Medicare and Medicaid Fraud and Abuse

2025-2026 Edition

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(Chapter 6 by Kevin E. Raphael and Jana Volante Walshak)

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Introduction to the 2025-2026 Edition

This edition of this book is our twenty-second annual edition since we took over authorship. Fraud and abuse in Medicare and Medicaid remain a dynamic area. Set forth here are the additions for this year.

In Chapter 1 all the statistics are updated. We note the change in work plan publication frequency; identify a new fraud alert; address the OIG focus on Medicare Advantage plans' risk adjustments; provide a new enrollment risk resource; describe the first industry specific compliance guidance for nursing facilities; and take into account the DOJ Criminal Division focusing on heath care among its priorities

Chapter 2 includes new caselaw regarding the link between kickbacks and false claims and that the false claims must result from the kickbacks, as well as a Court of Appeals case analyzing the application of the statute only to those who can influence the delivery of care and its non-application to others, like non-physician marketers, contrary to long-standing analyses of the law's effects. We confront a new special fraud alert regarding Medicare Advantage plans and offer updated information regarding 13 OIG advisory opinions

For the Stark statute, which is the focus of Chapter 3, it was a quiet year. We present updated self-referral disclosure protocol (SRDP) statistics as well as the first Stark Advisory Opinion since 2021.

In Chapter 4 we removed obsolete OIG work plan information in favor of providing information regarding the work plan archives and on-going updates.

As is typical and appropriate, Chapter 5 addressing False Claims is the densest with the most activity. We have added two new cases on what can qualify as a false claim and two new reverse false claims cases. There are many ways in which cases can fail to qualify as false claims act cases. We address a wide range of them including three Circuit Court cases on scienter, a Circuit Court case on falsity, and three district court opinions regarding how claims may be false. With respect to materiality and implied certification, we describe two different Circuit Court opinions and a number of district court cases struggling with the purportedly bright lines post *Escobar*. Twelve district court cases deal with particularity following their Circuit Court splits. We highlight a Circuit Court case overturning longstanding precedent regarding first to file, plus two district court cases in other districts, along

with another five differing Circuit Court cases on the public disclosure bar. There is a Court of Appeals case dealing with whether the relator is an 'original source'. We provide the source for statistics regarding when the government intervenes, when it declines and the resulting outcomes, as well as a Supreme Court case on what happens when the government intervenes and takes control of the case, plus a court of appeals case and two district court cases. We confront a Circuit Court case and district court cases addressing the relator's share, if any. We offer three differing Circuit Courts addressing the nuances of retaliation and a district court case addressing what actions qualify as retaliation against the relator who brings the case. In that vein we provide a Circuit Court case and a district court case addressing what actions by the employer are materially adverse to the relator for purposes of a retaliation claim. We include a shocking district court case finding the qui tam provisions of the False claims Act unconstitutional! The Chapter concludes its new material with three cases on the statute of limitations.

Closing the book is Chapter 6 on investigations by our colleagues Kevin Raphael and Jana Volante Walshak at Fox Rothschild which includes updated administrative initiatives, several Supreme Court cases which can affect investigations, subpoenas, civil investigative demands, search warrants and the other techniques of investigation which the government uses in the health care fraud context.

Helping clients to avoid fraud and abuse in its many forms, is a primary task of many health lawyers. This book is structured around the statutory predicates for problems, and is intended to elucidate both regulations and caselaw on point. We turn to the book ourselves during the year. We hope our readers find our work useful.

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, Esq.'s entire legal career has been restricted to health law with a focus on non-institutional reimbursement including from Medicare, managed care, fraud and abuse compliance and avoidance, medical staff issues and utilization management and quality issues including clinical integration, with an emphasis on representation of physicians and their group configurations. A graduate of Barnard College 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 Lawyers 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 19890 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 a member of several physician-organization sponsored consulting networks including those of the AMA, the American College of Physicians, the American Academy of Family Physicians, and the American Society of Plastic and Reconstructive Surgeons.

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 was the first Lawyer of the year (Health Law—Philadelphia) in 2010. 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 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. He was named Lawyer of the year (Health Law—Philadelphia) for 2026.

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 Regulatory Compliance 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 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, 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 Lawyers 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 Kappa.

JANA VOLANTE WALSHAK is a partner at Fox Rothschild and a member of the firm's White-Collar Criminal Defense & Regulatory Compliance Practice. She represents corporations, executives and professionals in high-stakes investigations and enforcement actions involving state and federal prosecutors.

When businesses need clarity on allegations of in-house wrongdoing, Ms. Walshak conducts meticulous internal investigations to uncover misconduct and identify the parties involved, the scope of their misdeeds and the methods used to perpetuate and conceal them. Using that information, she helps clients take corrective action, make voluntary disclosures, cooperate with external investigators, recover funds and make changes to mitigate the risk of similar conduct in the future.

In addition to serving as outside general counsel for a large health care provider, Ms. Walshak advises hospitals, physicians and other entities on a variety of regulatory, commercial and litigation matters specific to the industry, including professional licensing, prescription drug laws and contract negotiations. She also helps providers with disclosures and reimbursements to the Centers for Medicare & Medicaid Services. She often defends clients against claims brought under the False Claims Act, obtaining dismissals and other favorable dispositions.

Ms. Walshak's practice spans federal and state courts, as well as alternative dispute forums, where she handles complex civil and criminal matters involving fraud, breach of fiduciary duty, and injunctive relief, among other causes of action. She also speaks and writes on a variety of legal topics, including internal investigations, pool counsel, eyewitness testimony, restitution, and the drafting, revising and implementing of corporate compliance programs.

She is ranked in *Chambers USA* for Litigation: White Collar Crime & Government Investigations and has been recognized by *Benchmark Litigation* and *The Legal Intelligencer* for her work in white collar and commercial litigation. Actively involved in the legal and local community, Ms. Walshak is Chapter Leader of the Pittsburgh Chapter of the Women's White Collar Defense Association and a former trustee of Grove City College. She earned her J.D. from Harvard Law School, where she was a teaching assistant and a member of the *Journal on Legislation*, and her B.A., summa cum laude, from Grove City College.

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)

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.)