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Antitrust and Health Care: A Comprehensive Guide

SECOND EDITION

Christine L. White, Saralisa C. Brau, and David Marx Jr., authors and Editors
Joshua H. Soven, Shoshana Speiser, and Kati Williams, contributing authors

The first edition of this newly updated book won the Federal Trade Commission Award for Outstanding Scholarship. Now in its second edition, the *Guide* remains a must-have resource for informing your advice; understanding the inherent risks, opportunities, and alternative strategies for effective transactions; and evaluating the antitrust issues associated with marketplace conduct. It 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

Consult *Antitrust and Health Care* for guidance on any of the business activities your clients or organization are likely to be involved with: mergers, acquisitions, and other transactions; joint ventures, provider networks, and other collaborative arrangements—including:

- Clinically integrated networks and ACOs
- Pre-merger notification and transaction planning
- Exclusive contracting
- Medical staff membership, clinical privileges, and peer review activities
- Trade association and group-purchasing activities

Additionally, the publication provides invaluable “practice pointers” to help minimize antitrust risk and more successfully plan and execute business and litigation strategies. The expert 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

[See also *Healthcare Antitrust FAQ Handbook*, p. 15.]



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Clinical Research Practice Guide

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R. Harold McCard, Coordinating Editor

Monica R. Chmielewski, M. Leeann Habte, Jonathan M. Holda, E. Scott Johnson, Christopher F. Loney, Melissa L. Markey, Aaron J. Rabinowitz, Sarah E. Swank, Lawrence W. Vernaglia, David S. Weinstock, Jamie K. Wolszon, and Torrey K. Young, authors

Those who represent health care entities will gain insight into the growing interrelationship between health law and life sciences, as well as the growing risks and compliance issues facing clients involved in this complex area. The Second Edition is extensively enhanced and updated with coverage of:

- Changes to HIPAA that affect research and IRBs
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- HITECH and enhanced coverage of the Security Rule
- Requirements for group health plans and health insurers to cover routine patient costs in an approved clinical trial

Comprehensive coverage in the *Clinical Research Practice Guide* is both analytical and practical, with thorough treatment of:

- Information management, including the sources for human subject protection: the Federal Common Rule, FDA Guidance, and HIPAA
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Corporate Practice of Medicine: A Fifty State Survey

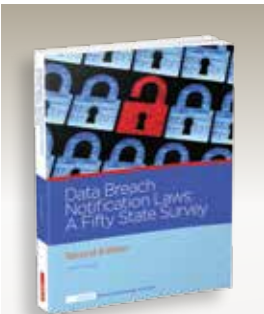
FIRST EDITION with CD-ROM

Stuart Silverman, Chair, AHLA Corporate Practice of Medicine Project

Anthony H. Choe, Terri A. DeSio, Alyson M. Leone, Glenn P. Prives, Daniel Z. Sternthal, and Rose J. Willis, team leaders; with numerous authors and editorial board members

The corporate practice of medicine doctrine (CPOM) 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.

This valuable resource is for anyone needing to determine how a particular state addresses the CPOM doctrine. The doctrine is most often invoked in contract disputes, such as enforcement of noncompetition agreements and the right to receive reimbursement from third parties. Some courts have cited the doctrine in refusing to enforce an insurance carrier's reimbursement to a medical corporation operating in violation of a state's CPOM.



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Data Breach Notification Laws: A Fifty State Survey

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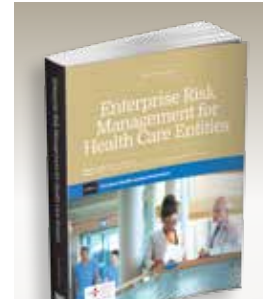
Jonathan M. Joseph

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. The latest edition of *A Fifty State Survey* is a one-stop guide to existing state data breach laws. And 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 the comprehensive state survey, 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

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Enterprise Risk Management Handbook for Health Care Entities

THIRD EDITION

Co-published with ASHRM, the American Society for Healthcare Risk Management

Sheila Hagg-Rickert, Editor in Chief

Roberta L. Carroll, Teresa L. Kielhorn, Erin Muellenberg, and Fay A. Rozovsky, Editors

Ellen Barron, Ellen L. Barton, Roberta L. Carroll, Peggy L. Crane, John R. Evancho, Mark Faccenda, Shaune E. Ferrara, Sheila Hagg-Rickert, Peter J. Hoffman, Susan R. Huntington, Mark A. Kadzielski, Brett J. Kaminsky, Christopher N. Kanagawa, Teresa L. Kielhorn, Jee-Young Kim, William M. Klimon, Marilyn Lamar, Eileen Lampe, R. Jeffrey Layne, William McDonough, Elizabeth M. Mills, Peggy Nakamura, Anjana D. Patel, Nancy T. Poblenz, Michaela Poizner, Richard S. Porter, Yvonne K. Puig, Fay A. Rozovsky, Joshua I. Rozovsky, Cynthia S. Siders, Brittany C. Wakim, and Kathryn K. Wire, authors

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. In order 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:

- Contract management
- Health information exchanges and electronic health records
- Environmental compliance
- Human research
- Peer review and credentialing
- Consent to treatment
- Medical identity theft

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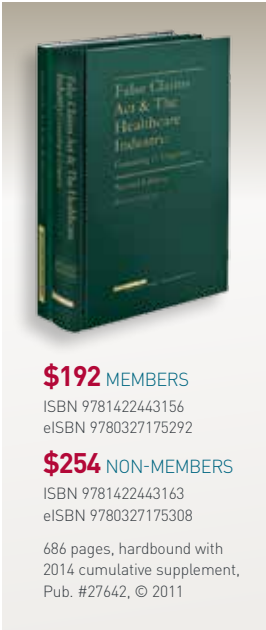
Robert S. Salcido

Significant events have occurred regarding the government's enforcement and administration of the False Claims Act (FCA) in the last few years.

In 2012, the Department of Justice announced that since the FCA was substantially amended in 1986, it had recovered more than \$30 billion under the FCA. In 2013 it recovered nearly \$3.8 billion, of which \$2.6 billion was from health-related FCA cases. In 2016 it recovered nearly \$4.7 billion, of which \$2.5 billion was from health-related FCA cases.

With the stakes this high, professionals involved in this area will benefit from this comprehensive work. Coverage in the 2014 Supplement includes:

- ▶ Actions alleging a violation of the Anti-Kickback Statute and Stark Law
- ▶ How courts have applied defenses to dismiss false claim actions
- ▶ Dismissing FCA actions under the FCA public disclosure jurisdictional bar
- ▶ Whether the plaintiff can establish that the defendant retaliated against the plaintiff for investigating fraudulent conduct
- ▶ Whether the tolling provisions of the FCA apply when the United States declines to intervene in a qui tam action



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AHLA Federal Health Care Laws and Regulations

2015 – 2016 EDITION with 2016 Supplement

William W. Horton, Editor

For those who must understand the latest regulatory activity generated by the Affordable Care Act and today's health care-related legal issues, this comprehensive compilation is essential. Gain insights into these and other issues.

Up-to-date coverage includes:

- ▶ Regulations relating to accountable care organizations
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FIRST EDITION with CD-ROM

Robert A. Griffith and Paul W. Shaw

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 a comprehensive 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. Understanding the powers, procedures, and remedies available to investigative and law enforcement agencies is critical for health care industry executives, managers, and attorneys who find themselves the focus of such investigations.

(See also *Legal Issues in Healthcare Fraud and Abuse, Fourth Edition*, p. 20.)

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The Fundamentals of Behavioral Health Care Law

FIRST EDITION

Peter J. Domas and Russell A. Kolsrud, Editors

Gerald "Jud" E. Deloss, Jena M. Grady, Alexandra A. Hall, Russell A. Kolsrud, Gregory W. Moore, Paige M. Steffen, and Serene K. Zeni, authors

The prevailing laws and policies surrounding treatment of mental health issues have evolved dramatically since the 1950s. At the same time, successful integration of behavioral and physical health requires that the applicable jurisprudence evolve at the same pace, and this faces resistance.

Despite state legislatures' policy decisions that persons with mental illness can live in our society as functioning individuals, our jurisprudence of tort and injury law is often an impediment to that goal.

This title covers a broad range of issues for health care institutions, social services providers, and the lawyers who represent them, and will be turned to time and again to gain a deeper understanding of unfamiliar areas.

Gain insight to a range of issues likely to impact your representation in the area of behavioral health law, including:

- › The move from institutionalization to a community-based outpatient system of care
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- › Hindsight bias and its effect on behavioral health jurisprudence
- › Criteria for when someone can be subjected to involuntary psychiatric treatment
- › The impact of patient's illness on the rules that govern treatment records
- › Integration of behavioral health with physical medical issues

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The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech, Second Edition, provides a solid grounding in the legal principles and issues inherent in this complex area. Both new practitioners and experienced attorneys alike will benefit from this unparalleled coverage.

The latest edition features contributions from some of the most 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:

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The Second Edition includes more than 300 forms, contracts, agreements, checklists, and other legal documents. Contents are updated regularly, and along with the latest supplement provide forms in the following areas:

- Accountable Care Organizations
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Healthcare Antitrust FAQ Handbook

FIRST EDITION with CD-ROM

Mark L. Mattioli, Alexander M. McIntyre Jr., David M. Narrow, Stephen P. Murphy, Patricia M. Wagner, and Hillary A. Webber

Here is an important resource for anyone needing to understand how antitrust issues impact health care organizations. Whether you are in-house counsel with a health care organization, a health care attorney not generally involved with antitrust issues, or even one more familiar with how issues impact health care organizations, you will benefit from this handy guide.

This book employs a practical question-and-answer approach for understanding the antitrust implications for structuring deals in this sector. The subjects covered include not only the traditional antitrust questions but other topics specific to health care, such as:

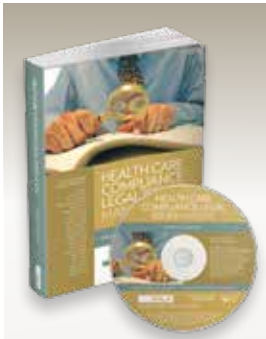
- Antitrust implications in the peer-review and medical-staff arena
- Physician and other health care provider networks
- Sharing health care price information

Questions include:

- When is it permissible to talk to a competitor about merging and what information can be shared?
- How do federal antitrust agencies determine when to challenge mergers?
- How can you take advantage of the immunity protection of the Health Care Quality Improvement Act of 1986 (HCQIA) in credentialing matters?
- When are exclusive contracts with primary payers permissible?
- What type of provider network arrangements can avoid per se condemnation?
- What authority do state attorneys general have to investigate federal antitrust violations?

The questions and answers are bolstered by extensive footnotes for further expanding research into each area of coverage.

(See also *Antitrust and Health Care: A Comprehensive Guide, Second Edition*, p.4.)



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The latest edition continues to act as the authoritative source for every stakeholder in the health care arena. With contributions from more than 20 esteemed authors and editors, coverage includes:

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(See also *Pharmaceutical and Medical Device Compliance Manual, First Edition*, p. 24.)



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Health Care Finance: A Primer

THIRD EDITION

Nathan F. Coco, Deborah Gordon, John P. Hammond, Patrick J. Martinez, Gary B. Rosenbaum

For those involved in health care financing, this is your ideal starting place for a full understanding of financing options and their potential implications. Now in its third edition, this guide addresses all the basics, from a discussion of the particular needs of various types of health care entities to specific financial arrangements and the attending documents that are integral to them. In addition, it includes various types of loans and sample representations and warranties for life sciences companies and health care facilities. The guide provides thorough coverage of:

- The critical importance of finance to the future of health care
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Health Plans Contracting Handbook: A Guide for Payers and Providers

SEVENTH EDITION

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Since the prior edition of *Health Plans Contracting Handbook*, new challenges have arisen in the financing and delivery of health care services, while increased regulatory oversight and monitoring are continually changing the landscape. With the how-to coverage in this *Guide*, you'll be prepared to efficiently provide the accurate, iron-clad documents your clients demand. And while the *Guide* has been both updated and enhanced, the practical, user-friendly approach remains. It is designed to help you provide contracting services to both providers and payers alike. Practical discussions and sample clauses are included for the myriad different contracts and situations you are likely to encounter.



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The passage of the Affordable Care Act has led to numerous changes to the delivery of health care, including new marketplaces to purchase insurance to cover health care expenses. As more people become insured, their health plan decisions become even more important to them and to the health plan industry in general.

Experienced practitioners Joseph Scott Schoeffel and Julie A. Simer provide thorough treatment of those areas likely to give rise to disputes. The book will be a welcome addition to the libraries of both new practitioners in this area and veteran practitioners alike.



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 Sara Kay Wheeler, authors

Savings from provider payments will be required to deliver health care services to more health care consumers. This will result in ever-increasing audit activity. 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
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- › 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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- › High Stakes
- › Effectively Managing Contractor Audits

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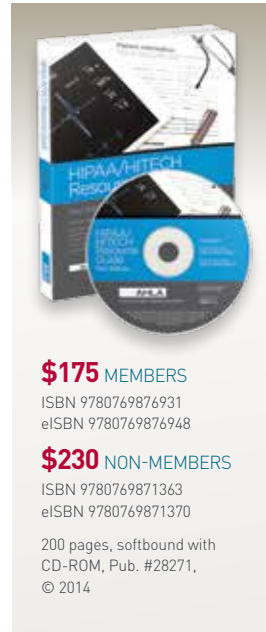
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- › Coverage Determinations
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- › Medicaid Integrity Program Manual
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- › The Notice of Overpayment
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With expert editorial oversight and authorship, this title from AHLA provides the latest guidance for understanding all aspects of the protection of patients' personal information. The changes, which culminated with the HIPAA Omnibus Rule, affect individuals, health systems, business associates, and many others. Includes:

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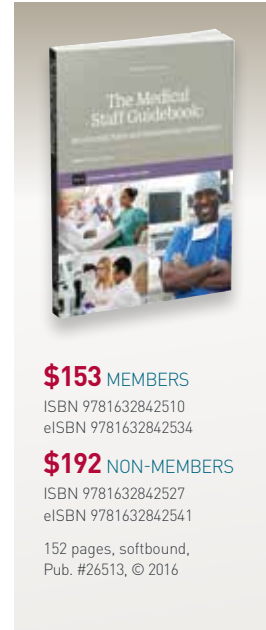
FOURTH EDITION with 2015 Supplement

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

The fight against fraud in the health care industry will increase in intensity and sophistication in the 21st century. 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

[See also *False Claims Act & The Healthcare Industry: Counseling & Litigation, Second Edition*, p. 8.]



The Medical Staff Guidebook: Minimizing Risk and Maximizing Collaboration

FOURTH EDITION

Karen S. Rieger

Increased interaction between health care entities and medical staff, along with scrutiny from both regulators and the market itself, continue to impact the relationship between physicians and the entities where they provide service. An increasing number of facilities that offer medical care, and the interrelationship can become even more complicated. At the heart of this balancing act are the medical staff bylaws.

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- ▶ An overview of the applicable regulatory matters, including conditions of participation, and the role that accreditation organizations play
- ▶ The protection afforded health care entities and physicians by the Health Care Quality Improvement Act of 1986 (HCQIA)
- ▶ The Joint Commission's changes incorporated in MS.01.01.01
- ▶ The underlying legal and business issues that will impact the drafting of appropriate bylaws
- ▶ An overview of key provisions of the bylaws related to: medical staff governance, medical staff appointment, procedures for determining clinical privileges, and fair hearing procedure

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- Ch. 2 Basic Statutory, Regulatory and Accreditation Matters
- Ch. 3 Underlying Legal and Business Issues Impacting the Hospital/Medical Staff Relationship
- Ch. 4 Organizational and Drafting Tips for Medical Staff Bylaws and Related Documents
- Ch. 5 Content of Key Provisions of Health Care Entity Bylaws
- Ch. 6 Overview of Medical Staff Bylaws
- Ch. 7 Credentialing Procedures
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- Ch. 9 Corrective Actions
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- Ch. 11 Conclusion



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Medicare Law

THIRD EDITION with CD-ROM

Thomas W. Coons, Editor in Chief

Emily Jane Cook, Gary Scott Davis, James F. Flynn, Anne W. Hance, John R. Hellow, David W. Hilgers, Rodney A. Johnson, William T. Mathias, Kathleen Ann Peterson, Adam J. Rogers, Donald H. Romano, Robert L. Roth, Elizabeth T. Thomas, and Matthew Philip Utech, authors

Since the last edition of *Medicare Law*, the rules that govern Medicare have changed substantially, with many changes being driven by the Affordable Care Act. Here are a few of the areas of coverage that were updated in the current edition:

- › New or modified payment systems
- › Medicare reimbursement rules, which are tied much closer to the quality of the services delivered
- › The addition of significant Medicare reporting requirements
- › Modified billing including new time limits on the filing of claims
- › Strengthening of the fraud and abuse rules
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Peer Review Guidebook

FIFTH EDITION

Barbara Blackmond, Charles J. Chulack, Joshua A. Hodges, Lauren M. Massucci, Daniel Mulholland, Editors

Peer Review Guidebook, now in its Fifth Edition, is an invaluable source for complying with Health Care Quality Improvement Act (HCQIA) procedural requirements. For institutions or individuals participating in a review action, following appropriate procedures is the key to securing immunity from monetary damages.

From credentialing, privileging or evaluating a physician, through potential reduction or denial of privileges, this comprehensive handbook provides critical guidance—as outlined in HCQIA.

Rely on this publication for complete coverage of:

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- › Recognizing and characterizing the issue
- › Informal dispute resolution
- › Injunctive relief from peer review actions
- › The formal hearing process
- › Utilization of legal counsel by both sides
- › Presentation of the case
- › Reporting requirements
- › Suspension of privileges

The publication includes a multitude of citations to cases, regulations, and other sources. Detailed appendices contain a listing of numerous cases that have addressed various aspects of the peer review process.

(See also *Peer Review Hearing Guidebook, Second Edition*, below.)



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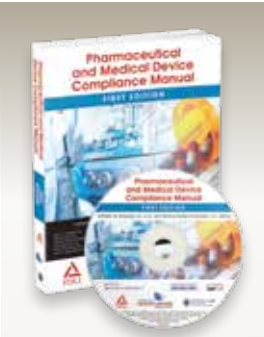
Peer Review Hearing Guidebook

SECOND EDITION with CD-ROM

S. Allan Adelman and Ann O'Connell, Co-Editors and authors

Peer Review Hearing Guidebook focuses on the peer review hearing process, including steps that should be taken long before a medical staff hearing is contemplated. This is a critical resource that will help you be sure that all necessary procedures are in place to facilitate an effective and fair hearing. The practical *Guidebook* includes:

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- › Practical steps for improving the peer review and hearing processes
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Pharmaceutical and Medical Device Compliance Manual

Kathleen M. Boozang and Simone Handler-Hutchinson, Editors

Bret A. Campbell, Sujata Dayal, Michael Andre Donnella, Katie Rose Fink, Brett R. Friedman, Gary F. Giampetruzzi, Christopher R. Hall, Patrick M. Hromisin, Elizabeth H. Kim, Daniel A. Kracov, Bruce A. Levy, Ann E. Lewis, Benjamin S. Martin, Joseph W. Metro, Lewis Morris, Kiaema R. Reid, Linda Pissott Reig, Margaret Renner, Mary Riordan, Lynn Shapiro Snyder, Brian Tretick, Robert E. Wanerman, and Mara E. Zazzali-Hogan, authors

Since 1996 the federal government has strengthened its efforts to detect and prevent fraud and abuse in health care. This *Manual* is your key to effectively protecting companies from investigation and prosecution.

The 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 the American Health Lawyers Association. It offers an in-depth overview of the federal and state enforcement agencies that are responsible for investigating and resolving violations of the law by health care entities, with an emphasis on pharmaceutical and medical device companies. 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

This *Manual* is a must-have for anyone involved in building a compliance program: health and life sciences attorneys, compliance officers, and other professionals in the industry.



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

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This invaluable guide provides insight into what's ahead for professionals in the field and the evolving compliance and regulatory issues, including:

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- › What to consider when building, buying, or selling a post-acute care facility
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- › Continuing care
- › Assisted-living facilities



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 comprehensive title. Coverage includes:

- Privacy and patient relations
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- Real estate and employment matters

Quality performance in this area is integral to the operation of the entity. Payment methodologies examined include:

- Medicare and Medicaid
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- Payment adjustment methods
- Private payers

The authors provide invaluable guidance for those who represent a health care business, including coverage of state licensing requirements, and the voluntary certification process authorized by the Centers for Medicare and Medicaid Services.

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Representing Physicians Handbook

FOURTH EDITION

A Task Force of the AHLA Physician Organization’s Practice Group

Michael F. Schaff, Task Force Chair; Lisa Gora, Coordinating Editor

This updated edition of the AHLA *Representing Physicians Handbook* addresses a wealth of issues confronting physicians and their legal representatives, including the latest Stark Law changes. With each edition, the expert authors have enhanced the resource to ensure up-to-date coverage in this complex and highly regulated area. Even if you own a past edition, it is critical that you secure the latest update. From regulatory compliance and business formation and operation, to tax consequences and reimbursement issues, this informative *Handbook* has become a go-to source for innumerable health law attorneys.

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The Stark Law: Comprehensive Analysis + Practical Guide

FIFTH EDITION

Charles B. Oppenheim

More than a summary of the law, this publication addresses the legal effect of final Stark Regulations, after the completion of the formal rule-making process. Written by Charles B. Oppenheim, a leading expert 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, as well as a look at what future direction the Stark regimen might take. Coverage includes:

- The legal effect of the regulations and the regulatory process
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- Key definitions and interpretive changes
- Impact on the physician practice world 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, as well as the recent guidance from CMS concerning the period of disallowance for referrals and claims, and analysis addressing the final rule

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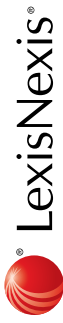
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