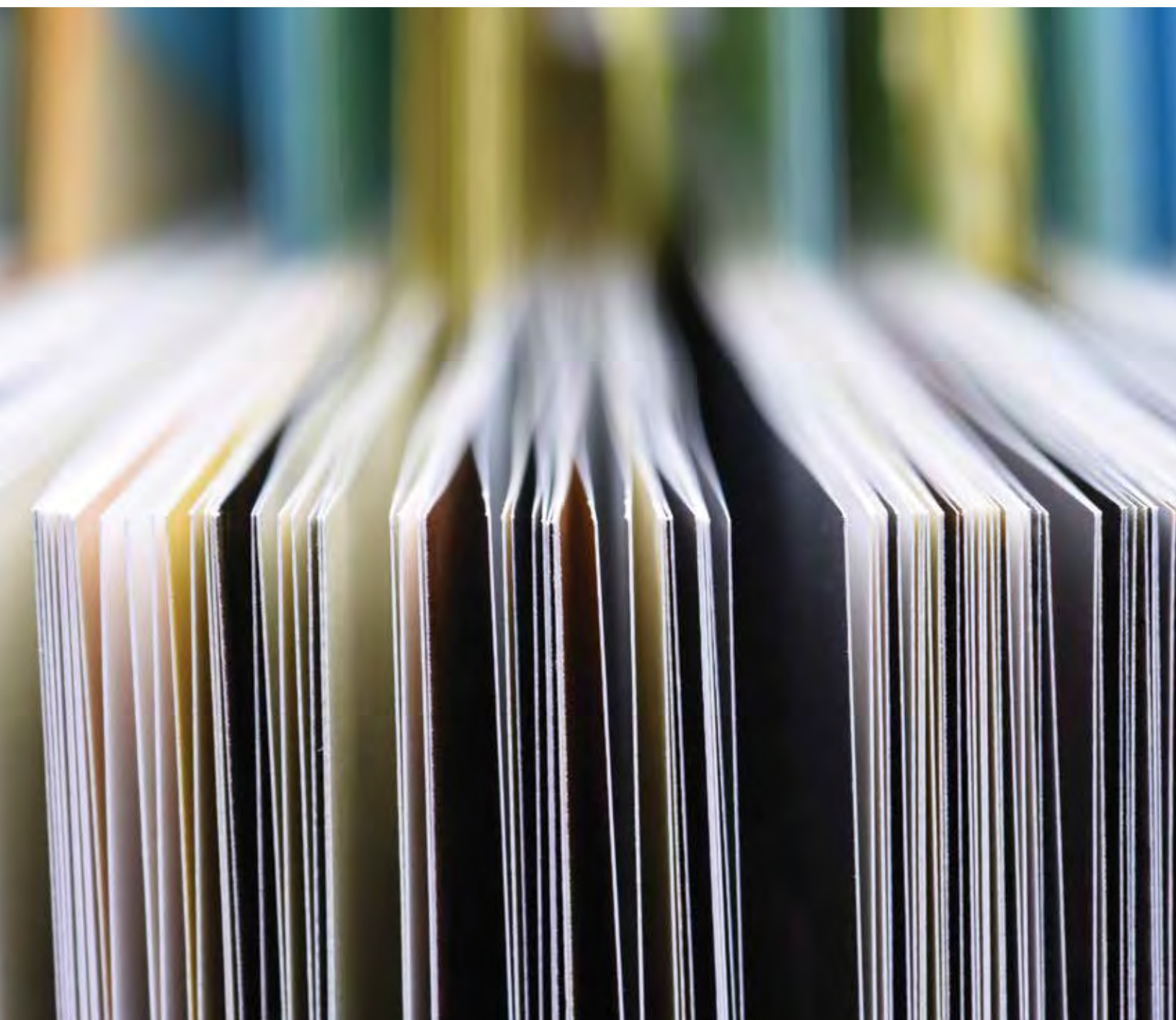


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This inaugural edition of *Health Law Watch 2019* offers accessible yet sophisticated articles on each of the 10 most important topics in health law this year. These short articles, authored by experts, will give you the big picture view that you need to stay competitive.

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- › Changes in FDA policy on acceptance of data from clinical investigations conducted outside the United States
- › New code provisions on executive compensation in tax-exempt organizations and partnership tax audit

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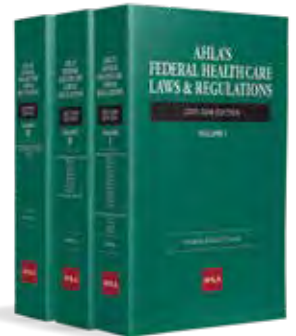
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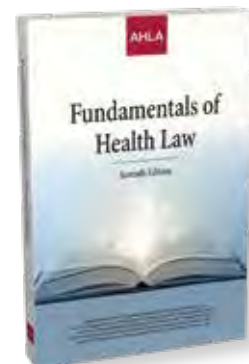


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The authors and editors of this invaluable guide provide an important view into the evolving compliance and regulatory issues governing this area. In-depth coverage includes:

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- › The importance of nursing facility agreements
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NEW EDITION

Ambulatory Surgery Centers: Legal and Regulatory Issues

SIXTH EDITION

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There are over 6,000 Ambulatory Surgery Centers (ASCs) operating in the United States, as the shift to outpatient surgery continues. Operators and owners of ASCs include hospitals, physicians, developers, management companies, financial sponsors, and others. Attorneys advising these owners need to keep pace with the latest developments. *Ambulatory Surgery Centers: Legal and Regulatory Issues, Sixth Edition* supplies the information and guidance you need. The authors not only cover the historical background behind the development of ASCs, but most importantly focus on current issues facing ASCs, offering practical and useful guidance for those giving legal advice to developers and owners.

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

This edition includes an all new chapter describing how to develop and assess an effective ASC compliance program. Downloadable materials include a revised and updated sample compliance plan, a sample operating agreement, and a sample policy for antitrust compliance.

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- Ch. 3 Tax-Exempt Status and Tax-Related Issues
- Ch. 4 State Self-Referral Issues
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- Ch. 6 Medicare Certification, Licensing, and CON (Certificate-of-Need) Issues for ASCs
- Ch. 7 Antitrust Considerations Affecting ASCs
- Ch. 8 Compliance **[NEW CHAPTER]**
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- Exhibit 2 Sample Compliance Plan
- Exhibit 3 Sample Operating Agreement
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SECOND EDITION

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Ela Bochenek, Carl H. Coleman, Editors

Marc Adler, Joseph S. Calarco, Bret A. Campbell, Colleen A. Conry, Scott Cunningham, Scott D. Danzis, Sujata Dayal, Marc I. Eida, Jacob T. Elberg, Brett R. Friedman, Gary F. Giampetruzzi, Christopher R. Hall, Patrick M. Hromisin, Mark Krueger, Bruce A. Levy, Veronica Lopez, Joseph W. Metro, Gregg Shapiro, Brian P. Sharkey, Anna Spencer, Robert E. Wanerman, Constance A. Wilkinson, Christopher D. Zalesky, Authors

This new edition synthesizes what can be an overwhelming quantity of authority into understandable analysis and practical action. The authors are among the leading experts in life sciences compliance. In these pages, they share their valuable perspectives on creating, managing, and monitoring an effective compliance program in today's complex enforcement and business environment.

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Ch. 3	False Claims Act	Ch. 11	Prescription Drug Price Regulation
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Institutional Review Boards: A Primer

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Gary W. Eiland, Richard G. Korman, Janet M. Lis, Teresa A. Williams, Editors

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The Third Edition explains the changes under the revised 2018 Common Rule requirements, providing solutions for both new and common problems faced by Institutional Review Boards (IRBs). Compliance with the revised Common Rule requires a close examination of IRB, facility, and research practices, and this publication contains full explanations of important changes including:

- > Changes in applicability and exemptions
- > Privacy Rule requirements for use/disclosure of protected health information (PHI)
- > Collection, use, and storage of private information and bio specimens
- > Use of broad consent



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Robert S. Salcido, Author

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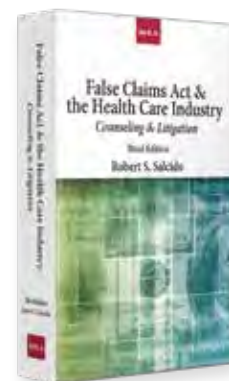


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- Ch. 2:02 The Meaning of "Cause" to Present a False or Fraudulent Claim
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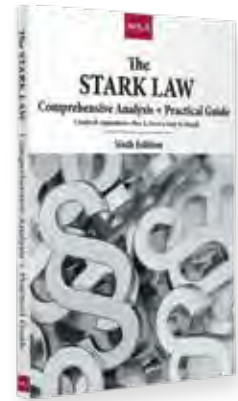
The Stark Law: Comprehensive Analysis + Practical Guide

SIXTH EDITION

Charles B. Oppenheim, Benjamin A. Durie, Amy M. Joseph, Authors

More than a summary of the law, this recently updated edition of an essential monograph offers in-depth critical analysis of this risky, complex area, as well as a wealth of practice pointers and advice for advising clients. Written by leading experts in the interpretation and application of Stark Law, the latest edition offers up to date information on the following topics:

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- › When a collection of documents can constitute a written agreement
- › Developments on the signature requirement
- › Revisiting fair market value over the course of a term
- › Liability under The False Claims Act with respect to Medicaid
- › Bankruptcy trustees and Stark Law
- › Updates to the self-referral disclosure protocol

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 Ch. 7 Addressing Potential Violations
 Ch. 8 Proposed Solutions to “Intractable” Stark Problems
 Ch. 9 Preventing Violations/Practical Tips
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David E. Matyas, Carrie Valiant, Jason Eric Christ, Anjali N.C. Downs, Authors

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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



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Robert A. Griffith, Paul W. Shaw, Authors

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

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

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

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

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

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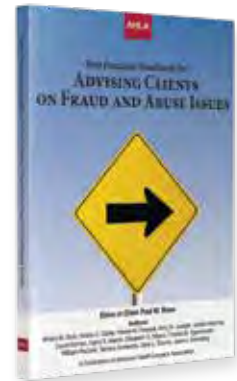
- › Ethical concerns when counseling in the gray areas
- › Responding to problematic conduct
- › Privilege protection in fraud and abuse matters, including distinguishing between legal and business functions
- › Providing a “fraud and abuse” opinion of counsel, the scope of the opinion, and internal and external reviews
- › The attorney’s role in conducting internal compliance audits and investigation, including developing an investigation plan
- › Self disclosure and voluntary disclosure, risks and benefits
- › Gathering documents in response to government demands, subpoenas, search warrants, and requests for electronic files
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Health Care Provider and Supplier Audits Practice Guide

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Jessica L. Gustafson, Abby Pendleton, Editors

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

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

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The Law of Digital Health

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

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

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

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

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

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



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Telehealth Law Handbook: A Practical Guide to Virtual Care

FIRST EDITION

Jennifer R. Breuer, Editor

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

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

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

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



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

- › The original HIPAA regulations
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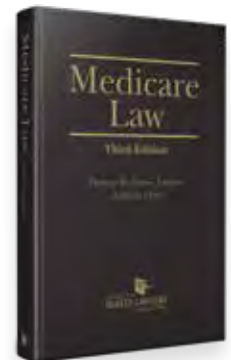
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