

TABLE OF CONTENTS

VOLUME ONE

Authors	iii
Introduction	v

CHAPTER 1

Overview of Health Care Fraud

§ 1.01	Introduction	1-3
	[1] Health Care Fraud: The Problem	1-3
	[a] Economic Impact & Projections	1-3
	[b] Negative Health Outcomes Among Medicare Beneficiaries	1-7
	[2] Health Care Fraud: Criminal, Civil, and Administrative Law	1-10
	[3] The Consequences of Being Found Liable for Health Care Fraud	1-14
§ 1.02	Historical Development of American Medicine	1-18
	[1] Early Healthcare Systems in the America	1-18
	[2] Development of the Modern American Healthcare System	1-19
	[a] Medicare	1-23
	[b] Medicaid	1-31
	[c] Becoming a Medicare or Medicaid Provider	1-34
	[3] Fraud and Abuse in the Healthcare System	1-34
	[a] Enforcement Waned Under First Trump Administration	1-36
	[b] Biden Administration Posted Initial Record Recovery, Then Continued Trump's Downward Trend	1-38.2
	[c] Opioid Crisis	1-38.3

HEALTH CARE FRAUD

	[d]	Telemedicine and Other New Technology	1-38.5
	[e]	COVID-19 Pandemic and the CARES Act of 2020.	1-38.8
	[f]	CARES Act Fraud Enforcement	1-38.12
	[g]	Healthcare Fraud Expected to Continue Downward Trend but Remain Nation’s Dominant Economic, Legal and Social Issue. . .	1-38.13
§ 1.03		Economics and Health Care	1-38.15
	[1]	The Changing Economics of American Health Care.	1-38.15
	[2]	Impact of Changing Economics on Health Care Fraud	1-40
	[a]	Fee for Service Reimbursement	1-40
	[b]	Capitation Reimbursement.	1-41
	[i]	False Cost Data.	1-42
	[ii]	Registration of Fictitious Enrollees	1-42
	[iii]	Failure to Provide Necessary Services	1-42
§ 1.04		Characteristics of Health Care Fraud.	1-44
	[1]	Hybrid Civil/Criminal Nature.	1-44
	[2]	Difficulty of Investigating and Proving Health Care Fraud	1-44.4
§ 1.05		Investigatory and Enforcement Agencies and Organizations.	1-44.9
	[1]	Federal Agencies	1-44.9
	[a]	Department of Justice	1-44.9
	[b]	Department of Health and Human Services (HHS).	1-44.12
	[i]	Office of Inspector General	1-44.12
	[ii]	Centers for Medicare and Medicaid Services (CMS).	1-44.14
	[c]	Inspector General, Railroad Retirement Board (IG/RRB)	1-44.15
	[d]	Inspector General, Office of Personnel Management (IG/OPM)	1-44.15
	[e]	The Defense Criminal Investigative Service (DCIS)	1-44.15
	[f]	The Federal Bureau of Investigation (FBI)	1-44.16
	[g]	The Postal Inspection Service.	1-44.16
	[h]	The Drug Enforcement Administration (DEA)	1-44.17

TABLE OF CONTENTS

[i] Inspector General, Department of Labor (IG/Labor) 1-44.17

[2] State Agencies 1-44.18

[a] Medicaid Fraud Control Units (MFCUs) 1-44.18

[b] Licensing Boards 1-44.19

[3] Private Insurance Companies 1-44.19

§ 1.06 Bibliography 1-45

CHAPTER 2

Types of Fraud by Health Care Providers

§ 2.01 Introduction 2-2

§ 2.02 Program Integrity Fraud 2-5

[1] National Provider Identification Numbers 2-7

[2] Medicare Fee-for-Service (Parts A and B) 2-7

[3] Medicare Managed Care (Parts C and D) 2-10

[4] Medicaid 2-11

§ 2.03 Fraudulent Billing 2-13

[1] Billing for Services Not Provided 2-14

[2] Billing for Services Not Reasonable and Necessary (the “Medical Necessity” Requirement) 2-17

[3] Misrepresentation of Services—Upcoding, Unbundling, and Duplicate Billing 2-24

[a] Upcoding 2-26

[b] Bundling 2-29

[c] Other Misrepresentation 2-31

[4] Cost Report Fraud 2-32

[5] Retaining Overpayments 2-35

[a] Historical Basis for Repayment 2-36

[b] The Federal Overpayment Statute 2-38

[c] Other Bases for Repayment 2-38

[6] Medicare Secondary Payor 2-39

[7] Off-Label Promotion 2-41

[8] Electronic Health Records 2-42.2

[a] Misrepresentation of Services 2-42.2

[9] Medicare Advantage (Medicare Part C) 2-42.3

§ 2.04 Kickbacks and Self-Referrals 2-42.6

[1] Overview of the Anti-Kickback and Stark Laws 2-42.6

[a] General Considerations 2-42.6

HEALTH CARE FRAUD

	[b]	The Anti-Kickback and Stark Laws and Their Relationship to the False Claims Act	2-43
	[c]	Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”).	2-45
	[2]	Miscellaneous Prohibitions of Improper Remuneration	2-46.1
	[a]	The Beneficiary Inducements Statute	2-46.1
	[b]	Federal Program Bribery	2-46.2
	[c]	HIPAA All-Payor Criminal Offenses.	2-46.2
	[d]	Antitrust and Unfair Competition Considerations.	2-46.3
	[e]	State Anti-Kickback and Self-Referral Statutes	2-46.4
	[f]	State Unfair Competition Statutes. . .	2-46.7
§ 2.05		Research Fraud	2-47
	[1]	Federally Funded Research	2-47
	[2]	Special Issues Relating to Human Subjects	2-53
	[3]	Reimbursement in Connection with Research Patients	2-56
	[4]	Anti-Kickback Issues in Research	2-59
	[5]	Conflicts of Interest in Medical Research	2-60
	[6]	Other Forms of Fraud	2-64

CHAPTER 3**Criminal Causes of Action**

§ 3.01		Introduction	3-6
§ 3.02		Offenses Against Federal Health Care Programs	3-10
	[1]	The Health Care Antikickback Statute: 42 U.S.C. § 1320a-7b(b).	3-10
	[a]	History	3-11
	[b]	Key Elements of the Offense.	3-19
	[i]	Remuneration and Inducement	3-19
	[ii]	Knowing and Willful Intent. . .	3-28.1
	[c]	Statutory Exemptions.	3-28.2
	[d]	Safe Harbor Regulations	3-32

TABLE OF CONTENTS

[i] Investment Interests in Large Entities, Small Entities, and Underserved Areas. 3-37

[ii] Space Rental. 3-41

[iii] Equipment Rental. 3-42

[iv] Personal Services and Management Contracts. 3-42

[v] Sale of Practice Including Sales in Health Professional Shortage Areas 3-43

[vi] Referral Services 3-44

[vii] Warranties. 3-44

[viii] Discounts 3-45

[ix] Employees. 3-46.3

[x] Group Purchasing Organizations (GPOs) 3-46.4

[xi] Waivers of Coinsurance and Deductibles 3-47

[xii] Benefits Offered by Health Plans: Increased Coverage, Reduced Cost-Sharing, Reduced Premiums. 3-48

[xiii] Price Reductions Offered to Health Plans. 3-49

[xiv] Practitioner Recruitment in Health Professional Shortage Areas 3-50

[xv] Obstetrical Malpractice Insurance Subsidies 3-52

[xvi] Investment in Group Practices Safe Harbor. 3-52

[xvii] Cooperative Hospital Service Organizations 3-53

[xviii] Ambulatory Surgical Centers 3-53

[xix] Specialty Referral Agreements Between Providers 3-55

[xx] Managed Care Exceptions. 3-56

[xxi] Safe Harbor for Restocking of Ambulances 3-62

[xxii] Safe Harbor for Health Centers 3-63

[xxiii] Safe Harbor for Electronic Prescribing Items and Services. 3-65

HEALTH CARE FRAUD

[xxiv]	Safe Harbor for Electronic Health Records Items and Services	3-66
[xxv]	Safe Harbor for Federally Qualified Health Centers and Medicare Advantage Organizations	3-67
[xxvi]	Safe Harbor for Medicare Coverage Gap Discount Program.	3-67
[xxvii]	Safe Harbor for Local Transportation.	3-68
[xxviii]	Safe Harbor for Care Coordination Arrangements	3-68
[xxix]	Safe Harbor for Value-Based Arrangements With Substantial Downside Financial Risk	3-70
[xxx]	Safe Harbor for Value-Based Arrangements With Full Financial Risk	3-70
[xxxi]	Safe Harbor for Patient Engagement and Support	3-71
[xxxii]	Safe Harbor for CMS-Sponsored Model Arrangements and Patient Incentives	3-72
[xxxiii]	Cybersecurity Technology and Services Donations Safe Harbor.	3-73
[xxxiv]	ACO Beneficiary Incentive Program.	3-73
[e]	Civil Remedies	3-74
[f]	Enforcement	3-74
[i]	Government Enforcement	3-74
[ii]	OIG Fraud Alerts	3-77
[iii]	HHS Antikickback Advisory Opinions and Public Safe Harbor Requests	3-82
[iv]	Private Enforcement.	3-82.1
[2]	False Statements Relating to Health Care Matters.	3-82.4

TABLE OF CONTENTS

xiii

	[a]	False Statements in Applications for Benefits: 42 U.S.C. § 1320a-7b(a)(1)	3-82.4
		[i] Knowingly and Willfully	3-82.4
		[ii] Making or Causing to Be Made	3-82.5
		[iii] False as to a Material Fact	3-82.6
		[iv] Use with Other Statutes	3-82.7
	[b]	Disposing of Assets to Obtain Medicaid Coverage: 42 U.S.C. § 1320a-7b(a)(6)	3-83
	[3]	Health Care Fraud: 18 U.S.C. § 1347	3-84
	[4]	Theft or Embezzlement in Connection with Health Care Fraud: 18 U.S.C. § 669	3-86
	[5]	False Statements Relating to Health Care Matters: 18 U.S.C. § 1035	3-87
	[6]	Obstruction of Criminal Investigations of Health Care Offenses: 18 U.S.C. § 1518	3-88
	[7]	Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”): 18 U.S.C. § 220	3-89
		[a] History	3-90
		[b] Elements of the Offense	3-91
		[c] Exceptions	3-92
		[d] EKRA, the Antikickback Statute, Stark, and State Laws	3-93
§ 3.03	Other	Federal Offenses	3-95
	[1]	Submitting False Claims: 18 U.S.C. § 287	3-95
		[a] The Elements	3-96
		[i] Making or Presenting a Claim	3-96
		[ii] False, Fictitious, or Fraudulent	3-97
		[iii] Materiality	3-98
		[iv] To a Department or Agency of the United States	3-99
		[v] At the Time the Claim Is Made, the Person Presenting It Knows It Is False, Fictitious, or Fraudulent	3-99
	[b]	Duplicity and Multiplicity	3-100

HEALTH CARE FRAUD

	[c]	Relationship to the False Claims Act, 31 U.S.C. §§ 3729 <i>et seq.</i>	3-101
[2]		False Statements: 18 U.S.C. § 1001	3-103
	[a]	Knowingly and Willfully.	3-104
	[b]	Materiality	3-105
	[c]	Concealment: Duty to Disclose.	3-107
	[d]	Falsity	3-108
	[e]	“Within the Jurisdiction of Any Department or Agency of the United States”.	3-108
	[f]	Venue	3-109
[3]		Mail Fraud and Wire Fraud: 18 U.S.C. §§ 1341 and 1343	3-110
	[a]	Scheme or Artifice to Defraud	3-111
	[b]	Intent.	3-114
	[c]	Materiality	3-114
	[d]	Use of the Mails in Execution of the Scheme	3-114
[4]		The General Anti-Kickback Act: 41 U.S.C. § 53	3-116
	[a]	Prime Contract	3-117
	[b]	Subcontract.	3-118
[5]		Money Laundering: 18 U.S.C. §§ 1956, 1957	3-119
	[a]	Elements of Section 1956	3-120
	[b]	Elements of Section 1957	3-124
[6]		RICO: 18 U.S.C. §§ 1961 <i>et seq.</i>	3-125
	[a]	Definitions	3-127
	[b]	Prohibited Conduct.	3-130
	[c]	Criminal Penalties	3-131
[7]		Conspiracy	3-132
	[a]	In General.	3-132
	[b]	18 U.S.C. § 371	3-134
	[i]	Conspiracy to Commit Any Offense Against the United States.	3-135
	[ii]	Conspiracy to Defraud the United States.	3-135
	[c]	18 U.S.C. § 286	3-138
[8]		Theft of Government Property: 18 U.S.C. § 641	3-139
[9]		Obstruction of Justice	3-140
	[a]	18 U.S.C. § 1503	3-141
	[b]	18 U.S.C. § 1505	3-142
	[c]	18 U.S.C. § 1512.	3-143
	[d]	18 U.S.C. § 1622	3-144.2

TABLE OF CONTENTS

	[10] Federal Program Fraud:	
	18 U.S.C. § 666	3-144.3
	[11] The Travel Act: 18 U.S.C. § 1952.	3-144.5
	[a] Path to Federal Jurisdiction for State Law Claims	3-144.5
	[b] The Elements	3-144.6
	[c] Application	3-144.7
§ 3.04	Sentencing for Federal Offenses.	3-144.9
	[1] Sentencing Individuals.	3-145
	[a] Determining “Base Offense Level”	3-146
	[b] Adjustments to the Base Offense Level	3-148.1
	[c] Criminal History	3-150
	[d] Departures	3-150
	[e] Calculating the Sentence from the Guidelines.	3-151
	[2] Sentencing Organizations	3-152
	[3] Forfeiture	3-154
	[a] Procedural Issues	3-154
	[b] Substantive Issues	3-155
§ 3.05	State Offenses	3-157
	[1] Conspiracy	3-157
	[2] Medicaid Fraud	3-157
	[3] Anti-Kickback and Anti-Self-Referral Statutes	3-163
	[4] Theft, Larceny, Etc.	3-163
	[5] Difficulties Encountered in State Prosecutions	3-164
	[6] Sentencing	3-167
	[7] Federal Jurisdiction for Violations of State Law	3-168
§ 3.06	Criminal Liability for Corporations.	3-171
	[1] The Standards of Corporate Criminal Liability.	3-171
	[2] The Doctrine of Collective Intent.	3-175
	[3] Criminal Liability of Successor Corporations	3-177
	[4] Department of Justice Guidelines Regarding the Federal Prosecution of Corporations.	3-178
	[a] Nature and Seriousness of the Offense	3-181
	[b] Pervasiveness of Wrongdoing	3-181
	[c] History of Similar Conduct.	3-181

HEALTH CARE FRAUD

	[d]	Cooperation and Voluntary Disclosure	3-182
	[e]	Corporate Compliance Programs . . .	3-183
	[f]	Restitution and Remedial Actions . . .	3-185
	[g]	Collateral Consequences	3-185
	[h]	Noncriminal Alternatives	3-186
	[i]	Selecting Charges	3-186
	[j]	Plea Agreement	3-186
	[5]	Deferred Prosecution Agreements	3-187
§ 3.07		General Defenses	3-189
	[1]	The Fair Warning Requirement	3-189
	[a]	Common Understanding vs. Specialized Learning	3-190
	[b]	<i>Mens Rea</i> and Fair Warning	3-193
	[c]	Application of the Fair Warning Requirement to Economic and Public Health Regulations	3-193
	[2]	Advice of Counsel	3-194
	[3]	The Rule of Lenity	3-196
§ 3.08		Bibliography	3-197

CHAPTER 4**Civil Causes of Action**

§ 4.01		The False Claims Act: Elements of an FCA Action	4-6
	[1]	Introduction	4-6
	[2]	Application of FERA Amendments of 2009	4-8
	[3]	FCA Elements	4-8
	[a]	<i>Mens Rea</i>	4-8
	[b]	Claim	4-12
	[c]	Prohibited Conduct	4-14
	[i]	Presenting a False Claim (Section 3729(a)(1)(A))	4-14
	[ii]	Making/Using a False Statement Material to a False Claim (Section 3729(a)(1)(B))	4-16.1
	[iii]	Conspiracy Involving False Claims (Section 3729(a)(1)(C))	4-16.1
	[iv]	Embezzlement by Government Contractors (Section 3729(a)(1)(D))	4-17

TABLE OF CONTENTS

xvii

	[v]	False Certification of Deliveries to the Government (Section 3729(a)(1)(E)).	4-18
	[vi]	Purchases on the “Black Market” (Section 3729(a)(1)(F)).	4-18
	[vii]	“Reverse False Claims” Avoiding an Obligation Owed to the Government (Section 3729(a)(1)(G)).	4-19
	[d]	False or Fraudulent.	4-21
	[i]	Theories of Falsity	4-25
	[ii]	Materiality.	4-28
	[e]	Presentment of Use of a “Claim”	4-32
	[f]	Damages	4-33
§ 4.01A	FCA	<i>Qui Tam</i> Provisions	4-34
	[1]	Background.	4-34
	[2]	Constitutionality.	4-37
	[3]	The Public Disclosure Bar and Original Source Exception	4-42
	[a]	Background of the Public Disclosure Bar	4-42.1
	[b]	Public Disclosure of Allegations.	4-45
	[i]	Public Disclosure of Claims Filed Prior to Patient Protection and Affordable Care Act.	4-45
	[ii]	Public Disclosure of Claims Filed After the Patient Protection and Affordable Care Act.	4-49
	[c]	“Original Source”.	4-51
	[i]	“Independent of”	4-53
	[ii]	“Materially Adds”	4-53
	[d]	Government Veto of Public Disclosure Dismissal	4-55
	[4]	Reconciling Sections 3730(e)(4) and 3730(d)(1).	4-56
	[5]	The “First-to-File Rule”.	4-57
	[6]	Government Employees as <i>Qui Tam</i> Plaintiffs	4-59
	[7]	Rights of the Parties in <i>Qui Tam</i> FCA Lawsuits	4-61
	[a]	Rights of the Government	4-61

HEALTH CARE FRAUD

		[i] Seal and Intervention	4-61
		[ii] Right to Dismiss.	4-62
		[iii] Alternate Remedy Provision.	4-65
		[iv] United States Authority to Veto Settlement.	4-66
	[b]	Rights of the Relator	4-68
	[c]	Rights of the Defendant.	4-72.1
§ 4.01B	Other FCA	Provisions and Consequences.	4-72.3
	[1]	Whistleblower Protection Provisions.	4-72.3
	[a]	False Claims Act Anti-Retaliation Provision	4-72.4
		[i] Protected Activity.	4-72.6
		[ii] Employer Knowledge	4-72.9
		[iii] Causal Connection	4-72.10
	[b]	Persons Covered by Whistleblower Protection Provisions	4-72.11
	[c]	Recovery Under Whistleblower Protection Provisions	4-72.14
	[2]	FCA Procedure.	4-72.15
	[a]	Discovery	4-72.15
	[b]	Pleading	4-72.19
	[c]	Statute of Limitations	4-72.26
	[d]	Non-intervened Litigation	4-72.27
	[3]	Damages and Penalties	4-72.29
	[a]	Damages.	4-72.29
		[i] Causation.	4-72.29
		[ii] Calculating Damages Sustained	4-72.30
		[iii] The Multiplier: Whether to Double or Triple the Single Damages.	4-72.32
		[iv] Credits.	4-72.33
	[b]	Penalties	4-72.34
		[i] What Is a “Claim” for Penalty Purposes?	4-72.34
		[ii] Assessing the Penalty Amount	4-72.35
	[4]	Collateral Estoppel: Relationship to Criminal Prosecutions and Administrative Proceedings.	4-72.38
§ 4.01C	Enforcement by State Attorneys General		4-72.42
	[1]	State False Claims Acts.	4-72.42
	[2]	State Consumer Protection Statutes	4-72.46
	[3]	Use of Contingency Fee Counsel by State Attorneys General.	4-72.48

TABLE OF CONTENTS

§ 4.02	RICO	4-72.50
	[1] The RICO Elements	4-72.50
	[2] Civil Damages and Penalties	4-72.50
§ 4.03	Injunctive Relief	4-73
§ 4.04	Civil Asset Forfeiture	4-77
	[1] Unique Characteristics of Civil Forfeiture	4-77
	[2] Background	4-78
	[3] How Civil Forfeiture Works	4-80
	[a] Arrest Warrant <i>In Rem</i>	4-80
	[b] Notice	4-81
	[c] Claimant’s Response	4-82
	[d] Stays	4-82
	[e] Discovery	4-83
	[f] Trial	4-83
	[g] Innocent Owner Defense	4-84
	[4] Relation Back Doctrine	4-85
	[5] Constitutional Considerations	4-86
§ 4.05	The “Stark” Law	4-89
	[1] Background of the Stark Law	4-90
	[2] Key Elements of Stark’s Prohibitions on Referrals and Billing	4-94
	[a] Designated Health Services	4-94
	[b] Financial Relationships That Trigger the Stark Statute	4-96
	[i] Direct and Indirect Financial Relationships	4-98
	[ii] Indirect Financial Relationships	4-99
	[iii] Determining Indirect and Direct Compensation Arrangements: “Stand in the Shoes” Provision	4-100
	[c] Referral Prohibition	4-101
	[d] Billing Prohibition and the “Knowledge” Exception	4-103
	[3] Exceptions to the Stark Prohibition	4-103
	[a] General Exceptions Relating to Both Ownership/Investment Interests and Compensation Arrangement Prohibitions	4-104
	[i] Physician Services	4-104
	[ii] In-Office Ancillary Services	4-105
	[iii] Prepaid Plans	4-109
	[iv] Academic Medical Centers	4-110

HEALTH CARE FRAUD

	[v] Exceptions for Certain Categories of DHS	4-111
[b]	Exceptions for Ownership/ Investment Interest by Physicians (or Immediate Family Member) in DHS Entity	4-112
[c]	Exceptions Relating to Other Compensation Arrangements	4-113
	[i] Office Space Rental	4-113
	[ii] Equipment Rental	4-115
	[iii] <i>Bona Fide</i> Employment Relationships	4-115
	[iv] Personal Services (with Special Provision for Physician Incentive Plans)	4-116
	[v] Remuneration Unrelated to Provision of DHS	4-118
	[vi] Physician Recruitment	4-119
	[vii] Isolated Transactions	4-121
	[viii] Certain Group Practice Arrangements with Hospitals	4-122
	[ix] Payments by Physician	4-122
	[x] Non-Monetary Compensation Up to \$300	4-123
	[xi] Fair Market Value Compensation	4-123
	[xii] Medical Staff Incidental Benefits	4-125
	[xiii] Risk-Sharing Arrangements	4-125
	[xiv] Compliance Training	4-126
	[xv] Indirect Compensation Arrangements Exception	4-126
	[xvi] Antikickback Safe Harbors	4-127
	[xvii] Professional Courtesy	4-127
	[xviii] Charitable Donations	4-128
	[xix] Community-Wide Health Information Systems	4-128
	[xx] Temporary Non-Compliance	4-129
	[xxi] Retention Payments	4-130
	[xxii] Electronic Prescribing Items and Services	4-131
	[xxiii] Electronic Health Records Items and Services	4-132

TABLE OF CONTENTS

	[xxiv] Assistance to Compensate a Nonphysician Practitioner	4-133
	[xxv] Timeshare Arrangements	4-135
	[xxvi] Flexibility for Nonabusive Business Practices (Proposed Rules)	4-136
	[xxvii] Cybersecurity Technology and Related Services (Proposed Rule)	4-138
[4]	Key Standards in the Stark Exceptions	4-139
	[a] Group Practice Definition	4-139
	[b] Fair Market Value	4-143
	[c] Compensation Must Be “Set in Advance” and “Not Take into Account the Volume or Value of Referrals or Other Business Generated Between the Parties”	4-146
	[i] Compensation Set in Advance	4-146
	[ii] Compensation That Does Not Take into Account the Value or Volume of Referrals or Other Business Generated	4-148
[5]	Consequences of Stark Violations	4-152
	[a] Period of Disallowance	4-152
	[b] Penalties for Violation; Enforcement	4-153
[6]	The Stark Reporting Provisions	4-154
[7]	Application of the Stark Statute to Medicaid	4-154.2
[8]	Overlap with Other Statutes	4-154.3
	[a] Antikickback Statute	4-154.3
	[b] Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”)	4-154.4
[9]	CMS Stark Advisory Opinions	4-154.5
§ 4.06	Program Fraud Civil Remedies Act	4-154.7
§ 4.07	Miscellaneous Causes of Action	4-157
§ 4.08	Civil and Administrative Liability of Successor Corporations	4-159
§ 4.09	Bibliography	4-162

HEALTH CARE FRAUD

CHAPTER 5

**Administrative Sanctions and
Collateral Consequences**

§ 5.01	Introduction	5-6
§ 5.02	Exclusion	5-7
	[1] Background	5-7
	[2] The Grounds for Exclusion	5-11
	[a] Introduction	5-11
	[b] Mandatory Exclusion	5-13
	[i] Grounds	5-13
	[ii] Length of Mandatory Exclusion	5-18
	[c] Permissive Exclusions	5-20
	[i] Convictions Relating to Fraud	5-22
	[ii] Conviction Relating to Obstruction of an Investigation or Audit	5-23
	[iii] Controlled Substances	5-24
	[iv] License Revocation or Suspension	5-24.1
	[v] Exclusion or Suspension Under Federal or State Health Care Program	5-24.2
	[vi] Filing Excessive Charges or Supplying Unnecessary Services or Substandard Services	5-24.3
	[vii] Failure to Furnish Medically Necessary Items and Services	5-24.4
	[viii] False or Improper Claims	5-24.6
	[ix] Fraud and Kickbacks	5-25
	[x] Entities Owned or Controlled by a Sanctioned Person	5-26
	[xi] Individuals Who Retain Ownership or Control Interest in Sanctioned Entities	5-28
	[xii] Failure to Disclose or Provide Ownership Information	5-30.3

TABLE OF CONTENTS

xxiii

	[xiii]	Failure to Provide Payment Information	5-30.4
	[xiv]	Failure to Grant Immediate Access to Records	5-30.4
	[xv]	Failure to Comply with a Corrective Action Plan	5-33
	[xvi]	Default of Health Education Loan or Scholarship Obligations	5-34
	[xvii]	Violations of the Limitations on Physician Charges	5-34
	[xviii]	Billing for Services of Assistant at Surgery During Cataract Operations	5-35
	[xix]	Aggravating and Mitigating Factors	5-35
	[xx]	Failure to Comply with a Corporate Integrity Agreement	5-36
	[xxi]	Making False Statements or Misrepresentations of Material Facts on Participation or Enrollment Documents	5-37
[3]		Procedure for Imposing Exclusion	5-37
	[a]	Introduction	5-37
	[b]	Notice and Statute of Limitations	5-40
	[c]	Submission of Written Response or Oral Argument	5-40
	[i]	Provider Entitled to Submit Written Information	5-41
	[ii]	Provider Entitled to Request Opportunity to Present Oral Evidence as Well as Written Information	5-42
	[iii]	Provider Entitled to a Hearing Before Exclusion Goes Into Effect	5-42
	[iv]	Provider Not Entitled to Submit Written or Oral Evidence Prior to Exclusion	5-43
	[d]	The ALJ Hearing	5-44
	[e]	Post-Hearing Briefs	5-48
	[f]	Appeal Procedures	5-49

HEALTH CARE FRAUD

	[g]	Stays Pending Appeal	5-51
	[h]	Notice to Other Agencies of a Provider's Exclusion	5-51
	[i]	Waivers of Exclusions	5-52
	[j]	Intermediate Sanctions for Medicare Health Maintenance Organizations	5-54
	[4]	Effect of Exclusion	5-54
	[5]	Reinstatement	5-57
	[6]	Exclusion Action by Medicaid Agencies	5-59
	[7]	Exclusion Actions by a Quality Improvement Organization	5-60
	[8]	Suspension of Payments Pending Exclusion	5-61
§ 5.03		Civil Monetary Penalties	5-63
	[1]	Intent	5-64.1
	[2]	Grounds for Imposing CMP	5-64.1
	[a]	False Claims	5-64.2
		[i] Seeking Reimbursement for a False Claim	5-64.2
		[ii] Using a False Record or a Material Statement	5-64.3
	[b]	Claims for Services Rendered by an Excluded Provider	5-64.3
	[c]	Claims for Services Rendered by a "Deficient" Physician	5-65
	[d]	Claims for Medically Unnecessary Services	5-65
	[e]	Claims for Payments that Violate an Agreement	5-65
	[f]	Improper Claims for Assistant During Cataract Surgery	5-66
	[g]	False Discharge Information	5-66
	[h]	Failure to Report Information to the National Practitioner Data Bank	5-66
	[i]	Improper Disclosure of Data in the National Practitioner Data Bank	5-67
	[j]	Improper Impression Regarding Coverage	5-67
	[k]	False Claims Filed by Health Maintenance Organizations, Competitive Medical Plans or Other Prepaid Health Plans	5-67

TABLE OF CONTENTS

[l]	Engaging in Prohibited Referral Arrangements	5-71
[m]	Waivers of Coinsurance or Deductibles	5-71
[n]	Excluded Individuals Who Retain an Ownership or Leadership Position in an Entity.	5-73
[o]	False Certification for Home Health Services.	5-73
[p]	Criminal Acts Involving Federal Health Care Program	5-74
[q]	Payments to Induce Reduction or Limitation of Services	5-74
[r]	False or Misleading Marketing Practices by Prescription Drug Discount Card-Endorsed Sponsor	5-77
[s]	Violation of a HIPAA Administrative Simplification Provision	5-77
[t]	Failure to Report Investment Data.	5-78.1
[u]	Prescribing Items or Services While Excluded from Participation in Federal Health Care Programs	5-78.1
[v]	Making False Statements in Applications to Participate.	5-78.1
[w]	Knowledge of Overpayments	5-78.1
[x]	Using a False Record to Claim Payment.	5-78.2
[y]	Failing to Grant Timely Access to the HHS Inspector General	5-78.2
[z]	Medicare Part D Coverage Gap Discount Program.	5-78.2
[2A]	Exceptions for Charitable and Innocuous Programs.	5-78.2
[3]	Determining the Amount of Penalties and Assessments.	5-78.3
[4]	Joint and Several Liability.	5-78.4
[5]	Imposition of CMP as Grounds for Exclusion.	5-78.5
[6]	Procedure for Imposing CMP.	5-78.5
[a]	Notice	5-79
[b]	Hearing Before the ALJ	5-80
[c]	Appeal to the DAB	5-80

HEALTH CARE FRAUD

	[d] Judicial Review	5-81
	[e] Injunctive Relief	5-81
	[7] Statute of Limitations	5-81
§ 5.04	Debarment and Suspension	5-82
	[1] Introduction	5-82
	[2] Procurement Debarment and Suspension	5-82
	[a] Debarment and Suspension Causes and Procedures	5-83
	[b] Mitigating Circumstances	5-85
	[c] Effect of Debarment and Suspension	5-86
	[d] Length and Scope of Debarment and Suspension	5-87
	[3] Non-Procurement Debarment and Suspension	5-88
§ 5.05	Licensing	5-90
	[1] Introduction	5-90
	[2] Conviction as Grounds for Licensure Discipline	5-90
	[3] Other Fraud-Related Grounds for Licensure Discipline	5-90.3
	[4] Procedures Before State Licensing Boards	5-90.4
§ 5.06	Staff Privileges	5-90.6
	[1] Background	5-90.6
	[2] Impact of Fraud and Abuse	5-92
	[a] Fraud and Abuse as a Basis for Terminating Staff Privileges	5-92
	[b] A Hospital's Civil or Criminal Liability for Fraud and Abuse Committed by Providers on the Hospital's Medical Staff	5-93
	[c] Staff Privileges Contracts That Violate Anti-Fraud Statutes	5-95
§ 5.07	Special Sanctions Considerations for Nursing Facilities	5-98
§ 5.08	The Beneficiary Inducements Statute	5-99
§ 5.09	Bibliography	5-103

TABLE OF CONTENTS

VOLUME TWO

CHAPTER 6

Pretrial Strategies in Health Care Fraud Cases

§ 6.01	Introduction	6-2
§ 6.02	Undercover Investigations	6-4
§ 6.03	Grand Jury Investigations	6-8
	[1] Grand Jury Secrecy	6-8
	[2] Scope of Grand Jury Investigations	6-12
§ 6.04	Inspector General Subpoena	6-14
§ 6.05	Civil Investigative Demands	6-16
§ 6.06	Search Warrants	6-20
	[1] Introduction	6-20
	[2] Particularity and Overbreadth in Search Warrants	6-23
	[3] Administrative Warrants in Criminal Investigations	6-29
	[4] Private Party Searches	6-30.1
§ 6.06A	Asset Freezes and Pre-Judgment Attachments	6-30.4
§ 6.07	Contacts with Represented Persons	6-31
§ 6.08	Privileges	6-35
	[1] Privilege Against Self-Incrimination	6-35
	[a] Self-Incrimination Rights of Fictional Entities	6-35
	[b] Fifth Amendment Privilege in Parallel Proceedings	6-37
	[2] Attorney-Client Privilege	6-40
	[3] Work Product Privilege	6-43
	[4] Changes Between Waiver for the Attorney-Client and Work Product Privileges	6-45
	[a] Inadvertent Disclosure	6-45

HEALTH CARE FRAUD

	[b] Voluntary Disclosure to the Government.	6-46
	[5] Crime Fraud Exception to Attorney-Client and Work Product Privilege	6-49
	[6] Attorney-Client and Work Product Privileges in a Corporate Setting.	6-52
	[7] Privileges in Joint Defense Agreements	6-52.2
§ 6.09	Protections for Medical Records and Communications	6-53
	[1] Constitutional Privacy Rights	6-54
	[2] Statutory and Regulatory Protections	6-55
	[a] Health Insurance Portability and Accountability Act	6-55
	[i] “Covered Entities”	6-55
	[ii] Use and Disclosure of “Protected Health Information”	6-56
	[iii] Medical Applications for Mobile Devices	6-56.2
	[b] Medical Records Relating to the Treatment of Drug and Alcohol Abuse	6-56.3
	[3] Patient-Provider Privileges in Federal Courts	6-59
	[4] Patient-Provider Privileges in State Courts	6-60.2
§ 6.10	Conflicts of Interest.	6-61
§ 6.11	Injunctive Relief	6-64
§ 6.12	Bibliography	6-67

CHAPTER 7**Evidence and Trial Strategies in Health Care Fraud Cases**

§ 7.01	Expert Witness Testimony	7-2
	[1] Federal Rules and <i>Daubert</i>	7-2
	[2] Billing Experts	7-7
	[a] General Standards.	7-8
	[b] Peer Group Evidence	7-9
	[c] Government Employed Experts	7-11
	[d] Jury Instructions	7-15
	[3] Damages Experts	7-15
§ 7.02	Use of Exhibits	7-17

TABLE OF CONTENTS

	[1] Exhibits Created for Trial	7-17
	[a] Foundation to Admit Summaries.	7-22
	[2] Patient Records.	7-24
	[3] Provider Manuals	7-26
	[4] Computerized Records.	7-27
	[a] Authentication of Computer-Generated Records	7-27
	[b] Admission of Computer-Generated Evidence	7-30
	[i] Records of a Regularly Conducted Activity	7-31
	[ii] Statement of a Defendant.	7-32.1
	[iii] Public Records and Reports.	7-32.2
§ 7.03	Special Issues Relating to <i>Scienter</i> Evidence	7-32.3
	[1] Advice of Counsel Jury Instruction	7-32.3
	[a] General Scope of the Advice of Counsel Jury Instruction.	7-32.3
	[i] Material Facts.	7-33
	[ii] Good Faith Reliance.	7-34
	[iii] Acting in Accordance with Advice	7-35
	[iv] Outside and Internal Company Counsel.	7-36
	[b] Effect of Asserting the Advice of Counsel Defense.	7-37
	[2] Evidence of Other Bad Acts	7-39
	[a] Background.	7-39
	[b] Admission of FRE 404(b) Evidence	7-40
	[i] Probative Value.	7-41
	[ii] Similarity.	7-41
	[iii] Proof of Extrinsic Act	7-41
	[iv] FRE 403 Balancing Test	7-42
	[c] Good Extrinsic Act Evidence	7-42
	[3] Character Evidence	7-42
§ 7.04	Jury Instructions	7-45
	[1] “Willfully”/Specific Intent	7-46
	[2] Knowingly	7-47
	[3] Deliberate Ignorance	7-47
	[4] Mistake	7-48
	[5] Reasonable Interpretation of Confusing Law	7-49
§ 7.05	Bibliography	7-51

CHAPTER 8

**Internal Investigations When Fraud Is Suspected:
Issues of Strategy**

§ 8.01	Introduction	8-3
§ 8.02	Who Should Conduct the Investigation	8-5
	[1] The Client	8-5
	[2] In-House Counsel	8-6
	[3] Regular Outside Counsel	8-7
	[4] Outside Counsel Specializing in Health Care Fraud/Internal Investigations	8-7
§ 8.03	Advising the Client	8-9
§ 8.04	Conducting Interviews	8-11
§ 8.05	Maintaining Privileges	8-12
	[1] Fifth Amendment Privilege	8-12
	[2] Attorney-Client Privilege	8-12.1
	[3] Work Product Privilege	8-12.2
	[4] Provider-Patient Privilege	8-12.3
§ 8.06	Voluntary and Mandatory Reporting	8-13
	[1] Preparing a Report	8-13
	[2] Duty to Report under the Sarbanes-Oxley Act	8-16
§ 8.07	Seeking a Stay or Procurement of a Protective Order in Parallel Civil Actions	8-19
§ 8.08	Protecting the Internal Investigator	8-21
§ 8.09	Pleas of Guilt	8-22
	[1] Collateral Consequences of a Guilty Plea	8-22
	[2] The Settlement Amount	8-22
	[3] Deferred Prosecution Agreements as an Alternative to a Guilty Plea	8-23
§ 8.10	Establishing a Corporate Integrity Program (“CIP”)	8-25
§ 8.11	Voluntary Disclosure of Wrongdoing	8-27
	[1] 1995 OIG Pilot Voluntary Disclosure Program	8-27
	[2] Voluntary Disclosure Protocols	8-28
	[3] Benefits of Voluntary Disclosure	8-30
	[a] Presumption Against Integrity Agreement Obligations	8-31
	[b] Lower Damages Payments	8-31
	[c] Mitigate Potential Exposure of “Retained Overpayments”	8-31
	[d] Good Faith, Cooperation and Expedited Resolution	8-32

TABLE OF CONTENTS

vii

[4]	Requirements for Self-Referral Disclosure Protocol	8-33
[a]	Requirements for All Disclosures	8-34
[b]	Disclosure Requirements for Conduct Involving False Billing	8-35
[c]	Disclosure Requirements for Conduct Involving Excluded Persons or Entities	8-36
[d]	Disclosure Requirements for Conduct Involving the Anti- Kickback Statute and Physician Self-Referral Law	8-37
[5]	The Department of Justice Charging and Prosecution Guidelines	8-38
[a]	DOJ Charging Guidelines	8-38
[6]	2015 Yates Memo	8-41
[a]	DOJ’s Focus on Individual Accountability	8-41
[b]	The Revised Yates Memo: Monetary Recovery	8-45
[c]	The Monaco Memo—A Return to Yates Memo Policies	8-47
[7]	Department of Justice Guidelines for Taking Disclosure, Cooperation, and Remediation into Account in False Claims Act Cases	8-48
[a]	Overview	8-48
[b]	Disclosure, Cooperation, and Remedial Action	8-49
[i]	Voluntary Disclosure	8-49
[ii]	Other Forms of Cooperation	8-50
[iii]	Remedial Measures	8-51
[c]	Credit for Disclosure, Cooperation, and Remediation	8-51
[d]	Additional Considerations	8-52
§ 8.12	Bibliography	8-54

CHAPTER 9

Corporate Compliance Plans

§ 9.01	Introduction	9-6
§ 9.02	The Importance of Corporate Compliance Plans	9-9

HEALTH CARE FRAUD

§ 9.03	Establishing an Effective Corporate Compliance and Ethics Program for a Health Care Provider	9-20
	[1] “Is the corporation’s compliance program well designed?”	9-24
	[a] Risk Assessment	9-24
	[b] Policies and Procedures	9-25
	[c] Training and Communications	9-28
	[d] Confidential Reporting Structure and Investigation Process	9-30
	[e] Third Party Management	9-30
	[f] Mergers and Acquisitions	9-30
	[2] “Is the Corporation’s Compliance Program Adequately Resourced and Empowered to Function Effectively?”	9-31
	[a] Commitment by Senior and Middle Management	9-32
	[i] Compliance Requirements for Board of Directors and Governing Bodies	9-32
	[ii] Role and Responsibility of the Senior Compliance Officer	9-34
	[b] Autonomy and Resources	9-38
	[c] Incentives and Disciplinary Measures	9-38
	[3] “Does the Corporation’s Compliance Program Work in Practice”	9-38.2
	[a] Continuous Improvement, Periodic Testing, and Review	9-38.3
	[b] Investigation of Misconduct	9-38.4
	[c] Analysis and Remediation of Any Underlying Misconduct	9-38.5
§ 9.04	OIG Compliance Program Guidances	9-39
	[1] Hospitals	9-40
	[a] Written Policies and Procedures	9-41
	[i] Standards of Conduct	9-41
	[ii] Risk Areas	9-41
	[iii] Claim Development and Submission Process	9-42
	[iv] Cost Reports	9-42.2
	[v] Other Concerns	9-42.2
	[b] Designation of a Compliance Officer and Compliance Committee	9-42.3

TABLE OF CONTENTS

- [c] Conducting Effective Training and Education. 9-42.3
- [d] Developing Effective Lines of Communication. 9-43
- [e] Disciplinary Guidelines 9-43
- [f] Auditing and Monitoring 9-43
- [g] Responding to Detected Offenses and Developing Corrective Action Initiatives 9-44
- [2] Supplemental Compliance Program Guidance for Hospitals. 9-45
 - [a] Evolving Risk Areas Related to the Submission of Claims 9-46
 - [b] Evolving Risk Areas Related to the Referral Statutes 9-47
 - [i] The Physician Self-Referral Law 9-47
 - [ii] The Federal Anti-Kickback Statute 9-48
 - [iii] Additional Areas of Evolving Risk 9-48
 - [c] Hospital Compliance Program Effectiveness 9-50
- [3] Clinical Laboratories 9-51
 - [a] Written Policies and Procedures 9-51
 - [i] Medical Necessity 9-51
 - [ii] Billing 9-52
 - [iii] Reliance on Standing Orders 9-53
 - [iv] Prices Charged to Physicians 9-53
 - [b] Conducting Effective Training and Education. 9-54
 - [c] Auditing and Monitoring 9-54
- [4] Home Health Agencies 9-54
 - [a] Written Policies and Procedures 9-55
 - [i] Standards of Conduct. 9-55
 - [ii] Risk Areas. 9-55
 - [iii] Claim Development and Submission Process. 9-56
- [5] Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 9-58
 - [a] Medical Necessity 9-58
 - [b] Certificates of Medical Necessity 9-59

HEALTH CARE FRAUD

	[c]	Billing for Drugs Used in Connection with DMEPOS Items and Services	9-60
	[d]	Capped Rentals	9-60
	[e]	Oxygen and Oxygen Equipment	9-61
[6]		Third-Party Medical Billing Companies	9-61
	[a]	Coding Services	9-62
		[i] Billing Companies That Provide Coding Services	9-62
		[ii] Billing Companies That Do Not Provide Coding Services	9-63
	[b]	Credit Balances	9-63
	[c]	Integrity of Data Systems	9-63
[7]		Hospices	9-64
	[a]	Written Policies and Procedures	9-64
		[i] Standards of Conduct	9-64
		[ii] Risk Areas	9-64
	[b]	General Eligibility Requirements	9-65
	[c]	Terminal Illness Requirement	9-65
[8]		Nursing Homes	9-66
	[a]	Written Policies and Procedures	9-66.1
		[i] Standards of Conduct	9-66.1
		[ii] Risk Areas	9-67
	[b]	Residents' Rights	9-67
[9]		Supplemental Compliance Program Guidance for Nursing Facilities	9-68
	[a]	Fraud and Abuse Risk Areas	9-69
		[i] Quality of Care	9-69
		[ii] Submission of Accurate Claims	9-70
		[iii] The Federal Anti-Kickback Statute	9-71
		[iv] Other Risk Areas	9-73
		[v] HIPAA Privacy and Security Rules	9-74
	[b]	Other Compliance Considerations	9-74
	[c]	Self-Reporting Requirements	9-75
[10]		Individual and Small Group Physician Practices	9-75
	[a]	Written Policies and Procedures	9-76
		[i] Standards of Conduct	9-76
		[ii] Policies and Procedures	9-76
		[iii] Risk Areas	9-76
	[b]	Compliance Officers	9-77

TABLE OF CONTENTS

	[c]	Developing Effective Lines of Communication	9-77
[11]		Pharmaceutical Manufacturers	9-78
	[a]	Integrity of Data Furnished by Manufacturers	9-78
	[b]	Kickbacks and Other Illegal Remuneration	9-79
		[i] In General	9-79
		[ii] Specific Areas of Potential Risk	9-79
	[c]	Compliance with Laws Regulating Drug Samples	9-82
[12]		Recipients of Extramural Research Awards from U.S. Public Health Service Agencies	9-82
	[a]	Written Policies and Procedures	9-84
		[i] Standards of Conduct	9-84
		[ii] Risk Areas	9-84
		[iii] Other Concerns	9-85
	[b]	Designating a Compliance Officer and Compliance Committee	9-86
	[c]	Conducting Effective Training and Education	9-86
	[d]	Developing Effective Lines of Communication	9-87
	[e]	Hotlines and Other Forms of Communication	9-87
	[f]	Auditing and Monitoring	9-87
	[g]	Enforcing Standards Through Well-Publicized Disciplinary Guidelines	9-87
	[h]	Responding to Detected Problems and Developing Corrective Action Initiatives	9-87
§ 9.05		Corporate Integrity Agreements	9-89
	[1]	Preamble	9-92
	[2]	Term and Scope	9-93
	[3]	Corporate Integrity Obligations	9-94
	[4]	Compliance Obligations of the Board of Directors, Executives, and Managers	9-97
		[a] Board Compliance Obligations	9-98
		[b] Management Accountability and Certifications	9-99
	[5]	Written Standards	9-100
	[6]	Training	9-101

HEALTH CARE FRAUD

	[7]	Monitor	9-101
	[8]	Independent Review Organization (IRO)	9-102
	[9]	Confidential Disclosure Program	9-104
	[10]	Ineligible Persons	9-105
	[11]	Notification of Proceedings	9-105
	[12]	Reporting Requirements	9-105
	[13]	Implementation and Annual Report	9-107
	[14]	OIG Inspection and Audit Rights	9-108
	[15]	Document and Record Retention	9-108
	[16]	Disclosure and Privileges	9-108
	[17]	Stipulated Penalties	9-109
	[18]	Exclusion for Material Breach	9-111
	[19]	Appellate Rights	9-113
	[20]	Effect on Successors and Assigns	9-113
§ 9.06		Bibliography	9-115

CHAPTER 10**Fraud and Abuse Issues in the Pharmaceutical Industry**

§ 10.01		Introduction	10-3
§ 10.02		Pharmaceutical Reimbursement	10-4
	[1]	Background	10-4
	[2]	Overview of the Medicare Program	10-5
	[a]	Part A Coverage and Reimbursement	10-7
	[b]	Part B Coverage and Reimbursement	10-8
	[i]	Types of Drugs and Services Covered Under Part B	10-8
	[ii]	Reimbursement Methodology	10-9
	[iii]	Post 2004 Reimbursement Methodology: ASP	10-12.1
	[iv]	Penalties	10-14
	[v]	Claims Processing	10-15
	[c]	Competitive Acquisition Program for Part B Drugs and Biologics	10-16
	[d]	Part C Coverage and Reimbursement	10-16
	[e]	Part D Coverage and Reimbursement	10-17
	[3]	Medicaid	10-26
	[a]	Drug Coverage	10-26

TABLE OF CONTENTS

xiii

	[b]	Up-Front Reimbursement	10-27
	[c]	The Medicaid Rebate System	10-31
	[d]	Overview of Significant Statutory and Regulatory Developments	10-33
	[i]	Significant Statutory Developments	10-34
	[ii]	Significant Regulatory Developments	10-36
	[e]	Definitions of Key Medicaid Terms	10-38
	[i]	Definition of Manufacturer	10-38
	[ii]	Definition of Covered Outpatient Drugs	10-39
	[iii]	Definition of Average Manufacturer Price	10-43
	[iv]	Definition of Best Price	10-45
	[v]	Definition of Nominal Price	10-47
	[f]	Manufacturer Reporting Requirements under the Medicaid Program	10-48
	[g]	Penalties	10-49
	[4]	“Public Health Service Act” Prices	10-49
	[5]	The Federal Supply Schedule and Federal Ceiling Prices	10-50.6
§ 10.03		Liability for Setting and Reporting Prices	10-56
	[1]	Inflated AWP or Direct Prices	10-56
	[2]	False Medicaid Rebates	10-60
	[a]	Failure to Report Cash Discounts, Free Goods Contingent on Purchase, Volume Discounts, and Commercial Rebates	10-62
	[b]	Nominal Price Manipulation	10-65
	[c]	Private Labeling, Repackaging, and Relabeling Arrangements	10-66
	[i]	Private Label Sales	10-68
	[ii]	Repackaging/Relabeling	10-69
	[3]	PHS Pricing	10-70
	[4]	FSS Pricing	10-71
	[5]	Direct Price Reporting	10-72
	[6]	ASP Reporting	10-73
§ 10.04		False Claims Act Liability for Claims Relating to Drugs That Are Not Approved or That Should Not Have Been Approved	10-75
	[1]	“Off-Label” Promotion	10-75

HEALTH CARE FRAUD

	[a]	<i>United States ex rel. Franklin v. Parke-Davis</i>	10-76.1
	[b]	Post- <i>Franklin</i> Decisions	10-80
	[c]	Settlements	10-85
	[2]	Fraud in the FDA Approval Process	10-86
§ 10.05		Liability for Marketing Products	10-87
	[1]	Marketing the “Reimbursement Spread”	10-88.3
	[2]	Grants	10-92
	[3]	“Switch Fees” to Physicians, Pharmacists, or Pharmacy Benefits Managers (PBMs)	10-102
	[a]	Payments to Physicians or Pharmacists	10-102
	[b]	Payments to PBMs	10-103
	[4]	Consulting and Other Personal Service Arrangements	10-106
	[a]	General Principles	10-106
	[b]	Special Issues Relating to Promotion and Advertising, Including “White Coat” Marketing	10-110
	[5]	Samples, Vouchers, and Coupons	10-112
	[a]	Samples	10-112
	[b]	Vouchers	10-114
	[c]	Coupons	10-114.1
	[6]	Discounts and Rebates	10-114.4
	[a]	Discount Safe Harbor Issues	10-114.4
	[i]	Free Goods	10-114.5
	[ii]	Bundled Sales	10-114.6
	[iii]	Sales to Wholesalers	10-114.8
	[iv]	Coupons	10-114.8
	[v]	Mixed Discount and Service Arrangements	10-114.9
	[b]	Issues Relating to Other Safe Harbors	10-114.10
	[7]	Gifts and Business Courtesies	10-115
	[8]	Fees and Rebates to Group Purchasing Organizations and Pharmacy Benefits Managers	10-119
	[9]	“Value Added” Services, Including Health Management and Reimbursement Services	10-122
	[10]	Purchase of Data or Goods	10-125

TABLE OF CONTENTS

xv

[11] Commission Sales Arrangements 10-126
[12] Charitable Contributions 10-128
§ 10.06 Liability for Pharmacies 10-135
§ 10.07 Bibliography 10-138

Appendices

Appendix A: Introduction A-3
OIG Advisory Opinion Subject Matter
Index A-5
Selected OIG Advisory Opinion
Summaries A-21
Appendix B: Selected CMS Stark Advisory Opinion
Summaries B-1
Appendix C: Universal Citation Changes of the 2009
FCA Amendments C-1
TABLE OF ABBREVIATIONS TA-1
INDEX I-1