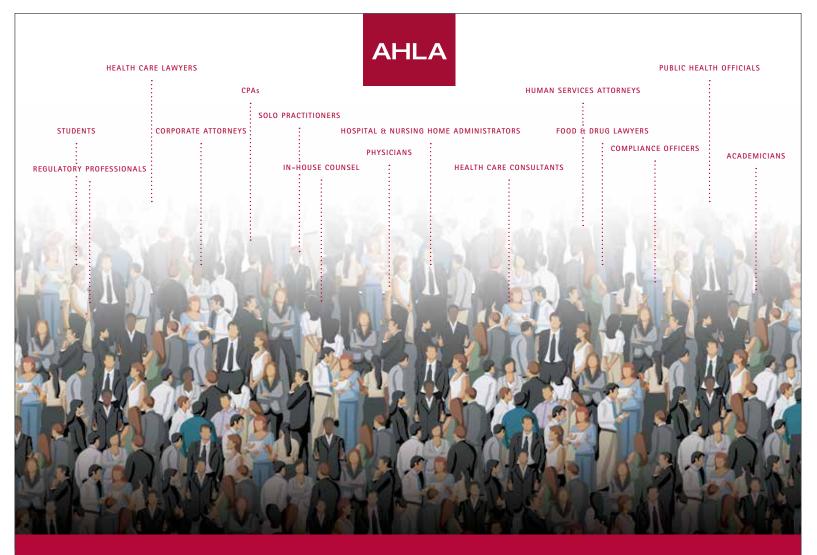


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William W. Horton, Editor

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Once the province of financial institutions, manufacturing, and government entities, enterprise risk management (ERM) has taken hold in the health care industry, and it is easy to understand why. To cost-effectively deliver quality services, the entire entity must share the risk and responsibility for the health of the operating environment, and ERM is a means to this end. The authors delineate how to manage risk in a variety of settings, including:

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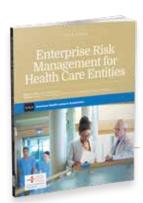
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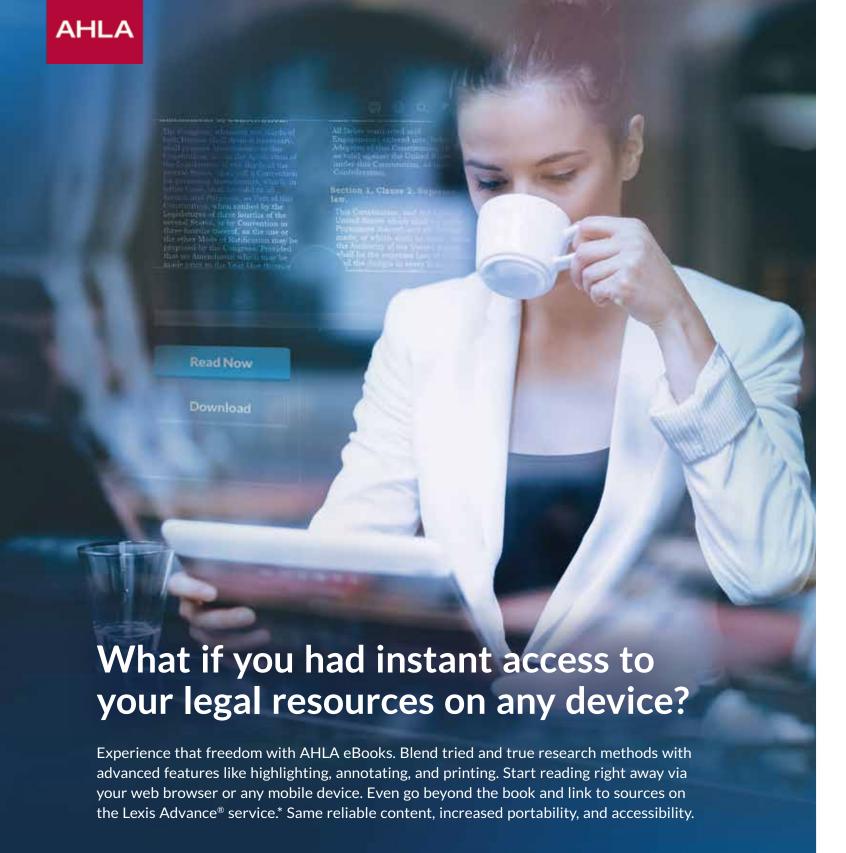
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The corporate practice of medicine doctrine has a long history as an effort by the American Medical Association to distinguish physicians from non-physicians offering services and cures for various afflictions. The doctrine seeks to prohibit a non-physician from interfering with a physician's professional judgment by prohibiting corporations not owned or controlled by physicians from employing physicians to practice medicine and charge for those professional services.

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A Task Force of the AHLA Physician Organizations Practice Group Michael F. Schaff, Task Force Chair Lisa Gora, Coordinating Editor with numerous Contributing Authors

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FIFTH EDITION WITH CD-ROM

Scott Becker, Meggan Michelle Bushee, LauraLee Lawley, Melissa Szabad, Anna Timmerman, Barton Walker, Amber Walsh, Authors

This publication addresses the unique nature of Ambulatory Surgery Centers (ASCs), emphasizing their physical and organizational separation from other providers, regardless of whether they are owned by a hospital, a physician practice, or another entity. Coverage includes: key trends and tensions facing ASCs; points of conflict that often arise between ASCs, hospitals, and physicians; Medicare and Medicaid fraud and abuse concerns; tax exemption and other tax-related issues; safe harbors for ASCs; relevant Stark Law issues, as well as the impact of state self-referral laws; and antitrust considerations for ASCs that face often intense competition.

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## Post-Acute Care Handbook: Regulatory, Risk, and Compliance Issues

FIRST EDITION

Ari J. Markenson, Editor in Chief

Caroline Berdzik, Joseph A. Donchess, Alan C. Horowitz, James F. Miles, Barbara L. Miltenberger, Michelle Peterson, Kelly A. Priegnitz, Christopher C. Puri, Lawrence W. Vernaglia, Editors with numerous Contributing Authors

The authors and editors of this invaluable guide provide an important view into the evolving compliance and regulatory issues governing this area. In-depth coverage includes:

- > The evolution of the nursing home survey process
- > Residents' rights and facility practices
- > The importance of nursing facility agreements
- > Compliance issues, including federal and state reimbursement requirements
- > Facilities' ability to challenge enforcement remedies imposed against them
- > Fraud and abuse issues that affect the industry
- > Development of new systems and relationships that respond to incentives under the Affordable Care Act

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## **Ancillary Providers in Health Care: A Primer**

FIRST EDITION

Doriann H. Cain, Anne B. Compton-Brown, Heather F. Delgado, Gayland O. Hethcoat II, Serj Mooradian, Claire M. Reed, Charles J. Schultz, Laura D. Seng, Julie A. Veldman, Authors

With the state-by-state regulatory scheme that governs physician assistants, nurse practitioners, and other ancillary providers, providing informed counsel can be challenging. This publication meets the need for succinct, thorough guidance to the growing area of ancillary care. If you advise clients in this area, you must be aware of your state's regulatory scheme, as well as emerging issues related to:

- > Potential new liability risks on the part of physicians employing ancillary providers
- > Differing scope of practice between types of ancillary providers
- > Policy arguments surrounding clinical privileging and the role of physician assistants and nurse practitioners
- > Increased risk and the need to understand and avoid severe penalties for improper care, as well as billing of services
- > The expanding role of pharmacists

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## Pharmaceutical and Medical Device Compliance Manual

FIRST EDITION WITH CD-ROM

Kathleen M. Boozang and Simone Handler-Hutchinson, Editors with numerous Contributing Authors

This publication is a joint project of the Center for Health & Pharmaceutical law & Policy at Seton Hall University School of Law, the Food and Drug Law Institute, and AHLA. It is a must-have for anyone involved in building, implementing, or monitoring a pharmaceutical and medical device compliance program. Coverage includes:

- > The federal Anti-Kickback Statute and the False Claims Act
- > Promotion of off-label uses for drugs and reimbursement for prescription drugs and medical devices
- > Distinctions between manufacturers' lawful dissemination of scientific information, and the unlawful promotion of off-label usage
- > The Foreign Corrupt Practices Act
- > Implications of extra-territorial reach outside the United States
- > Prescription drug price regulations

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## The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech

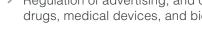
SECOND EDITION WITH CD-ROM

Kristian A. Werling, Editor in Chief

Jeffrey W. Brennan, Marie Connelly, Stefanie A. Doebler, Jennifer S. Geetter, Scott A. Memmott, Stephen J. Smith Jr, and Heather M. Zimmerman, Editors with numerous Contributing Authors

This publication provides a solid grounding in the legal principles and issues inherent in this complex area. It features contributions from experienced and respected practitioners of life sciences and health law. Whether you're looking for an introduction to this area, or you need a go-to reference on your shelf, the coverage includes:

- > Regulation of drugs
- > Antitrust
- > Regulation of medical devices > Privacy International Issues
- State regulation
- Clinical trials
- Intellectual property
- > Fraud and abuse > Payment and reimbursement
- > Regulation of biologics
- > Regulation of advertising, and of drugs, medical devices, and biologics





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## FRAUD AND ABUSE

## NEW IN 2018

## Best Practices Handbook for Advising Clients on Fraud and Abuse Issues

#### FIRST EDITION

Paul W. Shaw Editor in Chief

Kristin M. Bohl, Kristin C. Carter, Renee M. Howard, Amy M. Joseph, Jordan Kearney, Laura Koman, Ingrid S. Martin, Elizabeth G. Myers, Charles B. Oppenheim, William Pezzolo, Tamara Senikidze, Gina L. Simms, Jeremy Sternberg, Authors

This publication is a highly usable guide developed by health lawyers with extensive and diverse experience who lend a practical approach to the complex representation issues that permeate this area. Every health care attorney must consider and address potential fraud and abuse concerns in almost every transaction contemplated by a health care client.

From proactively managing risk, to disclosure and resolving disputes, you will have thorough guidance that spans the most frequently encountered areas and attendant issues. Timesaving sample forms and agreements are included throughout the work, along with guidance for completing the documentation.

Whether you are a general health care attorney or a fraud and abuse specialist, as you provide counsel in this complex and dynamic area, you will benefit from an understanding of:

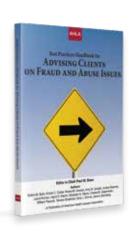
- > Ethical concerns when counseling in the gray areas
- Responding to problematic conduct
- > Privilege protection in fraud and abuse matters, including distinguishing between legal and business functions
- > Providing a "fraud and abuse" opinion of counsel, the scope of the opinion, and internal and external reviews
- > The attorney's role in conducting internal compliance audits and investigation, including developing an investigation plan
- > Self disclosure and voluntary disclosure, risks and benefits
- > Gathering documents in response to government demands, subpoenas, search warrants, and requests for electronic files
- > Preparing employees for government contact, including communicating interview strategies and rules of professional conduct
- > Resolving disputes with the government, including interacting with federal and state agencies, dealing with whistle blowers, and addressing collateral damage

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## NEW IN 2018

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

#### Robert S. Salcido, Author

False Claims Act & the Health Care Industry is a one-stop source for legislative and case law developments covering the gamut of potential false claims litigation, across all jurisdictions. With 1,080 pages of legal analysis, you'll be apprised of the impact of the latest developments. This publication provides analysis of key arguments, including:

- > Defenses that the defendant's claim is not "false"
- > Defenses that the defendant did not "know" that the claim or statement is "false"
- Defenses that the defendant's knowingly false claims or statements are not "material" to the government's determination to pay
- > The status of actions where the relator's action repeats public information



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- Ch. 1:06 The 2010 Amendments to the False Claims Act

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- 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

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## Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties

## FOURTH EDITION WITH CUMULATIVE SUPPLEMENT

David E. Matyas, Carrie Valiant, Jason Eric Christ, Anjali N.C. Downs, Authors

This bestselling road map describes the legal theories governments use to identify and eliminate fraud in health care. Highlights include:

- > A thorough review of governmental enforcement entities including the Department of Justice, the Department of Health and Human Services, as well as other federal agencies, state governments, and private payers
- > Discussion of major laws such as the Anti-Kickback Statute, the federal physician self-referral prohibitions (as well as the applicable safe harbors), the False Claims Act, and the administrative sanctions that are available to the enforcers
- > An overview of state counterparts to the federal laws addressing self-referrals, anti-kickback issues, false claims, other statutory authorities, and private initiatives

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Ch. 7 Compliance and Self-Reporting

Ch. 8 Fraud and Abuse Issues Affecting the Managed Care Industry

Ch. 9 Representing Healthcare Organizations in Fraud and Abuse Matters

Ch. 10 The Future of Fraud and Abuse



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495 pages, hardbound with 2015 supplement, Pub. #26985, © 2012

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## Fraud and Abuse Investigations Handbook for the Health Care Industry

#### FIRST EDITION WITH CD-ROM

Robert A. Griffith. Paul W. Shaw. Authors

Understanding the powers, procedures, and remedies available to the government during a health care fraud and abuse investigation, and acquiring a basic understanding of the issues and practical steps to employ during an audit or investigation, are keys to surviving the investigation and achieving a favorable outcome.

This Handbook is designed to provide health care administrators, executives, medical practice directors and managers, as well as attorneys with a broad overview of health care fraud investigations.

The authors' discussion is supplemented with an expansive set of sample government documents, including subpoenas and search warrants, as well as helpful letters and memoranda generated by experienced health care fraud and abuse defense attorneys. Learn what to expect and how to respond with coverage of:

- Requests to examine books and records
- > Interviews of employees by the OIG or the FBI
- > The power of HIPAA administrative subpoenas
- > Steps that should be taken in responding to the government's request
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- > Internal audits and investigations
- Voluntary disclosures

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## The Stark Law: Comprehensive Analysis + Practical Guide

## FIFTH EDITION

Charles B. Oppenheim, Author

More than a summary of the law, this publication addresses the legal effect of final Stark regulations. Written by Charles B. Oppenheim, a leading name in the interpretation and application of the Stark Law, this publication provides an in-depth critical analysis, and contains a wealth of pointers and practical advice. Coverage includes:

- > The legal effect of the regulations and the regulatory process
- Discussion of several key themes and trends that emerge in the regulations
- > Key definitions and interpretive changes
- > Impact on physician practice, including issues relating to physician recruitment, specialty hospitals, gain-sharing arrangements, and Stark-compliant physician joint ventures
- > Analysis of group practices and the exceptions applicable to them

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## **Health Care Provider and Supplier Audits Practice Guide**

## FIRST EDITION

Jessica L. Gustafson, Abby Pendleton, Editors

Darby C. Allen, Lauren M. Gaffney, Anna M. Grizzle, Jessica L. Gustafson, Stephanie Fuller Johnson, B. Scott McBride, Sydney R. Nash, Abby Pendleton, and Sarah Kay Wheeler, Authors

This Practice Guide will become your go-to source for understanding the intricacies of the Medicare, Medicaid, and commercial payer audit environments. With this comprehensive publication, you will have the background you need on:

- > Reporting and repayment
- Contractor audit methodologies
- > Statistical sampling used by contractors to calculate overpayment demands
- > The appeals process applicable to each type of review and determination
- > Common focus areas when providers receive overpayment demands
- > Developing mandatory compliance programs

The publication also includes a 50-State Medicaid RAC Contractor Information Chart.

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## **HEALTH INFORMATION**

## **NEW IN 2018**

## The Law of Digital Health

#### **FIRST EDITION**

Bernadette M. Broccolo, Lisa Schmitz Mazur, Editors in Chief and Authors Shelby Buettner, Vanessa K. Burrows, Jiayan Chen, Amanda Enyeart, Ryan S. Higgins, Sarah Hogan, Marshall E. Jackson Jr., Ryan B. Marcus, Anisa Mohanty, Amy C. Pimentel, Michael W. Ryan, Dale C. Van Demark, Christine M. Wahr, Scott A. Weinstein, Authors

Digital health is a highly dynamic ecosystem of technological innovation with profound effects on all facets of health care. The key components of today's digital health are:

- > Electronic health records and other health information technology
- > Big data and data analytics
- Telemedicine
- Mobile personal engagement tools

This book explains how, taken together, these developments transform the provider-patient relationship, change the way research is conducted, trigger privacy and security concerns, alter relationships with health plans, and give rise to a new generation of innovation. Digital health participants face an outdated and ambiguous legal and regulatory framework and enforcement by state and federal regulatory agencies, including:

- > State attornevs general
- > State licensure and accreditation agencies
- > Food and Drug Administration
- > Federal Trade Commission
- > Federal Communications Commission
- > Department of Health and Human Services Offices of Civil Rights, Human Research Protection, and Inspector General, among others

This book provides both the fundamental understanding and tactical foresight you need to develop a comprehensive digital health strategy.

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- 2.3 Digital Health Value Proposition
- 2.4 Unique Legal and Regulatory Considerations Applicable to Health IT
- 2.5 Planning, Due Diligence, and Contracting Considerations

Appx. A Overview of MACRA Quality Payment Program

Appx. B Summary of Medicare EHR Incentive Program Stage 3 Meaningful Use Requirements for Eligible Hospitals and Critical Access Hospitals

Appx. C Overview of 2015 Edition CEHRT Criteria for Medicare EHR Incentive Program Meaningful Use Program

Appx. D Overview of HIPAA Security Assessment Requirements

### Ch. 3 "Big Data" and Data Analytics

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- 3.2 Applications and Use Cases
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- 3.4 Compliance and Liability, and Contracting Considerations and Strategies

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The Law of Digital Health

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## Ch. 5 Patient Engagement and Consumer Wellness Tools

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- 5.2 Value Proposition
- 5.3 Unique Legal and Regulatory Considerations Applicable to Personal Health Tools
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- 5.5 Planning, Due Diligence, and Contracting Considerations and Strategies

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## NEW IN 2018

## Telehealth Law Handbook: A Practical Guide to Virtual Care

Jennifer R. Breuer, Editor

Soleil Teubner Boughton, Andrea Frey, Jennifer Hansen, Nathaniel Lacktman, Vivek J.Rao, Emily Wein, Christine Burke Worthen, Yanyan Zhou, Authors

Telehealth Law Handbook: A Practical Guide to Virtual Care will help you navigate the highly dynamic and state-lawdependent practice of telehealth. Telehealth is changing relationships not only between physicians and patients, but also among providers, and between providers and payers. As state and federal legislators and regulators take note of these changed relationships, the law is changing as well. This up-to-date guide contains information on:

- > Telemedicine licensure requirements in all 50 states
- > Types of state licensure, exceptions, and how licensure laws apply in particular practice situations
- > Telehealth regulatory requirements
- > Telehealth practice and communication models
- > Payment and reimbursement considerations, including telehealth payment and reimbursement rules under Medicare and Medicaid programs
- > Telehealth commercial insurance and payment parity statutes
- Medical staff credentialing
- > Ethics and liability issues
- > Fraud and abuse compliance
- > Corporate practice of medicine prohibitions
- > Privacy and security issues
- Mobile health technology

This book is useful in developing your understanding of the complex rules surrounding this method of health care delivery.



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- Introduction
- Medicare Coverage of Telehealth Services
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- 3.5 Eligible Distant Site Practitioners
- 3.6 Eligible Telecommunications Technology
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## **HIPAA/HITECH Resource Guide**

#### FIRST EDITION WITH CD-ROM

Patricia D. King, Editor

Jeffry Adest, Lara Jean Ancona, Ann M. Bittinger, Damon G. Carpenter, Alisa L. Chestler, Lisa L. Dahm, William P. Dillon, Gregory Ewing, Valita Marie Fredland, Jill M. Girardeau, Jennifer J. Hennessy, Caroline Kubovy, Morris A. Landau, Wendy C. Maneval, Valerie Breslin Montague, John Murdoch, Cheryl Camin Murray, Stephen Page, Jennifer L. Rathburn, Lisa Pierce Reisz, Stephen D. Rose, Amita A. Sanghvi, Sarah E. Swank,

With informed editorial oversight and authorship, this title provides guidance for understanding the protection of patients' personal information. The HIPAA Omnibus rule affects individuals, health systems, business associates, and many others. Coverage includes:

- > The original HIPAA regulations
- > HITECH Act privacy provisions and rulemaking
- > Modifications to HIPAA Privacy, Security, and Enforcement rules
- > Valuable practice tools such as sample business associate agreements, sample privacy practice notices, authorizations, policies, and training materials
- > State-by-state survey of health care privacy laws

HIPAA/HITECH Resource Guide provides not only the history of the development of the rules and standards, but also the latest practical guidance for ensuring compliance.

Available in print and eBook formats

200 pages, softbound with CD-ROM, Pub. #28271, © 2014

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## Data Breach Notification Laws: A Fifty State Survey

SECOND EDITION

Jonathan M. Joseph, Author

Data breaches can occur in the best-run organizations, and when they do, you must be prepared to react quickly. When your operation or customer base spans state lines, knowing how to respond in multiple jurisdictions becomes critical. With breaches occurring at the state level with more and more frequency, legislatures are enacting an ever-increasing array of notification laws that you must consider. In addition to providing a survey that includes all states, the book enables you to:

- > Tap into a collection of state-specific reporting forms for CA, MA, NY, NC, OR, VT, and VA
- > Understand the timing and content of notification to those affected
- > Determine which states require notification of a breach to specific state agencies or attorneys general

Available in print and eBook formats

174 pages, softbound, Pub. #28156, © 2017

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## **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. Turn to it for guidance on any of the business activities your clients or organization are likely to be involved with; mergers, acquisitions, and other transactions; or joint ventures, provider networks, and other collaborative arrangements. The *Guide* covers:

- Substantive antitrust law
- > Important case law developments
- > Formal and informal guidance issued by federal and state enforcement agencies
- > Expanded coverage of the pharmaceutical and medical device industries

The publication provides invaluable "practice pointers" to help you minimize antitrust risk and more successfully plan and execute business and litigation strategies. 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

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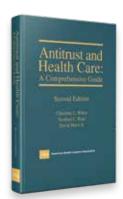
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- Ch. 10 The Robinson Patman Act
- Ch. 11 Exemptions and Immunities
- Appx. A State Legislation Relating to Provider Cooperation Agreements

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

#### SEVENTH EDITION

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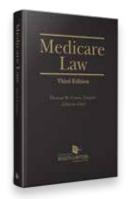
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