

Medicare and Medicaid Fraud and Abuse

2026-2027 Edition

Issued in September 2026

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(Chapter 6 by Kevin E. Raphael and Saverio S. Romeo)

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Mat #43384649

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ISBN: 979-8-350-23930-0

Introduction to the 2026-2027 Edition

This is our 23rd edition of this book. The dynamism in Medicare and Medicaid Fraud and Abuse can be seen in the updates, even though some chapters have had less activity than others.

In Chapter 1, the overview, we have renewed statistics, addressed three major national anti-fraud initiatives—one from the OIG, one from the White House, and the third from the DOJ. The OIG published a special bulletin regarding marketing drugs to consumers, additional FAQs, and heightened screening for enrollment for home health agencies, hospice and DME with a moratorium on new provider numbers for all of those. They have increased focus on Medicare Advantage including the second industry specific Compliance Guidance and a first ever DOJ enforcement policy regarding voluntary disclosure in relation to enforcement.

Chapter 2 on the anti-kickback statute examines the first appellate court case relating to EKRA, and updates two prior cases addressed in previous years. A 5th circuit case explores further developments in when commissions for advertising services are permissible under the Anti-Kickback Statute, and when they cross into impermissible influence on referrals. New advisory opinions have been added, with a more detailed exploration of the only two unfavorable advisory opinions issued in 2025, both of which related to device manufacturers being influenced to use various third-party software for purposes that primarily benefited their customers, rather than the manufacturers.

The world of Stark addressed in Chapter 3 includes no major initiatives, but refinements and clarifications, particularly regarding profit sharing. We have cited one new case regarding the indirect compensation exception.

Chapter 4, dealing with administrative penalties has no updates.

Chapter 5, addressing False Claims Act issues, as is typical year to year, has the most analyzed and cited cases as well as policy developments. The 4th circuit reversed the dismissal of a reverse false claims act case, citing the 6th, 10th and 11th circuits as well; The updates examine scienter in the wake of the SuperValue case in the 1st, 5th, and 7th circuits; looks at falsity through one district and three circuit court cases in the 3rd, 6th, and 7th circuits; add a circuit court case on materiality; analyzes four Circuit court cases on particularity and cites another 6;

updates the volumes of qui tam cases, and notes the remarkable new collaboration between the government and data mining whistleblowers. We have added a 4th circuit case on the first-to-file requirement; two D.C. circuit cases on the “original source” exception; four circuit court cases and one district court case on the public disclosure bar; a 5th circuit case on the government’s right to intervene to dismiss an FCA case; a new DOJ memorandum on the timing of the government’s decision to intervene as well as to investigate claims, with the intent of accelerating the process. We have added a 1st Circuit case on the causation standard for an employee’s retaliation claim, citing conformity with six other circuits; 4 cases on damages where some courts lowered calculated penalties, while others upheld them despite their range. Chapter 5 is always a heavy lift.

Although the substantive processes of investigation have not changed much since 2025, Chapter 6 has been revised to reflect recent developments in what will instigate investigations. The updates incorporate FY 2025 enforcement and new content on Trump Administration enforcement initiatives such as Medicaid fraud, Medicare Advantage kickback schemes, and DEI-related FCA theories. The chapter also discusses notable recent settlements involving IBM, Aetna, and Kaiser Permanente; analyzes new appellate decisions addressing issues such as FCA causation and constitutional challenges to a private relator’s ability to bring qui tam actions; and covers the latest developments regarding proposed amendments to the U.S. Sentencing Guidelines.

Updating this book annually keeps us on our toes in this arena. Kevin and Saverio, our contributors on investigations, address the topics we don’t in our day-to-day work, but they do. We hope our readers find what is here useful as a good foundation to go further in their own work.

Alice G. Gosfield

Daniel F. Shay

Foreword

The current authors took over the authorship of this publication in 2003. We have updated and edited it since. The substance of the laws which we address throughout the book determine both the risk and the reality of enforcement. The government waxes and wanes in its initiatives around specific industry sectors, but the real message is that everyone who is in the food chain of benefiting from federal health care dollars in Medicare and Medicaid, is potentially at risk for both bad behavior and technical violations. Still further, in the HEALTH LAW HANDBOOK, published by West as a new book every year since 1989, there has been an annual fraud and abused update, which documents for that year, noteworthy developments in the prior year. For those interested in the development of the issues from year to year, each of those articles is a useful resource. As is discussed in Chapter 5 on false claims, the reach of the government goes well below the provider or payer receiving dollars directly, reaching far into their subcontractors and vendors who financially benefit from these programs indirectly.

Alice G. Gosfield

Daniel F. Shay

About the Author

ALICE G. GOSFIELD's entire legal career has been restricted to health law with a focus on non-institutional reimbursement including from Medicare, as well as managed care contracting, fraud and abuse compliance and avoidance, medical staff issues and utilization management and quality issues including clinical integration. Throughout her career she has maintained an emphasis on representation of physicians and their group configurations, as well as those who would seek to do business with physicians. A graduate of Barnard College of Columbia University and New York University School of Law, since 1973 her varied health law career has ranged from an OEO ("War on Poverty") and then DHEW funded research program to develop a consumer-oriented analysis of the PSRO law, to drafting codes of regulations for state health care agencies, and since 1978 to include the private practice of law.

Ms. Gosfield served as Chairman of the Board of Directors of the National Committee for Quality Assurance (www.ncqa.org), reelected to serve five terms from 1998 through 2002. She was a member of the Board from 1992 through 2002. In the public policy arena, she has served on four committees of the Institute of Medicine of the National Academy of Sciences studying issues involving utilization management and clinical practice guidelines and has served as an advisor to the Agency for Health Care Policy and Research in both evaluating one of their first three clinical practice guidelines and in developing methodologies to translate guidelines into medical review criteria, performance measures and standards of quality. She has been called on by the Congressional Budget Office, the General Accounting Office, the Robert Wood Johnson Foundation, the Federal Agency for Healthcare Research and Quality and others to advise on issues pertaining to Medicare reimbursement, medical evidence, legislation dealing with medical necessity in managed care and tort reform.

A highly sought after speaker, Ms. Gosfield has been invited to lecture throughout the country and internationally to diverse audiences including physicians and other health care professionals, chief executives and chief financial officers, boards of trustees and directors, group managers, managed care executives and others throughout the health care industry. She is noted for her practical yet provocative, incisive, down-to-earth style and ability to make complex technical information understandable as well as entertaining. She lectures often for a variety of organizations

including the American Health Law Association (AHLA), the American Medical Association (AMA), the Medical Group Management Association (MGMA), the American Association of Health Plans (AAHP), the Health Care Compliance Association, and the American College of Cardiology as well as other national, state and regional groups.

A frequent author in a wide range of health care publications, she has authored or co-authored more than 200 published articles, 11 monographs and three other books. Her first book “*PSROs: The Law and The Health Consumer*” was published in 1975. Her second book – *Guide to Key Legal Issues in Managed Care Quality*– was written primarily for non-lawyers and published in 1996 by Faulkner and Gray. Since 1989 she has been the editor of this HEALTH LAW HANDBOOK. She also co-authors with Daniel F. Shay MEDICARE AND MEDICAID FRAUD AND ABUSE, an annually updated treatise. She has served on the editorial boards of multiple diverse journals and newsletters including *Healthplan* (published by AAHP), *Medical Economics*, *Managed Care*, *Family Practice Management*, and *The Journal of Health Care Compliance*.

Ms. Gosfield served as President of the American Health Law Association (formerly the National Health Lawyers Association, (www.healthlawyers.org) from 1992-1993 and Chaired their Physician and Physician Organizations Institute for six years. She also chaired their last and final Masters Program. She has been listed in *The Best Lawyers in America* (Health Law) in every edition since the inception of the health law category in 1991. She has been recognized internationally for her health law expertise by the International Centre for Commercial Law in the United Kingdom as one of The Legal 500, a select group of 500 law firms in the United States recommended for their specific abilities in particular areas of the law. She is recognized as a band 1 national lawyer by Chambers which describes her as a “luminary” in the field. She was named one of the top 30 health lawyers in the country in 2007 by the Best of the Best and among the top 25 health lawyers nationally in 2009. She is listed in many other rankings of top lawyers nationally, including being named by CEO Time magazine as one of the most visionary women leaders of 2024.

DANIEL F. SHAY is an attorney with Alice G. Gosfield and Associates, P.C. His practice is restricted to health law and health care regulation focusing primarily on physician representation, fraud and abuse compliance, Medicare Part B reimbursement, and HIPAA compliance in the physician context. He also has a keen interest in intellectual property issues, including copyright, trademark, data control, and confidentiality. He has also focused his attention on provider control of commerce in data, electronic

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health records license agreements, physician advertising, enrollment in Medicare, quality reporting and quality measurement, physician use of non-physician practitioners, and physician use of social media. He has published on all of these topics both in the trade press and in major articles in previous years of the HEALTH LAW HANDBOOK. Mr. Shay received his Bachelor of Science degree *cum laude* in 2000 from Vanderbilt University and his juris doctorate degree from Emory University School of Law in 2003. Mr. Shay is admitted to the Pennsylvania Bar, is a member of the American Health Law Association. He was listed in Best Lawyers in America (Health Law) 2024 and 2025.

About The Contributors to Chapter 6

KEVIN E. RAPHAEL is a partner at Fox Rothschild, LLP, where he is a member of the White-Collar Criminal Defense and Government Investigations practice group and leader of the False Claims Act practice group. He also frequently counsels educational institutions, medical facilities, and employers on how to respond to allegations of sexual misconduct. Mr. Raphael speaks and writes extensively on white collar and healthcare litigation issues, including fraud and abuse compliance. Mr. Raphael served as an Assistant District Attorney for the Philadelphia District Attorney's Office, where he tried a wide range of criminal trials to verdict. He has handled a wide variety of federal and state grand jury investigations and white-collar criminal defense cases across the country on behalf of both entities and individuals, including Health Care Fraud, Medicare and Medicaid Fraud, Food and Drug Administration ("FDA") criminal investigations and public corruption cases. Mr. Raphael is often retained to conduct internal investigations. His clients include publicly traded and privately held corporations, hospitals, home care and home health agencies, durable medical equipment ("DME") companies, compound, genetic, and specialty pharmacies, physician practices, licensed professionals, and other individuals.

Mr. Raphael routinely represents health care entities and providers in civil litigation, such as: the defense of False Claims Act matters, RICO and fraud investigations/suits, overpayment, billing, and reimbursement disputes Recovery Audit Contractor ("RAC") disputes and Medicaid Integrity Program ("MIP") audits; Medicare appeals; and issues involving non-competes, restrictive covenants, and other business disputes.

Mr. Raphael is ranked by Chambers and Partners for Litigation: White Collar Crime and Government Investigations. He repeatedly has been selected as a *Pennsylvania Super Lawyer* (Health Care) and by Best Lawyers of America for Health Care Law. In addition, Lexis Nexus® Martindale-Hubbel® recognizes Mr. Raphael as an AV® Preeminent-rated attorney, the highest such rating available to any individual lawyer in both legal ability and ethical standards.

Mr. Raphael is a member of the American Health Law Association, for which he served for six years as Vice Chair for the Fraud and Abuse Practice Group. He served as Adjunct Professor of Health Law at Delaware Law School – Widener University and Thomas Jefferson University College of Population Health. Mr. Raphael received his J.D., *cum laude*, from the State University of New York Buffalo Law School. He earned his B.A., *magna cum laude*, from St. Lawrence University, where he was Phi Beta

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Table of Abbreviations

ALJ.....	Administrative Law Judge
ABNs.....	Advanced Beneficiary Notices (The acknowledgment of the patient that the provider knows that service will not be paid, is not covered and the patient will accept financial responsibility for what Medicare does not pay.)
ASC.....	Ambulatory Surgery Center
BBA.....	Balanced Budget Act of 1997
CHSO.....	Cooperative Hospital Service Organization
CMN.....	Certificate of Medical Necessity (A document completed by a physician to establish the medical necessity of another Medicare service, particularly durable medical equipment.)
CMP.....	Civil Monetary Penalty (also Competitive Medical Plan)
CIA.....	Corporate Integrity Agreement (A government imposed compliance plan.)
CMS.....	The Center for Medicare and Medicaid Services
CMHC.....	Community Mental Health Center
CPT.....	Common Procedure Terminology (The AMA copyrighted numbering system to describe physician services rendered.)
DRG.....	Diagnosis Related Group (A resource utilization and payment system for Medicare payment to hospitals which establishes a single payment for all services rendered within that hospital stay.)
DOJ.....	Department of Justice
DHS.....	Designated Health Services (The specific services subject to the Stark statute.)
DHHS.....	Department of Health and Human Services
DAB.....	Departmental Appeals Board (The body to which ALJ decisions are appealed.)
DME.....	Durable Medical Equipment
DMEPOS.....	Durable Medical Equipment, Prosthetics, Orthotics and Supplies
EMTALA.....	The Emergency Medical Treatment and Active Labor Act
ESRD.....	End Stage Renal Disease (That condition which qualifies patients for payment for kidney dialysis; it allows Medicare to pay kidney dialysis centers.)
FOIA.....	Freedom of Information Act
FQHC.....	Federally Qualified Health Center
GAO.....	General Accountability Office
GPO.....	Group Purchasing Organization
HCFA.....	Health Care Financing Administration (obsolete)

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HCPP.....	Health Care Prepayment Plan (obsolete)
HHA.....	Home Health Agency
HIPAA.....	Health Insurance Portability and Accountability Act of 1986
HIPDB.....	Healthcare Integrity and Protection Databank
HPSA.....	Health Professional Shortage Area
ICL.....	Independent Clinical Laboratory
IRO.....	Independent Review Organization
MA.....	Medicare Advantage Program
MA-DP.....	Medicare Advantage Drug Plan
MCO.....	Managed Care Organization
MEDICS.....	Medicare Drug Integrity Contractors under Part D
MFCU.....	Medicaid Fraud Control Unit
MMAAA.....	Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977
MMPPA.....	Medicare and Medicaid Patient and Program Protection Act of 1987
MUA.....	Medically Underserved Area
NPDB.....	National Practitioner Data Bank
OIG also IG.....	Office of the Inspector General
PATH.....	Physicians at Teaching Hospitals
PDP.....	Prescription Drug Plan
PPS.....	Prospective Payment System (The Medicare payment system for hospitals and home health agencies.)
PHP.....	Prepaid Health Plan
PRO.....	Peer Review Organization (obsolete)
PSO.....	Patient Safety Organization
PSQIA.....	Patient Safety and Quality Improvement Act of 2005
PSWP.....	Patient Safety Work Product
QIO.....	Quality Improvement Organization (New name of PROs)
RVU.....	Relative Value Unit (A Medicare physician reimbursement concept pertaining to establishing the fee for a procedure.)