Hearing Date and Hearing Rights
- > Hearing Officer Checklist
- > Outline for Hearing Committee Report
- > Sample Index for Medical Staff Hearing Exhibit Book
- > Sample Application Materials

Available in print and eBook formats 400 pages, softbound with downloadable content, Pub. #27903, © 2022

# Member

**\$185** | ISBN 9781663334688 **\$180** | eISBN 9781663334701

# Non-member

**\$225** | ISBN 9781663334695 **\$220** | eISBN 9781663334718



#### **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

Mazen Asbahi, Adam Cella, Lymari Martinez Cromwell, John W. Dawson IV, Alexis J. Gilman, J. Andrew Goddard, Jay Hardcastle, Justin R. Hickerson, Rick Hindmand, Johnathan D. Holbrook, Lauren B. Jacques, Jason J. Krisza, Neil B. Krugman, Nathan H. Lykins, Lauren B. Patterson, Michael F. Schaff, Susan V. Sidwell, G. Scott Thomas, Rodrigo N. Valle, Kimberly S. Veirs, John R. Washlick, Authors

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:

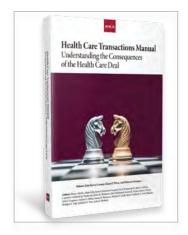
- > When seemingly straightforward business terms can veer toward health care fraud and abuse
- > How health care organization and/or management structure can impact the deal
- > The need to comply with both non-disclosure terms and federal and state privacy laws when conducting due diligence
- How increased collaboration between health care entities may give raise 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.

Exhibit 1	Sample Preliminary Legal Due Diligence Request List
Exhibit 2	Sample Medical Group Due Diligence Request List
Exhibit 3	Sample Physician Practice Acquisition Due Diligence Request
Exhibit 4	Sample Real Estate Due Diligence Request
Exhibit 5	Sample HIPAA Due Diligence Request List
Exhibit 6	Sample Common Interest Agreement
Exhibit 7	Sample Confidentiality and Nondisclosure Agreement
Exhibit 8	Sample Antitrust Compliance Transaction Guidelines
Exhibit 9	Summary of Selected Potentially Relevant Legal Considerations
Exhibit 10	CMS Open Payment Registry Review Checklist
Exhibit 11	Sample Health Information Provisions
Exhibit 12	Typical Private Equity Fund Structure
Exhibit 13	Sample Affiliation Provisions
Exhibit 14	Typical JV Formation/Governance Issues to Consider
Exhibit 15	10 Common Health Care Compliance Concerns Related to
	Hospital/Physician Transactions
Exhibit 16	Physician Contract Review Checklist
Exhibit 17	Appraisal and Fair Market Value Assessment Checklist for Attorneys
Exhibit 18	Sample Proposal to Purchase Assets
Exhibit 19	Sample Letter of Intent to Purchase Assets of a Medical Practice
Exhibit 20	Sample Closing Checklist for Health System Integration of a Medical Practice
Exhibit 21	Real Estate Compliance Questionnaire
Exhibit 22	Checklist for Lease Transactions

# **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
- Ch. 6 Acquisitions, Sales, Mergers, and Joint Ventures: Transaction and Liability Issues for Hospitals
- Ch. 7 Physician Practice Acquisitions and Affiliations
- Ch. 8 Private Equity-Owned Practice
  Management Company Acquisitions of
  Physician and Dental Practices



Available in print and eBook formats 404 pages, softbound with select downloadable forms content, Pub. #28260, © 2020

### Member

**\$185** | ISBN 9780769866161 **\$180** | eISBN 9780769865621

### Non-member

**\$225** | ISBN 9780769866178 **\$220** | eISBN 9780769865638

# **Corporate Practice of Medicine: A 50 State Survey**

# SECOND EDITION

Andrew G. Jack, Glenn P. Prives, Jed A. Roher, Joel C. Rush, Editors

Kelsey Anderson, Carole M. Becker, Scott Bennett, Elise Dunitz Brennan, Matthew M. Brohm, Stacey L. Callaghan, Brad Cave, Ali Deatherage, Dana Dombey, Richard Eiler, Maura Fleming, Arthur J. Fried, Megan R. George, Paulina Grabczak, Maleaka Guice, Jesse D. Hale, M. Brian Hall IV, Gabriel Hamilton, Dawn R. Helak, Jennifer L. Hilliard, Breanne L. Hitchen, Marshall E. Jackson, Jr., Ellen L. Janos, Amanda Jester, David H. Johnson, Robert J. Johnston, Jeffrey L. Kapp, John W. Kaveney, Richard G. Korman, Kristin E. Laubach, Leonard Lipsky, Robert Low, Carrie Noonan, Cassandra L. Paolillo, Tristan A. Potter–Strait, Brianna Powell, Kathleen M. Premo, Elena M. Quattrone, Russell C. Ramzel, Chelsea Rogers, Jane Rugg, Kevin J. Ryan, Elizabeth Scarola, Shine Chen Schattgen, Tricia Shackelford, Parampreet Singh, Melissa A. Soliz, Cori Casey Turner, Nina Wall, Li Wang, Kyle D. Weber, Esther Chang Weese, Renee Zerbonia, Authors

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

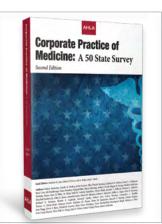
This survey is invaluable to attorneys who represent health care entities, organizations, businesses, physicians, and investors looking for opportunities in this complex regulatory sector. Use it to efficiently gain a thorough exploration of the doctrine in each state and the District of Columbia.

Available in print and eBook formats 664 pages, softbound, Pub. #28278, © 2020

Member

Non-member

**\$209** | ISBN 9781522186250 **\$204** | eISBN 9781522186274 **\$269** | ISBN 9781522186243 **\$264** | eISBN 9781522186267



# SAMPLE STATE SURVEY TABLE OF CONTENTS

# Chart of Sources Summary Key Professions

- Medicine
- Dentistry
- > Chiropractic Medicine
- > Optometry
- > Podiatry
- Physical Therapy and Occupational Therapy
- > Midlevel Providers
- > Behavioral Health
- > Psychology
- Registered Dental Hygienists

# **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.

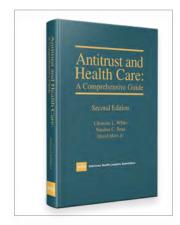
The authors draw on their significant government enforcement and private sector counseling and litigation experience to provide practical insights for:

- 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
- 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
- Trade Associations, State Regulatory Ch. 7 Bodies, and Group Purchasing Organizations
- Ch. 8 Medical Staff Privileges, Exclusive Physician Contracts, and Peer Review
- Monopolization Ch. 9
- Ch. 10 The Robinson Patman Act
- Ch. 11 Exemptions and Immunities

Appendix State Legislation Relating to **Provider Cooperation Agreements** 



Available in print and eBook formats 750 pages, hardbound, Pub. #28252, © 2017

#### Member

\$197 | ISBN 9781522135203 \$192 eISBN 9781522135227

#### Non-member

**\$254** ISBN 9781522135210 \$249 eISBN 9781522135234

# Complimentary digital downloads included with many titles

Print and eBook customers of these titles gain access to downloadable. customizable content—included with purchase.

Ambulatory Surgery Centers: Legal and Regulatory Issues, p. 25

Fraud and Abuse Investigations Handbook for the Health Care Industry, p.12

AHLA's Guide to Health Care Legal Forms, Agreements, and Policies, p.3

AHLA's Health Care Fraud Settlement Index (NEW), p.7

Health Care Transactions Manual: Understanding the Consequences of the Health Care Deal, p. 20

AHLA Health Plans Contracting Handbook: A Guide for Payers and Providers, p.23 Health Care Contracts: A Clause-By-Clause Guide to Drafting and Negotiation, p.5 Telehealth Law Handbook (NEW), p.13



# Health Insurance

# Health Plans Contracting Handbook: A Guide for Payers and Providers

# EIGHTH EDITION WITH DOWNLOADABLE FORMS

Robin J. Fisk, Editor in Chief

Christina DeGraff-Murphy, Gregory R. Mitchell, Editors

Gerald "Jerry" L. Aben, Matthew Amodeo, Adam C. Aseron, Brooke Bennett Aziere, John C.J. Barnes, James W. Boswell, Aimee DeFilippo, Lisa G. Han, Andrew C. Helman, John M. Kirsner, David E. Kopans, Mark S. Kopson, Kathrin E. Kudner, Jacqueline B. Penrod, Christian Puff, Michael F. Schaff, Debra Silverman, Andrew Stein, Leah B. Stewart, Adam C. Varley, Amanda M. Wilwert, Authors

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

### **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

Available in print and eBook formats

556 pages, softbound with select downloadable forms content, Pub. #27092, © 2021

**Members** 

**\$209** | ISBN 9781663313867

Non-members

\$249 | ISBN 9781663313881

**\$204** | eISBN 9781663313874 **\$244** | eISBN 9781663313898





# Health Care Delivery Models

# Representing Hospitals and Health Systems Handbook

FIRST EDITION

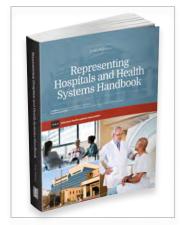
Dinetia Newman, Robert G. Homchick, Co-Editors

Emily Black Grey, Michael Lampert, Travis G. Lloyd, Claire Turcotte, Coordinating Editors 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:

- > Establishment of facilities
- > Certification process
- > State and federal fraud and abuse regulations
- > State licensing requirements
- > 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.



Available in print and eBook formats 870 pages, softbound, Pub. #29965, © 2016

#### Member

**\$194** | ISBN 9781632813473 **\$189** | eISBN 9781632813763

#### Non-member

**\$269** | ISBN 9781632813480 **\$264** | eISBN 9781632813770

# **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

Ask us about the upcoming new edition

# **Ambulatory Surgery Centers:** Legal and Regulatory Issues

# SIXTH EDITION WITH DOWNLOADABLE FORMS

Scott Becker, Erin E. Dine, LauraLee R. Lawley, Lauren M. Ramos, Bradley A. Ridlehoover, Helen H. Suh, Melissa Szabad, Anna M. Timmerman, Gretchen Heinze Townshend, Kerri A. Zelensek, Authors

The authors provide an expert overview of the growth, trends, benefits, legal issues, and tensions associated with ASCs, followed by a comprehensive analysis of the issues particular to ASCs, emphasizing:

- > Physical and organizational differences from other providers, whether they are owned by a hospital, a physician practice, or other entity
- > Key trends and tensions facing ASCs, such as the conflicts that often arise between ASCs, hospitals, and physicians
- > The benefits of joint ventures between hospitals and physicians
- > Federal fraud and abuse concerns
- > 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

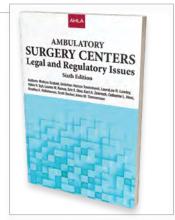
Available in print and eBook formats 344 pages, softbound with select downloadable forms content. Pub. #26900. © 2019

### Member

**\$149** | ISBN 9781522177500 **\$144** | eISBN 9781522177524

Non-member

**\$199** | ISBN 9781522177517 **\$194** | eISBN 9781522177531



# **INDEX**

Ambulatory Surgery Centers: Legal and Regulatory Issues25
Antitrust and Health Care: A Comprehensive Guide22
The Complete Medical Staff, Peer Review, and Hearing Guidebook19
Corporate Practice of Medicine: A 50 State Survey21
False Claims Act & the Health Care Industry: Counseling & Litigation11
AHLA's Federal Health Care Laws & Regulations2
Federal Health Care Discrimination Law4
Fraud and Abuse Investigations Handbook for the Health Care Industry12
Fundamentals of Health Law4
AHLA's Guide to Health Care Legal Forms, Agreements, and Policies
Health Care Compliance Legal Issues Manual6
Health Care Contracts: A Clause-by-Clause Guide to Drafting and Negotiation
Health Care Fraud Law: A 50 State Survey9
AHLA's Health Care Fraud Settlement Index7
Health Care Transactions Manual: Understanding the Consequences of the Health Care Deal20
Health Information Privacy & Breach: A 50 State Survey 14
Health Plans Contracting Handbook: A Guide for Payers and Providers23
Legal Issues in Health Care Fraud and Abuse10
Market Access, Pricing, and Reimbursement of Drugs and Devices: Legal Principles and Practice15
Pharmaceutical and Medical Device Compliance Manual16
Representing Hospitals and Health Systems Handbook24
Representing Physicians Handbook18
The Stark Law: Comprehensive Analysis + Practical Guide8
Telehealth Law Handbook13
Vaccine, Vaccination, and Immunization Law17

To receive future updates for AHLA publications, call 866.471.0909 to become a subscriber under the Automatic Shipment Subscription Program and to obtain full terms and conditions for that program.

# PRODUCT TERMS

Prices listed in this catalog and on the AHLA home page are before shipping and tax are calculated; shipped to a U.S. address. Prices current as of 6/1/2023. Prices subject to change without notice. Sales to federal government customers may be subject to specific contract pricing and not discounted additionally. Other restrictions may apply. Void where prohibited.

LexisNexis and the Knowledge Burst logo are registered trademarks of RELX Inc. American Health Law Association is a registered trademark of the American Health Law Association. Other products or services may be trademarks or registered trademarks of their respective companies.

© 2023 LexisNexis. OFF05142-0 0623



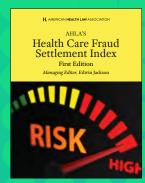
9443 Springboro Pike Miamisburg, OH 45342 PRSRT MKTG U.S. POSTAGE **PAID** LexisNexis 22901

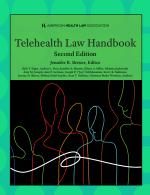
# AMERICAN **HEALTH LAW** ASSOCIATION













**ORDER TODAY** 

ONLINE at lexisnexis.com/AHLA CALL 866.471.0909

Educating and Connecting the Health Law Community