Option to individuals to obtain other health insurance protection, 42 U.S.C. §1395b

2. Eligibility 48
   Description of program, 42 U.S.C. §1395c 49

3. Benefits 49
   a. Part A 50
      Scope of benefits, 42 U.S.C. §1395d 50
      Definitions, 42 U.S.C. §1395x 51
   b. Part B 52
      Establishment of supplementary medical insurance program for the aged and the disabled, 42 U.S.C. §1395j 52
      Eligible individuals, 42 U.S.C. §1395o 52
   c. Part C 53
      Eligibility, election, and enrollment, 42 U.S.C. §1395w-21 53
      Payments to health maintenance organizations and competitive medical plans, 42 U.S.C. §1395mm 55
   d. Part D 56
      Eligibility, enrollment, and information, 42 U.S.C. §1395w-101 57
      Prescription drug benefits, 42 U.S.C. §1395w-102 59

4. Payment: Fee for Service, Prospective Payment Systems, and Alternatives 60

Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates, 79 Fed. Reg. 27,978 (May 15, 2014) 63

Transitional Hospitals Corp. of Louisiana, Inc. v. Shalala, 222 F.3d 1019 (D.C. Cir. 2000) 66

5. The Power of Government Reimbursement to Change Provider Behavior 73


6. Medicare Appeals Processes 83

In the Case of the Estate of W.D. (Department of Health & Human Servs. Departmental Appeals Bd., Decision of Medicare Appeals Council 2009) 84

Judicial review, 42 U.S.C. §405(g) 87

Finality of Commissioner’s decision, 42 U.S.C. §405(h) 88

C. Medicaid 89

1. Legislative History 89

2. Structure 90
   Appropriations, 42 U.S.C. §1396-1 90
   Definitions, 42 U.S.C. §1396d 90
   a. State Plans for Participating in Medicaid 91
      Payment to States, 42 U.S.C. §1396b 91
      Definitions, 42 U.S.C. §1396d(b) 92
   b. State Medicaid Waivers and Medicaid Managed Care 93
      Demonstration projects, 42 U.S.C. §1315 (SSA §1115) 93
CHAPTER 3 Regulation of Private Health Insurance 151

A. Introduction 151
1. Cost Sharing in Private Health Insurance 151
2. Duty to Provide Health Care 152
3. Market for Privately Purchased Health Insurance 152

B. Expanding Coverage Through the Private Market 156
1. Insurance Risk Pooling 156
   Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic, 157
   65 F.3d 1406 (7th Cir. 1995)
2. State Regulation of Managed Care 159
3. Federalism and Health Insurance Regulation 163
   Regulation by State law; Federal law relating specifically to insurance; 164
   §1012
   Emergency services requirements; restrictive formulary requirements, 164
   Requirement to maintain minimum essential coverage, 26 U.S.C.
   §5000A 168
C. Employer-Sponsored Health Insurance

1. Employer Shared Responsibility


2. ERISA Preemption

Other laws, 29 U.S.C. §1144 (ERISA §514)

Civil enforcement, 29 U.S.C. §1132 (ERISA §502)


3. Substantive Federal Regulation of Employer-Sponsored Health Plans

*McGann v. H & H Music Co.,* 946 F.2d 401 (5th Cir. 1991)

Increased portability through limitation on preexisting condition exclusions, 29 U.S.C. §1181

Prohibiting discrimination against individual participants and beneficiaries based on health status, 29 U.S.C. §1182

No lifetime or annual limits, 29 C.F.R. §2590.715-2711

D. Individual and Small-Group Markets

1. Coverage Through the Exchanges


Congressional Budget Office, Repealing the Individual Health Mandate: An Updated Estimate (November 2017)

2. Government Subsidies for Private Health Insurance Purchase

Refundable credit for coverage under a qualified health plan, 26 U.S.C. §36B

3. Prohibition on Health Status Discrimination

Fair health insurance premiums, 42 U.S.C. §300gg

Guaranteed availability of coverage, 42 U.S.C. §300gg-1

Guaranteed renewability of coverage, 42 U.S.C. §300gg-2

Prohibition of preexisting condition exclusions or other discrimination based on health status, 42 U.S.C. §300gg-3

Prohibiting discrimination against individual participants and beneficiaries based on health status, 42 U.S.C. §300gg-4

4. Essential Health Benefits

Essential health benefits requirements, 42 U.S.C. §18022

Coverage of preventive health services, 42 U.S.C. §300gg-13

5. State Innovation Waivers

Basis and purpose, 31 C.F.R. §33.100

Coordinated waiver process, 31 C.F.R. §33.102


PART II  THE BUSINESS OF HEALTH CARE

CHAPTER 4  Structure and Governance of Health Care Entities

A. Overview of Health Care Business Entities
CHAPTER 5 Tax-Exempt Health Care Charitable Organizations

A. Introduction 281

B. Health Care as a Charitable Purpose 281

Exemption from tax on corporations, certain trusts, etc., 26 U.S.C. §501 281

Revenue Ruling 69-545, 1969-2 C.B. 117 282

C. Federal Requirements for Tax-Exempt Hospitals 287

1. Community Health Needs Assessments and Other Requirements Under Section 501(r) 287


Failures to satisfy section 501(r), 26 C.F.R. §1.501(r)-2 291

Community health needs assessments, 26 C.F.R. §1.501(r)-3 292

Financial assistance policy and emergency medical care policy, 26 C.F.R. §1.501(r)-4 294

2. Joint Ventures with For-Profit Entities 297

St. David's Health Care System v. United States, 349 F.3d 232 (5th Cir. 2003) 297

3. Intermediate Sanctions for Excess Benefit Transactions 304

Taxes on excess benefit transactions, 26 U.S.C. §4958 304

D. Related Issues Under State Tax Law 307

Provena Covenant Medical Center v. Department of Revenue, 236 Ill. 2d 368 (2010) 307

Hospital credit, Illinois Income Tax Act §223 317
CHAPTER 6 Health Care Fraud and Abuse

A. Introduction

DOJ Press Release, National Health Care Takedown Results in Charges Against over 412 Individuals Responsible for $1.3 Billion in Fraud Losses (July 13, 2017)
Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at the Taxpayers Against Fraud Education Fund Conference (Sept. 17, 2014)

B. Federal False Claims Act

1. Civil Liability and Penalties
2. Reverse False Claims
   * Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654 (Feb. 12, 2016)
3. Scienter Requirement
   * Definitions, 31 U.S.C. §3729(b)
4. Materiality
5. Qui Tam Actions
6. Criminal Sanctions for False Claims
   * False, fictitious or fraudulent claims, 18 U.S.C. §287
   * Making or causing to be made false statements or representations, 42 U.S.C. §1320a-7b(a)

C. Anti-Kickback Statute

1. Criminal Statute
   * Illegal remunerations, 42 U.S.C. §1320a-7b(b)
   * Press Release, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges (Oct. 3, 2001)
2. Scienter Requirement Under the Anti-Kickback Statute
   * United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011)
3. Safe Harbors
   * 42 U.S.C. §1320a-7b(b)(3)
   * 42 C.F.R. §1001.952
4. Advisory Opinions
5. Fraud Alerts and Other Guidance
   * Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability (June 9, 2015)
D. Stark Law
Ethics in Patient Referrals Act, 42 U.S.C. §1395nn

1. Financial Relationship
   DOJ Settlement Announcement

2. Designated Health Services
   Group practice, 42 U.S.C. §1395nn(h)(4)
   In-office ancillary services, 42 C.F.R. §411.355(b)

3. Exceptions
   In-office ancillary services, 42 U.S.C. §1395nn(b)(2)
   Group practice, 42 U.S.C. §1395nn(h)(4)
   Definitions — Member of the group or member of a group practice, 42 C.F.R. §411.351
   Council for Urological Interests v. Burwell, 790 F.3d 212 (D.C. Cir. 2015)
   United States ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Cir. 2015)

E. Other Sanctions, Compliance Programs, and State Laws

1. Administrative Sanctions
   Mandatory exclusion, 42 U.S.C. §1320a-7(a)

2. Private Contractors

3. Compliance and Self-Disclosure

4. State Fraud and Abuse Laws
   State false claims act requirements for increased State share of recoveries, 42 U.S.C. §1396h
   Letter from OIG to State of New Mexico Attorney General’s Office (July 24, 2008)
   Civil penalties, Ga. Code Ann. §23-3-121

CHAPTER 7 Competition in Health Care Markets

A. Introduction

B. Health Care Market Imperfections

C. Introduction to Antitrust Law
   Trusts, etc., in restraint of trade illegal; penalty, 15 U.S.C. §1 (Sherman Act section 1)
   Monopolizing trade a felony; penalty, 15 U.S.C. §2 (Sherman Act section 2)
   Acquisition by one corporation of stock of another, 15 U.S.C. §18 (Clayton Act section 7)
   Unfair methods of competition unlawful; prevention by Commission, 15 U.S.C. §45(a) (FTC Act section 5)

D. Increasing Market Power Through Merger
   1. Hospital Mergers
      ProMedica Health System, Inc. v. Federal Trade Commission, 749 F.3d 559 (6th Cir. 2014)
   2. Remedies
      In the Matter of Evanston Northwestern Healthcare Corp., FTC Docket No. 9315 (Aug. 6, 2007)
E. Collaborations with Competitors 428
1. Physician Price Fixing 429
2. Pro-Competitive Physician Collaborations 433
3. Accountable Care Organizations 436
   Federal Trade Commission & Department of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program 436

F. Laws Limiting Competitive Market Entry 442
1. Scope of Practice 442
   Letter from FTC to the Alabama State Board of Medical Examiners (Nov. 3, 2010) 443
2. Certificate of Need Laws 445
   Certificate of need required for new institutional health services; exemption, Ga. Code Ann. §31-6-40 445
   Antitrust Division, U.S. Department of Justice, Competition in Healthcare and Certificates of Need (Mar. 25, 2008) 447
   United States v. Siegelman, 640 F.3d 1159 (11th Cir. 2011) 452

G. The Role of States in Antitrust Enforcement 456
1. State Attorney General Actions 456
   Office of Attorney General Martha Coakley, Examination of Health Care Cost Trends and Cost Drivers (Mar. 16, 2010) 456
2. State Action Doctrine 459

PART III  PATIENT PROTECTIONS 465

CHAPTER 8 Duties Related to Patient Care 467
A. Introduction 467
B. Duty to Treat 468
1. Health Care Providers 468
   a. Common Law 468
      Hurley v. Eddingfield, 59 N.E. 1058 (Ind. 1901) 468
   b. Statutory Exceptions: EMTALA 469
      Emergency Medical Treatment and Active Labor Act — Examination and treatment for emergency medical conditions and women in labor, 42 U.S.C. §1395dd 470
   c. Federal Nondiscrimination Statutes 473
      Discrimination prohibited 42 C.F.R. §80.3 474
Prohibition of discrimination by public accommodations,
42 U.S.C. §12182 475
Nondiscrimination, 42 U.S.C. §18116 477

2. Insurers
Guaranteed renewability of individual health insurance coverage,
45 C.F.R. §148.122 478

C. Content of the Duty to Treat

1. In Tort: Medical Malpractice and Informed Consent 479
   a. Duty of Informed Consent 480
   b. Vicarious Liability of Managed Care Organizations 484
      *Petrovich v. Share Health Plan of Illinois, Inc.*, 188 Ill. 2d 17 (1999) 484

2. In Contract: Waivers and Warranties 495
   a. Waivers 495
      *Laizure v. Avante at Leesburg, Inc.*, 109 So. 3d 752 (Fla. 2013) 495
   b. Warranties 502

   Francois de Brantes, Guy D’Andrea, & Meredith B. Rosenthal,
   *Should Health Care Come with a Warranty?*, 28 Health Aff. no. 4,
   at w678-w687 (July/Aug. 2009) 502
   c. Reimbursement Policy 504
      Press Release, Eliminating Serious, Preventable, and Costly Medical
      Errors — Never Events (May 18, 2006) 504

3. Direct Government Regulation of Quality 508
   a. State Licensure 508
      Virginia Board of Medicine, Regulations Governing the Practice
      of Medicine, Osteopathy, Podiatry and Chiropractic 508
      Prerequisites to licensure, 18 Va. Admin. Code §85-20-120 508
      Educational requirements: Graduates of approved institutions,
      18 Va. Admin. Code §85-20-121 509
   b. Report Cards and Databases 510
      Certain data required, Va. Code §54.1-2910.1 510
      When information must be reported, 45 C.F.R. §60.5 511
      Information which hospitals must request from the National
      Practitioner Data Bank, 45 C.F.R. §60.17 512
   c. Peer Review 512
      *Kadlec Medical Center v. Lakeview Anesthesia Associates*, 527 F.3d 412
      (5th Cir. 2008) 513
      Standards for professional review actions, 42 U.S.C. §11112 522
      *Sithian v. Staten Island University Hospital*, 189 Misc. 2d 410
      (N.Y. Sup. Ct. 2001) 523

4. Comparative Effectiveness Research 526
   Comparative clinical effectiveness research, 42 U.S.C. §1320e 526
   Limitations on certain uses of comparative clinical effectiveness
   research, 42 U.S.C. §1320e-1 527
## CHAPTER 9  Regulation of the Beginning and End of Life  529

### A. Introduction  529

### B. Regulation of Reproduction  530


Special rules, 42 U.S.C. §18023  
TRAP Laws  

### C. Autonomy and Decision Making at the End of Life  572

#### 1. Judicially Recognized Protections at the End of Life  572

- Oregon Death with Dignity Act  

#### 2. Statutory Facilitation of End-of-Life Decision Making  591


- Medicare Hospice Conditions of Participation  
- Condition of participation: Patient’s rights, 42 C.F.R. §418.52  
- Definition, 42 C.F.R. §489.100  
- Requirements for providers, 42 C.F.R. §489.102  

##### b. State Law Facilitating Substituted Judgment  594

- Florida Health Care Advance Directives, Fla. Stat. ch. 765  
- Massachusetts Medical Orders for Life-Sustaining Treatment Form  

## CHAPTER 10  Health Privacy in the Digital Age  611

### A. Introduction  611

Press Release, HIPAA Settlement Reinforces Lessons for Users of Medical Devices (Nov. 25, 2015)  

### B. Federal Protections for Privacy, Confidentiality, and Security  613

Preamble to Pub. L. No. 104-191 (HIPAA)  
Subtitle F—Administrative Simplification  
Purpose, Sec. 261  

#### 1. Structure of Health Privacy and Confidentiality  614

- Administrative Data Standards and Related Requirements  
- Privacy of Individually Identifiable Health Information  
- Applicability, 45 C.F.R. §164.500  
- Definitions, 45 C.F.R. §164.501  
- Uses and disclosures of protected health information: General rules, 45 C.F.R. §164.502  
- Uses and disclosures: Organizational requirements, 45 C.F.R. §164.504  

---

**Contents**
Uses and disclosures to carry out treatment, payment, or health care operations, 45 C.F.R. §164.506
Uses and disclosures for which an authorization is required, 45 C.F.R. §164.508

2. Compliance and Enforcement

Press Release, $750,000 HIPAA Settlement Underscores the Need for Organization-Wide Risk Analysis (Dec. 14, 2015)

Security standards: General rules, 45 C.F.R. §164.306
Administrative safeguards, 45 C.F.R. §164.308
Physical safeguards, 45 C.F.R. §164.310
Notification to individuals, 45 C.F.R. §164.404
Notification to the media, 45 C.F.R. §164.406
Notification to the Secretary, 45 C.F.R. §164.408
Notification by a business associate, 45 C.F.R. §164.410

Cyber-Attack Notification Letter: Anthem Security Breach

C. State-Based Privacy Protections

Effect on State law, 42 U.S.C. §1320d-7
General rule and exceptions, 45 C.F.R. §160.203
Byrne v. Avery Center for Obstetrics & Gynecology, P.C., 102 A.3d 32 (Conn. 2014)
Walgreen Co. v. Hinchy, 21 N.E.3d 99 (Ind. 2014)

D. Telemedicine

Telehealth services, 42 C.F.R. §410.78
Teladoc, Inc. v. Texas Medical Board, 2015 WL 8773509 (W.D. Tex. 2015)

CHAPTER 11 Regulation of Biomedical Research on Humans

A. Introduction

Moore v. Regents of University of California, 51 Cal. 3d 120 (1990)

B. Ethical Principles

Nuremberg War Crimes Indictments
Nuremberg Code
Declaration of Helsinki (The Helsinki Accord) (2013 ed.)
The Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research)

C. Federal Law Pertaining to Clinical Research on Humans

Common Rule, 45 C.F.R. §§46.101-46.505
Grimes v. Kennedy Krieger Institute, Inc., 782 A.2d 807 (Md. 2001)
Complaint, Gelsinger v. Trustees of the University of Pennsylvania
<table>
<thead>
<tr>
<th>Contents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Rule, Research on Children, 45 C.F.R. §46.404-46.408</td>
<td>729</td>
</tr>
<tr>
<td>Investigation Letter from Office for Human Research Protections (Jan. 16, 2015)</td>
<td>731</td>
</tr>
<tr>
<td>Table of Cases</td>
<td>735</td>
</tr>
<tr>
<td>Table of Statutes and Regulations</td>
<td>739</td>
</tr>
<tr>
<td>Index</td>
<td>751</td>
</tr>
</tbody>
</table>