

Preface to the Second Edition

In the five years since publication of the first edition of this book in 2002, there have been a tremendous number and variety of new legal developments related to health care fraud and abuse. With regard to applicable laws, there have been several important statutory changes that impact health care fraud and abuse, such as the creation of the new prescription drug benefit program, Medicare Part D; the enactment of the Sarbanes-Oxley Act; and the promulgation of numerous new state false claims acts as a result of the provision in the Deficit Reduction Act of 2005 encouraging the adoption of state laws comparable to the federal civil False Claims Act. Regulatory changes in certain areas have been equally extensive and far-reaching, such as the long-awaited publication of the Stark II/Phase II regulations in 2004, followed just recently by the issuance of the Stark Phase III regulations as well as numerous Stark (and other) regulatory changes in the 2008 Proposed Physician Fee Schedule. During the intervening years, important regulations related to health information technology also have been issued creating new safe harbors under the Anti-Kickback Statute and new Stark Law exceptions.

Many of these laws and regulations, like those already on the books, are extremely complex and leave numerous “gray” areas. Frequent lawsuits result, some initiated by the government and others by whistleblowers under the *qui tam* provisions of the False Claims Act. However, in this unique area of the law, few health care providers can afford to have their day in court and challenge allegations of fraud, because of the government's broad discretionary powers to exclude individuals and entities from participation in federal health care programs, a virtual financial death sentence. As a result, there continue to be relatively few cases providing legal precedents, and few opportunities to have an independent third party resolve the issues in question.

In the absence of case law, providers and other companies doing business in the health care industry must rely heavily on manual provisions and other guidance documents. Perhaps for this reason, there has been a steadily increasing stream of guidance materials emanating from the Centers for Medicare and Medicaid Services, the Office of Inspector General of the Department of Health and Human Services (OIG), and other government and private entities: everything from Compliance Program Guidance documents for most segments of the health care industry to Special Advisory Bulletins to advisory opinions to trade association codes of conduct. On occasion, new guidance materials have been issued on particular substantive issues, ranging from the OIG's Voluntary Disclosure Protocol to hospital charges for uninsured patients to patient assistance programs. There also have been a growing number of settlements and corporate integrity agreements, which seasoned fraud and abuse lawyers often scrutinize, seeking additional guidance on what behavior will trigger government allegations of fraud or abuse.

Government enforcement priorities also have been changing over time. While it is difficult to generalize, in 2002 when the first edition of this book was published, much of the fraud and abuse enforcement activity seemed to focus on hospitals and nursing homes. Prior enforcement efforts against home health agencies and durable medical equipment (DME) providers continued but at a seemingly slower pace. In the subsequent five years we have seen an explosion of cases in the pharmaceutical industry (primarily focusing on kickbacks and pricing), increased activity in quality of care cases and an expanded number of cases against individual

physicians. Most recently, there appears to be a renewed focus on DME providers as a result of sting operations in several states.

Due to the lack of bright line guidance in many areas and the fact that standards often are revised, it can be extremely challenging, as a lawyer, to counsel health care clients. Fraud and abuse issues are potentially inherent in virtually every claim or transaction, yet they can be extremely difficult to identify, let alone to analyze and resolve with any degree of certainty. The risks of failure to do so are staggering: clients may have to enter civil settlements for hundreds of millions of dollars or face criminal penalties or imprisonment or some combination of these sanctions. Moreover, lawyers themselves are at risk, as most recently exemplified by the civil False Claims Act case brought against a former general counsel of Tenet.

This book originally was developed in 2002 as a resource for attorneys dealing with these types of issues. Based on the tremendously positive response that the book has received, it seems clear that the need for this type of publication continues to grow. The 2007 edition has been expanded and updated throughout, and is designed to serve as a desk reference for experienced health law practitioners as well as for the relative novice (who may find it helpful to read the first chapter, “An Introduction to Health Care Fraud and Abuse,” before delving into the other chapters). For this reason, the book includes an extensive collection of appendices that contain many of the laws, regulations and guidance documents that are critical to addressing fraud and abuse issues in the health care context. Because of the growing volume of the appendices, and in light of the benefits of being able to search documents electronically, the appendices in the 2007 edition are being provided on a CD Rom.

The topics covered in each chapter reflect the types of issues that health lawyers frequently face in practice. It has been particularly valuable to have different authors for each chapter who can bring their unique expertise to these issues. As a result, certain topics may be covered in more than one chapter, and I encourage you to review the different analyses and perspectives that each author brings to the topic. Moreover, because the authors are experienced health lawyers, they bring an invaluable real world perspective and practical advice to each chapter. Please note, however, that the content of this book is designed for general information purposes only, and should not be construed as legal advice or an opinion on any specific facts or circumstances. 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 of this volume.

The book has evolved, along with this rapidly changing field. Accordingly, the 2007 edition contains 10 chapters as indicated below, as well as the appendices:

Chapter 1: An Introduction to Health Care Fraud and Abuse, Linda A. Baumann

Chapter 2: Federal Physician Self-Referral Restrictions, Thomas S. Crane

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 & Amanda S. Abbott

Chapter 5: Legal Issues Surrounding Hospital and Physician Relationships, Dennis M. Barry

Chapter 6: Managed Care Fraud and Abuse: Risk Areas for Government Program Participants, Christine C. Rinn and Barbara H. Ryland

Chapter 7: Corporate Compliance Programs, Linda A. Baumann

Chapter 8: Potential Liabilities for Directors and Officers of Health Care Organizations, Leigh Walton, Angela Humphreys, and Clevonne Jacobs

Chapter 9: The Disclosure Dilemma: How, When, and What to Tell Stockholders and Stakeholders About Your *Qui Tam* Suit or Investigation, William W. Horton, & Monty G. Humble

Chapter 10: Controlling Fraud, Waste, and Abuse in the Medicare Part D Program, Larri A. Short & Richard S. Liner

Appendices: Carol Poindexter, Appendix Editor

Each of the chapters has been updated to be current through May 2007. However, individual authors may have updated their chapters beyond this date in order to reflect major new developments. In this regard, I am very pleased that Tom Crane was able to create a special addendum to his chapter on the Stark Law in order to reflect the new Stark III regulations that were just issued in Sept. 2007.

I would like to take this opportunity to thank the many people who so generously contributed to the success of this book. It has been an honor to work with the chapter authors, experts in the field, who have taken innumerable hours away from their busy practices. My special thanks to those authors who have responded so graciously for each of the past five years: Dennis Barry, Tom Crane, Patric Hooper, and Robert Salcido. I also am very appreciative of those authors who have joined the team, enriching the book by bringing unique perspectives and covering new topics: Bill Horton, Monty Humble, Carol Poindexter, Angela Humphries, Larri Short, Richard Liner, Amanda Abbott, Christine Rinn, Leigh Walton, and Clevonne Jacobs. In addition, I would like to express my thanks and appreciation to Jim Fattibene and Elizabeth Turqman from BNA Books for their exceptional expertise and guidance. This book also would not have been possible without the support of the leaders and staff of the ABA Health Law Section, including Paul DeMuro, Andy Demetriou, Michael Clark, and Jill Peña. Last, but not least, I would like to thank my family, including my sons Greg, Doug, and Daniel Faron, for their patience, understanding and appreciation of the final product.

On behalf of the authors and publishers, we hope that the 2007 edition of *Health Care Fraud and Abuse: Practical Perspectives* will help readers understand these complex, continually evolving legal issues. Further, we hope the practical perspectives each author provides will help you effectively address these issues as they may arise in your legal practice, reducing the risks for you, as well as for your clients.

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December 2007