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HEALTH CARE COMPLIANCE LEGAL ISSUES MANUAL

FOURTH EDITION

AHLA

American Health Lawyers Association

Health Care Compliance Legal Issues Manual

Fourth Edition

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BY

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Preface

AHLA is pleased to bring you *Health Care Compliance Legal Issues Manual, Fourth Edition*. We are grateful to Harry R. Silver and Cynthia F. Wisner, Editors, and the many authors for their dedication in writing this newly updated guide to a continually critical facet of the health care landscape.

The world of health care compliance continues to evolve, and the potential ramifications for everyone in the health care arena have grown. Both state and federal governments have beefed up their enforcement efforts against fraud and abuse in health care, and having an effective compliance plan is a must. The importance of understanding the legal issues that create the foundation for and affect compliance programs is tremendous. Numerous state and federal governmental agencies continue to pursue multi-million dollar recoveries through litigation and settlements against those who don't have effective compliance plans. Since 1996, qui tam cases alone have increased from 363 filed that year to 647 cases in 2012, with health care qui tam cases bringing recoveries of \$2.6 billion in 2013. And since the passage of the Affordable Care Act in 2010, entities that participate in the Medicare program are required to have a compliance program as a condition of participation.

The governments' enforcement efforts have focused not only on the Medicare and Medicaid programs, but the changing dynamics of health care delivery and the increased efforts by the industry to align and consolidate have led the Department of Justice and the Federal Trade Commission to take a much stronger look at the health care industry and to challenge certain mergers and consolidations. Marketing efforts, joint ventures, and group purchasing activities related to drugs, device and equipment suppliers continue to be closely scrutinized. In addition, the Internal Revenue Service has been issuing guidance, collecting information, and generally increasing its scrutiny of providers, as have state and local governments.

This Fourth Edition continues to offer important guidance as to what constitutes a compliance program, how to conduct internal investigations, audit basics, what to consider prior to deciding on repayments and disclosures, substantive overviews of the false claims act, the Stark and Anti-Kickback laws, HIPAA privacy and security, and issues in life sciences entities as well as tax compliance.

AHLA recommends this publication to all in the health care field who need to understand the legal issues that impact their compliance efforts. We believe that *Health Care Compliance Legal Issues Manual, Fourth Edition*, will continue to be an invaluable guide for those who need to understand the legal issues of a compliance program.

Introduction to the Fourth Edition

Welcome to the Fourth Edition of the *Health Care Compliance Legal Issues Manual*. Due to the ongoing implementation of the Patient Protection and Affordable Care Act (referred to throughout this edition as the Affordable Care Act, or ACA), especially in the complex field of health care compliance, this edition updates both the initial publication and the sections added in the Third Edition after enactment of the ACA.

Health care compliance is now an integral component of the delivery of health care services by all providers, ranging from traditional types of providers, such as hospitals, to newly created care delivery organizations, such as accountable care organizations (ACOs). Under the ACA, compliance plans are now required for all providers and suppliers as a condition of enrollment in the Medicare program. Those plans are required to contain the “core elements” specified by HHS. Regulations detailing the “core elements” are overdue. This Fourth Edition also includes recent developments in physician compensation issues under the Stark law.

The most dramatic changes in health care compliance continue to be the government’s success in fraud and abuse enforcement following the enactment of the ACA. For example, False Claims Act settlements in excess of \$1 billion are no longer unusual. In addition, RACs, ZPICs, and other contractors with audit and enforcement powers continue to recover significant funds from providers and suppliers.

Among the other significant new developments covered in this edition are new security and privacy standards under HIPAA; the increased emphasis on transparency, as exemplified by the Sunshine Act’s requirement that drug and device companies report certain payments to physicians and teaching hospitals; and HHS’s Healthy People 2020 initiative, which highlights the importance of addressing the social determinants of health (Population Health).

Many regulations implementing the ACA have not yet been issued, and therefore readers can expect that new editions of this Manual will be forthcoming.

We welcome comments from our readers, and hope that you will send them to us, care of Will Harvey wharvey@healthlawyers.org at AHLA, at your convenience. Without your input, our job in successfully preparing the next iteration will be that much more difficult.

We believe that you will find this latest edition to be useful in your practice.

Harry R. Silver
Cynthia F. Wisner
Editors

Acknowledgments

This is the Fourth Edition of the Manual, and we wanted to acknowledge the authors who worked on the First, Second, and Third Editions.

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About the Editors

Harry R. Silver (Author Sections 3.1 and 5.1) is with the Potomac Law Group in Washington, D.C. He received his JD from Columbia Law School, where he was on the editorial board of the *Columbia Law Review*. Mr. Silver served as law clerk to the Hon. Harold R. Medina, U.S. Court of Appeals for the Second Circuit, and subsequently worked for the Appellate Section of the Civil Division of the United States Department of Justice.

Since entering private practice in 1979, Mr. Silver's practice has concentrated on defending health care providers in investigations and litigation stemming from allegations of fraud and abuse, representing health care providers before federal and state courts and agencies, in Medicare and Medicaid reimbursement disputes, and advising providers on compliance and reimbursement issues.

Mr. Silver was co-editor of the Third Edition of AHLA's "Healthcare Compliance, Legal Issues Manual," author of the False Claims Act chapter for all four editions of the Manual, and co-author of the Legal Considerations and Compliance chapter in the Third and Fourth Editions of the Manual. He also authored the Fundamentals of Fraud and Abuse Laws chapter in AHLA's "Deciphering Codes: Fraud & Abuse for Coders and Coding Insight for Healthcare Lawyers." as well as numerous articles on health care fraud and abuse. He has spoken extensively on health care fraud and abuse issues. Mr. Silver has been a member of AHLA's Quality Council. He is AV® Preeminent™ Peer Review Rated by Martindale Hubbell, has been named by ALM as one of Washington D.C. and Baltimore's Top Rated Lawyers for 2014, named by ALM as one of the Top Rated Lawyers in Health Care Law for 2014, Listed in *Washington, D.C. Super Lawyers*, 2013, and has been listed in *Who's Who in America* (1994-2010), *Who's Who in American Law* (1987-1991, 2002-2010, 2014), *Who's Who in the East* (2002-2010) and *Who's Who in the World* (2006-2009).

Cynthia F. Wisner (Author Chapter 1, Section 3.1, and 4) practices health law in the State of Michigan in the Office of Legal Services of Trinity Health where she serves as Associate Counsel assigned to provide legal assistance for Compliance and Integrity, HIPAA and HITECH, Information Services, Revenue Excellence, Supply Chain, and advises on policies and procedures. She served as Vice President and General Counsel for Detroit Medical Center from June 1994 through the end of 1999. Prior to 1994 she was in private practice with several prestigious Detroit law firms, including Honigman Miller Schwartz and Cohn. She is a member of the Michigan bar, admitted to practice law in the State of Michigan in 1981.

Ms. Wisner is currently involved in system-wide projects facilitating compliance with HIPAA HITECH, Health Insurance Exchanges, information security, interoperable health care records, Stark, legal hold, billing compliance, physician relationships, supply chain contracts, provider-based status, reimbursement including PRRB appeals, and various investigations and updates.

Ms. Wisner graduated *summa cum laude* with a B.S. with University Honors from Kent State University in 1978. She graduated *magna cum laude* with a J.D. from the The University of Michigan

School of Law in 1981, where she was elected to the Order of the Coif. She is past President of the Health Law Section of the State Bar of Michigan and the Michigan Society of Health Care Attorneys and a past Member of the Board of the American Health Lawyers Association (AHLA) and past Chair of the In-House Counsel Practice Group of AHLA. She is currently Editor in Chief of the AHLA Journal of Health and Life Sciences, and an adjunct professor of health law at University of Detroit Mercy. In 1994 she was named as one of Crain's Detroit Business' 40 Under 40.

About the Authors

Amy Bailey (Section 3.5) CHC, CPC, CPC-H, CPC-I, CCS-P is a Principal with HC Healthcare Consulting and has over 17 years of health care experience and specializes in regulatory compliance for coding and billing with emphasis in documentation, coding and billing reviews; due diligence and risk assessment reviews; internal investigations, and litigation support services. Amy has extensive experience working with publicly traded health care companies, large hospital systems, law firms and physician group practices. Amy's experience ranges from handling routine compliance issues to provider defense of government false claims and fraudulent coding and billing cases. Amy is Certified in Healthcare Compliance and is also a certified coder for both physician and hospital coding, and an approved coding instructor for the American Academy of Professional Coders. She has taken many leadership roles in the industry, including currently serving as an Auditing and Monitoring Tools Editorial Board Member for the Healthcare Compliance Association and is also a former Regional Governor and Examination Committee Chair American College of Medical Coding Specialists. Amy has published articles featured in Compliance Today and Health Lawyers Weekly. She has also been selected as a speaker for groups including the American Health Lawyers Association, American Academy of Professional Coders, Healthcare Compliance Association, Georgia Hospital Association, Idaho Medical Group Management Association and the Idaho Association of Home Care.

Douglas A. Blair (Section 5.2) currently serves as Director of Legal Services for BJC HealthCare in St. Louis, Missouri, where he is the primary counsel for several hospitals and long-term care facilities, as well as BJC's real estate and construction departments. BJC HealthCare is one of the largest nonprofit health care systems in the U.S. At BJC, Mr. Blair counsels his clients on a wide variety of matters, including fraud and abuse, privacy and confidentiality, medical staff issues, and complex corporate transactions. Mr. Blair is the author of a number of law journal and professional newsletter articles pertaining to health law-related topics. He is a graduate of Cornell University (B.A.), Indiana University-Bloomington (J.D. *cum laude*), and St. Louis University (LL.M. in Health Law). Mr. Blair is also a candidate to earn a Masters in Healthcare Administration from Webster University in Fall 2014. He is admitted to practice in Missouri and California.

Nancy E. Bonifant (Section 5.11) is an associate in the Washington, D.C. office of Reed Smith. She is a member of the Life Sciences Health Industry Group, practicing in the area of health care regulatory law. Nancy works with all types of health industry clients, including acute and post-acute institutional providers, medical device and pharmaceutical manufacturers, pharmacies, independent diagnostic testing facilities, DMEPOS suppliers, and hospice programs. Her practice focuses on fraud and abuse compliance (for example, compliance with the Federal Anti-Kickback Statute, the Stark Law, and beneficiary inducement prohibition), False Claims Act defense, government investigations, and Medicare reimbursement. Nancy also counsels health care providers and their vendors on health information privacy and security compliance (HIPAA and state law). Nancy graduated from the University of Maryland School of Law with a Health Law Certificate and received a Bachelor of Arts degree in Chemistry from Wake Forest University.

Elizabeth Carder-Thompson (Section 5.11) is a partner in the Washington, DC office of Reed Smith LLP, and has been practicing health care law for over 30 years. Elizabeth represents a variety of manufacturers, associations and individual providers and suppliers of health services, including hospitals, physicians, pharmaceutical and device manufacturers, hospices, medical equipment suppliers, long-term care facilities, home health agencies, CORFs, physical and respiratory therapists, and suppliers of diagnostic, laboratory, and other services, as well as financial services firms that support the health care industry. Her specific areas of responsibility in the life sciences area include coding, coverage, and reimbursement, fraud and abuse counseling and representation, and regulatory, legislative, and enforcement issues, primarily involving Medicare, Medicaid, and third-party payers. She is Past President of the American Health Lawyers Associations, and an AHLA Fellow. She graduated magna cum laude from Brown University, where she was elected to Phi Beta Kappa, and from the College of William & Mary School of Law.

Thomas S. Crane (Section 3.4) is a Member at Mintz, Levin, Cohn, Ferris, Glovsky and Pope, P.C. and practices in the Health Law Section and the firm's Health Care Enforcement Defense practice group in both its Boston, MA and Washington, DC offices. He is nationally recognized for his experience with fraud and abuse. Tom advises medical device and health care provider clients on structuring complex strategic affiliation arrangements and transactions to comply with the applicable fraud and abuse laws as well as the variety of other regulatory requirements to meet today's health reform challenges. His work in defending clients against anti-kickback, Stark Law, false claims, and whistleblower allegations includes litigation, internal investigations, voluntary disclosures, and negotiating settlements and Corporate Integrity Agreements (CIA's). He has appeared before numerous U.S. Attorneys' offices, the FBI and OIG around the country. In addition, Tom's practice focuses on Medicare and Medicaid fraud and abuse compliance and reimbursement issues and related laws, including the federal Physician Payments Sunshine Act, 'meaningful use' of EHR technology, under arrangement and provider-based rules, and OIG issues. Recent engagements include counseling cardiologists in a qui tam False Claims Act case alleging medical device company kickbacks, and lead counsel in *Thulin v. Shopko Stores Operating Co., LLC*, 2013 U.S. Dist. LEXIS 158170 (W.D. Wis. Nov. 5, 2013), in which the court dismissed with prejudice a qui tam FCA case alleging Medicaid pharmacy billing fraud. Prior to the formal litigation, Tom and Mintz Levin obtained the declination of the Department of Justice and all eight states in which the relator filed state FCAs actions.

He has been included in *The Best Lawyers in America* since 2011 for his expertise in health care law. In 2004, Tom was honored as one of the nation's "Outstanding Fraud and Compliance Lawyers" by *Nightingale's Healthcare News*. Tom was also named to the Massachusetts *Super Lawyers* Criminal Defense: White Collar list each year from 2004 to 2012 and to *Chambers USA: America's Leading Lawyers for Business* for Massachusetts Healthcare from 2009 to 2012. He is a frequent speaker at AHLA seminars and contributor to various publications.

He received his undergraduate degree from Harvard College (1972), a Master's degree in health administration from the University of Michigan (1976), and his law degree from Antioch School of Law in Washington, D.C. (1983).

Gerald “Jud” E. DeLoss (Sections 5.4 and 5.10) is the Managing Attorney at Popovits & Robinson, which he joined in 2012 and has been practicing health law since 1995. Mr. DeLoss represents physicians, treatment providers, medical groups, federally-qualified health centers, trade associations, health information exchanges, and vendors in health information privacy, HIPAA, corporate transactions, regulatory compliance, contracting, credentialing/privileging, and other legal disputes. In his leadership capacity with the American Health Lawyers Association (AHLA) as Chair of the Health Information and Technology Practice Group and currently as Co-Chair of the AHLA Behavioral Health Task Force, Mr. DeLoss has authored and presented on a wide variety of health law issues, both nationally and internationally, including numerous articles and presentations on health information privacy and security, and other health care compliance requirements.

Mr. DeLoss is a member of the Advisory Committee to the Board of Directors of the Illinois Health Information Exchange (ILHIE) and also serves on the ILHIE Authority Data Security and Privacy Committee. He serves on the Advisory Board to the Guide to Medical Privacy and HIPAA, a national publication on health privacy issues.

In addition to his extensive regulatory and compliance experience, Mr. DeLoss has engaged in medical malpractice defense litigation and represented physicians in credentialing and privileging disputes. He served as lead counsel in: *Welchlin v. Tenet Healthcare Corp.*, 366 F. Supp. 2d 338 (D. S.C. 2005), which was successfully resolved in favor of his client.

Mr. DeLoss earned his B.B.A. and J.D. (with Distinction) from the University of North Dakota.

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on disqualified person status of physicians (PLR 201336020). Gerry also has considerable experience in structuring physician relationships with hospitals, nonprofit governance, executive compensation, academic medical center relationships, voluntary disclosures, and fraud and abuse and Stark Law compliance. He has represented hospital systems, academic medical centers, physician organizations, health maintenance organizations, and colleges and universities. Gerry is Past President of the American Health Lawyers Association and a member of its Nominating Committee. He is also a member of the advisory board for BNA's *Health Law Reporter*, and he served as chair of the Health Care Law Section of the State Bar of Michigan.

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Ann T. Hollenbeck (Section 5.5) is a partner and co-chair of Honigman's Health Care Practice Group. She counsels clients in various aspects of health care transactional and regulatory matters, including clinical research, institutional review board matters, cooperative research projects and research payment and reimbursement issues. Ms. Hollenbeck is active in the American Health Lawyers Association and has co-chaired the Academic Medical Centers Conference since 2009. Admitted to practice in Illinois and Indiana, as well as Michigan, she has lectured and published extensively in various areas of health care law. A fellow of the Michigan State Bar Foundation, she has also been named "Top Lawyer" in 2010, 2011 and 2012 by DBusiness and recognized by Michigan Super Lawyer in 2009, 2010, 2011, 2012 and 2013.

Kenneth E. Hooper (Section 3.5) CPA/CFF, CFE, CHC is a Principal with HC Healthcare Consulting. He has over 30 years of experience in public practice including consulting and litigation support services for health care providers. He is a licensed CPA in Idaho, Washington and Georgia, as well as a Certified Fraud Examiner and Certified in Healthcare Compliance. Ken's health care consulting experience includes provider compliance and litigation matters including due diligence, internal investigations, self-reporting and forensic services. Ken has testified, been deposed, or consulted on cases in both Federal and state courts. He has also served as the interim National Director of Audit and Monitoring for a national third-party billing company and as a chief compliance officer for a health care system while a permanent replacement was recruited.

Gabriel L. Imperato (Section 3.3) is the Managing Partner of Broad and Cassel's Fort Lauderdale office and Co-Chair of the Firm's White Collar/Health Care Criminal and Civil Fraud Practice. He has practiced health care law in both the public and private sectors for over thirty years and is Board Certified as a specialist in health law by the Florida Bar. He is also Certified in Healthcare Compliance by the Health Care Compliance Association where he sits on the Board of Directors and is the Vice President. Mr. Imperato's personal area of practice involves the representation of individuals

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Mr. Levine assists enterprises and individuals that are subject to government regulation or investigation. He consults on compliance plans, conducts internal corporate investigations of alleged misconduct, and defends enterprises, directors, officers and other professionals accused of misconduct at criminal or civil trials and on appeal. Mr. Levine has taught or spoken on pharma and med device law enforcement issues, internal investigations, white collar crime, criminal procedure or trial advocacy at law schools, universities and continuing education seminars. He sits on the editorial advisory board of the *Business Crimes Bulletin* and the U.S. Sentencing Commission Practitioners Advisory Group, and he has consulted for the National Institute of Justice.

Mr. Levine is a graduate of the University of Pennsylvania Wharton School, Oxford University and Harvard Law School.

Melissa L. Markey (Section 5.9) is a shareholder with Hall, Render, Killian, Heath & Lyman, one of the nation's top health law firms, in the Troy, Michigan office, and is licensed as an attorney in both Michigan and Texas. Melissa's practice focuses on technology and life sciences issues, especially data privacy and security, electronic medical records, mobile medical applications, e-Discovery, health information exchange, innovations in health technology, and software licensing. She leads the Life Sciences team at Hall Render and has a particular interest in legal issues at the developing edge of technology. Ms. Markey is a paramedic, is on the Board of Directors of the American Health Lawyers Association, and is a member of the Healthcare Information and Management Systems Society (HIMSS) and the Michigan chapter of HIMSS, and the computer law sections of the American Bar Association as well as the State Bars of Texas and Michigan. She is a nationally recognized author and presenter on electronic medical records, data privacy and security, clinical research and human subject protection, the clinical-technology interface, research misconduct, and emergency preparedness and response law.

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Mr. Pelaia served as an Adjunct Professor of Health Law at Florida Coastal School of Law. He has written numerous articles and is a frequent regional and national speaker on issues related to health care fraud and abuse, compliance and coding. He has spoken at seminars sponsored by various industry groups including the American Health Lawyers Association, the American Bar Association, the Health Care Compliance Association, the Association of American Medical Colleges, the National Association of College and University Attorneys and the AAPC.

Vanessa A. Reynolds (Section 5.3) is a partner in the Fort Lauderdale office of the statewide law firm Broad and Cassel. She is a member of the Firm's Health Law Practice Group and is Board Certified as a specialist in health law by the Florida Bar. She also is certified in Healthcare Privacy Compliance (CHPC) by the Health Care Compliance Association's Compliance Certification Board, and has achieved an AV® Peer Review Rating from Martindale-Hubbell.

With more than 25 years of experience in health law, Ms. Reynolds has extensive experience in provider operations, privacy of health care information (HIPAA), Medicare, Medicaid and other third party reimbursement, telemedicine, and facility and practitioner licensure and regulatory compliance. She has successfully represented both institutional and individual health care providers in administrative and appellate proceedings, and was lead appellate counsel in *Harry v. Marchant*, a groundbreaking EMTALA case decided by the United States 11th Circuit Court of Appeals.

She is a frequent speaker before medical and legal professional associations, authors numerous articles for medical and legal trade publications, and has served as an adjunct professor for St. Thomas University's School of Business Graduate Health Care Management Program.

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