

## MAJOR FEDERAL LAWS THAT CREATE EXPOSURE IN THE HEALTH INDUSTRY

### Clayton Act, Section 7

- Relevant Product Market
- Relevant Geographic Market
- Identification of Competitors
- Calculation of Each Competitors Market Share
- Merging Firms Post-Merger Market Share, Level of Market Concentration and Increase in Market Concentration

### Federal Trade Commission Act

- Red Flag Rules: Anti-identity Theft Measures

### Statements of Antitrust Enforcement Policy in Health Care

- Safety Zones
- Mergers Among Hospitals
- Hospital Joint Ventures Involving High Technology or other Expensive Health Care Equipment

- Hospital Joint Ventures Involving Specialized Clinical or other Expensive Health Care Services
- Providers' Collective Provision of Non-Fee-Related Information to Purchasers of Health Care Services
- Providers' Collective Provision of Fee-Related Information to Purchasers of Health Care Services
- Provider Participation in Exchanges of Price and Cost Information
- Joint Purchasing Arrangements Among Health Care Providers
- Physician Network Joint Ventures
- Multiprovider Networks

### Food, Drug and Cosmetics Act

- Marketing Practices
- Stem Cells
- Medical Marijuana
- Pharmaceuticals
- Medical Devices

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## MAJOR FEDERAL LAWS THAT CREATE EXPOSURE IN THE HEALTH INDUSTRY

### Social Security Act

- Medicare Part A Hospital, Extended Care or Skilled Nursing Services, Home Health Services, Hospice Services, Other PPS (inpatient rehabilitation, long term care and psychiatric hospitals)
- Medicare Part B Physicians, Non-Physician Practitioners, Outpatient Providers and Freestanding Supplier Entities
- Medicare Part C Medicare Advantage (managed care)
- Medicare Part D Drug Program
- Medicaid
- Program Administration, CMS
  1. Enrollment and NPI
  2. Conditions of participation
  3. Certification
  4. Payment: DRG, RBRVS, Fee Schedules, Capitation
- Medicare Administrative Contractors and Fiscal Agents (MAC, QIC, RAC)
  1. National Coverage Decisions and Local Determinations of Coverage
  2. Appeals
- Office of Inspector General (OIG)
- Provider Reimbursement Review Board (PRRB)

### Anti-Kickback Statute

- Qui Tam
- Statutory Prohibition
- Judicial Interpretations
- Special Fraud Alerts
- Advisory Opinions
- Safe harbors
  - Large Investment Interests
  - Small Investment Interests
  - Investments in Entities in MUAs
  - Space & Equipment Rental, & Personal-Services & Management
  - Contracts
  - Sale of Practice
  - Referral Services
  - Warranties
  - Discounts
  - Employees
  - Group Purchasing Organizations
  - Coinsurance & Deductible Waivers
  - Beneficiary Incentives Offered by Managed-Care Organizations
  - Price Reductions Offered to Group Health Plans
  - Practitioner Recruitment
  - Obstetrical Malpractice-Insurance Subsidies

- Investments in Group Practices
- Cooperative Hospital-Services Organizations
- ASCs
- Referral Agreements for Specialty Services
- EHR and E-Prescribing
- Ambulance Replenishing/Restocking
- Risk Sharing Arrangements

### Physician Self-Referral (Stark)

- Per Click Changes
- Stand in the Shoes
- Statutory Prohibition
- Designated Health Services (DHS)
- Stark Exceptions
- Ownership and Compensation Exceptions
  - Physician Services
  - In-Office Ancillary Services
  - Prepaid Plans
  - Academic Medical Centers
  - Implants in ASCs
  - Additional Regulatory Exceptions Applicable to both Ownership and Compensation Arrangements
- Ownership Exceptions
  - Ownership in Publicly Traded Securities and Mutual Funds
  - Hospitals
  - Rural Providers
- Special Rules for Compensation
  - Definition of Fair Market Value
  - Compensation Methodologies
  - Physician's Compensation can be Conditioned on Referrals to a Particular Provider
- Compensation Arrangement Exceptions
  - Rental of Office Space and Equipment
  - Bona Fide Employment Relationships
  - Personal-Service Arrangements
  - Unrelated Payments
  - Physician Recruitment and Retention
  - Isolated Financial Transactions
  - Certain Group Practice Arrangements with a Hospital
  - Payments for Items and Services
  - Fair Market Value Exception
  - Non-Monetary Compensation Up To \$300
  - Medical Staff Incidental Benefits
  - Managed-Care Risk-Sharing Arrangements
  - Compliance Training
  - Exception for Indirect Compensation
  - Additional Compensation Exceptions

## MAJOR FEDERAL LAWS THAT CREATE EXPOSURE IN THE HEALTH INDUSTRY

### Federal Criminal Prohibitions Against False Claims and Fraudulent Billing Practices

- General Prohibition
  1. Making of False Statements
  2. Theft or Embezzlement
- Mail and Wire Fraud
- Racketeering Violations
- Money-Laundering

### Federal Civil Prohibitions Against False Claims and Fraudulent Billing Practices

- Program Fraud and Civil Remedies Act
- Federal False Claims Act and Qui Tam Actions

### Corporate Compliance Programs

- Federal Sentencing Guidelines
- OIG Compliance Program Guidelines
- Corporate Integrity Agreements

### Health Insurance Portability and Accountability Act (HIPAA)

- Privacy Rules
- Security Rules
- Transaction and Code Sets
- Sanctions and Enforcement
- Administrative Requirements and Training
- Use and Disclosure of Protected Health Information
- Patient Access to Own Information
- Notice of Privacy Practices
- Business Associate Agreements and Policies

### Federal Regulation of Private Healthcare Plans

- ERISA
- COBRA
- Mental Health Parity Act
- State Laws that "Relate to" an ERISA Plan
- Business of Insurance
- Deemer Clause

### Tax-Exempt Issues

- New Form 990
- Organizational Test
- Operational Test
- Stand Alone Exemption
- Derivative or Integral Part Exemption
  1. parent corporations
  2. joint operating companies
- Private Benefit-Inurement Prohibition
- Intermediate Sanctions and the Rebuttable Presumption of Reasonableness
  1. intermediate sanctions excise taxes
  2. excess benefit transactions and rebuttable presumption
  3. disqualified persons
- Unrelated Business Activities
- Political Activity Prohibition and Lobbying Limitation
- Physician Practice Acquisitions
- Physician Incentive Compensation
- Executive Compensation
- Taxable Affiliates
- Joint Venture Arrangements Involving Exempt and Non-Exempt Participants
  1. Relatedness Test
  2. Conflict of Interest Test
  3. Control Test
  4. Revenue Ruling 98-15
  5. Redlands
  6. St. Davids

### Emergency Medical Treatment and Active Labor Act (EMTALA)

- Emergency Treatment
- Non-Emergency Treatment

### Sherman Act, Section 1

- Agreement
- Restraint on Competition
- Conduct with Potential Section 1 Ramifications

### Sherman Act, Section 2

- Monopolization
- Attempted Monopolization