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Ambulatory Surgery Centers: Legal and Regulatory Issues

Fifth Edition with CD-ROM

Scott Becker, Megan Michelle Bushee, LauraLee Lawley, Melissa Szabad, Anna Timmerman, Barton Walker, and Amber Walsh

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Pub. #26900, softbound with CD-ROM, 280 pages, © 2014

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

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Pub. #28278, softbound with CD-ROM, 416 pages, © 2014

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

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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. 18.)



Fundamentals of Health Law

Sixth Edition with CD-ROM

Barry D. Alexander, Bernadette M. Broccoli, Anthea R. Daniels, Sandra M. DiVarco, Anjali N.C. Downs, Geoff A. Drucker, Catherine A. Hurley, Cynthia B. Hutto, Raymond J. Lindholm, Carol Colborn Loeper, Vicki L. Lung, David E. Matyas, Thomas Wm. Mayo, John J. Miles, Eli A. Poliakoff, Jouya Rastegar, Ross E. Sallade, Michael F. Schaff, Susan O. Scheutzw, Daniel J. Schwartz, Nancy A. Sheliga, and Kerrin B. Slattery

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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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- Ch. 10 Post-Acute Providers and Suppliers
- Ch. 11 Health Care Transactions and Contracting
- Ch. 12 Bioethics
- Ch. 13 Dispute Resolution in Health Care



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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

Authors: Jeremy M. Alexander, Lauren Battaglia, Brian A. Bohnenkamp, Nancy E. Bonifant, Eve M. Brunts, Elizabeth Carder-Thompson, Carl H. Coleman, Susan A. Edwards, Paige A. Fillingame, David C. Gibbons, Daniel G. Gottlieb, Eric C. Greig, Simone Handler-Hutchinson, Clinton D. Hermes, Stuart S. Kurlander, Robert F. Leibenluft, Vicki L. Lung, Melissa L. Markey, Juliet M. McBride, Leigh L. Oliver, Jordan K. Paradise, Heather H. Pierce, Jennifer L. Pike, Preeya Noronha Pinto, Thomas J. Quinlan, Kelly N. "Nikki" Reeves, Corey W. Roush, Jason W. Sapsin, Richard B. Smith, Judith L. Toffenetti, Susan L. Walker, and Constance A. Wilkinson

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

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
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HIPAA/HITECH Resource Guide

First Edition with CD-ROM

Patricia D. King, editor; Jeffrey 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, Leslie M. Tector, authors

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 years' 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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The ACO Handbook, A Guide to Accountable Care Organizations, Second Edition

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AHLA's Federal Healthcare Laws & Regulations

2013 – 2014 Edition with CD-ROM

William W. Horton, editor; W. Scott Hardy, Alan M. Kirschenbaum, Arthur N. Lerner, 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
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- The HIT certification program
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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 Narrow, Joshua H. Soven, 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 “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

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.)

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Clinical Research Practice Guide

Second Edition with CD-ROM

R. Harold McCard, coordinating editor; Monica R. Chmielewski, M. Leeann Habte, Jonathan M. Holda, E. Scott Johnson, Christopher F. Lonegro, Melissa L. Markey, Aaron J. Rabinowitz, Sarah E. Swank, Lawrence W. Vernaglia, David S. Weinstock, Jamie K. Wolszon, 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:

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- › 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. Browne, 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. Prives, Toby G. Singer, Harvey M. Tettlebaum, Danielle L. Trostorff, 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.



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CD-ROM, 1,900 pages, © 2013

AHLA'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 AHLA, 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

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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 Dustman, editors; Katherine Abel, Nicole Benjamin, Richard J. Brooderson, Rhonda Buckholtz, Gregory A. Chaires, Julie E. Chicoine, Shelly Cronin, Kerin Draak, Stephanie G. Ellis, Brad Ericson, Amy E. Fouts, Michael A. Gardner, Nate Gilmer, Deborah Grider, JoAnn M. Guerrero, Jillian Harrington, Raemarie Jimenez, Jodi B. Laurence, Terry Leone, Kelly Loya, Theresamarie Mantese, Jonnie Massey, Robert E. Mazer, Leslie Murphy, Gregory M. Nowakowski, Christopher A. Parrella, Abby Pendleton, Liston E. Radney III, David L. Rogers, Donna SanGiovanni, Harry R. 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.



Enterprise Risk Management Handbook for Healthcare Entities

Second Edition with CD-ROM

Roberta L. Carroll, Editor in Chief; Peggy Nakamura and Rachel V. Rose, editors; Jessica K. Bae, Ellen Barron, Ellen L. Barton, India K. Brim, Patchin C. Curtis, John R. Evancho, Mark Faccenda, Amanda J. Flanagan, Phyllis F. Granade, Steven O. Grubbs, Sheila Hagg-Rickert, Daniel G. Hale, Peter J. Hoffman, Mark A. Kadzielski, Christopher N. Kanagawa, Jee-Young Kim, Marilyn Lamar, Eileen Lampe, R. Jeffrey Layne, Dana B. Mehlman, Elizabeth M. Mills, Jennifer C. Monroe, Joshua Moore, Cheryl Camin Murray, Deborah Martin Norcross, Amy Norris, Gisele Norris, Richard S. Porter, Yvonne K. Puig, Steven M. Puiszis, Emily Rhinehart, Fay A. Rozovsky, Joshua Rozovsky, Mary S. Schaefer, and Kathryn K. Wire

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The Second Edition of this popular handbook addresses the need for and implementation of a comprehensive risk management process that encompasses the entire enterprise and crosses departmental barriers. Coverage begins with an overview of enterprise risk management (ERM) and its evolution, and goes on to address the structuring of an ERM system, as well as risk financing methods.

The authors delineate how to manage risk in a variety of settings, including:

- Contract management
- Claims management
- Environmental compliance
- Human research
- Peer review and credentialing
- Due diligence in business transactions
- Consent to treatment
- And numerous others

The publication also includes insight on the impact that electronic health record (EHR) systems, combined with the advent of e-discovery rules, will have on traditional documentation issues.



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 declines to intervene in a qui tam action

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

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Health Plans Contracting Handbook: A Guide for Payors and Providers

Sixth Edition with CD-ROM

Cynthia F. Reaves, Anne W. Hance, and Robert M. Keenan III, co-editors; Matthew P. Amodeo, George W. Bodenger, 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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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?

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(See also *Antitrust and Healthcare: A Comprehensive Guide*, p. 7.)

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Healthcare Compliance Legal Issues Manual

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Harry R. Silver and Cynthia F. Wisner, editors; Amy Bailey-Muckler, Douglas A. Blair, Elizabeth Carder-Thompson, Thomas S. Crane, Gerald "Jud" E. DeLoss, Andrew A. Dick, Gerald M. Griffith, Kenneth E. Hooper, Gabriel L. Imperato, Louise M. Joy, Richard G. Korman, Ronald H. Levine, Melissa L. Markey, Sandra Park, Robert A. Pelaia, Mary Romine, Albert W. Shay, E. John Steren, Paul Sheives, and Howard J. Young, authors

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



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Karen S. Rieger and Eric S. Fisher

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- 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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Institutional Review Boards: A Primer

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Teresa A. Williams, Richard G. Korman, Janet M. Lis, Melinda G. Murray, Kate Bowen, Amy L. Bradshaw, Tara R. Cowell, Amy K. Dow, Kimberly H. Gillespie, Jennifer R. Henderson, Marta J. Hoffman, Veronica A. Marsich, Tamara J. O'Black, Kay M. Perry, Carol A. Poindexter, Stacey A. Ries, Martha C. Romney, Jennifer Sharp, Sarah Shulman Swank, Alexandra Trinkoff, Leah A. Voigt, and Catherine M. With

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(See also *Clinical Research Practice Guide, Second Edition*, p. 8.)



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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.

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

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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.

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- 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. 14.]

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The Medical & Healthcare Facility Lease: Legal and Business Handbook

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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.

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Medicare Law

Third Edition

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 have been updated in the latest edition:

- New or modified payment systems
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Comprehensive coverage also includes in-depth examinations of:

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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 Mutholland, 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.

[See also *Peer Review Hearing Guidebook, Second Edition*, p. 9.]

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Pharmaceutical and Medical Device Compliance Manual

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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.

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.]



Physician Recruitment and Compensation Arrangements Practice Guide

Third Edition with CD-ROM

Gerald M. Griffith

This *Practice Guide* offers expert guidance in the complex area of physician recruitment and retention by exempt organizations. It addresses the three most critical elements impacted by physician recruitment and compensation: the Medicare and Medicaid Anti-Kickback Statute, the Stark Law, and federal tax-exemption rules and implications for tax-exempt entities. These issues are analyzed primarily as to incentives and payments made directly and indirectly by exempt organizations.

Summary Table of Contents

- Related Tax and Non-Tax Topics
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- Impact of the Stark Law and Anti-Kickback Statute on Compensation
- Worker Classification of Physicians
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- Practice Acquisitions

[See also *Representing Physicians Handbook, Third Edition*, p. 22.]



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Representing Physicians Handbook

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Michael F. Schaff, Task Force Chair; Glenn P. Prives, coordinating editor; Bradford E. Adatto, Steven R. Antico, Todd R. Bartos, Philip F. Berg, Brian C. Betner, Ann M. Bittinger, Andrew E. Blustein, Mark A. Bonanno, Steven J. Chananie, Nora A. Colangelo, Kathleen L. DeBruhl, Richard E. Gardner III, Nicholas J. Giampetro, Peter A. Greenbaum, Rick L. Hindmand, David J. Hyman, Bernard E. Jacques, Kimberly Kempton-Serra, Tara Kepler, Mark S. Kopson, Alyson M. Leone, David T. Lewis, Kim Harvey Looney, Rolf E. Lowe, Theresamarie Mantese, Jay A. Martus, Jeremy N. Miller, Gregory M. Nowakowski, Mark W. Peters, Cynthia Y. Reisz, Todd A. Rodriguez, David L. Rogers, Stephanie A. Roth, Joseph Rugg, Gary S. Sastow, James W. Saxton, Andrew Stathopoulos, Jennifer Pearson Taylor, Rhonda Teitelbaum, Mark R. Thompson, and Sidney S. Welch, authors

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 | ➤ Physician Joint Ventures |
| ➤ Telemedicine | ➤ The Sale and Purchase of a Medical Practice |
| ➤ Employment Agreements | ➤ Hospital-Based Physician Representation |
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(See also *Physician Recruitment and Compensation Arrangements Practice Guide, Third Edition*, p. 21.)



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Stark Final Regulations: A Comprehensive Analysis of Key Issues and Practical Guide

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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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