Fraud and Abuse Investigations Handbook for the Health Care Industry

Second Edition

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AMERICAN
HEALTH LAW
ASSOCIATION

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Preface

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. This second edition of *Fraud and Abuse Investigations Handbook for the Health Care Industry* provides not only the legal context surrounding health care fraud investigations, but also the insight critical to managing the process—and potentially the outcomes that follow.

The American Health Law Association's tremendous gratitude goes to authors Paul W. Shaw and Robert A. Griffith for revising this new and necessary Handbook. They bring not only their prior experience as prosecutors, but also decades of experience as private practitioners representing health care businesses and professionals under federal and state criminal and civil fraud and abuse investigations. 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. Taken together, the materials in this book provide a true Handbook for anyone who needs to quickly and thoroughly understand the complex nature of a government fraud and abuse investigation.

Highlights of the expanded and updated coverage in this new edition include:

- Critically important changes in the handling of mandated and voluntary disclosures of overpayments, a result of regulatory activity since the first edition:
  - The Final 60-Day Overpayment Rule
  - The Revised Stark Self-Disclosure Protocol
  - New Department of Justice voluntary disclosure guidelines for False Claims Act cases
- A new chapter on responding to Medicare and Medicaid audits and initiating appeals, with insight into the postpayment audit process, practical advice on how to respond to a request for records or audit findings, and a description of each step of the appeal process, including settlement procedures
- A new chapter on administrative sanctions, discussing the potential risk of sanctions under the Civil Monetary Penalties law, exclusion from Medicare and/or Medicaid, mandatory vs. permissive exclusion, due process, Medicare and Medicaid program payment suspensions, enrollment denials, and revocations
- A new chapter on audits by private payers, examining audit-generating conduct and how to respond to a private payer audit and findings
- 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

Also new with this edition, readers are invited to download 30 of the more than 85 exhibits included in this book, and adapt them to suit their own practice and client needs.

We are confident that this new edition of *Fraud and Abuse Investigations Handbook for the Health Care Industry* will prove to be a useful guide not only for attorneys, but also health care administrators, executives, medical practice managers, and others navigating the fraud enforcement landscape.

About the Authors

Paul W. Shaw is a member of the litigation and health law departments of Verrill Dana LLP in Boston, MA, where he concentrates in representing businesses and professionals in health care fraud and abuse investigations. Paul has represented numerous health care clients subject to criminal fraud and abuse and civil false claims act investigations by the federal government and state Medicaid Fraud Control Units. These clients include academic medical centers, pharmaceutical service providers, hospitals, physicians, medical practice groups, behavioral health providers, clinical laboratories, durable medical equipment suppliers, home health agencies and other health care providers. He has also represented *The New England Journal of Medicine* for many years in connection with litigation involving the *Journal*. Paul has lectured and written extensively in the area of fraud and abuse before the American Health Law Association, state medical societies, and bar associations. He is Editor-in-Chief of the AHLA publication, *Best Practices Handbook for Advising Clients on Fraud and Abuse Issues*. He is also co-author of the handbook jointly published by the American Medical Association and AHLA, entitled *Avoiding Fraud and Abuse in the Medical Office*. Paul is a member of the Editorial Board of the *Journal of Health & Life Sciences Law*. Paul has been consistently recognized in *Chambers USA: America's Leading Lawyers for Business under Healthcare*. Paul graduated from Georgetown University Law Center in 1975.

Robert A. Griffith manages Gargiulo/Rudnick's health law practice. Bob began his career as an Assistant Attorney General in the Massachusetts Attorney General's Office assigned to the Medicaid Fraud Control Unit, one of the first such units in the country. Since entering private practice, he has represented hospitals, psychiatric facilities and institutions, physicians, medical group practices, clinical laboratories, pharmaceutical company executives, pharmacies, walk-in centers, nursing homes, durable medical equipment providers, home health agencies, physicians, dentists, nurses, podiatrists, and psychologists. Bob is the author of numerous articles and book chapters on health law topics in the area of fraud and abuse, and a frequent speaker at health law continuing education programs for the legal and medical professions. He has served on the Board of Directors of the American Health Lawyers Association (now American Health Law Association) and the Massachusetts Supreme Judicial Court's Mental Health Advisors Committee. Bob is a former Chairperson of the Massachusetts Bar Association's Health Law Section and the Medicine and Law Committee of the Tort and Insurance Practice Section of the American Bar Association. He has participated in over 820 health care fraud and abuse investigations and prosecutions in no fewer than 32 different state and federal jurisdictions and has tried numerous health care fraud and abuse cases on the federal and state level. Mr. Griffith specializes in the representation of health care providers in all matters concerning federal, state, and private fraud and abuse investigations and prosecutions, overpayment demands, billing, compliance, and professional discipline. Bob is a graduate of Boston College Law School.

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We would like to thank a number of people who contributed to the development and publication of this Handbook. Initially, we would like to thank Will Harvey, the retired AHLA Director of Business Development and Publishing. Will conceived the idea for this Handbook in 1999. As with all other AHLA publications over a twenty-year period, Will was a true partner in the process of creating and publishing the forerunner 2000 edition and the reconceived version in 2014. Most importantly at this current stage, we want to thank Kara Kinney Cartwright, the present Director of AHLA's Non-Dues Publications, for asking us to revamp and transform the 2014 edition of the Handbook into the 2021 comprehensive and updated version that is now available. We are most appreciative of her efforts to seamlessly shepherd our work through publication.

For the countless hours spent researching, editing, and proofreading the contents of this Handbook, we extend our heartfelt appreciation to Anuj Khetarpal, an associate at Verrill Dana. We also want to thank Verrill Dana associates Cecilie McIntyre and Alicia Siani for their assistance as well. And for the many hours formatting the chapters and numerous exhibits, thanks go to Will Schulman, a legal assistant at Verrill Dana and Gina Gonsalves, a legal assistant at Gargiulo/Rudnick.

About the American Health Law Association

Excellence in health care starts with excellence in health law. The American Health Law Association (AHLA) is the nation's largest, nonpartisan, 501(c)(3) educational organization devoted to legal issues in the health care field. AHLA maintains excellence in health law by educating and connecting the health law community.

With a diverse membership of over 13,000 health law professionals, representing the entire spectrum of the health care industry, AHLA is able to leverage the deep expertise of practitioners to produce high-quality, just-in-time educational resources that help members of the health law community provide analysis, assess risk, ensure compliance, and make informed recommendations to their organizations and clients. AHLA's trusted resources benefit anyone who advises physicians, hospitals, health systems, specialty providers, payers, life sciences companies, vendors, investors, and many other health care stakeholders.

If you have an interest in health law, you have a home in AHLA. For more information about our educational, professional development, and networking opportunities, please visit us at americanhealthlaw.org

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ACA	The Patient Protection and Affordable Care Act of 2010 (PPACA), aka The Affordable Care Act
AKS	Anti-Kickback Statute
ALJ	Administrative Law Judge
CHIP	Children's Health Insurance Program
CIA	Corporate Integrity Agreement
CID	U.S. Army Criminal Investigation Command
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
DCIS	Defense Criminal Investigative Service
DEA	Drug Enforcement Administration
DHHS	The United States Department of Health and Human Services
DHS	Designated Health Services
DME	Durable Medical Equipment
DOJ	The United States Department of Justice
DPA	Deferred Prosecution Agreement
EOMB	Explanation of Medical Benefits
ESI	Electronically stored information
FBI	United States Federal Bureau of Investigation
FCA	False Claims Act
FDA	United States Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
FERA	Fraud Enforcement and Recovery Act of 2009
HFPP	Healthcare Fraud Prevention Partnership
HH+H	Home Health and Hospice
HIPAA	Health Insurance Portability and Accountability Act of 1996
IRO	Independent Review Organization
IRS	Internal Revenue Service
IT	Information Technology
MAC	Medicare Administrative Contractor
MCM	Medicare Contractor Beneficiary and Provider Communications Manual, formerly Medicare Carriers Manual
Medi-Medi	Medicare-Medicaid data match program

MFCU	Medicaid Fraud Control Units
MRPC	Model Rules of Professional Conduct
NAMFCU	National Association of Medicaid Fraud Control Units
NCIS	U.S. Naval Criminal Investigative Service
NHCAA	National Health Care Anti-Fraud Association
NPDB	National Practitioner Data Bank
OIG	The United States Department of Health and Human Services, Office of Inspector General
OMHA	Medicare Office of Hearings and Appeals
OSI	US Air Force Office of Special Investigations
OTCLPR	Overly Time Consuming with Little Potential Return
PIM	Medicare Program Integrity Manual
PPACA	The Patient Protection and Affordable Care Act of 2010, aka The Affordable Care Act (ACA)
QIC	Qualified Independent Contractor
RAC	Recovery Audit Contractor
SDP	OIG's Provider Self-Disclosure Protocol
SOX	Sarbanes-Oxley Act of 2002
SRDP	CMS Voluntary Self-Referral Disclosure Protocol
TRO	Temporary Restraining Order
UPICs	Unified Program Integrity Contractors
USAO	United States Attorney's Office
USPS-OIG	U.S. Postal Service, Office of Inspector General
ZPIC	Zone Program Integrity Contractor

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Introduction

If you are a health care administrator, executive, medical director, office manager, physician, medical practice manager, or supplier, it is incumbent on you to be familiar with the subjects addressed in this *Handbook*. Regulatory and administrative minefields unique to the health care industry trap significant numbers of the unwary and uninformed every year. Institutions are compromised and individual careers imperiled because general concepts of what constitutes fraud and abuse are not fully appreciated until it is too late. In other words, compliance is not an easy path to follow.

Virtually everyone is familiar with the concept of "fraud," generally understood to mean an intentionally deceptive act designed to provide an unlawful gain or deny the victim of some right. Most would agree that fraud involves the false representation of facts, whether by intentionally withholding important information or providing false statements. In the health care industry, however, commonly used terms often take on a whole new meaning. The Centers for Medicare & Medicaid Services' (CMS's) caution that "(a)nyone can commit health care fraud" must be taken to heart by every institution, provider, and supplier in the industry. This is even more so when it comes to "abuse." Webster's defines abuse as a corrupt practice or custom, but CMS defines abuse as "practices that may directly or indirectly result in unnecessary costs to the Medicare Program."

We hope that the compilation of material in this *Handbook* will provide you with the information to detect the warning signs and react appropriately and effectively. In our cumulative experience, we have seen millions repaid in restitution for abuse that, had the alleged "abuser" had a more robust understanding of the issues and appropriate reactions, may have been avoided altogether. Situations such as this are the primary motivation for this *Handbook*. If this *Handbook* can assist any provider or supplier in successfully or more effectively handling a fraud and abuse inquiry, we have achieved our purpose.

The numbers are nothing short of staggering. While total health care expenditures were in excess of $3.6 trillion in 2018,[1] according to some estimates, health care fraud exceeds $300 billion annually.[2] As more money is lost to fraud and abuse from an already strained health care system, government and private insurers' efforts to detect and punish conduct that undermines the cost and quality of health care increase. For the fiscal year ending September 30, 2019, the Department of Justice and Office

[1] CMS, National Health Expenditure Fact Sheet (Mar. 24, 2020), www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

[2] Nat'l Health Care Anti-Fraud Ass'n, The Challenge of Health Care Fraud, www.nhcaa.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud/.

of Inspector General reported expected recoveries of over $2.6 billion.[3] Recoveries are destined to significantly increase, as they have in the past 20 years, during which time the government has more than tripled the number of exclusions, convictions, and civil actions.

When this *Handbook* was first published in 2000, the amount allocated to health care fraud enforcement was approximately $250 million and the government recovered approximately $717 million.[4] The current total funding for health care fraud and abuse enforcement is approximately $1.06 billion per year. In 2000, 467 individuals or entities were criminally convicted for engaging in crimes against government health programs and 233 civil actions were initiated.[5] In FY 2019, 826 individuals or entities were criminally convicted; and 1,796 civil health care fraud and administrative actions were initiated. Additionally, in FY 2019, 2,640 individuals and entities were excluded from participation in federal health care programs.[6] These figures do not track the number of entities and individuals compelled to reimburse private insurers for alleged overpayments.

The government and private insurers have a vast array of powers, procedures, and remedies to address fraud and abuse. There is significant coordination of investigative and enforcement efforts among the various regulatory and enforcement agencies. For those involved in this heavily regulated industry, understanding the powers, procedures, and remedies available to the government and private payers 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—is an absolute key to survival and first step toward an acceptable outcome.

This *Handbook* provides health care administrators, executives, medical directors, office managers, physicians, medical practice managers, and suppliers, as well as attorneys new to health care fraud and abuse issues, with an overview of the wide range of health care fraud and abuse investigations. Clear and concise explanations of the law are combined with sample government documents, affidavits, and subpoenas, as well as typical and helpful pleadings and memoranda prepared by defense attorneys. We trust that, taken together, the materials in this *Handbook* provide a practical understanding of this complicated and industry-specific area of government and private enforcement.

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[3] Dept. of Health and Human Svcs. and Dept. of Justice (DHHS and DOJ), Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2019, at 1-2 (June 2020) (hereinafter 2019 Annual Report), www.oig.hhs.gov/reports-and-publications/hcfac/index.asp.

[4] DHHS and DOJ, Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2000, at 1 (Jan. 2001), www.oig.hhs.gov/reports-and-publications/hcfac/index.asp.

[5] *Id*.

[6] 2019 Annual Report, at 1.