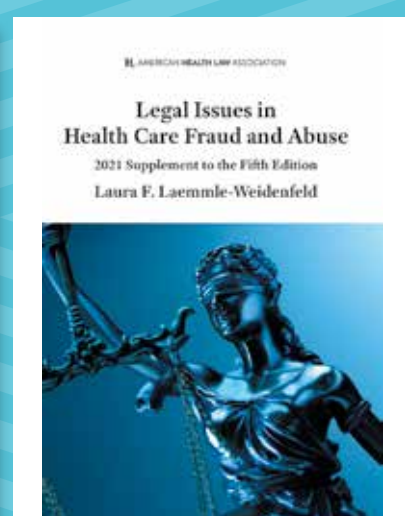
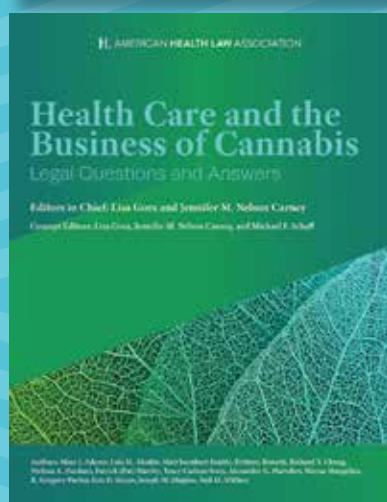
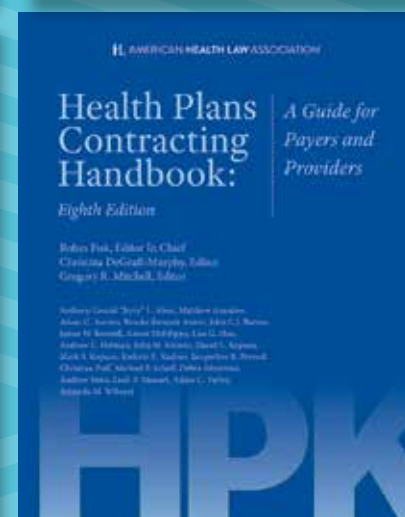
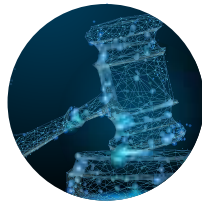


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William W. Horton, Editor

W. Scott Hardy, Dee Anna Hays, John A. Meyers, Daniel F. Murphy, Serra J. Schlanger,  
Paul W. Shaw, Donald B. Stuart, Kelly A. Thompson, Judith A. Waltz, Editorial Advisory Board

This collection incorporates not only the fundamental statutes and regulations every health care practitioner consults again and again, but also annual updates to federal authority:

- > Key provisions of the SUPPORT for Patients and Communities Act, Congress's sweeping legislation in response to the opioid epidemic
- > The Eliminating Kickbacks in Recovery Act (EKRA), the all-payer kickback law covering remuneration in connection with referrals to a recovery home, clinical treatment facility, or laboratory
- > Rules on classification as a sole community hospital or Medicare dependent small rural hospital
- > Changes to the Merit-Based Incentive Payment System (MPS) and Alternative Payment Model Incentive (APM) programs
- > Health insurance reform in the group and individual markets
- > Changes effected by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, as well as the Medicaid Services Investment and Accountability Act of 2019
- > Regulatory changes for Medicare Advantage and Medicare Part D
- > Final Affordable Care Act (ACA) payment rule for the health insurance marketplaces

The 2020 Supplement includes more recent landmark changes, including final rules on interoperability and data sharing, price transparency, and federal legislation in response to COVID-19, including: Families First Coronavirus Response Act, CARES Act, Paycheck Protection Program and Health Care Enhancement Act, and associated rules.

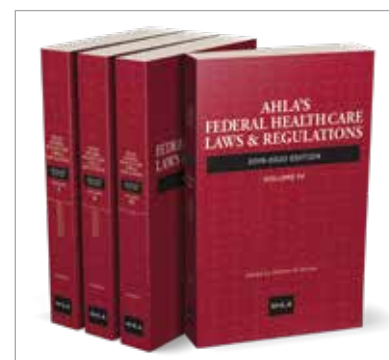
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With three volumes of material, the *Guide* offers an unprecedented collection spanning: health care transactions, corporate compliance, facility operations, fraud and abuse, governance, health information, contracting, labor and employment, physician practices, reimbursement, and more.

In the 2021 Supplement, AHLA has expanded its reach in collecting practice tools, by reviewing and selecting sample forms and policies from outside sources, including professional associations, health care providers, and legal experts, which has enriched the content of the *Guide*.

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As even a casual observer of health law knows, the COVID-19 public health emergency highlighted obstacles and accelerated change in health care delivery and regulation, as policymakers, providers, and patients struggled to adapt. What experienced health law professionals understood is that these changes were not the first attempts to address numerous longstanding challenges facing our industry.

In this edition of *Health Law Watch*, health lawyers share their insight to explain the bases for those challenges, take stock of where we are, and foreshadow what may come next. With the benefit of this close analysis, readers of this new edition will understand the tensions that health care industry stakeholders will face in both the short and long term.

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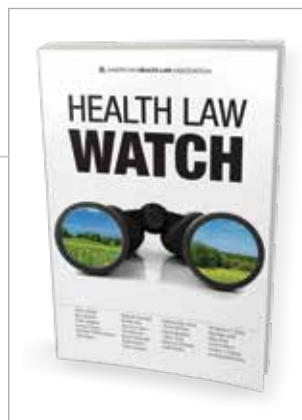
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# Fundamentals of Health Law

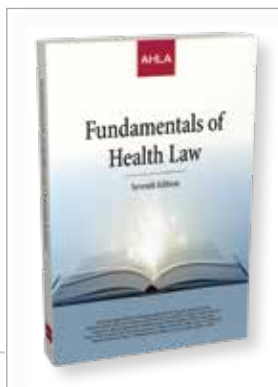
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- > Legislative and regulatory changes, United States Supreme Court decisions, and more



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 Drew Stevens, Sarah E. Swank, Teresa A. Williams, Amanda M. Wilwert, Howard J. Young, Authors

The latest edition of the *Health Care Compliance Legal Issues Manual* continues to be the authoritative source for every health care stakeholder. Reorganized, expanded, and updated, this book provides strategies for addressing the full scope of legal issues critical to health care compliance. Users will want to consult this instructional text for answers to these questions and more:

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Paul W. Shaw, Robert A. Griffith, Authors

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The quest to stamp out fraud, waste, and abuse in the nation's health care system has drawn dramatically increased scrutiny of health care billing and reimbursement practices over the years. For those involved in this heavily regulated industry, understanding the powers, procedures, and remedies available to the government during an investigation is paramount.

The authors examine each stage of a fraud and abuse investigation, beginning with an overview of federal and state enforcement agencies, and concluding with a discussion of the potential collateral consequences of an investigation. They have supplemented their analysis extensively with sample documents, including indictments, requests for records, subpoenas, internal response memoranda, and responses to auditors, prosecutors, and more.

Highlights in this new Second Edition include:

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- > A new chapter on the collateral consequences that may follow a health care fraud and abuse investigation, including impact on private health insurance participation, state medical board licenses, and more

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## Legal Issues in Health Care Fraud and Abuse

### FIFTH EDITION

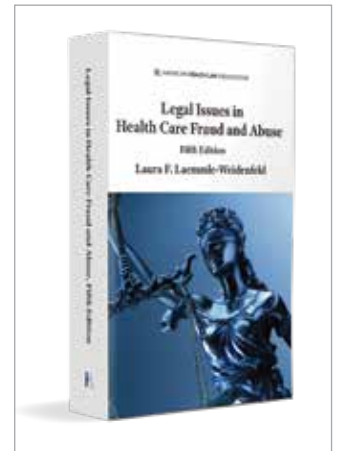
Laura F. Laemmle-Weidenfeld, Author

This completely updated fifth edition offers broad coverage of the full range of U.S. fraud and abuse prohibitions, with practical application for your work in health care today. Completely updated to address the latest trends in investigation, enforcement, and interpretations of the law, *Legal Issues in Health Care Fraud and Abuse* addresses the sweeping changes seen in the health care industry, with over 600 pages of expert explanations and fully referenced real-world examples.

With in-depth coverage of the Anti-Kickback Law, Stark Law, False Claims Act, and more, this book is a necessity for anyone who needs to understand the intricacies of how fraud and abuse laws are structured and enforced in the health care context, providing a foundation for your work in health law, covering:

- > How health care is regulated in the U.S.
- > How fraud and abuse laws are enforced by federal and state entities
- > Practical advice on assessing and addressing risk
- > Guidance on navigating relationships with the agencies and individuals enforcing the law's prohibitions

As health care and society evolve, so too, does fraud and abuse law and governmental enforcement activity. Since the previous edition, the risks relating to fraud and abuse have evolved significantly, for reasons ranging from the proliferation of health care data, to the expansion of the use of technology in health care, to changes in the regulatory scheme resulting from the shift toward value-based payment. Every chapter analyzes the impact of these changes.



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- The increased use of data analytics
- Changes in the operations of Program Integrity Contractors

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- Safe harbor for electronic health records, items and services
- The Eliminating Kickbacks in Recovery Act of 2018

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- Recruitment of non-physician practitioners
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#### Ch. 4 Administrative Sanctions Available to Federal Enforcers

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- The impact of Medicare Access and CHIP Reauthorization Act (MACRA), the 21st Century Cures Act, and the Bipartisan Budget Act of 2018

#### Ch. 5 The False Claims Act and Other Means of Federal Enforcement of Health Care Fraud and Abuse Laws

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- Express and implied false certification and the Escobar decision
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# False Claims Act & the Health Care Industry: Counseling & Litigation

THIRD EDITION WITH 2020 SUPPLEMENT

Robert S. Salcido, Author

*False Claims Act & the Health Care Industry* is a one-stop source for legislative and case law developments covering the gamut of potential false claims litigation, across all jurisdictions. This publication provides analysis of key arguments, including:

- > Defenses that the defendant's claim is not "false"
- > Defenses that the defendant did not "know" that the claim or statement is "false"
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The 2020 supplement includes coverage of:

- > Relator's ability to pursue new claims and defendants after government intervention when the government declines to pursue the relator's additional claims
- > Plaintiff's ability to predicate an FCA action upon subregulatory guidance in light of supervening Supreme Court precedent
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Charles B. Oppenheim, Benjamin A. Durie, Amy M. Joseph, Authors

More than a summary of the law, this 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 analyzes the following topics:

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The 2020 supplement covers several developments that signal the potential for a more permissive era to come:

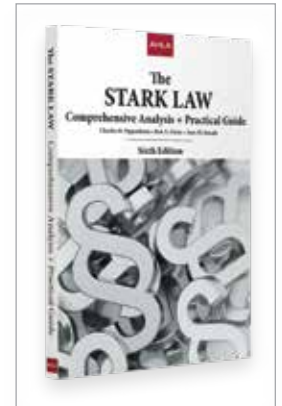
- > The Centers for Medicare and Medicaid Services (CMS) issued proposed regulations clarifying the agency’s current interpretations of existing regulations and proposing new exceptions that may ultimately expand the scope of permitted activities.
- > In the shadow of the COVID-19 pandemic, CMS issued blanket waivers permitting providers to undertake a range of activities that would not have otherwise complied with the Stark Law.
- > CMS issued further clarification of the blanket waivers, helping to clarify certain issues in the Stark regulations more generally.

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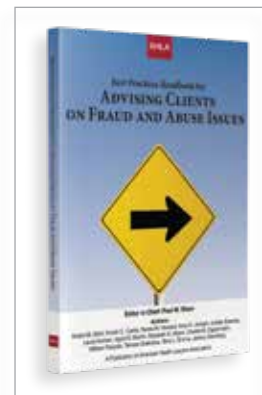
Kristin M. Bohl, Kristin C. Carter, Renee M. Howard, Amy M. Joseph, Jordan Kearney, Laura Koman, Ingrid S. Martin, Elizabeth G. Myers, Charles B. Oppenheim, William Pezzolo, Tamara Senikidze, Gina L. Simms, Jeremy Sternberg, Authors

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

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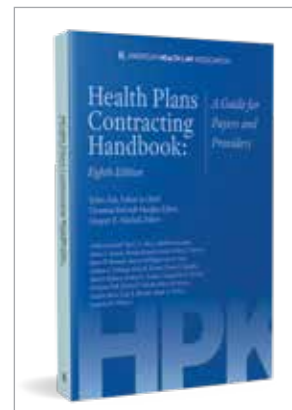
The authors have thoroughly updated each chapter and added new chapters to address emerging issues in managed care contracting, including:

- > Managed care penetration into Medicare and Medicaid
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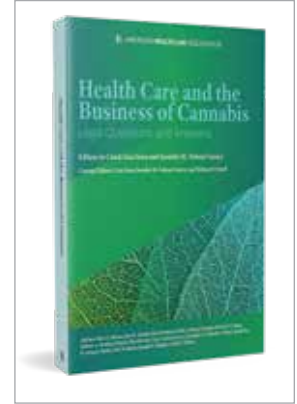
This practical new book will help guide readers through the legal haze surrounding the interplay between medical marijuana and the traditional health care industry, as well as business opportunities surrounding cannabis and its by-products.

Written and edited by a diverse group of seasoned professionals, coverage in this First Edition includes analysis of the unique issues faced by health care providers whose residents, patients, and employees may participate in state cannabis programs. Whether readers are working with hospitals or long-term care facilities, physicians or mid-level practitioners, they will have guidance for providing informed counsel and tackling tough questions such as:

- > How do post-acute care providers reconcile federal laws with state legalized medical cannabis reforms?
- > What types of policies should be created, and what are the influencing factors and options that exist when creating policies and procedures if a long-term care facility permits medicinal cannabis?
- > What are the potential legal implications for a health care practitioner who recommends medicinal cannabis pursuant to a state-legalized medical cannabis program?
- > May a patient use medical cannabis while in a hospital or any of its facilities?
- > How does medicinal cannabis use get noted in the patient's medical record?

The authors provide full coverage of the business transactions involving the manufacturing, possession, or distribution of medicinal marijuana. They also take a close look at opportunities related to:

- > The research of medicinal cannabis
- > The creation of wellness products or topical creams using hemp or its derivatives
- > Establishing laboratories or educational programs to educate patients about the effects of cannabis
- > Obtaining a license to operate a center for dispensing medicinal cannabis



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## Health Care Transactions Manual: Understanding the Consequences of the Health Care Deal

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Michael F. Schaff, Susan V. Sidwell, G. Scott Thomas, Rodrigo N. Valle, Kimberly S. Veirs,  
John R. Washlick, Authors

Health care transactions pose unique and complex legal questions arising from intense federal and state regulation and enforcement. This first edition *Manual* is the ideal guide for gaining an understanding of the legal landscape, and for managing the risks involved in structuring health care deals.

What makes sense in the business world does not always make sense in the health care world, and this publication is your key for knowing the difference and avoiding potential pitfalls. The *Manual* will help you understand nuances such as:

- > When seemingly straightforward business terms can veer toward health care fraud and abuse
- > How health care organization and/or management structure can impact the deal
- > The need to comply with both non-disclosure terms and federal and state privacy laws when conducting due diligence
- > How increased collaboration between health care entities may give rise to antitrust issues
- > How tax-exempt status may be impacted in the course of a deal between exempt and non-exempt entities
- > The need to consider state and federal environmental implications as they relate to radioactive materials used in patient care

With contributions from more than a dozen attorney practitioners, the *Manual* provides invaluable practical guidance covering everything from the transactional basics to deep-dive discussions for negotiating complicated deals. The book also contains more than 20 exhibits, ranging from a Sample Preliminary Due Diligence Request to a Sample Closing Checklist.

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**BEST SELLER**

## Corporate Practice of Medicine: A 50 State Survey

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Andrew G. Jack, Glenn P. Prives, Jed A. Roher, Joel C. Rush, Editors  
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The corporate practice of medicine (CPOM) doctrine seeks to keep non-physician corporation owners from interfering with a physician's professional judgment. It prohibits corporations that are not owned or controlled by physicians from employing physicians to practice medicine and charge for those professional services. CPOM application is far from simple, and adoption and enforcement vary by state. States adopt various models—with exceptions—and others eliminate the prohibition completely, while some states have CPOM prohibitions that are not enforced.

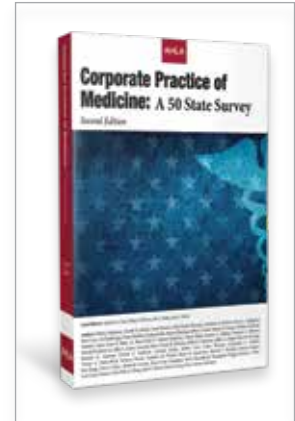
In the latest edition of this popular guide, the authors have expanded coverage to include an even broader range of health care professionals. You will find the latest information on practice restrictions by state as they relate to: behavioral health providers, chiropractors, optometrists, and more. CPOM researchers typically need to review a tangled web of statutes, regulations, case law, and attorney general or agency opinions to gain useful insight. The authors have provided a time-saving roadmap to help you:

- > Learn which model of the doctrine a specific state follows
- > Discover sources to consult for more detail
- > Explore related issues like fee splitting and the unlicensed practice of medicine

This survey is invaluable to attorneys who represent health care entities, organizations, businesses, physicians, and investors looking for opportunities in this complex regulatory sector. Use it to efficiently gain a thorough exploration of the doctrine in each state and the District of Columbia.

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# Antitrust

## Antitrust and Health Care: A Comprehensive Guide

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

The Second Edition of this publication squarely meets the practitioner's need for a clear, concise overview of general antitrust principles, along with analyses of their application to the health care sector. Turn to it for guidance on any of the business activities your clients or organization are likely to be involved with: mergers, acquisitions, and other transactions; or joint ventures, provider networks, and other collaborative arrangements. The *Guide* covers:

- > Substantive antitrust law
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The publication provides invaluable “practice pointers” to help you minimize antitrust risk and more successfully plan and execute business and litigation strategies. The authors draw on their significant government enforcement and private sector counseling and litigation experience to provide practical insights for:

- > Developing antitrust compliance and “sensitivity training” programs
- > Identifying conduct and language that could create antitrust “red flags”
- > The creation, distribution, and use of emails, electronic documents, and other materials
- > Antitrust safety zones, defenses, and immunities

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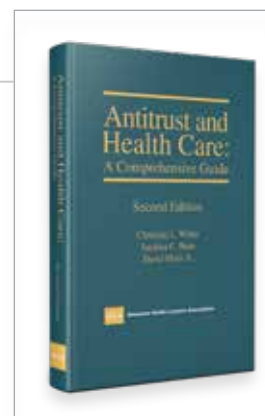
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A Task Force of the AHLA Physician Organizations Practice Group

Michael F. Schaff, Task Force Chair

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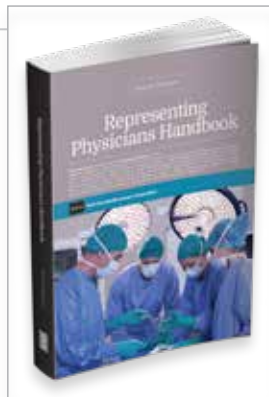
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*Corporate Practice of Medicine*, p. 15

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# Health Care Delivery Models and Settings

## 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 *Handbook*. Coverage includes:

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- > Payment methodologies
- > Operational issues, including patient relations, privacy, grievance rights, and consent to treatment

From attorneys to providers to lenders, anyone who needs to understand the intricacies and complexities of hospitals and health systems will consider this book an indispensable resource.



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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 changing 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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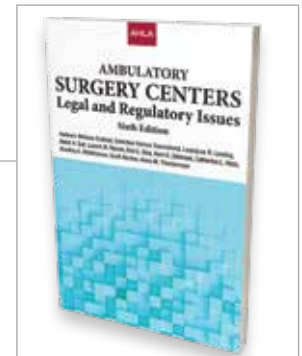
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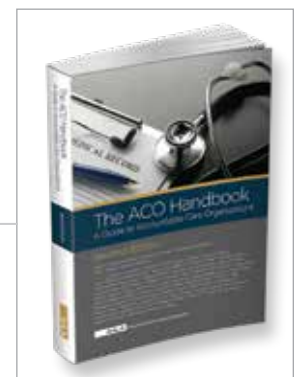
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# Health Information

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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:

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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. This guide contains information on:

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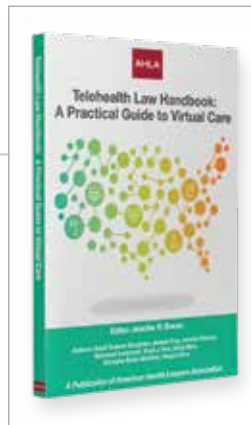
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## Pharmaceutical and Medical Device Compliance Manual

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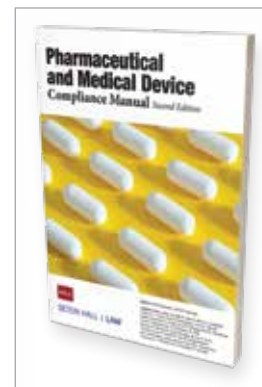
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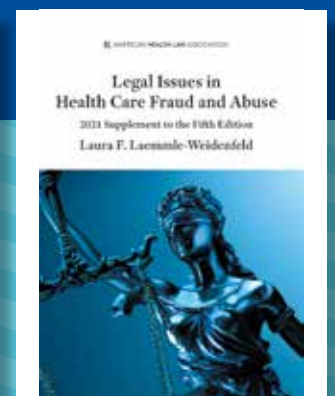
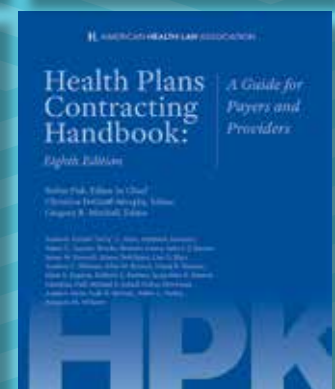
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