

DETAILED TABLE OF CONTENTS

	<i><u>Main Volume</u></i>	<i><u>Supple- ment</u></i>
Preface	vii	v
Summary Table of Contents	xv	vii

PART I INTRODUCTION

CHAPTER 1. INTRODUCTION	3	3
I. The Development of Antifraud Measures	3	—
II. Health Care Prosecutions: Fad or Long-Term Trend?	5	—
III. Structural Defects in the System	8	—
A. Inverse Incentives	8	—
B. Erosion of Copayments	10	—
IV. An Overview of Fraud in Medicare	12	—
V. Conclusion: The Increasing Rate of Prosecutions, Convictions, and Exclusions	13	3
CHAPTER 2. LITIGATION AND COUNSELING: AN OVERVIEW ..	15	5
I. Litigation in a Complex Environment	15	5
A. Investigative Tools	15	—
B. Understanding the Regulatory Environment	16	—
C. Sanctions	17	5
II. Determining the Provider’s Risk and Organizing a Strategic Response	18	—
Figure 2-1: Advising the Client: FDA, Patient Abuse, and Referral Issues	20	—
Figure 2-2: Advising the Client: Billing and Referral Issues	21	—

PART II THEORIES OF FRAUD LIABILITY IN HEALTH CARE CASES

CHAPTER 3. FALSE BILLING AND MEDICARE REIMBURSEMENT RULES AND THE MEDICAID PROGRAMS [SUBSTITUTE TEXT: THIS CHAPTER REPLACES CHAPTER 3 IN THE MAIN VOLUME.]	—	9
I. Introduction	—	10
II. Overview of the Medicare Reimbursement System	—	11
A. Legislative History	—	11
B. Administration and Operation	—	12
C. Structure of Medicare Reimbursement	—	12
III. Medicare Part A in General	—	13
A. Eligibility and Enrollment	—	13
1. The Aged and the Disabled	—	13
2. Uninsured Elderly Individuals	—	14
3. Disabled Individuals	—	14
B. Extent of Insurance Coverage Under Part A	—	14
1. Hospital Insurance Coverage	—	15
2. Skilled Nursing Facility (SNF) Insurance Coverage	—	16
3. Home Health Care Insurance Coverage	—	17
C. Payment of Claims Through Fiscal Intermediaries	—	19
D. Part A: Reimbursement Methodology	—	20
1. The Early Years: Cost-Based Reimbursement	—	20
2. Prospective Payment System (PPS)	—	21
a. Overview of the PPS	—	21
b. Costs Covered by the PPS	—	22
c. Exclusions From the PPS	—	23
i. Hospitals and Hospital Units Not Covered	—	23
ii. Hospital Costs Not Covered	—	24
iii. Other Costs Not Covered	—	24
d. Diagnosis-Related Groups (DRG) Classification Under the PPS	—	24
E. Implications for Counsel: Part A Billing	—	25
IV. Medicare Part B	—	27
A. Eligibility and Enrollment	—	27
B. Extent of Insurance Coverage Under Part B	—	28
1. Coverage in General	—	28
2. Coverage for Physician Services	—	30
3. Coverage for Anesthetic Services	—	32
4. Coverage for Certain Diagnostic Tests	—	32
5. Coverage for Ambulance Services	—	33
6. Coverage for Outpatient Physical Therapy Services and Speech Pathology Services	—	34
7. Coverage for Services Provided “Incident to” a Physician’s Services	—	35

	<u>Main Volume</u>	<u>Supple- ment</u>
8. Coverage for Durable Medical Equipment	—	36
C. Payment of Claims Through Carriers	—	37
D. Implications for Counsel: Part B Billing	—	38
V. Medicare Part C	—	38
A. The Addition of HMO Coverage	—	38
B. Provision of Care	—	39
C. HMO Reimbursement and Opportunities for Fraud	—	40
VI. Medicare Part D	—	41
A. Development of Medicare Part D	—	41
B. The Structure of Medicare Part D	—	42
1. Enrollment Eligibility	—	42
2. Specific Rules Regarding Prescription Drug Plan Sponsors	—	43
VII. The Section 340B Program	—	47
VIII. The Medicaid Programs	—	48
A. “Best Price”	—	49
B. Payment for Drugs Used Off-Label	—	50
C. Conclusion	—	51
CHAPTER 4. THE CIVIL FALSE CLAIMS ACT		
[SUBSTITUTE TEXT: THIS CHAPTER REPLACES		
CHAPTER 4 IN THE MAIN VOLUME.]	—	53
I. Introduction	—	54
II. Background and Application	—	57
A. Background	—	57
B. False Claims Act (FCA) Suits and Health Care Fraud ..	—	58
C. Types of Health Care Fraud Schemes Alleged Under the FCA	—	59
III. Elements of an FCA Action	—	61
A. Claim	—	63
B. Submission of the Claim	—	65
C. Falsity of the Claim	—	67
1. False Statements	—	67
2. False Certifications	—	71
3. Knowledge of the Claim’s Falsity	—	75
D. Damages and Penalties	—	77
E. <i>Respondeat Superior</i> Liability	—	79
IV. <i>Qui Tam</i> Provisions of the FCA	—	80
A. Basic Procedure	—	80
1. Complaint and Disclosure Statement	—	80
2. Intervention	—	81
3. Declination	—	82
B. Award to the Relator	—	83
C. Whistleblower Protection	—	85
V. Legal Issues Under the <i>Qui Tam</i> Provisions	—	87
A. Public Disclosure Jurisdictional Bar	—	87
1. “Public Disclosure”	—	89

	<u>Main Volume</u>	<u>Supple- ment</u>
2. “Allegations or Transactions”	—	90
3. “Based Upon”	—	91
4. “Original Source”	—	92
5. Comment	—	94
B. Suits Against States	—	95
C. Proceeds of an FCA Case	—	97
D. Constitutionality	—	97
E. Collateral Estoppel Impact of Prior Guilty Pleas	—	98
VI. Implications for Counsel	—	98
VII. State False Claims Act Statutes	—	99
VIII. Conclusion	—	100
CHAPTER 5. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT		
[SUBSTITUTE TEXT: THIS CHAPTER REPLACES		
CHAPTER 5 IN THE MAIN VOLUME.]	—	101
I. Introduction	—	103
A. Potential for Health Care Billing Fraud	—	103
B. Liability of Manufacturers	—	104
1. Criminal Prosecution	—	104
2. Private Litigation	—	107
II. Medicare Reimbursement Policies	—	108
A. Coverage for New Procedures, Drugs, and Devices	—	108
B. Coverage for Investigational Devices	—	111
1. Experimental/Investigational (Category A) Devices	—	112
2. Nonexperimental/Investigational (Category B) Devices	—	112
III. Structure of the Federal Food, Drug and Cosmetic Act	—	113
A. Overview	—	113
B. Purpose of the Act	—	114
C. Drugs	—	115
1. Investigational Use of a New Drug	—	117
2. Premarket Approval of Drugs	—	120
a. New Drugs	—	120
b. Generic Drugs	—	121
3. Supplements to an Approved Nonexperimental Drug Application or an Approved Abbreviated Nonexperimental Drug Application	—	123
4. Required Records and Reports	—	125
D. Medical Devices	—	125
1. Classification	—	126
a. Class I Devices	—	126
b. Class II Devices	—	127
c. Class III Devices	—	127
d. Classification Panels	—	128
2. Premarket Approval	—	128
a. Concept of Substantial Equivalence and the 510(k) Process	—	128

	<u>Main Volume</u>	<u>Supple- ment</u>
b. Class III Devices	—	130
c. Labeling and Intended Use	—	131
3. Determining Safety and Effectiveness	—	132
4. Changes to a Device	—	134
E. The Manufacturing of Drugs and Devices	—	135
1. The Manufacturing Process	—	136
2. The Registration and Inspection Process	—	137
3. The “Current Good Manufacturing Practice” (CGMP) Requirements and Vagueness	—	138
IV. Prohibited Activities	—	139
A. Adulterated Drugs and Devices	—	140
1. Manufacturing Problems	—	140
2. Additional Adulteration Related to Drugs	—	141
3. Additional Adulteration Related to Devices	—	141
B. Misbranded Drugs and Devices	—	142
C. Prohibitions Regarding Samples	—	144
V. Criminal Prosecutions	—	145
A. The Broad Prohibitions Against Adulteration and Misbranding	—	146
1. Distribution Prohibitions	—	146
2. Manufacturing Prohibitions	—	147
3. Wholesale Distribution Prohibitions	—	148
4. Samples Prohibitions	—	149
B. The Crimes	—	149
1. Misdemeanor Culpability	—	149
a. In General	—	149
b. Individual Liability	—	151
2. Felony Culpability	—	153
a. In General	—	153
b. In the Sale of Drug Samples	—	159
3. Each Shipment or Sale Is a Separate Crime	—	159
4. Charging Issues	—	159
5. Off-Label Promotion of Drugs and Devices	—	161
a. The Legal Requirements	—	162
i. Drugs	—	162
ii. Devices	—	163
iii. The Concepts of Adulteration and Misbranding	—	164
b. The Practice of Medicine	—	164
c. Evaluating the Economic Incentives	—	165
d. First Amendment Rights of Drug and Device Manufacturers	—	167
i. FDA Guidance and the Passage of the Food and Drug Administration Modernization Act of 1997	—	169
ii. The FDAMA Safe Harbor	—	170
e. False Claims Act Liability for Off-Label Prescriptions	—	172
f. Collateral Consequences From Off-Label Promotion	—	172
g. Implications for Counsel	—	173

	<u>Main Volume</u>	<u>Supple- ment</u>
6. Importation of Drugs	—	174
C. Commencement of Criminal Proceedings	—	175
1. Section 305 Proceedings	—	175
2. Grand Jury Investigations	—	177
VI. Debarment and Suspension	—	177
VII. Miscellaneous Matters Not Covered	—	179

PART III THE ANTI-KICKBACK STATUTE, STARK PROHIBITIONS, AND ANTI-KICKBACK ADVISORY OPINIONS

CHAPTER 6. THE ANTI-KICKBACK STATUTE AND RELATED SAFE HARBORS [SUBSTITUTE TEXT: THIS CHAPTER REPLACES CHAPTER 6 IN THE MAIN VOLUME.]	—	183
I. Introduction	—	185
II. The Anti-Kickback Statute: An Overview	—	185
A. Legislative History	—	185
B. Purpose of the Statute	—	187
C. The Prohibitions: An Overview	—	188
D. The Safe Harbors: An Overview	—	188
E. Void-for-Vagueness Challenges	—	189
F. Practical Implications for Counsel	—	190
III. Elements of the Anti-Kickback Statute	—	191
A. The Criminal Prohibitions	—	191
B. Remuneration	—	193
1. Remuneration Defined	—	193
2. Examples of Remuneration	—	194
3. Business Relationship Between Payer and Payee ...	—	197
a. General Agreements	—	197
b. Joint Ventures	—	198
4. Purpose of the Payments	—	200
a. The Applicable Legal Standard	—	200
b. Expressions of Purpose	—	203
C. Inducement	—	205
D. “Knowingly and Willfully”	—	205
1. Debate Surrounding the Terms	—	205
2. <i>United States v. Starks</i>	—	209
E. “Directly or Indirectly” and “Overtly or Covertly”	—	209
IV. The Exceptions to the Anti-Kickback Statute Prohibitions and the Safe Harbor Regulations	—	210
Table 6.1. Referral Restrictions: Overlapping Exceptions and Safe Harbors	—	212
Table 6.2. Safe Harbor Treatment in OIG Anti-Kickback Advisory Opinions	—	215
A. Discounts	—	217
1. In General	—	217
2. Restrictions	—	219
a. Restrictions on the Statutory Exception	—	219

	<u>Main Volume</u>	<u>Supple- ment</u>
b. Restrictions on the Regulatory Safe Harbor	—	220
3. Practice Pointers	—	222
B. Employee Bonuses	—	223
C. Payments to Group Purchasing Agent	—	224
D. Waiver of Coinsurance	—	225
E. Risk-Sharing Arrangements	—	226
1. The Statutory Exception	—	227
2. Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans to Enrollees	—	228
3. Price Reductions Offered to Health Plans by Contract Providers	—	229
4. Price Reductions Offered to Eligible Managed Care Organizations	—	231
5. Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations	—	234
6. Comment on These Safe Harbors	—	237
F. Investment Interests	—	237
1. Large, Publicly Traded Entities	—	238
2. Small Entities With Active and Passive Investors ..	—	239
3. Small Entities, With Active and Passive Investors, in an Underserved Area	—	240
4. Investments in Group Practices	—	240
5. Ambulatory Surgical Centers	—	241
a. Surgeon-Owned, Single-Specialty, and Multispecialty ASCs	—	241
b. Hospital/Physician ASCs	—	242
c. Comment	—	243
G. Lease of Space and Equipment Rental	—	243
1. Lease of Space	—	243
2. Equipment Rental	—	245
H. Personal Services and Management Contracts	—	245
I. Sale of Practice	—	247
J. Referral Services	—	249
K. Warranties	—	250
L. Practitioner Recruitment	—	252
M. Obstetrical Malpractice Insurance Subsidies	—	253
N. Cooperative Hospital Service Organizations	—	253
O. Referral Arrangements for Specialty Services	—	253
P. Ambulance Supply Replenishment	—	254
Q. Waiver of Coinsurance by Pharmacies Under Medicare Part D	—	256
R. Rural Health Center in Medically Underserved Area ...	—	256
S. Electronic Prescribing Items and Services	—	257
T. Electronic Health Records Items and Services	—	258
V. Sanctions	—	260
VI. State Statutes	—	262
VII. Implications for Counsel	—	263

	<u>Main Volume</u>	<u>Supple- ment</u>
CHAPTER 7. THE STARK PROHIBITIONS AND RELATED SAFE		
HARBORS	219	265
I. Introduction	220	266
II. Scope of the Stark Prohibitions	222	267
A. “Referral”	223	268
B. “Designated Health Services”	224	269
C. “Financial Relationship”	225	270
D. Remuneration	225	—
III. The Stark Safe Harbors	227	272
A. Safe Harbors Relating to Ownership and Investment Interests	228	272
1. Publicly Traded Securities and Mutual Funds	230	272
2. Hospitals in Puerto Rico, Rural Entities, and Certain Hospitals	230	—
B. Safe Harbors Relating to Compensation Arrangements	231	272
1. Rental of Office Space and/or Equipment	231	—
2. Bona Fide Employment Relationships and Personal Service Arrangements	233	—
3. Hospital Remuneration	236	—
4. Physician Recruitment	236	273
5. Isolated Transactions	238	—
6. Arrangements Between Hospitals and Physician Group Practices	238	—
7. Payments by a Physician for Items and Services	239	—
8. Nonmonetary Compensation up to \$300	240	—
9. Fair-Market-Value Compensation	240	274
10. Medical Staff Incidental Benefits, Risk-Sharing Agreements, and Compliance Training	241	—
11. Indirect Compensation Arrangements	242	274
C. Safe Harbors Relating to Both Ownership and Investment Interests and Compensation Arrangements	242	275
1. Physician Services Provided in a Group Practice	242	—
2. In-Office Ancillary Services	243	—
3. Prepaid Health Plans	244	—
4. Certain Clinical Laboratory Services	244	—
5. Academic Medical Centers	244	275
6. Implants in Ambulatory Surgical Centers	245	—
7. EPO and Other Dialysis-Related Outpatient Prescription Drugs	246	—
8. Preventive Screening Tests, Immunizations, and Vaccines	246	—
9. Eyeglasses and Contact Lenses Following Cataract Surgery	247	275
D. Additional Miscellaneous Safe Harbors [New Topic] ...	—	275
1. Referral Services [New Topic]	—	275

	<u>Main Volume</u>	<u>Supple- ment</u>
2. Obstetrical Malpractice Insurance Subsidies [New Topic]	—	275
3. Professional Courtesy [New Topic]	—	276
4. Retention Payments in Underserved Areas [New Topic]	—	276
5. Communitywide Health Information Systems [New Topic]	—	277
6. Electronic Prescribing Items and Services [New Topic]	—	277
7. Electronic Health Records Items and Services [New Topic]	—	278
IV. Reporting Requirements	247	—
V. Penalties	248	279
A. Refund for Prohibited Services	248	—
B. Penalty for Each Billed Service	248	—
C. Penalty for Each Prohibited Referral Arrangement	249	279
D. Penalty for Failing to Identify Prohibited Referral Arrangements	249	—
E. Cumulative Effect of Penalties	249	—
VI. Advisory Opinions	250	279
Main Volume Footnote Updates	—	279

**CHAPTER 8. THE ANTI-KICKBACK ADVISORY OPINIONS
[SUBSTITUTE TEXT: THIS CHAPTER REPLACES
CHAPTER 8 IN THE MAIN VOLUME.]**

I. Introduction	—	281
II. The Advisory Opinion Process	—	289
A. Requesting an Advisory Opinion	—	289
1. Subject Matter	—	289
2. Required Contents	—	291
3. Consultation With Department of Justice and U.S. Attorneys' Offices	—	292
4. Time Frame for Response	—	293
B. Effect of an Advisory Opinion	—	293
C. Other Considerations	—	295
1. Legal Considerations	—	295
2. Advisory Letters Authored by HCFA in the 1970s	—	296
3. The Entrapment-by-Estoppel Defense	—	297
III. The Advisory Opinions	—	297
Table 8.1. Index to Advisory Opinions by Health Care Industry Sector	—	300
A. Arrangements That Affect Medicare or Medicaid Program Beneficiary Payment Obligations	—	304
1. Grant Programs Funded by Providers, Which Programs Cover Patient Copayments	—	304

	<u>Main Volume</u>	<u>Supple- ment</u>
a. Donor-Blind Disease-Specific Program (Dialysis Program Funded by Dialysis Companies)	—	305
i. Implications for Counsel	—	307
b. Donor-Blind Grant Programs Run by Independent Charitable Organizations: Variations on a Theme	—	308
c. Donor-Specific Programs by Pharmaceutical Companies Intended to Benefit Patients Using Only Company Drugs	—	311
i. Implications for Counsel	—	312
2. State-Funded Program to Pay Dialysis Patients’ Premiums	—	312
a. Implications for Counsel	—	313
3. Privately Funded Program to Pay Dialysis Patients’ Premiums	—	313
4. Waiver of Copayments for All Patients as a Business Tactic	—	314
5. Waiver of Copayments Through “Coordination of Benefits” Between Nursing Home and Health Plan	—	316
a. The Facts	—	316
b. The First Opinion	—	318
c. The Second Opinion	—	318
d. Implications for Counsel	—	319
6. Waiver of Patient Copayments and Deductibles for Clinical Trials	—	319
a. Clinical Trial of Experimental Surgical Procedure	—	320
b. NIH-Sponsored Clinical Trials	—	321
c. CMS-Sponsored Clinical Trials [New Topic] ...	—	322
d. Implications for Counsel	—	322
7. Waiving Copayment Obligations for Program Beneficiaries Receiving Emergency Ambulance Services	—	323
a. Limited Waiver of Copayments and Deductibles for Back-up Emergency Ambulance Services	—	323
b. Arrangements Involving Broad Waiver of Copayments and Deductibles for Municipal or County Residents Receiving Emergency Ambulance Services	—	325
c. Proposed Waiver of Copayments by Hospital Seeking to Assure Transportation of Patients From Referral Sources	—	326
d. Implications for Counsel	—	326
8. Waiver of Copayments by Children’s Research Hospital	—	327
a. Implications for Counsel	—	328
9. Waiver of Copayments Under the National Eye Care Policy	—	328

	<u>Main Volume</u>	<u>Supple- ment</u>
a. Implications for Counsel	—	329
10. Providing Free Services and Items of Care to Program Beneficiaries	—	329
a. Free Transportation Services to Patients	—	330
b. Free Vision Screening Tests for Infants	—	331
c. Free On-Site Screening Services as Part of a Telemedicine Network	—	331
d. Requirement That an Ambulance Company Provide Free Ambulance Services to Indigent Patients	—	332
e. Provision of Free Items by Home Health Agencies	—	333
f. Gifts to Patient-Customers	—	333
g. Free Drugs Provided to Patients Through Patient Assistance Plans (PAPs)	—	335
h. Free Dialysis Care Provided by Hospital	—	337
i. Implications for Counsel	—	337
11. Waiver of Copayments Between Hospital Providers and Indian Tribe	—	338
12. Waiver of Copayments for Screening and Follow- up Services by Breast Cancer Center	—	339
a. Implications for Counsel	—	339
13. Waiver of Premiums and Copayments in the Context of the Delivery of Managed Care	—	340
14. Waiver of Coinsurance for Nursing Home Residents	—	341
15. Year-End Percentage Rebate Payment by Retailer to Pharmacy Customers	—	342
B. Arrangements That Involve the Provision of Free Supplies, Services, or Gifts to Referral Sources	—	342
1. Remuneration Arrangements Involving Ambulance Providers	—	343
a. Free Supplies Provided to Ambulance Companies by a Hospital Chain	—	343
b. Gift of an Ambulance to a Municipality	—	344
i. Comment	—	345
c. Second Ambulance Restocking Opinion: Free Supplies Provided by All Hospitals to All Ambulance Providers	—	345
d. Third Ambulance Restocking Program: Supplies Charged to the Patient and Provided Free to All Ambulance Providers	—	347
i. Implications for Counsel	—	348
e. Fourth Ambulance Restocking Plan: Differing Controlling Entities	—	348
f. Ambulance Restocking Plan for Volunteer Ambulance Providers	—	349
g. Ambulance Restocking Plan Variant: Hospital Donation to Ambulance Provider	—	349
h. Ambulance Restocking Agreement: The New Safe Harbor Applies	—	350

	<u>Main Volume</u>	<u>Supple- ment</u>
i. Payments by Ambulance Companies to Local Government in Exchange for Exclusive Contract in a Specified Territory	—	350
j. Equipment Leased at a Nominal Charge to Ambulance Companies	—	351
k. In-Kind Swap of Services Between Ambulance Provider and Municipality	—	352
2. Provision of Free Pharmacy Services to Hospital Organ Transplant Centers	—	352
a. Implications for Counsel	—	353
3. Kickback Implications of Charitable Gift From Hospital to a Referral Source, Whether Physician, Medical School, or Another Hospital	—	354
a. Implications for Counsel	—	356
4. Exchanging Free Podiatry Services for Access to Shoe Retailer Customers	—	357
a. Implications for Counsel	—	359
5. Providing Free Employees to Potential Referral Sources	—	359
a. Free Psychiatric Residents Provided to Potential Referral Sources	—	359
b. Free Lab Assistants Provided by Laboratory Company to Dialysis Facility	—	360
c. Implications for Counsel	—	361
6. Free Goods and Services Among Referral Participants in Telemedicine Network	—	362
7. Free Care and Services to Institutional Referral Sources	—	362
a. Implications for Counsel	—	364
8. Gifts From a Hospital to Other Institutional Providers	—	365
a. Hospital Gifts to a Hospice	—	365
b. Hospital Gifts to a Nursing Home	—	366
9. Free Items Provided by Manufacturers or Suppliers of Durable Medical Equipment	—	367
10. Transfer of Money From State Authority to Medical Education and Research Funds	—	368
11. Free Blood Drawing Supplies and Services Provided by Laboratory Company to Referral Sources	—	368
C. Arrangements That Involve Discounts, Financial Incentives, the Provision of Services, or Other Business Transactions Between Providers and Referral Sources	—	369
1. Advisory Opinions Regarding Joint Ventures (Other Than Ambulatory Surgical Centers)	—	369
a. The Hospital Radiology Joint Venture	—	370
i. No Safe Harbor	—	370
ii. No Within-the-Venture Prohibited Remuneration	—	371
iii. The Venture Is Not a Cover	—	373

	<u>Main Volume</u>	<u>Supple- ment</u>
iv. Implications for Counsel	—	373
b. Joint Ventures for Magnetic Resonance Imaging (MRI) Centers	—	374
i. Comment	—	375
c. Joint Venture Helicopter Ambulance Services ..	—	375
d. Joint Physician Investment and Cross Referrals to Physical Therapy Center	—	376
e. Joint Venture Pathology Laboratory Company	—	377
f. Joint Venture Pediatric Psychiatric Day Treatment Facility	—	378
g. Joint Venture Imaging Clinic in Medically Underserved Area	—	378
h. Joint Venture Rural Medical Practice [New Topic]	—	379
2. Advisory Opinions Regarding Ambulatory Surgical Centers	—	379
a. Joint Venture Between Orthopedic Surgeons and Anesthesiologist to Establish an Ambulatory Surgical Center	—	379
i. Structure of the Ambulatory Surgical Center	—	380
ii. Referrals to the Ambulatory Surgical Center	—	380
iii. Technical Violation but No Sanctions	—	380
iv. Implications for Counsel	—	381
b. Joint Venture Ambulatory Surgical Center Coupled With Rental Agreement and Personal Services Contracts With Investors	—	382
i. Implications for Counsel	—	383
c. Ambulatory Surgical Center Jointly Owned by a Hospital and Physicians	—	384
d. Physician-Owned Ambulatory Surgical Centers	—	386
3. Arrangements Between Hospitals and Physicians or Physician Groups (That Do Not Involve Joint Ventures)	—	387
a. Sharing of Enhanced Profits Resulting From Cost-Cutting Implemented by a Hospital and a Physician Group	—	388
b. Physician Recruitment Payments by a Hospital to Encourage Physician Relocation	—	390
c. Hospital Payments for On-Call Coverage Designed to Enhance Emergency Services Coverage	—	392
4. The Orthopedic Consignment and Loaner Program—The Effect of Insufficient Facts	—	392
a. Problems With the Percentage Compensation ...	—	395
b. Problems With the Training Services Clause	—	395
c. Problems With the Loaner Program	—	395
d. Implications for Counsel	—	396

	<u>Main Volume</u>	<u>Supple- ment</u>
5. Discount Pharmaceutical Arrangement	—	396
a. Implications for Counsel	—	398
6. Discounted Ambulance Services When Bundled With Services Paid for by Medicare	—	399
a. Implications for Counsel	—	400
7. Bundled Pricing in the Sale of Therapeutic Mattresses to Skilled Nursing Facilities	—	401
a. Pricing Bundling	—	402
b. Independent Sales Representatives	—	402
c. Implications for Counsel	—	403
8. Leases and Other Business Arrangements and Patient Referrals Between Physicians	—	404
a. Ophthalmologist to Optometrist	—	404
i. Implications for Counsel	—	405
b. Oncologists and Urologists [New Topic]	—	406
9. Independent Provider Association Ownership Interest in a Managed Care Organization	—	407
a. Implications for Counsel	—	409
10. Podiatry Provider Network Assuming Employer’s Copayment Obligations for Supplemental Coverage	—	409
11. Network Payments for Provider Referrals	—	411
12. Payment of Fee for the Referral of Elderly Patients for Housing, Including Nursing Homes	—	411
a. Implications for Counsel	—	413
13. Insurance Guarantee Plan for Injectable Pharmaceutical	—	413
a. Implications for Counsel	—	414
14. Referral and Payment Arrangement Between a Hospice and a Nursing Home for Dually Eligible Individuals	—	415
15. Durable Medical Equipment Supplier’s Discount Practices	—	416
16. Arrangements That Involve Internet Advertising ...	—	417
a. Implications for Counsel	—	419
D. Miscellaneous Opinions	—	419
1. Business Arrangements That Create or Cause Price or Service Differentials in the Care Provided to Federal Program Beneficiaries Versus Privately Insured Patients	—	419
a. Charging Higher Prices to Medicare Program Beneficiaries	—	419
i. Implications for Counsel	—	420
b. Swapping Discounted Nonfederal Business for Nondiscounted Federal Business	—	421
i. Implications for Counsel	—	422
c. Incentive Payments to Change Quality of Care Provided to Private Patients [New Topic]	—	423
2. Giving Something of Value in Absence of Ability to Make Referrals	—	423

	<u>Main Volume</u>	<u>Supple- ment</u>
3. Pay-to-Play and Other Fees Charged by a Municipality in Exchange for Ambulance Service Rights	—	424
4. Incentives Offered to Employees in a Collective Bargaining Agreement	—	425
5. Group Purchasing Organization Safe Harbor Applied to Electricity Purchases	—	426
6. Outpatient Pharmacy Program Implemented Under the Veterans Health Care Act	—	427
7. Contribution by Pharmaceutical Company to Charitable Organization	—	427
8. Advisory Opinions Concerning Marketing Programs	—	428
a. Management and Marketing Services for Physician-Owned Clinic	—	428
i. Implications for Counsel	—	429
b. “White Coat” Marketing Program	—	430
c. Incentives Offered to Induce Physicians to Complete Marketing Surveys	—	431
9. Percentage Payments to Consultants Reviewing Provider Billings	—	431
a. Implications for Counsel	—	432
10. Payments to Employees and Independent Contractors	—	433
a. Payments to Employees to Encourage Cost Savings	—	433
b. Payments to Referring Physician by Nursing Home for Continuing Consultation	—	433
c. Sharing Credit Card Frequent Use Points With Employees	—	434
d. Incentive Payments to Independent Manufacturer’s Representative	—	434
i. Implications for Counsel	—	435
e. Payments to Part-time Physicians [New Topic]	—	435
11. Golf Tournament Paid for by Referral Sources	—	436
a. Implications for Counsel	—	436
12. Warranty on Bundled Product	—	437
a. Implications for Counsel	—	438
13. Advisory Opinions Regarding Employment of Excluded Individuals	—	438
a. Employment of Excluded Physician in a Nontreatment Role	—	438
b. Employment of Excluded Physician for Business Development	—	439
c. Comment	—	440
d. Transfer of Invention of Excluded Individual to Independent Corporation	—	440
14. Automatic Refund in the Event of Denial of Medicare Coverage	—	441
15. Business Reorganization	—	441

	<u>Main Volume</u>	<u>Supple- ment</u>
16. “Per Patient,” “Per Click,” and “Per Order” Management Fees	—	441
17. Malpractice Insurance Subsidy by Hospital to Specific Individual Physicians	—	442
IV. Conclusion	—	443

PART IV THE INVESTIGATION AND CHARGING DECISION

CHAPTER 9. THE INVESTIGATION	347	447
I. Introduction	348	—
A. The Prosecutor’s Perspective	349	—
B. The Defense Perspective	350	—
II. Civil Versus Criminal Enforcement	350	—
A. The Rise and Fall of <i>Halper</i>	351	—
B. <i>Qui Tam</i> Provisions	353	—
C. Grand Jury Secrecy	353	—
III. Investigative Tools and Techniques	354	449
A. Audit Data and Analysis	355	—
1. Audit Data	355	—
2. Audit Analysis	355	—
B. Subpoenas for Documents	357	449
1. Types of Subpoenas	358	449
a. Grand Jury Subpoenas	358	449
i. Subpoena Duces Tecum Request	358	—
ii. Secrecy	359	449
b. Inspector General Subpoenas	361	—
i. Scope of Subpoena	361	—
ii. Secrecy	362	—
iii. Enforcement	363	—
c. Administrative Subpoenas in Criminal Health Care Fraud Cases	364	450
i. Appealability [New Topic]	—	451
ii. Enforcement of Administrative Subpoenas [New Topic]	—	451
2. Responding to a Subpoena	366	452
a. Time for Production	367	—
b. Form of Production	368	—
c. Burdensomeness Challenges [New Topic]	—	452
C. Privileges	369	453
1. Attorney-Client Privilege	369	454
a. Availability of the Privilege	370	454
b. Assertion of the Privilege	370	—
c. Waiver of the Privilege	372	454
d. The Crime-Fraud Exception	372	—
2. Fifth Amendment Privilege	373	—
3. Psychotherapist-Patient Privilege	374	—
4. Peer Review Privileges [New Topic]	—	455
D. Confidentiality Issues	376	456

	<u>Main Volume</u>	<u>Supple- ment</u>
1. Confidentiality of Alcohol and Drug Abuse Patient Records	376	456
2. Patient Confidentiality Under State Law	380	—
3. Confidentiality Under HIPAA [New Topic]	—	457
a. Purpose of the Rules [New Topic]	—	458
b. Structure of the Regulations: The Prohibition [New Topic]	—	459
i. “Covered Entity” [New Topic]	—	459
ii. “Business Associate” [New Topic]	—	459
iii. “Protected Information” [New Topic]	—	460
c. Structure of the Regulations: Exceptions to the Rule and Other Requirements [New Topic]	—	461
d. Limitation on the Scope of the Regulations [New Topic]	—	463
e. Relevant Permitted and Required Uses and Disclosures [New Topic]	—	463
i. Disclosures by Whistleblowers [New Topic]	—	463
ii. Disclosures to Health Oversight Agencies and Law Enforcement [New Topic]	—	464
f. Interaction With the Food, Drug, and Cosmetic Act [New Topic]	—	467
g. Marketing [New Topic]	—	467
i. Implications for Counsel [New Topic]	—	469
E. Search Warrants	380	470
1. Probable Cause	381	473
2. Execution of the Warrant	383	474
a. Potentially Privileged Materials at the Search Site	383	476
b. Computers at the Search Site	384	476
c. Access to Patient and Financial Records	384	—
3. Photographs and Videotapes	385	—
4. Interviews	385	—
5. Length of Search	385	—
6. Rule 41 Motion	386	—
7. Standing to Challenge Search [New Topic]	—	477
8. Consent to Search [New Topic]	—	479
F. Administrative Searches [New Topic]	—	479
G. Trash Runs [Renumbered Topic (Formerly III.F.)]	386	480
H. Obtaining Documents From Witnesses [Renumbered Topic (Formerly III.G.)]	386	480
I. Witness Testimony [Renumbered Topic (Formerly III.H.)]	387	480
1. Contacting Represented Persons or Parties	387	—
2. Grand Jury Testimony	389	—
3. <i>Qui Tam</i> Relators	391	—
4. Civil Investigative Demands	392	—
J. Recordings [Renumbered Topic (Formerly III.I.)]	392	481
1. Consensual Recordings	392	481
2. Wiretaps	393	482
IV. Conclusion	394	—

	<u>Main Volume</u>	<u>Supple- ment</u>
Main Volume Footnote Updates	—	483
CHAPTER 10. THE CHARGING DECISION [SUBSTITUTE TEXT: THIS CHAPTER REPLACES CHAPTER 10 IN THE MAIN VOLUME.]	—	485
I. Introduction	—	487
II. Statutory Offenses	—	488
A. Title 18 Offenses: The General Conspiracy Statute	—	489
1. Conspiracy Statute, 18 U.S.C. §371	—	489
a. Objects of the Conspiracy	—	490
b. Manner and Means of the Conspiracy	—	492
c. Overt Acts	—	492
d. Strategic Opportunities for the Prosecution	—	492
B. Title 18 Offenses Involving Fraud Schemes	—	494
1. Mail Fraud, 18 U.S.C. §1341	—	495
2. Wire Fraud, 18 U.S.C. §1343	—	499
3. Health Care Fraud, 18 U.S.C. §1347	—	500
a. Purpose of the Statute	—	501
b. “Willfully”	—	502
c. “Executes or Attempts to Execute”	—	502
d. “Scheme or Artifice to Defraud”	—	503
e. “In Connection With the Delivery”	—	504
f. Affecting Commerce	—	505
g. Vagueness Challenge	—	505
h. Implications for Counsel	—	505
C. Title 18 Offenses Involving False Claims and False Statements	—	506
1. False Claim to the United States, 18 U.S.C. §287, and the Related Conspiracy Statute, 18 U.S.C. §286	—	506
a. 18 U.S.C. §287	—	506
b. 18 U.S.C. §286	—	510
2. False Statements to the United States, 18 U.S.C. §1001	—	511
3. False Statements Relating to Health Care Matters, 18 U.S.C. §1035	—	513
D. Title 18 Offenses Involving Theft or Bribery	—	514
1. Theft or Bribery Concerning Programs Receiving Federal Funds, 18 U.S.C. §666	—	514
2. Theft or Embezzlement in Connection With Health Care, 18 U.S.C. §669	—	517
E. Title 18 Offenses Involving Obstruction of Audits and Investigations	—	518
1. Obstruction of Agency Investigations, 18 U.S.C. §§1505 and 1503	—	518
2. Obstruction of Criminal Investigations, 18 U.S.C. §1510	—	520
3. Obstruction of Federal Audit, 18 U.S.C. §1516	—	520

	<u>Main Volume</u>	<u>Supple- ment</u>
4. Obstruction of Criminal Investigations of Health Care Offenses, 18 U.S.C. §1518	—	521
F. Offense Traditionally Charged Under Title 21	—	521
1. Unlawful Distribution of a Controlled Substance, 21 U.S.C. §841(a)(1)	—	521
G. The Title 42 Medicare/Medicaid Fraud Statutes	—	524
1. Making or Causing to Be Made False Statements or Representations, 42 U.S.C. §1320a-7b(a)	—	525
2. The Medicare/Medicaid Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b)	—	528
3. False Statements or Representations With Respect to Condition or Operation of Institutions, 42 U.S.C. §1320a-7b(c)	—	531
4. Illegal Patient Admittance and Retention Practices, 42 U.S.C. §1320a-7b(d)	—	531
5. Violation of Assignment Terms, 42 U.S.C. §1320a-7b(e)	—	531
6. Wrongful Disclosure of Individually Identifiable Health Information Under HIPAA, 42 U.S.C. §1320d-6	—	532
a. “In Violation of This Part”	—	532
b. Felony Intent	—	533
H. Criminal Forfeiture Involving Health Care Offenses	—	534
1. Criminal Forfeiture, 18 U.S.C. §982(a)(7)	—	534
III. Special Statute of Limitations	—	536
IV. Implications for Counsel	—	537
Figure 10.1. Potential Exposure to Criminal Health Care Fraud Charges	—	538

PART V SETTLEMENT AND LITIGATION

CHAPTER 11. GLOBAL RESOLUTIONS	433	541
I. Introduction	433	542
II. Overview of Global Resolutions	434	542
A. Determining the Government’s Case	434	—
B. Approaching the Government	435	542
1. Civil Investigations	435	—
2. Criminal Investigations	436	—
3. Program Exclusions	437	542
a. Mandatory Exclusion	437	—
b. Permissive Exclusion	439	542
III. Negotiating a Global Resolution	441	543
A. Individual Defendants	442	544
B. Corporate Defendants	443	545
1. Criminal Resolutions	443	548
2. Civil Resolutions	445	—
3. Corporate Integrity Agreements	446	549
4. Corporate Compliance Plans [New Topic]	—	550
C. Administrative Exclusion	447	551

	<u>Main Volume</u>	<u>Supple- ment</u>
D. Exposure to State Criminal Charges	448	—
E. Other Potential Consequences	451	552
IV. Conclusion	451	—
Appendix 11-A—Health Care Fraud Settlements of at Least \$1 Million (1991–2009)	—	11-A-1

**CHAPTER 12. CRIMINAL TRIAL [SUBSTITUTE TEXT: THIS
CHAPTER REPLACES CHAPTER 12 IN THE MAIN
VOLUME.]**

I. Introduction	—	555
II. Trial Strategy	—	557
A. Prosecution Theory	—	558
B. Defense Theory	—	561
C. Practice Pointers	—	562
1. Overview	—	562
2. The Pretrial Skirmishing	—	563
3. The Post-Guilty-Verdict Motion for a New Trial or for Acquittal	—	566
4. Particular Cases	—	567
a. An Unsuccessful Defense: The Regulations Were Too Ambiguous	—	567
b. A Successful Defense: Defendants’ Interpretation of Regulation Was Reasonable ...	—	569
c. Prosecution Focus on Defendant’s Intent to Defraud Amidst Confusing Rules	—	570
d. Conflicting Expert Interpretations of the Governing Regulation	—	571
e. Intent to Cheat Versus “My Interpretation Must Be Reasonable Because Everyone Is Doing It”	—	572
f. “Greedy Doctor Performing Unnecessary Surgeries” Versus “Kind, Caring Practitioner” [New Topic]	—	574
III. Common Evidentiary Issues	—	576
A. Medical Experts	—	579
B. Billing and Regulatory Experts	—	580
1. Billing Experts	—	580
2. Regulatory Experts	—	582
C. Audit Data	—	584
1. In General	—	584
2. Presenting Audit Data	—	585
a. Billing Information	—	585
b. Statistical Inferences	—	586
i. Statistical Profiles	—	586
ii. Statistical Sampling	—	588
c. Summary Charts	—	590
D. Evidence of Past Regulatory Violations and Global Settlements	—	591

	<u>Main Volume</u>	<u>Supple- ment</u>
IV. Common Defenses and Rebuttals	—	592
A. Lack of Knowledge or Intent Defense	—	593
1. The Provider Was Unaware	—	593
2. Rules and Regulations Are Ambiguous, Complex, or Confusing	—	598
3. Risks Associated With Asserting Lack of Knowledge or Intent Defense	—	601
B. The “Happy Patient” Defense	—	602
1. Evidence That Alleged Fraud Did Not Occur	—	602
2. Evidence to Determine Scope of Fraud	—	603
3. Evidence on the Medical Necessity of the Services	—	603
C. The Entrapment-by-Estoppel Defense	—	604
V. Jury Instructions	—	606
A. The Good Faith Instruction	—	606
B. The Conscious Avoidance Instruction	—	609
VI. Conclusion	—	611

**CHAPTER 13. SENTENCING [SUBSTITUTE TEXT: THIS CHAPTER
REPLACES CHAPTER 13 IN THE MAIN
VOLUME.]**

I. Introduction	—	613
II. The Federal Sentencing Process	—	617
A. Scheduling and the Presentence Report	—	617
B. Notice of Issues and the Sentencing Hearing	—	618
III. The Sentencing of Individuals	—	621
A. Sentence Enhancements	—	623
1. Loss Enhancement	—	623
a. Loss and Unlicensed Providers	—	627
b. Loss and Relative Culpability	—	629
c. Loss and the Identity of the Victim	—	631
d. Loss Where No Direct Financial Loss Presents	—	632
i. Loss and the Sale of Adulterated Products	—	633
ii. Loss in Kickback Cases	—	636
e. Calculating the Loss	—	638
f. Offenses Otherwise Involving Sophisticated Means	—	642
g. Offenses Involving Multiple Victims or Mass Marketing	—	644
2. Role in the Offense	—	645
3. Use of Special Skill	—	650
4. Abuse of Position of Trust	—	653
a. General Application	—	653
b. Abuse of Trust and the Necessity of a License	—	660
5. Taking Advantage of Vulnerable Victims	—	661
6. Reckless Endangerment	—	665

	<u>Main Volume</u>	<u>Supple- ment</u>
7. Obstruction of Justice	—	667
B. Sentence Reductions	—	669
1. Minimal Role in the Offense	—	669
2. Acceptance of Responsibility	—	669
C. Sentences Outside the Guideline Sentencing Range	—	670
1. Departures	—	671
a. Upward Departures	—	672
b. Downward Departures	—	674
i. Collateral Consequences and Prior Good Works	—	676
ii. Diminished Capacity	—	679
2. Deviations	—	680
a. “The Nature and Circumstances of the Offense” [New Topic]	—	680
b. The History and Characteristics of the Defendant [New Topic]	—	681
c. The Need for the Sentence Imposed to Meet Certain Criteria [New Topic]	—	682
d. Additional §3553 Factors [New Topic]	—	683
D. Financial Consequences	—	685
1. Fine	—	685
2. Restitution	—	686
E. Unusual Sentences	—	687
IV. The Sentencing of Organizations	—	688
A. Principles Guiding Federal Sentencings	—	690
1. Remedy the Harm	—	691
2. Determine the Fine Range	—	692
a. Determining the Fine Within the Range	—	693
b. Payment of the Fine	—	694
3. Impose Probation	—	695
B. Assess Costs of the Prosecution	—	696
V. Conclusion	—	697
APPENDIX LIST	539	699
Appendix A: Civil False Claims Act (31 U.S.C. §§3729–3733)	541	—
Appendix A-1: Civil False Claims Act (31 U.S.C. §§3729–3733), as Amended [by FERA]	—	701
Appendix B: The Anti-Kickback Statute (42 U.S.C. §1320a- 7b(b))	559	719
Appendix C: Stark Self-Referral Law (42 U.S.C. §1395nn)	563	723
Appendix D: Table of State Laws Restricting Referrals by Health Care Providers and Providing for False Claims Causes of Actions [False Claims Entries New in Supplement]	575	735
Appendix E-1: Office of Inspector General (Department of Health and Human Services) Anti-Kickback Advisory Opinions: Cumulative Index by Opinion Number	585	—

Detailed Table of Contents

xxxiii

	<u>Main Volume</u>	<u>Supple- ment</u>
Appendix E-2: Office of Inspector General (Department of Health and Human Services) Anti-Kickback Advisory Opinions: Cumulative Index by Subject Matter	588	—
Appendix E-3: Office of Inspector General (Department of Health and Human Services) Anti-Kickback Advisory Opinions: Full Text of Opinions	591	—
Appendix F: Selected Text From Privacy Regulations (Department of Health and Human Services): Disclosure of Patient Information	925	747
Appendix 1: Exclusion From Participation in Government Health Care Programs (42 U.S.C. §1320a-7)	—	751
Appendix 2: Criminal Penalties for Acts Involving Federal Health Care Programs (42 U.S.C. §1320a-7b(a), (c)–(f))	—	761
Appendix 3: False Claims Act Enforcement and Anti-Kickback Statute Violations: Letter From Center for Medicare and Medicaid Services (CMS) and Department of Justice to Congress (July 23, 2002)	—	765
Table of Cases	929	769
Subject Index	939	787

