

Index

ABUSE

- Digital health, risks, 20
- Representations and warranties, in healthcare, 107

AI

- See Artificial Intelligence

ALTERNATIVE DISPUTE RESOLUTION (ADR)

- Generally, 131
- Allocating costs, 139
- Attorneys' fees, 139
- Award flexibility, 137
- Baseball arbitration, 139
- Choice
 - Arbitration over court litigation
 - Allocating costs, 139
 - Attorneys' fees, 139
 - Award flexibility, limiting, 137
 - Award flexibility, providing of, 137
 - Confidentiality, 137
 - Creative methods, baseball arbitration, 139
 - Expedited process, 135
 - Expert tribunal, 134
 - Finality, 135
 - Court litigation over arbitration, 139
- Confidentiality, 137
- Expedited process, 135
- Expert tribunal, 134
- Governs arbitration
 - Law, 132
 - Agreement, 132
 - Statutes, 133

ALTERNATIVE DISPUTE RESOLUTION (ADR)

—Cont'd

- Governs arbitration—Cont'd
 - Mode of dispute resolution, only if the parties agree to it, 132
 - Rules, 132, 134
- Healthcare, 131
- Tailoring ADR
 - Allocation of fees, costs
 - Considerations, 170
 - Options, 169
 - Recommendation, 170
- Appeal clause
 - Considerations, 172
 - Options, 171
 - Recommendations, 173
- Applicable law
 - Considerations, 148
 - Options, 148
 - Recommendations, 150
- Applicable rules
 - Considerations, 157
 - Options, 156
 - Recommendations, 158
- Arbitrator selection
 - Considerations, 159
 - Options, 158
 - Recommendations, 161
- Award, form, scope
 - Considerations, 167
 - Options, 167
 - Recommendations, 168
- Discovery, scope
 - Considerations, 164
 - Options, 163
 - Recommendations, 166

**ALTERNATIVE DISPUTE
RESOLUTION (ADR)**

—Cont’d

Tailoring ADR—Cont’d

Mandatory ADR

Considerations, 143

Options, 143

Recommendations, 144

Mediation

Considerations, 155

Options, 154

Recommendations, 155

Opt-out ADR

Considerations, 143

Options, 143

Recommendations, 144

Provider

Considerations, 157

Options, 156

Recommendations, 158

Scope of ADR clause

Considerations, 152

Options, 152

Recommendations, 153

Statement of purpose

Considerations, 146

Options, 145

Recommendations, 147

Venue

Considerations, 148

Options, 148

Recommendations, 150

ANTI-KICKBACK STATUTE

Law influencing private equity, 46

ANTITRUST ENFORCEMENT

Agencies, 76

Law influencing private equity, 50

M&A policies, guidelines, 76

Merger, 73

Private equity, 50, 65

Trends in merger enforcement, 82

**APPLICABLE LAWS AND
GUIDANCE**

Artificial intelligence (AI)

ASTP HT-1, 10

EU AI Act, 14

Executive orders, 9

FDA guidance, discussion
papers, and action plans,
11

Generally, 9

ONC’s HT-1, 10

State legislation, 15

Digital health, 7

**ARTIFICIAL INTELLIGENCE
(AI)**

Generally, 3

ASTP’s HT-1, 10

Bias, risk of, 23

Business practices, risk of, 21

Compliance costs, risk of, 21

Definition, 3

Enforcement actions

See Enforcement Actions and
Litigation

EU AI Act, 14

Executive orders, 9

FDA guidance, discussion papers,
action plans, 11

Governance, increased, 21

Intellectual property, risk of, 24
Liability, for healthcare providers,
21

Litigation

See Enforcement Actions and
Litigation

Misinformation, risk of, 23

ONC’s HT-1, 10

Privacy, risk of, 21

Regulators, 4

Risks

Bias, 23

Changes to business practices,
21

Generally, 20

INDEX

ARTIFICIAL INTELLIGENCE

(AI)—Cont'd

Risks—Cont'd

- Increased governance and compliance costs, 21
- Intellectual property, 24
- Liability for healthcare providers, 21
- Misinformation, 23
- Privacy, 21
- Security, 21
- Security, risk of, 21
- State legislation, 15

ASTP HT-1

- Applicable laws of AI, 10

AUDIT

- Generally, 322
- Closing thoughts, 347
- Defense
 - Importance of audit defense, 338
 - Medicare appeals process, 334
- Employees regarding routing of government communications, 342
- Government healthcare audit
 - Auditors, 323
 - Audit Types, 327
- Identifying and returning overpayments, 331
 - 60-day Rule, 331
- Inventory internal resources, 341
- Meaningful internal audits, 345
- Medicare payment suspension, 329
- Multi-disciplinary audit response team, 340
- Proactive strategies for successful audit defense, 340
- Targeted probe and educate audits, 328
- Vigorously defend all denials, 343

AWARD

- Alternative Dispute Resolution (ADR)
 - Flexibility, providing, 137
 - Form of, 167
 - Scope, 167

BIAS

- Risks of artificial intelligence (AI), 23

BURDEN OF PROOF

- Clinical validation
 - Utilization management, the treating physician rule, 504

CHANGING HEALTHCARE SYSTEM

- See Artificial Intelligence (AI)
- See Digital Health

CLAIM ADJUSTMENT REASON CODES (CARC)

- Clinical validation
 - Development CARC and RARC combination rules, 480
 - Outcome of DRG and clinical validation, 478
 - Selection of CARC and RARC adjustment denial, 482

CLINICAL VALIDATION

- Accuracy through validation, 473
 - Clinical validation, 475
 - DRG validation, 473
- Assigning ICD diagnosis and procedure codes to a medical record, 469
- Background, 464
 - International Classifications of Diseases (ICD) and diagnostic related groups, 467
- Burden of proof
 - Utilization management, the treating physician rule, 504
- Code assignment, 467

CLINICAL VALIDATION

—Cont'd

- Diagnostic Related Group (DRG), assigning, 470
- Further examination
 - Clinical validation determinations and their classification, 487
 - DRG validation determinations and their classification, 485
- Implications of clinical validation, 494
 - Clinical validation decisions as utilization review decisions, 500
- Examination of the definition for the practice of medicine, 494
- Review activities must be made using appropriate criteria, 499
- Utilization review activities must be performed by qualified reviewers, 497
- Validation in practice, clinical, 504
- Introduction, 463
- Outcome of DRG and clinical validation, 477
 - Claim Adjustment Reason codes (CARC) and Remittance Advice Remark Codes (RARC), 478
 - Development CARC and RARC combination rules, 480
 - Selection of CARC and RARC adjustment denial, 482
- Transparency in health plan communication of DRG and clinical validation findings, 490

COMPULSION TEST

- State actor, 245

DIGITAL HEALTH

- Generally, 2

DIGITAL HEALTH—Cont'd

- Abuse, 20
- Applicable laws, 7
- Corporate practice, risk of, 17
- Definition, 2
- Enforcement actions
 - See Enforcement Actions and Litigation
- Fee-splitting, 18
- Fraud, 20
- Licensure, 18
- Litigation
 - See Enforcement Actions and Litigation
- Privacy, 19
- Regulators, 4

ENFORCEMENT ACTIONS AND LITIGATION

- Generally, in healthcare, 25
- Department of Justice (DOJ), 26
- Federal Trade Commission (FTC), 25
- Food and Drug Administration (FDA), 26
- Health and Human Services Office of Inspector General (HHSOIG), 26

EU AI ACT, 14

FALSE CLAIMS ACT

- Reimbursement and payment
 - Constitutionality of Qui Tam provision, 371
- Damages, 385
- Knowledge/scienter, 379
- Pleading and proving falsity, 374
- Pleading and proving materiality, 376
- Public disclosure bar, 382
- Retaliation, 388
- Submission of claims and fraudulent scheme, 372

INDEX

FOOD AND DRUG

ADMINISTRATION (FDA)

- Artificial intelligence (AI)
 - Applicable laws
 - Action plans, 11
 - Discussion papers, 11
 - Guidance, 11
 - Enforcement actions, 25
 - Litigation, 25
- Digital health
 - Enforcement actions, 25
 - Litigation, 25

FRAUD

- Digital health, risks, 20
- Healthcare fraud
 - Criminal enforcement, 390
- Representations and warranties, in healthcare, 107

HEALTHCARE PROVIDERS

- Risks of Artificial Intelligence (AI)
 - Liability for, 21

HEALTHCARE

TRANSACTIONS

- Issues, transactional, 101
- Representations and warranties
 - Generally, 101
 - Abuse, 107
 - Compliance with defined healthcare laws, 104
 - Definitions, 125
 - Excluded parties, 109
 - Fraud, 107
 - Licensure, 108
 - Privacy, 110
 - Qualifiers, 113
 - Regulatory compliance programs, 112
 - Reimbursement, 105
 - Seller, of, 118
- Representations and warranties
 - qualifiers
 - Knowledge qualifiers, 113

HEALTHCARE

TRANSACTIONS—Cont'd

- Representations and warranties
 - qualifiers—Cont'd
 - Look-back periods, 115
 - Materiality qualifiers, 114
 - Survival periods, 117

HEALTH INSURANCE

PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- Data privacy, law influencing private equity, 48

JOINT VENTURES

- Reimbursement and payment, 219

LICENSURE

- Digital health, risks, 18
- Representations and warranties, in healthcare, 108

MEDICARE ENROLLMENT DEFENSES

- Advising clients
 - Allina in the defense context, 434
 - Escobar in the defense context, 437
 - Genera advice approach, 433
 - Legal defense approach, 434
- Enrollment history, 426
 - 2001 to 2009, 427
 - 2010 and increased scrutiny, 427
- Changes, enrollment form, 431
- Introduction, 425
- Practical advice real world scenarios, 454
 - Harry does not work here anymore, 456
 - Lost in the mail, 457
 - Reassignment whistleblower, 458

**MEDICARE ENROLLMENT
DEFENSES—Cont'd**

- Regulatory hierarchy overview,
441
 - Forms, 441
 - Manuals, 442
- Why does the hierarchy matter?,
449

MISINFORMATION

- Risks of artificial intelligence
(AI), 23

**MODERN PRIVATE EQUITY
FIRMS**

- See private equity

NON COMPETES

- American medical associations,
183
- Argument for allowing non
competes in healthcare, 187
- Balance of competing interests,
176
- Banning non competes in
healthcare, 190
 - Harm to patients, 191
 - Harm to physicians, 190
- Evolution in the United States,
179
- Federal regulatory attempts to ban
or restrict, 192
- Federal Trade Commissions 2023
and 2024, 196
- Future of non competes in
healthcare, 204
- Historical use, 176
- Introduction, 176
- NLRB 2023 and 2024
 - Attacks on non competes, 200
- Non Competition Agreement,
enforcement of, 176
- Precursors to the FTCs 2024 final
rule, 193
- Rise and role of non competes,
183
- State-level reforms to limit, 203

NON COMPETES—Cont'd

- Use and the legal foundations, 176

OIG

- Generally, 393
- Early non face time services, 394
 - Care plan oversight, 398
 - Incident to, 394
 - Split/shared visits, 400
- Enforcement risks given case law,
417
 - Allina, 420
 - Escobar, 418
 - Loper bright, 424
- Today's coordination of care
codes, 402
 - Advanced primary care
management services, 414
 - Chronic care management, 406
 - Remote physiologic monitoring,
411
 - Transitional care management,
403

ONC'S HT-1

- Applicable laws of AI, 10

OVERPAYMENTS

- Generally, 290
- Considerations for different payor
sources
 - Payments from
 - Federal health care program
beneficiaries, 318
 - Medicaid FFS programs, 311
 - Medicare advantage
organizations and
medicaid managed care
organizations, 314
- Current lay of the land
 - The new rule, 282
- Demise of reasonable diligence,
280
- Down to brass tacks mechanics of
the overpayments statute, 273
 - Look back period, 274

INDEX

OVERPAYMENTS—Cont'd

- Down to brass tacks mechanics of the overpayments statute, 273
 - Cont'd
- Report and return requirement, 273
- Federal Overpayment Statute, 265
- Identified, defined, 276
- Introduction, 264
- Landmark supreme court cases, 293
 - Allina, 297
 - Escobar, 293
 - Kisor, 308
 - Loper Bright, 306
 - Super Valu, 303
- Legal background and context, 267
 - Enforcement under the overpayment statute, 270
 - Before the overpayment statute, 268
- Takeaways for providers, 318
- Trip down memory lane, 276

PRIVACY

- Data privacy, HIPAA
 - See Health Insurance Portability and Accountability Act (HIPAA)
- Digital health, risks, 19
- Representations and warranties, in healthcare, 110

PRIVATE EQUITY

- Federal litigation, 65
- Fund formation, operations
 - Capital deployment, 35
 - Capital raising, 34
 - Formation, 33
 - Realization, 37
 - Structure, 33
- Future, 57
- Modern private equity firms, origin, 31
- State legislation, evolving, 64

PRIVATE EQUITY IN THE CROSSHAIRS

- Generally, 29
- Crosshairs, a framework for analyzing the four factors, 39
- External factor influencing, 38
- Four external factor influencing
 - Economics, 41
 - Cycles, 41
 - Inflation, 41
 - Interest rates, impact of, 42
 - Limitations of the economic view, 44
 - Law, legal, 45
 - Anti-kickback statute, 46
 - Antitrust enforcement, 50
 - Corporate Practice of Medicine (CPOM), 46
 - Data privacy, 48
 - Health Insurance Portability and Accountability Act (HIPAA), 48
 - Limitations of the legal view, 53
 - Post-closing liability (RWI), 52
 - Stark law, 46
 - Philosophy
 - Disconnect from consumers, 54
 - Ethics, 55
 - Innovation, ethics, 55
 - Limitations of the philosophical viewpoints, 56
 - Politics
 - Disconnect from consumers, 54
 - Ethics, 55
 - Innovation, ethics, 55
 - Limitations of the political viewpoints, 56

PUBLIC FUNCTION TEST

- State actor, 244

**REIMBURSEMENT AND
PAYMENT**

Generally, 350
 Advantages
 340B eligibility, 226
 Access to hospital resources, 222
 Bad debt, 223
 Graduate medical education payments, 224
 Key considerations, 225
 Residents working at provider-based facilities, 225
 Higher reimbursement rates, 221
 Inclusion in the main providers licensure contracts, 226
 Uncompensated care, 223
 Advisory opinions, OIG, 354
 Anti Kickback Statute and Stark Law, 351
 Causation, 361
 Impact of loper bright, 365
 Intent, 363
 Settlements
 Hospital/physician kickback schemes, 366
 Settlements
 Other, 368
 CMS updates, 356
 Overpayment rule revisions, 356
 Self-referral disclosure protocol settlements, 359
 Disadvantages, 227
 Impact on off-campus provider based facilities, 228
 Patient confusion and dissatisfaction, 230
 Physician dissatisfaction, 231
 Site neutral payments, 227
 Stringent and complicated requirements with big consequences, 229

**REIMBURSEMENT AND
PAYMENT—Cont'd**

Enrollment, 220
 False Claims Act, developments
 Constitutionality of Qui Tam provision, 371
 Damages, 385
 Knowledge/scienter, 379
 Pleading and proving falsity, 374
 Pleading and proving materiality, 376
 Public disclosure bar, 382
 Retaliation, 388
 Submission of claims and fraudulent scheme, 372
 General nursing facility compliance program, 351
 Healthcare fraud
 Criminal enforcement, 390
 Interaction with other payors, 234
 Joint ventures, 219
 Management and under arrangement
 Contracts, 217
 OIG updates, 351
 Overview, 210
 Requirements for PBS, 212
 Corporate structure and operational organization, 215
 Location, 213
 Other considerations, 217
 Provision of services, 216
 Public awareness, 217
 Special fraud alert on medicare advantage marketing arrangements, 352

REMITTANCE ADVICE

REMARK CODES (RARC)

Clinical validation
 Development CARC and RARC combination rules, 480

INDEX

REMITTANCE ADVICE

REMARK CODES (RARC)

—Cont'd

Clinical validation—Cont'd

Outcome of DRG and clinical validation, 478

Selection of CARC and RARC adjustment denial, 482

RISKS

Artificial intelligence (AI)

Bias, 23

Changes to business practices, 21

Generally, 20

Increased governance and compliance costs, 21

Intellectual property, 24

Liability for healthcare providers, 21

Misinformation, 23

Privacy, 21

Security, 21

Digital health

Abuse, 20

Corporate practice, 17

Fee-splitting, 18

Fraud, 20

Licensure, 18

RISKS—Cont'd

Digital health—Cont'd

Privacy, 19

STARK LAW

Law influencing private equity, 46

Reimbursement

Anti Kickback Statute and Stark Law, 351

STATE ACTOR

Compulsion test, 245

Considerations for cases involving the state action requirement and MCO, 259

Entwinement test, 248

Public function test, 244

Section 1983

General requirements, 241

Private parties, 242

State action joint action test, nexus, 246

State action requirement, 249

Decisions

2010, 253

2020, 258

Early 2000, 251

In the 1990, 250

Unique role of medicaid MCO in state medicaid programs, 239