

Preface

2011 was the year that implementation of the health care reform legislation, now commonly referred to as the Patient Protection and Affordable Care Act (PPACA), began in earnest. PPACA was an extensive overhaul of the United States health care system, and affects almost every aspect of the health care industry and the laws affecting its operations.

PPACA is already having a substantial impact on the health care fraud and abuse laws, both directly and indirectly. Numerous provisions in PPACA revised laws specifically relating to fraud and abuse enforcement, such as modifications to the False Claims Act, the anti-kickback statute and the Stark law prohibiting physician self-referrals. Other PPACA provisions enacted new program integrity requirements, such as the physician payment sunshine provisions requiring manufacturers of a drug, device, biological or medical supply to report any payments made to a physician or teaching hospital with certain limited exceptions. PPACA also contained provisions creating greater linkage between provider enrollment in federal health care programs and compliance with the fraud and abuse laws, including the requirement for certain providers and suppliers to establish a compliance program with certain core elements. Another provision required overpayments to be reported and returned within 60 days after the overpayment has been identified or the date any corresponding cost report is due, whichever is later. New bases for civil monetary penalties are created and penalty provisions are enhanced under PPACA which also expanded the Recovery Audit Contractor program to Medicaid. Moreover, PPACA authorized a tremendous increase in funding for fraud and abuse enforcement as the commonly stated expectation by the Obama administration was that such enforcement would help cover PPACA's \$940 billion costs.

While some PPACA provisions took effect immediately upon passage, many are being phased in over time, and a number of these changes to the health care laws and regulations occurred in 2011. As a result, it is critical for individuals and entities doing business in the health care industry (and their legal counsel) to be up to date on these issues, many of which are addressed in the *2011 Cumulative Supplement to Health Care Fraud and Abuse: Practical Perspectives*. The current through date of this *2011 Cumulative Supplement* is May 1, 2011, and a number of chapter authors also have provided information on significant events that occurred up through September 2011.

The *2011 Cumulative Supplement* focuses on several important new developments including the increasing exposure that individuals are facing, even when their involvement in the allegedly improper conduct is indirect, e.g., through the Responsible Corporate Officer Doctrine and the “Controlling Person” theory. These issues are addressed in Chapters 8 and 1. Chapter 3 contains an extensive analysis of the False Claims Act amendments enacted in 2010, such as revisions to the public disclosure jurisdictional bar, overpayment reporting requirements, and whistleblower retaliation provisions. Chapter 10 contains substantial new material on the new regulations and increasing enforcement actions related to fraud and abuse in the Part D context including the 2012 Final Rule on Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, suspension of sponsor marketing and enrollment activities and various new Centers for Medicare and Medicaid Services initiatives including guidance to part D Plan sponsors and audits of sponsor operations. Chapter 2 and several other chapters address new Stark law developments including regulations implementing PPACA changes to the Stark law’s requirements. Finally, virtually every chapter provides an update, from a different practitioner’s perspective, on the increasing scope and extent of fraud and abuse enforcement activities in the health care industry.

The content of the *2011 Cumulative Supplement* is for general informational 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 of the chapter, and do not reflect the views of their firm, the firm’s clients, myself or the other authors of this volume.

Speaking on behalf of myself, the ABA Health Law Section and BNA Books, I would like to take this opportunity to express our tremendous appreciation for all the contributions of the authors of chapters in the *2011 Cumulative Supplement*: Robert G. Homchick, Robert Salcido, Patric Hooper, Alexandra N. Thomas, David W. Hilgers, Ana E. Cowan, Richard W. Westling, Leigh Walton, Angela Humphries, William W. Horton, Larri A. Short, Stephanie L. Trunk, Robyn S. Shapiro, Julie M. Rusczyk, and Carol A. Poindexter. As experienced practitioners, the analysis, perspective and practical guidance that they provide in this complex legal area are invaluable.

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I invite and welcome comments and suggestions on ways to improve future supplements. On behalf of the authors and publishers, we hope that this volume will help readers better understand and address this dynamic area of the law.

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