

Preface to the Third Edition

“All our work, our whole life is a matter of semantics, because words are the tools with which we work, the material out of which laws are made, out of which the Constitution was written. Everything depends on our understanding of them.”

—*Felix Frankfurter*

I was honored when Bloomberg BNA and the ABA Health Law Section asked me to create a Third Edition of *Health Care Fraud and Abuse: Practical Perspectives*. When the book was first published in 2002, the topic was just beginning to attract attention. Few people could have realized how the fraud and abuse laws would evolve over time, ultimately creating tremendous potential liability for providers, suppliers, and others doing business in the health care industry, as well as a huge source of revenue for the government. Since there are few bright lines in this area of the law, the interpretation of a single word or phrase can lead to criminal exposure or make a multi-million dollar difference. As a result, practical perspectives can be invaluable.

Why a New Edition?

In light of the many new developments that occurred in the first five years after publication, including multiple new laws and regulations, a Second Edition of the book was published in 2007. However, the health care industry has continued to change, perhaps even more dramatically since then. One of the most notable changes involves the enactment of the Affordable Care Act in 2010 (the ACA), the law that seeks to revolutionize the provision of health care to millions of people and continues to be a political lightning rod. Up to this point, much of the media attention has focused on issues related to the health care exchanges mandated by the ACA. As we approach the end of 2013, the industry is in turmoil because the exchanges have been rolled out but many people have been unable to enroll due to problems with the government’s online enrollment system. It is still unclear whether efforts to repeal the ACA, in whole or in part, will end.

While perhaps not receiving quite as much publicity as the exchanges thus far, health care fraud and abuse is inextricably linked with the ACA. Regulation has expanded and enforcement has increased dramatically; in part because of the new legal authorities the ACA gives the government, such as the law requiring identified overpayments to be returned to the government within

60 days. In addition, the Self-Referral (Stark) Disclosure Protocol that was created by the ACA has led to 35 settlements thus far. Other provisions in the ACA that have not yet been implemented will give the government additional bases for enforcement, such as the compliance program mandate. Another example of the interdependence between the ACA and health care fraud is the fact that monetary recoveries from fraud enforcement are to be used to help fund ACA implementation (as well as federal program operations).

In addition, even before enactment of the ACA (but after publication of the Second Edition), fraud and abuse enforcement was accelerating. For example, the first Medicare Fraud Strike Force was launched in 2007 in South Florida, and has since been expanded to nine cities. In May 2009, the Department of Justice and the Department of Health and Human Services created the Health Care Fraud Prevention and Enforcement Action Team (HEAT) to enhance fraud and abuse enforcement coordination between the two agencies. Other new laws, in addition to the ACA, have expanded the government's arsenal including the Fraud Enforcement and Recovery Act of 2009.

One need only consider the data to see the tremendous growth in enforcement, e.g., the 2007 OIG Semiannual Report (Oct. 2006–March 2007) reported expected recoveries of \$2.9 billion, 1278 exclusions of individuals and entities, 209 criminal actions and 123 civil actions related to health care fraud and abuse. By 2013 the numbers had increased substantially with \$3.8 billion in expected recoveries (a 30 percent increase); and 1661 exclusions (a 30 percent increase). However, an even more dramatic escalation occurred with regard to criminal and civil actions, i.e., in 2013 the OIG reported 484 criminal cases (almost a 150 percent increase); and 240 civil cases (almost a 100 percent increase) from 2007. A further testimonial to the striking number of new developments in health care fraud and abuse since 2007 is the fact that the 2012 supplement was almost as long as the Second Edition itself.

What's New in the Third Edition

In light of these remarkable changes in health care law, regulation and enforcement since 2007, and the wide use of this book (it is Bloomberg BNA's best-selling volume on health law), Bloomberg BNA and the ABA Health Law Section suggested that we publish a new edition. The 2013 Third Edition has been extensively updated and reorganized to better reflect the multitude of fraud and abuse issues that lawyers currently face in advising their clients who do business in the health care industry. While the federal anti-kickback statute (AKS) was addressed in numerous chapters in prior editions, the Third Edition contains a new separate chapter on the AKS in light of the notable increase in cases being brought based on AKS allegations. (The increase is likely due to the ACA provision authorizing the use of the FCA to prosecute AKS violations. In addition, the theories being used by the government, and relators, to "demonstrate" a violation of the AKS are becoming increasingly creative and expansive.) As a result, a thorough understanding of the AKS, as it currently is being interpreted, is critical for health law practitioners.

The Third Edition also contains a comprehensive, updated chapter on "Fraud and Abuse Issues Surrounding Clinical Trials" that was first added in 2009. In

addition, the 2007 chapters on “The Federal Physician Self-Referral Restrictions” and “Legal Issues Surrounding Hospital and Physician Relationships” have been completely rewritten while the chapter on “The Disclosure Dilemma: How, When and What to Tell Stockholders and Stakeholders About Your *Qui Tam* Suit or Investigation” has been removed because there have been few recent developments in this area. Other major issues, new since the 2012 Supplement, that are addressed in this volume include: two key new documents just issued by the OIG in 2013: the OIG Provider Self-Disclosure Protocol, and the OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (both superseding prior guidance); recent Stark law developments, including the *Tuomey* case, one of the few Stark cases to go to trial; and increasing enforcement in the Part D arena.

The Third Edition contains the following 11 chapters:

- Chapter 1: An Introduction to Health Care Fraud and Abuse, Linda A. Baumann
- Chapter 2: Federal Physician Self-Referral Restrictions, Robert Homchick
- Chapter 3: The False Claims Act in Health Care Prosecutions: Application of the Substantive, *Qui Tam*, and Voluntary Disclosure Provisions, Robert Salcido
- Chapter 4: Practical Considerations for Defending Health Care Fraud and Abuse Cases, Patric Hooper and Tracy Jessner
- Chapter 5: Legal Issues Surrounding Hospital and Physician Relationships, David W. Hilgers and Ana E. Cowan
- Chapter 6: Managed Care Fraud and Abuse: Risk Areas for Government Program Participants, Richard W. Westling
- Chapter 7: Corporate Compliance Programs, Linda A. Baumann and Samuel C. Cohen
- Chapter 8: Potential Liabilities for Directors and Officers of Health Care Organizations, Leigh Walton, Angela Humphreys, and Nesrin Tift
- Chapter 9: The Past, Present, and Future of the Anti-Kickback Statute: A Practical History, William W. Horton
- Chapter 10: Controlling Fraud, Waste, and Abuse in the Medicare Part D Program, Larri A. Short and Stephanie L. Trunk
- Chapter 11: Fraud and Abuse Issues Surrounding Clinical Trials, Robyn S. Shapiro and Julie M. Ruczek

Each of these chapters has been updated to be current through May 1, 2013. However, individual authors may have updated their chapters beyond this date in order to reflect major new developments. The Third Edition also contains numerous, updated appendices that help make this book a unique desk reference.

Using This Book to Best Advantage

The book is designed to provide guidance in this complex area of the law for seasoned health law fraud and abuse practitioners as well as for lawyers who do not regularly practice in this area. (Reviewing Chapter 1 which provides a broad overview and introduction to health care fraud and abuse law may be

particularly helpful for this latter group.) One of the continuing strengths of the book's format is the fact that various topics are addressed in several different chapters, so the reader has the benefit of advice on a particular topic from several experienced practitioners; the "practical perspectives" of the title.

Please note that this book is designed for general informational purposes, and should not be construed as legal advice or an opinion on any specific factual situation. The views expressed in the chapters are those of the individual authors, and do not reflect the views of the authors' firms, the firms' clients, my views or the views of the other authors.

Recognizing the Many Invaluable Contributors

I would like to take this opportunity to thank all of the chapter authors for their outstanding contributions to this volume. They all are very busy health lawyers and take a considerable amount of time to update their chapters, describing relevant new laws, regulations, cases and other materials as well as providing practical guidance on how to deal with them. My special thanks to Robert Salcido and Patric Hooper, who have contributed to this book since its inception in 2002. I also would like to recognize those authors who have worked with us since 2007 when the Second Edition was published (if not before) bringing invaluable new topics and perspectives: Leigh Walton, Angela Humphreys, William W. Horton, Larri A. Short and Carol Poindexter. Similarly, we all owe a debt of gratitude to the more recent additions to the team who have done an incredible job, in some cases creating or rewriting entire chapters: Robert Homchick, David Hilgers, Robyn Shapiro, Richard Westling, Ana Cowan, Tracy Jessner, Samuel Cohen, Nesrin Tift, Stephanie Trunk, and Julie Rusczek.

None of these editions would have been possible without the dedicated support and expertise of Jim Fattibene and Elizabeth Turqman of Bloomberg BNA, who have worked tirelessly with me and all the authors. I also would like to thank the leaders and staff of the ABA Health Law Section, including Kathleen Scully-Hayes, Michael E. Clark, Sharon Dostmann, Adrienne Dresevic, and Wanda Workman for all their support. Finally, I would like to express my love and gratitude to my three sons, Greg, Doug and Daniel Faron, for all their support during a sometimes arduous writing process, and their pride in the result.

On behalf of the authors and publishers, we hope that the 2013 Third Edition of *Health Care Fraud and Abuse: Practical Perspectives* will provide essential guidance in this extremely complex and continually changing area of the law, and help lawyers reduce the risks for their clients (and for themselves) when working in this area.

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