Leading health law to excellence through education, information, and dialogue, the American Health Lawyers Association (AHLA) is the nation's largest nonpartisan, 501(c)(3) educational organization devoted to legal issues in the health care field. AHLA provides resources to address the issues facing its active members who practice in law firms, government, in-house settings, and academia and who represent the entire spectrum of the health industry: physicians, hospitals and health systems, health maintenance organizations, health insurers, managed care companies, nursing facilities, home care providers, and consumers.

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Ambulatory Surgery Centers: Legal and Regulatory Issues

Fifth Edition with CD-ROM

Scott Becker, Megan Michelle Busea, Lauralae Lawley, Melissa Szabad, Anna Zimmerman, Barton Walker, and Amber Walsh

This publication addresses the unique nature of ASCs, emphasizing their physical and organizational separation from other providers, regardless of whether they are owned by a hospital, a physician practice, or other entity. This revised and updated edition focuses on current issues for ASCs, and offers practical and useful guidance for those involved in giving legal advice to them. Coverage includes: key trends and tensions facing ASCs, such as the 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, and the safe harbors for ASCs; relevant Stark issues, as well as the impact of state self-referral laws; and antitrust considerations for ASCs that face often intense competition.

Corporate Practice of Medicine: Fifty State Survey

First Edition with CD-ROM

Stuart Silverman, Chair, AHLA Corporate Practice of Medicine Project
Anthony H. Choe, Terri A. DiSio, 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 corporate practice of medicine doctrine. The doctrine is most often invoked in contract disputes, such as enforcement of non-competition 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.

Fraud and Abuse Investigations Handbook for the Healthcare Industry

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 memoraanda 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. 18.)

Fundamentals of Health Law

Sixth Edition with CD-ROM


This edition covers the basic issues of health-law practice, from patient to facility issues, from permits and regulation issues to compliance and investigation issues, and includes issues raised by new laws, regulations, and guidelines promulgated since the Fifth Edition.

This publication covers fundamental legal principles and issues to assist:

- New practitioners or experienced attorneys entering their first years of health-law practice
- Professors of health law searching for a comprehensive text for their students
- Users of any law library looking for answers on the health law resource shelf

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Chapter 6 Antitrust
Chapter 7 The Source of Payment: The State and Federal Regulation of Private Health Plans
Chapter 8 Regulation of Hospitals
Chapter 9 Representing Physicians
The Fundamentals of Life Sciences Law: Drugs, Devices, and Biotech
Second Edition with CD-ROM

Kristian A. Werling, Editor in Chief


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.

This new 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:

 › Regulation of Drugs
 › Regulation of Medical Devices
 › Regulation of Biologics
 › Clinical Trials
 › Fraud and Abuse
 › Federal Agencies
 › Regulation of Advertising, and Promotion of Drugs, Medical Devices, and Biologics
 › Antitrust
 › Privacy
 › State Regulation
 › Intellectual Property
 › Payment and Reimbursement
 › International Issues
 › Life Sciences Licensing Transaction

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ISBN 9781630440176
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HIPAA/HITECH Resource Guide
First Edition with CD-ROM


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 last year’s HIPAA Omnibus Rule, affect individuals, health systems, business associates, and many others. Includes:

 › The original HIPAA regulations
 › HITECH Act Privacy provisions and rulemaking
 › Modifications to HIPAA Privacy, Security, and Enforcement Rules
 › Includes 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 insuring compliance.

(See also Law of Health Information Technology, p. 18.)

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Watch for these new titles/new editions coming soon!


Diagnostic Imaging Centers: Legal and Regulatory Issues, Third Edition

Health Care Compliance Legal Issues, Fourth Edition


Stark Final Regulations, Fifth Edition

Check www.healthlawyers.org/bookstore regularly for the latest publishing events!
AHLA’s Federal Healthcare Laws & Regulations
William W. Horton, editor; W. Scott Nardy, Alan M. Kirchenbaum, Arthur N. Larner, Patricia A. Marcus, John A. Meyers, Daniel F. Murphy, Paul W. Shaw, Donald B. Stuart, and Judith A. Waltz, editorial advisory board

Federal Healthcare Laws & Regulations from AHLA is a comprehensive three-volume compilation that incorporates the most significant and timely federal statutes and regulations for the health care practitioner. It includes:

- The Affordable Care Act and the many new regulations that accompany it
- E-prescribing
- Enhanced enrollment requirements
- The HIT certification program
- Health insurance reform requirements for individual and group markets
- The Stark Law
- The HIPAA Privacy and Security Standards
- Key regulations governing CMS and the Office of Inspector General
- Rules and regulations on many other critical aspects of your healthcare law practice

A fully searchable CD-ROM allows you to research more efficiently and copy and paste the text of statutes and regulations easily into your documents.

Volume I
Selected Sections from the United States Code Service
Title 5 Government Organizations and Employees
Title 15 Commerce and Trade
Title 18 Crimes and Criminal Procedure
Title 21 Food and Drugs
Title 29 Labor
Title 31 Money and Finance
Title 35 Patents
Title 38 Veterans’ Benefits
Title 42 The Public Health and Welfare

Volume II
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CD-ROM
The companion CD-ROM contains the complete contents of the 3 volumes in a fully searchable Folio format.

Antitrust and Healthcare: A Comprehensive Guide
First Edition with CD-ROM
Christine L. White, Saralisa C. Brau, and David Marx Jr., authors and editors; David A. Argue, Martin Bienstock, Robert S. Canterman, David Norrow, Joshua H. Sevin, and Shoshana Speiser, contributing authors

If you represent clients in the health care arena, or are a professional with business interests in this area, Antitrust and Healthcare: A Comprehensive Guide is 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. The accessible Guide covers:

- Substantive antitrust law
- Important case law developments
- Formal and informal guidance issued by federal and state enforcement agencies

Consult Antitrust and Healthcare 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
- Dominant firm conduct

Additionally, Antitrust and Healthcare 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:

- Pre-merger notification and transaction planning
- Developing antitrust compliance and “sensitively 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

Antitrust and Healthcare explains the application of antitrust principles to the different segments of the health care industry—including providers and third-party payers—and the specific issues they confront.

[See also Healthcare Antitrust FAQ, p. 15.]
Clinical Research Practice Guide
Second Edition with CD-ROM

R. Harold McCard, coordinating editor; Monica R. Chmielowski, M. Leann Habte, Jonathan M. Holda, E. Scott Johnson, Christopher F. Lonergo, Melissa L. Markay, Aaron J. Rabineowitz, Sarah E. Swank, Lawrence W. Vernaglia, David S. Wunstoxel, Jamie K. Wolczon, and Torrey K. Young, authors

With this important book, 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 of the popular Practice Guide is extensively enhanced and updated with coverage of:

- Changes to HIPAA that affect research and IRBs
- New Food and Drug Administration guidances and finalization of draft guidances
- Changes to patent law due to the America Invents Act
- HITECH and enhanced coverage of the Security Rule
- New 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:

- The development of human subject protections
- The federal approval process for pharmaceuticals, medical devices, and biologics
- The responsibility for regulatory oversight and investigations, with a discussion of which agency in the U.S. Department of Health and Human Services has responsibility for ensuring compliance
- Intellectual property considerations, including an extensive discussion of the basics
- Information management, including the sources for human subject protection: the Federal Common Rule, FDA Guidance, and HIPAA
- Insurance payments for clinical trial services, whether through private insurance or federal reimbursement

(See also Institutional Review Boards: A Primer, Second Edition, p. 17.)

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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 new Guidebook includes:

- Coverage of all of the legal issues involved in peer review hearings
- Practical steps for improving the peer review and hearing processes
- A companion CD-ROM that provides sample forms, checklists, bylaws, and fair hearing provisions—customizable for individual clients
- A survey of statutes, regulations, and cases from all 50 states relating to the right to and conduct of peer review hearings

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The ACO Handbook: A Guide to Accountable Care Organizations
First Edition with CD-ROM

Peter A. Pavarini, Charlene L. McGinty, Michael F. Schaff, editors; Thomas E. Bartrum, Elisabeth Belmont, Rudolf M. Blumentritt, Mark W. Brown, Timothy J. Cahill, Lauren N. Haley, Robert G. Homchick, Travis F. Jackson, Marilyn Lamar, Alyson M. Leone, Nathan L. Lutz, Barbara L. Miltenberger, Kimberly A. Mobley, Jan E. Murray, David R. Pearl, Glenn P. Prowa, Toby G. Singer, Harvey M. Tettelbaum, Danielle L. Trettlof, John R. Washlick, authors

It is the importance of accountable care organizations (ACOs), as much as the uncertainty about their future, that makes The ACO Handbook: A Guide to Accountable Care Organizations necessary for those grappling with the changes brought about by health care reform. The contributors to this Handbook are among the best professionals in America today who are seriously considering what it will take to succeed under the new health care environment. Their astute observations about the legal issues, both novel and familiar, likely to be encountered by those contemplating ACO development will be useful to the reader no matter what role these organizations ultimately play in the reformed U.S. health care system.

The authors begin with a discussion of the importance of this new model, review the integration models used by hospitals and physicians prior to enactment of the PPACA, and continue with examinations of issues such as cost containment as envisioned in the “Medical Home,” as well as waivers by the federal government of aspects of the Stark Law, the Anti-Kickback Statute, and certain provisions of the Civil Monetary Penalties Law.

AHLLA’s Guide to Healthcare Legal Forms, Agreements, and Policies
Second Edition with 2014 Supplement and CD-ROM

Collected from expert health law attorneys and members of AHLLA, this resource is designed to meet the needs of health law attorneys who must regularly create documents for their clients. It is conveniently organized by topic in a loose-leaf format for easy updating.

The Second Edition of this best-selling forms set includes more than 300 new forms, contracts, agreements, checklists, and other legal documents. For even further utility you’ll also have access to form completion tips, pointers, and other references. Here is a sampling of some of the areas for which you’ll find forms and practice aids for completion:

- Accountable Care Organizations
- Alternative Dispute Resolution
- Business Transactions
- Clinical Trials and Research
- Conflicts of Interest
- Corporate Compliance Programs
- Facility Operations
- Fraud and Abuse
- Governance
- Health Information Exchanges
- Health Information Technology
- Health Plan Contracting
- Internal Investigations
- Labor and Employment
- Legal Services
- Long Term Care
- Medical Group Practices
- Patient Care Policies
- Patient Safety and Adverse Outcomes
- Physician Employment
- Reimbursement
- Risk Management

The Guide comes complete with a companion CD-ROM which contains all the documents in an electronic .rtf format.
Data Breach Notification Laws: A Fifty State Survey
First Edition with 2013 Supplement

Jonathan M. Joseph

The risk of a data breach has increased tremendously in recent years. While the U.S. Congress has enacted breach notification requirements in a number of Acts, data breach concerns are not limited to federal law. This is due to actual breaches of state information systems, and has led state legislatures to enact an array of data breach notification laws.

This publication is a guide to existing state laws, and includes selected statutes for a number of states to illustrate not only the approach that larger states have taken, but also to highlight some of the more unusual approaches that some states have followed.

Highlights include:
- A fifty state survey of data breach notification statutes
- The text for the relevant act in CA, NY, IL, TX, FL, MA, MD, MI, NH, NJ, NC, WV, and WI
- Sample data breach notification to consumers, reporting forms, sample letter to a state Attorney General, and breach notification requirements for the Commonwealth of Virginia

The 2013 Supplement brings the information in this publication up to date with changes enacted in numerous states and also includes additional sample notice letters and forms.

Deciphering Codes: Fraud & Abuse for Coders and Coding Insight for Healthcare Lawyers
First Edition with CD-ROM

Rhonda Buckholtz and Robert A. Pelaia, project leaders; Brad Ericson and Renee Dusman, editors; Katharina Abel, Nicole Benjamin, Richard J. Brodersen, Rhonda Buckholtz, Gregory A. Chaires, Julie E. Chicoine, Shelly Cronin, Keni Draak, Stephanie G. Ellis, Brad Ericson, Amy E. Fouts, Michael A. Gardner, Nala Gilmer, Deborah Grider, Joken M. Guerrers, Jillian Harrington, Raamaria Jimenez, Joël B. Laurence, Kelly Loya, Theresamarie Manteis, Jonnie Massey, Robert E. Maier, Leslie Murphy, Gregory M. Nowakowski, Christopher A. Parrella, Abby Pendleton, Lisbon E. Radney III, David L. Rogers, Donna Sandhioain, Harry W. Silver, Kevin Solinsky, and Jennifer L. Weaver, authors

This unique publication is designed to help coders and attorneys understand and navigate the complex intersection of health care coding and the law. This valuable manual discusses the nuances of coding, why proper coding is essential for health care facilities and professionals, and the legal implications of improper coding.

It covers the various sources for codes, provides an overview of the applicable fraud and abuse statutes and regulations, and then discusses ten specific health care settings where coding is a critical element. The importance of a detailed compliance plan for coding is discussed throughout the book, as are cases brought by federal and state governments against health care providers for improper coding. Also included is a searchable CD-ROM containing the full text of the manual with links to selected cases, statutes, and regulations.
Sixth Edition with CD-ROM
Cynthia F. Reaves, Anne W. Hance, and Robert M. Keenan III, co-editors; Matthew P. Amodeo, George W. Biedenger, Robin J. Fisk, Lisa G. Han, John M. Kirsner, Mark S. Kopson, Kathrin E. Kudner, Steven J. Lauwers, Thomas P. O'Donnell, Richard H. Sanders, Michael F. Schaff, and Adam C. Varley, contributing authors

This publication traces the managed care contracting process from preparing to negotiate the contract, to formation and implementation, to termination issues. It identifies key questions typically encountered in preparing such agreements with a perspective that incorporates the current environmental challenges confronting managed care organizations. All the sample clauses are included on the CD-ROM, so you can customize and create your own contracts.

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Pub. #27092, softbound with CD-ROM, 330 pages, © 2011

False Claims Act & The Healthcare Industry: Counseling & Litigation
Second Edition with 2013 Cumulative Supplement
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, and in 2013 it recovered nearly $3.8 billion, of which $2.6 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 2013 Supplement includes:

 ACTIONS ALLEGING A VIOLATION OF THE ANTI-KICKBACK STATUTE AND STARK LAW
 HOW DEFENSE COURTS HAVE APPLIED 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 DECLARES TO INTERVENE IN A QUI TAM ACTION

(See also Legal Issues in Healthcare Fraud and Abuse, Fourth Edition, p. 18.)

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eISBN 9780327175308
Pub. #27642, hardbound with 2013 cumulative supplement, 886 pages, © 2011

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.

The 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 Healthcare: A Comprehensive Guide, p. 7.)

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Healthcare Compliance Legal Issues Manual
Third Edition with CD-ROM

The Manual addresses important topics such as what a compliance program is, how to conduct internal investigations, audit basics, what to consider prior to deciding on repayments and disclosures, substantive overviews of the False Claims Act, the Stark and Anti-Kickback Laws, HIPAA privacy and security, issues in life sciences entities, tax compliance, and many others. Coverage includes:

- Impact of the creation of RACs, ZPICs, and other contractors with audit and enforcement powers
- Changes to the False Claims Act enacted as part of the Fraud Enforcement and Recovery Act
- Analysis of the fraud and abuse provisions in the Health Reform statute
- Changes to the Federal Sentencing Guidelines
- A searchable CD-ROM containing the full text of the Manual with links to selected cases, statutes, and regulations

(See also Pharmaceutical and Medical Device Compliance Manual, First Edition, p. 20.)

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Healthcare Compliance Legal Issues Manual
Third Edition with CD-ROM

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ISBN 9781422497593
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Pub. #26190, softbound with CD-ROM, 190 pages, © 2011

Healthcare Finance: A Primer
Second Edition with CD-ROM
Deborah Gordon

For those involved with the health care industry, an understanding of the underlying principles of health care finance is a must. This publication 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 sample documents for various types of loans, and sample representations and warranties for life sciences companies and health care facilities. The companion CD-ROM contains the full text of the sample documents so you can customize them for use with your clients.

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Pub. #26190, softbound with CD-ROM, 135 pages, © 2011

Healthcare Entity Bylaws and Related Documents: Navigating the Medical Staff/Healthcare Entity Relationship
Third Edition with CD-ROM
Karen S. Reiger and Eric S. Fisher

This practice guide provides an excellent framework for drafting bylaws that will establish an appropriate legal and professional relationship between the medical staff and the health care entity. Highlights include:

- An overview of basic statutory, regulatory, and accreditation matters
- Identification and discussion of underlying legal and business issues that will impact the drafting of appropriate bylaws
- Guidance for incorporating The Joint Commission’s changes to MS.01.01.01
- Organizational and drafting tips, as well as suggested language that should be included in key provisions of the bylaws
- Discussion of the nature of medical staff appointment, procedures for determining clinical privileges, and fair hearing procedures
- Companion CD-ROM with sample bylaw language, so that you can create comprehensive medical staff bylaws and related documents

(See also Peer Review Hearing Guidebook, Second Edition, p. 9.)

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eISBN 9780327174189

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eISBN 9780327174189
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Institutional Review Boards: A Primer
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Teresa A. Williams, Richard S. Korman, Janet M. Lis, Melinda G. Murray, Kate Bowen, Amy L. Bradshaw, Tara R. Cowell, Amy K. Droe, Kimberly H. Gillisap, Jennifer R. Hendersen, Marta J. Hoffman, Veronica A. Marsich, Tamara J. D’Black, Kay M. Parry, Carol A. Poindexter, Stacey A. Rivas, Martha C. Romney, Jennifer Sharp, Sarah Shulman Swank, Alexandra Trinkoff, Leah A. Voigt, and Catherine M. With

The expanded second edition of Institutional Review Boards: A Primer outlines the regulatory requirements and legal challenges associated with the evolving area of human subject research, and presents a thorough discussion of the role that institutional review boards serve in this area. This useful guide not only explains the difference between the various regulations that govern human subject research, but it also details the steps to take to set up an institutional review board that can adequately perform its role. Also included is a searchable CD-ROM that contains the full text of the guide with valuable forms and checklists in Microsoft® Word format.

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(See also Clinical Research Practice Guide, Second Edition, p. 8.)
The Law of Health Information Technology

First Edition with CD-ROM

Gary L. Kaplan

This publication provides a road map to health information technology (HIT) and its challenges. The ever-evolving world of HIT requires a new way of planning for subjects as disparate as delivery of health care, retention of records for standard business reasons, and preparation for litigation. Successful HIT projects necessitate coordination between four critical constituencies: medical, business, technical, and legal. This practice guide delineates many of the considerations that health systems and other providers face today, and offers detailed guidance on complying with laws and regulations concerning privacy, security, copyright infringement, as well as marketing and advertising rules.

Highlights include:
- Guidance on how to avoid the pitfalls of negotiating for new technology systems
- In-depth discussion of HIPAA, HITECH, and Red Flag Rules, as well as their impact on the health care arena
- The effect of HIT on telemedicine, electronic discovery, and the rules that govern the Internet and social media
- A searchable CD-ROM containing the full text of the practice guide with valuable forms in Microsoft Word format

[See also HIPAA/HITECH Resource Guide, p. 5.]

Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties

Fourth Edition with 2014 Cumulative Supplement

David E. Matyas, Carrie Valliant, Jason Eric Christ, and Anjali N.C. Doms

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


The Medical & Healthcare Facility Lease: Legal and Business Handbook

First Edition with CD-ROM

Gregory G. Gosfield

This publication on health care facility leases covers the basics such as the important distinctions between contract law and the law governing leases, contracts that precede the lease agreement, the provisions that create the business positions for the respective parties, and advanced issues that apply specifically to health care-facility leases. The author’s continuing theme throughout the book is the motivations and goals of the key parties, including not only the landlord and tenant, but also the landlord’s mortgagee, the working capital loan lender, and the subtenant. This method reveals the underlying dynamics of the parties’ negotiations, their concerns and the source of same, and the resolution of these issues.

Medicare Law

Third Edition

Thomas W. Coons, Editor in Chief; Emily Jane Cook, Gary Scott Davis, James F. Flynn, Anne W. Hanca, John R. Hollis, David W. Hilger, 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 have been updated in the latest 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
- New payment approaches, such as Accountable Care Organizations, that are being or have been introduced

Comprehensive coverage also includes in-depth examinations of:
- Payment for hospital services, including PPS and PPS-exempt hospitals
- The DRG system
- The urban/rural distinctions
- Outlier payments
- The physician fee schedule
- Cost reimbursement
- Prohibited acts under the Anti-Kickback and Stark Laws
- Administrative and judicial appeals processes
- The new incentive payment programs

This publication provides a thorough understanding of Medicare, whether you are just beginning the journey or are continuing to learn about this complex and important aspect of health care law.
Peer Review Guidebook
Fourth Edition with CD-ROM
Daniel Mulholland, Lauren M. Massucci, and Charles J. Chulack, editors

Peer Review Guidebook is a comprehensive resource for understanding the peer review process and disciplinary proceedings involving physicians. The fourth edition contains information about the new Joint Commission standards on Focused Professional Practice Evaluation and Ongoing Professional Practice Evaluation, a discussion of the Patient Safety and Quality Improvement Act, as well as the latest from the National Practitioner Data Bank. Also included is a searchable CD-ROM containing the full text of the publication with links to selected cases, statutes, and regulations.

Pharmaceutical and Medical Device Compliance Manual
First Edition
Kathleen M. Boozang and Simone Handler-Hutchinson, editors; Bret A. Campbell, Sujata Dayal, Michael Andre Donella, 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, Kauma 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.

The Manual 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.

(See also Healthcare Compliance Legal Issues Manual, Third Edition, p. 16.)
Representing Physicians Handbook
Third Edition with CD-ROM

The world of physician practice continues to evolve, as do the complexities facing both physicians and the attorneys who represent them. With the advent of health care reform, the increased consolidation of medical practices, and ownership by physicians of ancillary services, a greater understanding of the issues impacting solo and small practices is more and more vital.

The latest edition of this popular Handbook thoroughly addresses:
- The need to understand the Stark regulations
- Compliance issues
- Business and reimbursement
- The growing effort by state and federal government agencies to attack fraud and abuse
- And many other areas

Broad scope of coverage can be seen from this sampling from the table of contents:
- Regulatory Issues Affecting Physicians
- Telemedicine
- Employment Agreements
- Life Cycle of Association: The Buy-In and the Buy-Out
- Tax Principles Concerning Buy-Outs and Related Post-Withdrawal Compensation Issues
- Practice Breakups and Physician Departures
- Physician/Hospital Relationships
- Malpractice Insurance and Risk Management
- Physician Joint Ventures
- The Sale and Purchase of a Medical Practice
- Hospital-Based Physician Representation
- Use of Non-Competition Covenants in Physician Employment Relationships
- Compliance, Compliance Plan, and Process for the Physician Practice
- Non-Physician Practitioners
- Physician Ancillary Services
- Physician Recruitment Agreements
- Concierge Medicine


Stark Final Regulations: A Comprehensive Analysis of Key Issues and Practical Guide
Fourth Edition with Supplement
Charles B. Oppenheim

This fourth edition of the Stark Final Regulations monograph addresses the legal effect of Phase III of the “Final” regulations, which completes the formal rule-making process. Written by Charles B. Oppenheim, a leading expert in the interpretation and application of Stark law, this publication provides practical guidance for advising clients on complying with the current iteration of the regulations, as well as a look at what future direction the Stark regimen might take.

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